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DIVISION 2

STANDARDS FOR REGISTRY ENROLLMENT, QUALIFICATION AND CERTIFICATION OF HEALTH CARE INTERPRETERS

333-002-0000
Purpose

(1) These rules establish the Health Care Interpreter (HCI) program, a central registry, and a process for certification and qualification of health care interpreters for persons with limited English proficiency.

(2) These rules help the Oregon Health Authority comply with Title VI of the Civil Rights Act of 1964 which mandates that no person in the United States shall, on grounds of race, color or national origin, be excluded from participation in, denied the benefits of, or subjected to discrimination under any program or activity receiving federal financial assistance.

(3) Any individual providing health care interpreting services, either on-site or remotely may elect to participate in the Health Care Interpreter program.

Stat. Auth.: ORS 413.558
Stats. Implemented: ORS 413.556 & 419.558
Hist.: PH 18-2006, f. & cert. ef. 8-2-06; PH 2-2011, f. & cert. ef. 3-1-11; PH 18-2016, f. 6-9-16, cert. ef. 7-1-16

333-002-0010
Definitions

As used in chapter 333, division 2 the following definitions apply:

(1) "Applicant" means any individual who applies for qualification or certification as a health care interpreter under OAR 333-002-0050.

(2) "Authority" means the Oregon Health Authority.

(3) "Central registry" means the record maintained by the Authority of enrolled individuals recognized as approved certified or qualified health care interpreters.

(4) "Certified health care interpreter" means an individual who has been issued a valid letter of certification by the Authority under these rules to perform health care interpreting services.

(5)"Formal training" means instruction obtained in an academic setting, seminars, in-service instruction, or by other means of substantive distance learning.

(6)"Health care interpreting services" means the provision of services to limited English proficient individuals through the process of fully understanding and analyzing a spoken or signed message, then faithfully rendering the message into another spoken or signed language in order to ensure access to any medical, surgical or hospital intervention including physical, oral or behavioral health treatment.

(7) "Interpreting knowledge" means an entry-level range of interpreting knowledge and skills that includes but is not limited to: language fluency, ethics, cultural competency, terminology, integrated interpreting skills and translation of simple instructions.

(8)"Interpreting skills and ability" means the demonstrated capacity to perform interpreting modes and apply medical interpreting ethics, cultural competency, terminology, integrated interpreting skills, and translation of simple instructions.

(9)"Limited English proficient" means the legal concept referring to a level of English proficiency that is insufficient to ensure equal access to public services without an interpreter.

(10) "Person with limited English proficiency" means a person who, by reason of place of birth or culture, speaks a language other than English and does not speak English with adequate ability to communicate effectively with a health care provider.

(11) "Qualified health care interpreter" means an individual who has been issued a valid letter of qualification by the Authority under these rules.

(12)"Translation" means the conversion of written text into a corresponding written text in a different language.

(13)"Written verification" means providing proof in a way that establishes the authenticity of submitted documents in a reasonably reliable manner and may include official transcripts, a certificate of completion, or an endorsement from an agency or institution whose training curriculum is approved by the Authority.

Stat. Auth.: ORS 413.558
Stats. Implemented: ORS 413.556 & 413.558
Hist.: PH 18-2006, f. & cert. ef. 8-2-06; PH 26-2006, f. & cert. ef. 11-16-06; PH 2-2011, f. & cert. ef. 3-1-11; PH 18-2016, f. 6-9-16, cert. ef. 7-1-16

333-002-0020
Health Care Interpreter Services

Any individual providing health care interpreting services as defined in this division may voluntarily meet the eligibility standards established in OAR 333-002-0040 and be:

(1) Added to the central registry; and

(2) Issued a valid letter of certification or qualification by the Authority.

Stat. Auth.: ORS 413.558
Stats. Implemented: ORS 413.556 & 413.558
Hist.: PH 18-2006, f. & cert. ef. 8-2-06; PH 2-2011, f. & cert. ef. 3-1-11; PH 18-2016, f. 6-9-16, cert. ef. 7-1-16

333-002-0030
Central Registry

(1) The Authority shall maintain a central registry of individuals who are certified or qualified to provide health care interpreting services as provided in OAR 333-002-0020.

(2) The Oregon Health Authority shall maintain a list of languages for which health care interpreter certification or qualification is available.

(3) The Authority shall maintain and publish a list of Authority approved training centers where applicants may receive the education required for certification or qualification.

(4) Certified or qualified health care interpreters may withdraw from the registry by providing written notification to the Authority.

Stat. Auth.: ORS 413.558
Stats. Implemented: ORS 413.556 & 413.558
Hist.: PH 18-2006, f. & cert. ef. 8-2-06; PH 2-2011, f. & cert. ef. 3-1-11; PH 18-2016, f. 6-9-16, cert. ef. 7-1-16

333-002-0035
Fees

Applicants for enrollment or renewal shall submit a processing fee in the amount of $25 with the required application or renewal materials.

Stat. Auth.: ORS 413.558
Stats. Implemented: ORS 413.556 & 413.558
Hist.: PH 18-2006, f. & cert. ef. 8-2-06; PH 26-2006, f. & cert. ef. 11-16-06; PH 2-2011, f. & cert. ef. 3-1-11; PH 18-2016, f. 6-9-16, cert. ef. 7-1-16

333-002-0040
Eligibility Standards for Registry Enrollment, Qualification and Certification

(1) Individuals enrolled in the Health Care Interpreter (HCI) registry shall:

(a) Be at least 18 years of age.

(b) Have a high school diploma or a GED from an accredited school in the United States of America or an equivalent education from another country.

(A) Individuals from other countries may apply to the Authority for an exception to this requirement when documentation to prove education is not available.

(B) Exceptions are at the sole discretion of the Authority.

(c) Not be on the Medicaid Exclusion list.

(d) Pass a background check in accordance with ORS 181A.200, OAR chapter 125-divison 7 and OAR chapter 943 Division 007.

(e) Abide by the National Code of Ethics and National Standards of Practice for Interpreters in Health Care.

(f) Abide by the Registry of Interpreters for the Deaf Code of Professional Conduct, if applicable.

(g) Submit the required forms and documentation to become a certified or qualified health care interpreter as defined by these rules.

(2) Applicants seeking to become a qualified health care interpreter for a spoken language or languages shall:

(a) Comply with the requirements set out in section (1) of this rule;

(b) Provide written verification of at least 60 hours of formal training as defined in OAR 333-002-0060, unless they meet the requirements outlined in section 3 of this rule; and

(c) Demonstrate health care interpreting knowledge by passing a skill evaluation offered by an Authority approved language proficiency testing center on the Authority maintained list provided for in OAR 333-002-0070, or meet equivalent language proficiency requirements set by the Authority.

(3) Educators and trainers of health care interpreters who have worked in the field for two consecutive years at any time from January 2, 2010 to the present may receive credit for 40 hours of the 60 hour requirement by providing valid documentation from an established registry or institution for time spent training health care interpreters.

(4) Applicants seeking to become a qualified healthcare interpreter for American Sign Language shall:

(a) Comply with the requirements set out in section (1) of this rule;

(b) Provide written verification of certification in American Sign Language interpreting from the Registry of Interpreters for the Deaf;

(5) Applicants seeking to become a certified healthcare interpreter in a spoken language or languages shall:

(a) Comply with the requirements set out in section (1) and (2) of this rule; and

(b) Pass an approved certification test at a medical interpreter certification testing center on the Authority maintained list provided for in OAR 333-002-0070.

(6) Applicants seeking to become a certified healthcare interpreter in American Sign Language shall:

(a) Comply with the requirements set out in section (1) and (4) of this rule;

(b) Provide written verification of at least 60 hours of formal training from an Authority approved training center as defined in OAR 333-002-0060.

(7) The Authority may accept formal training from entities outside of Oregon that demonstrate their criteria are equal to or exceed Oregon's criteria as established by these rules.

Stat. Auth.: ORS 413.558
Stats. Implemented: ORS 413.556 & 413.558
Hist.: PH 18-2006, f. & cert. ef. 8-2-06; PH 26-2006, f. & cert. ef. 11-16-06; PH 15, 2010(Temp), f. 7-13-10, cert. ef. 7-15-10 thru 1-10-11; Administrative correction 1-25-11; PH 2-2011, f. & cert. ef. 3-1-11; PH 18-2016, f. 6-9-16, cert. ef. 7-1-16

333-002-0050
Application Procedure

(1) Upon request, the Authority shall provide an application packet or a link to the Health Care Interpreter (HCI) application to any individual seeking certification or qualification as an HCI.

(2) Applicants shall submit required forms and supplemental materials, including proof of formal training, and any required fees to the Authority.

(3) To meet testing requirements, applicants shall authorize an Authority approved testing center to provide the Authority with a copy of their test results.

(a) Requests for language proficiency testing or certification testing shall be made directly to the approved testing center.

(b) Required testing fees shall be paid directly to the approved testing center.

(c) Test results shall become part of the applicant's permanent record.

(4) Supplemental materials in languages other than English shall be accompanied by:

(a) An accurate translation of those documents into English; and

(b) A translator's certificate, from a translator other than the applicant and not related to the applicant by blood or marriage, stating that the documents provided are a true and accurate translation.

(c) The applicant shall pay for any translation costs for documents required by the Authority.

(5) If the Authority determines that the application is not complete or that the required documentation is not acceptable, the Authority shall notify the applicant within 30 days of receipt.

(6) Applicants may withdraw from the process at any time by providing written notification to the Authority.

Stat. Auth.: ORS 413.558

Stats. Implemented: ORS 413.556 & 413.558
Hist.: PH 18-2006, f. & cert. ef. 8-2-06; PH 26-2006, f. & cert. ef. 11-16-06; PH 2-2011, f. & cert. ef. 3-1-11; PH 18-2016, f. 6-9-16, cert. ef. 7-1-16

333-002-0060
Formal Training and Work Experience Requirements

(1) Applicants seeking Health Care Interpreter (HCI) certification or qualification shall provide written verification of the successful completion of at least 60 hours of Authority approved formal training, including a minimum of:

(a) Fifty-two hours of integrated medical terminology, anatomy and physiology, introductory health care interpreting concepts and modes; and

(b) Eight hours of Health Care Interpreting Ethics.

(2) HCI applicants shall provide written verification of work experience as an interpreter:

(a) 15 hours for qualification; or

(b) 30 hours for certification.

Stat. Auth.: ORS 413.558
Stats. Implemented: ORS 413.556 & 413.558
Hist.: PH 18-2006, f. & cert. ef. 8-2-06; PH 15, 2010(Temp), f. 7-13-10, cert. ef. 7-15-10 thru 1-10-11; Administrative correction 1-25-11; PH 2-2011, f. & cert. ef. 3-1-11; PH 18-2016, f. 6-9-16, cert. ef. 7-1-16

333-002-0070
Approval of Testing Centers, Skill Evaluation and Assessment

(1) The Authority shall enter into a memorandum of agreement with medical interpreter certification testing centers and language proficiency testing centers establishing the manner and means for testing Oregon applicants for health care interpreter certification and qualification, and including a process for sharing testing information with the Authority and the applicant.

(2) Authority approved medical interpreter testing centers shall test interpreting skills and ability.

(3) The Authority shall maintain and make readily available to the public a list of approved medical interpreter certification testing centers and language proficiency testing centers.

(4) The Authority may proctor testing and determine testing locations if the approved testing centers do not have their own testing centers and the ability to verify the applicant's identity before testing.

(5) Government issued photo identification showing the name and address of the applicant such as a valid driver's license, state identification card, military identification, current passport, or immigration or naturalization documents shall be presented before an individual enters an evaluation or assessment.

(6) An applicant whose conduct interferes with or disrupts the testing process may be dismissed and disqualified from future evaluations and assessments. Such conduct includes but is not limited to the following behaviors:

(a) Giving or receiving evaluation or assessment data, either directly or indirectly, during the testing process.

(b) Failing to follow written or oral instructions related to conducting the evaluation or assessment, including termination times and procedures.

(c) Introducing unauthorized materials during any portion of the evaluation or assessment.

(d) Attempting to remove evaluation or assessment materials or notations from the testing site.

(e) Falsifying or misrepresenting educational credentials or other information required for admission to the evaluation or assessment.

(7) Applicants needing accommodation because of a disability may apply to the testing center for accommodations to complete an evaluation or assessment.

(8) Test questions, scoring keys, and other data used to administer evaluations and assessments are exempt from disclosure under ORS 192.410 through 192.505.

(9) The Authority may release statistical information regarding evaluation or assessment pass or fail rates by group, evaluation or assessment type, and subject area to any interested party.

Stat. Auth.: ORS 413.558
Stats. Implemented: ORS 413.556 & 413.558
Hist.: PH 18-2006, f. & cert. ef. 8-2-06; PH 26-2006, f. & cert. ef. 11-16-06; PH 2-2011, f. & cert. ef. 3-1-11; PH 18-2016, f. 6-9-16, cert. ef. 7-1-16

333-002-0080
Skill Evaluation or Assessment Appeal

(1) Applicants who fail to pass a test at an Authority approved testing center may appeal the results with the testing center directly and pay any fees associated with the appeal.

(2) The testing center's determination is final.

(3) Applicants have no appeal rights with the Authority.

Stat. Auth.: ORS 413.558
Stats. Implemented: ORS 413.556 & 413.558
Hist.: PH 18-2006, f. & cert. ef. 8-2-06; PH 26-2006, f. & cert. ef. 11-16-06; PH 2-2011, f. & cert. ef. 3-1-11; PH 18-2016, f. 6-9-16, cert. ef. 7-1-16

333-002-0120
Continuing Education

(1) To qualify for registry renewal, certified and qualified health care interpreters shall sign and submit to the Authority the designated forms and verification showing the individual has completed the required continuing education.

(2) To maintain eligibility for registry renewal, certified and qualified health care interpreters shall complete 24 hours of Authority approved continuing education during the 36 month registry period, including:

(a) Six hours of continuing education on health care interpreter ethics.

(b) Six hours of continuing education on interpretation skills.

(c) An additional 12 hours that cover any topics accepted for continuing education by interpreter certification testing centers on the Authority maintained list provided for in OAR 333-002-0070.

(3) Continuing education records shall be maintained by registered health care interpreters for a minimum of three years.

(4) Continuing education hours taken in excess of the required number in a renewal period may not be carried over to the next renewal period.

Stat. Auth.: ORS 413.558
Stats. Implemented: ORS 413.556 & 413.558
Hist.: PH 18-2006, f. & cert. ef. 8-2-06; PH 26-2006, f. & cert. ef. 11-16-06; PH 2-2011, f. & cert. ef. 3-1-11; PH 18-2016, f. 6-9-16, cert. ef. 7-1-16

333-002-0140
Letter of Qualification

(1) If the Authority determines that the qualification requirements in OAR 333-002-0040, 333-002-0050, and 333-002-0060 and any applicable renewal requirements have been met, a letter of qualification shall be issued.

(2) Letters of qualification are valid for 36 months from the date of issue and are not renewable for languages for which certification is available.

Stat. Auth.: ORS 413.558
Stats. Implemented: ORS 413.556 & 413.558
Hist.: PH 18-2006, f. & cert. ef. 8-2-06; PH 26-2006, f. & cert. ef. 11-16-06; PH 2-2011, f. & cert. ef. 3-1-11; PH 18-2016, f. 6-9-16, cert. ef. 7-1-16

333-002-0150
Letter of Certification

(1) If the Authority determines that the certification requirements in OAR 333-002-0040, 333-002-0050 and 333-002-0060 and any applicable renewal requirements have been met a letter of certification shall be issued.

(2) Letters of certification are valid for 36 months from the date of issue and are renewable.

Stat. Auth.: ORS 413.558
Stats. Implemented: ORS 413.556 & 413.558
Hist.: PH 18-2006, f. & cert. ef. 8-2-06; PH 26-2006, f. & cert. ef. 11-16-06; PH 2-2011, f. & cert. ef. 3-1-11; PH 18-2016, f. 6-9-16, cert. ef. 7-1-16

333-002-0170
Certification and Qualification Renewal

(1) Certified or qualified health care interpreters who intend to maintain enrollment in the registry shall renew their certification or qualification every 36 months.

(2) To continue participating in the registry, qualified interpreters may not apply for renewal of their qualification if

certification is available in the qualified language or languages, they must become certified instead.

(3) At least 45 days before the expiration of certification or qualification, an applicant for renewal shall submit:

(a) A completed Authority renewal form and background check application.

(b) Any applicable fees.

(c) A signed copy of the Authority provided commitment form acknowledging that the applicant has read and agrees to abide by the National Code of Ethics for Interpreters in Health Care or the Registry of Interpreters for the Deaf Code of Professional Conduct, as applicable.

(d) Written verification showing the individual has maintained eligibility for registry renewal by completing the continuing education required:

(A) For qualification, the continuing education required by OAR 333-002-0120.

(B) For certification, the continuing education required by OAR 333-002-0120 and any additional hours required by the applicant's national certifying body during the preceding three years. Actual recertification by the national body is not required.

(4) The date of submission shall be considered to be the date materials are received by the Authority by fax, mail, email or hand delivery.

Stat. Auth.: ORS 413.558
Stats. Implemented: ORS 413.556 & 413.558
Hist.: PH 18-2006, f. & cert. ef. 8-2-06; PH 26-2006, f. & cert. ef. 11-16-06; PH 2-2011, f. & cert. ef. 3-1-11; PH 18-2016, f. 6-9-16, cert. ef. 7-1-16

333-002-0190
Denial, Revocation, Suspension or Refusal to Renew Status for Certification and Qualification

(1) The Authority shall deny, revoke, suspend or refuse to renew a letter of certification or qualification if:

(a) An applicant for an initial certification or qualification fails to meet the eligibility standards of OAR 333-002-0040.

(b) An applicant for certification or qualification renewal fails to comply with the requirements of OAR 333-002-0170.

(c) An applicant submits information that cannot be verified.

(d) An applicant engages in conduct or practices found by the Authority to be in violation of the National Code of Ethics for Interpreters in Health Care, the National Standards of Practice for Interpreters in Health Care, or the Registry of Interpreters for the Deaf Code of Professional Conduct, as applicable.

(2) The Authority may deny, revoke, suspend, or refuse to renew a certification or qualification, or impose remedial education or corrective actions on an applicant or registry enrollee, if the individual engages in any of the following conduct:

(a) Representing that the applicant or enrollee is an Oregon certified or qualified health care interpreter without having been issued a valid letter of certification or qualification by the Authority.

(b) Knowingly giving false information to the Authority.

(c) Violating the credentialing process by:

(A) Falsifying or misrepresenting education credentials or other information required for admission to an evaluation or assessment.

(B) Having an impersonator take an evaluation or assessment on the applicant or enrollee's behalf.

(C) Impersonating an applicant or enrollee.

(d) Having a credential to provide health care interpreting services in another state, territory or country, or issued by another certifying entity denied, revoked or suspended based on behavior by the individual similar to acts described in this rule.

(e) Being convicted of a state or federal crime which demonstrably relates to the provision of health care interpreting services in this or any other state, territory or country.

(f) Allowing the use of an Authority issued credential by a non-credentialed person.

(g) Presenting another person's credential as the applicant or enrollee's own credential.

(h) Impersonating another Oregon certified or qualified HCI.

(i) Practicing health care interpreting services under a false or assumed name.

(j) Using or attempting to use a credential that has been revoked, suspended, or lapsed.

(k) Practicing or offering to practice beyond the scope of the National Code of Ethics or National Standards of Practice for Interpreters in Health Care, or the Registry of Interpreters for the Deaf Code of Professional Conduct, as applicable.

(l) Engaging in false, deceptive or misleading advertising of the applicant or enrollee's certification or qualification credentials.

(A) False, deceptive or misleading advertising includes but is not limited to advertising health care interpreting services using the terms "Oregon qualified" or "Oregon certified" health care interpreter in any private or public communication or publication when not credentialed by the Authority.

(B) Advertising includes telephone directory listings, business cards, social media networking, or any other source of public communication.

(m) Failing to comply or cooperate with an Authority request in any way, including but not limited to a credentialing action or disciplinary proceeding, including:

(A) Failing to submit requested papers or documents.

(B) Failing to submit a written response to complaints filed with the Authority.

(C) Failing to respond to requests for information issued by the Authority whether or not the applicant or enrollee is accused in the proceeding.

(n) Failing to comply with an "assurance to desist" the applicant or enrollee entered into with the Authority.

Stat. Auth.: ORS 413.558
Stats. Implemented: ORS 413.556 & 413.558
Hist.: PH 18-2006, f. & cert. ef. 8-2-06; PH 2-2011, f. & cert. ef. 3-1-11; PH 18-2016, f. 6-9-16, cert. ef. 7-1-16

333-002-0210
Complaints

(1) Any affected individual or their representative may submit a complaint against a certified or qualified health care interpreter (HCI).

(2) The Authority shall accept a complaint in writing, in a verbal report or in any other format that contains enough information to allow the Authority to investigate the report.

(3) The Authority shall ask the complainant or affected individual to sign a release of information indicating authorization for the Authority to access information to assist the investigation.

(4) If the complaint justifies an investigation, the Authority shall notify the respondent of the allegations and allow for response within a reasonable time with the required deadline for response provided in the notification.

(5) A summary of the complaint allegations shall be made available to the accused HCI.

(6) The Authority shall evaluate the complaint using available evidence.

(7) The complainant, the affected individual and the respondent shall be notified of the outcome in writing.

(8) The Authority may revoke, suspend, or refuse to renew a certification or qualification, or impose remedial education or corrective actions for substantiated complaints that meet the criteria in OAR 333-002-0190.

(9) Reports of discrimination based on protected class shall be submitted and investigated under the requirements of OAR 943 Section 5.

Stat. Auth.: ORS 413.558
Stats. Implemented: ORS 413.556 & 413.558
Hist.: PH 18-2006, f. & cert. ef. 8-2-06; PH 26-2006, f. & cert. ef. 11-16-06; PH 2-2011, f. & cert. ef. 3-1-11; PH 18-2016, f. 6-9-16, cert. ef. 7-1-16

333-002-0230
Hearings

An individual who wishes to contest the denial, non-renewal, suspension or revocation of their registry enrollment, qualification or certification may request a contested case hearing. The contested case hearing process is conducted in accordance with ORS 183.441

through 183.497 and the Attorney General's Uniform and Model Rules of Procedure for the Office of Administrative Hearings, OAR 137-003-0501 through 137-003-0700.

Stat. Auth.: ORS 413.558
Stats. Implemented: ORS 413.556 & 413.558
Hist.: PH 18-2006, f. & cert. ef. 8-2-06; PH 26-2006, f. & cert. ef. 11-16-06; PH 2-2011, f. & cert. ef. 3-1-11; PH 18-2016, f. 6-9-16, cert. ef. 7-1-16

DIVISION 3

PUBLIC HEALTH PREPAREDNESS

333-003-0010
Definitions

For purposes of OAR 333-003-0020 through 333-003-0080, the following definitions apply:

(1) "Authority" means the Oregon Health Authority.

(2) "Bioterrorism" has the meaning given that term in ORS 433.442.

(3) "Communicable disease" has the meaning given that term in ORS 431.260.

(4) "Condition of public health importance" has the meaning given that term in ORS 431.260.

(5) "Health care provider" has the meaning given that term in ORS 433.443.

(6) "HIPAA" means the Health Insurance Portability and Accountability Act of 1996 and regulations adopted there under by the United States Department of Health and Human Services.

(7) "Individually identifiable health information" has the meaning given that term in ORS 433.443.

(8) "Local public health administrator" has the meaning given that term in ORS 431.260.

(9) "Local public health authority" has the meaning given that term in ORS 431.260.

(10) "Public health emergency" has the meaning given that term in ORS 433.442.

(11) "Public health law" has the meaning given that term in ORS 431.260.

(12) "Reportable disease" has the meaning given that term in ORS 431.260.

(13) "State Public Health Director" is the person appointed by the Director of the Oregon Health Authority under ORS 431.035(3) or his or her designee.

(14) "Strategic National Stockpile (SNS)" means the national repository of antibiotics, chemical antidotes, antitoxins, life-support medications, IV administration, airway maintenance supplies, and medical/surgical items, designed to supplement and re-supply state and local public health agencies in the event of a national emergency anywhere and at anytime within the U.S. or its territories.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 431.264 & 433.441 - 433.452
Hist.: PH 25-2004, f. & cert. ef. 7-16-04; PH 8-2008, f. & cert. ef. 5-5-08; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 11-2011, f. & cert. ef. 10-27-11

333-003-0020
Authority of the Public Health Director During a Public Health Emergency

(1) If the Governor declares a Public Health Emergency under ORS 433.441 the Public Health Director may take any action authorized in 433.443 or 431.264.

(2) If the Governor has not declared a public health emergency but the Public Health Director determines that public health actions in addition to those routinely taken by the Authority, the Public Health Director, the local public health authority or local public health administrator are necessary to respond to a public health threat, the Public Health Director may, with approval from the Governor, take any action authorized in ORS 431.264

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 431.262, 431.264 & 433.441 - 433.452
Hist.: PH 25-2004, f. & cert. ef. 7-16-04; PH 8-2008, f. & cert. ef. 5-5-08

333-003-0040
Diagnostic and Treatment Protocols

(1) If the Public Health Director creates diagnostic and treatment guidelines or protocols in response to an emergency under ORS 431.264 or a declared public health emergency under 433.441, the Director shall consult with appropriate medical experts.

(2) Appropriate medical experts may include but are not limited to staff at the Centers for Disease Control and Prevention, a medical advisory group, and Public Health Division staff.

(3) To the extent feasible the Public Health Director shall make every effort to consult with local practicing health care providers regarding the development of diagnostic and treatment guidelines or protocols.

(4) Required diagnostic and treatment guidelines or protocols issued by the Public Health Director shall be in writing, and shall be provided to health care providers, institutions and facilities by one or more of the following means:

(a) Releases through print, radio or television media outlets;

(b) Releases in health care provider publications when timely; or

(c) Mailings, faxes, and/or e-mail or other electronic notification to affected health care providers, facilities and institutions.

(5) If the Governor or Public Health Director requests Strategic National Stockpile (SNS) materials and such a request has been approved, the State Public Health Director may:

(a) Distribute SNS materials to any local health department, hospital, point of dispensing, medical care point, or other health care facility; and

(b) Provide the local public health administrator with permission to dispense SNS materials as needed.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 431.264 & 433.44 1- 433.452
Hist.: PH 25-2004, f. & cert. ef. 7-16-04; PH 8-2008, f. & cert. ef. 5-5-08

333-003-0050
Access to Individually Identifiable Health Information

(1) During a declared public health emergency the Public Health Director and local public health administrators shall be given immediate access to individually identifiable health information.

(2) If the Public Health Director has been authorized to take a public health action under ORS 431.264, the Public Health Director may adopt reporting requirements for health care providers, institutions and facilities for the purpose of obtaining information directly related to the public health threat presented, including the reporting of individually identifiable health information for individuals with or exposed to:

(a) A communicable disease;

(b) A reportable disease; or

(c) A condition of public health importance.

(3) To the extent possible, whenever access to individually identifiable health information is needed under subsections (1) or (2) of this rule the Public Health Director or local public health administrator will provide the request for information in writing.

(4) A written request for information, when provided, shall include, but is not limited to:

(a) The legal authority for requiring the information;

(b) An explanation of why the access to individually identifiable health information is necessary;

(c) A description of the information needed; and

(d) An explanation of how the information must be provided or made available to public health officials.

(5) To the extent possible, the Public Health Director and local public health authority will coordinate requests for information to avoid duplicate requests to the same facility or provider.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 431.264 & 433.441 - 433.452
Hist.: PH 25-2004, f. & cert. ef. 7-16-04; PH 8-2008, f. & cert. ef. 5-5-08

333-003-0065
Civil Penalties

(1) Any person or entity that fails to comply with a protocol, order, other requirement imposed by the Public Health Director

under ORS 431.262, 431.264, or 433.443 or these rules is subject to the imposition of civil penalties not to exceed $500 per day per violation.

(2) In determining the amount of a civil penalty the Authority shall consider whether:

(a) The Authority made repeated attempts to obtain compliance;

(b) The person or entity has a history of noncompliance with public health laws; and

(c) The violation poses a serious risk to the public's health.

(3) Each day a violation continues will be considered an additional violation.

(4) A notice of imposition of civil penalties shall comply with ORS 183.745.

Stat. Auth.: ORS 413.042, 433.441 - 433.452
Stats. Implemented: ORS 433.441 - 433.452
Hist.: PH 8-2008, f. & cert. ef. 5-5-08; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 11-2011, f. & cert. ef. 10-27-11

333-003-0070
Temporary Restriction of Movement

(1) If the Public Health Director or the local public health administrator reasonably believes a person within his or her jurisdiction may have been exposed to a communicable reportable disease or a condition that is the basis for a declaration of a Public Health Emergency under ORS 433.441, the person may be detained for as long as necessary in order to obtain personal contact information and to convey information about the disease or condition.

(2) An individual subject to temporary restriction of movement will be provided with information including but is not limited to:

(a) Information on the disease or other hazard that the person may have been exposed to;

(b) Symptoms of the disease or resulting from exposure to the hazard and what to do in the event such symptoms occur; and

(c) How the person will be notified if it is determined that the individual was exposed to the disease or hazard.

(3) Restriction of movement shall be limited to the shortest duration of time reasonably required to provide health information to the individual and for the individual to provide contact information.

(4) The Authority or the local health public health administrator restricting movement shall use reasonable resources to deliver and collect information in a timely manner.

(5) Any individual failing to comply with the provisions of this section may be subject to the imposition of a public health measure as described in ORS 433.121 or 433.123.

(6) Individually identifiable contact information shall be held in a secure location and destroyed in accordance with applicable record retention schedules when no longer needed.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 433.441 - 433.452
Hist.: PH 25-2004, f. & cert. ef. 7-16-04; PH 8-2008, f. & cert. ef. 5-5-08

333-003-0080
Effect of Declaration Ending

Immediately upon termination of the declaration of the public health emergency, all actions taken pursuant to these rules are terminated unless an emergency related to the declaration has been proclaimed under ORS 401.055 or continuation of the actions is otherwise authorized by law.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 433.441 - 433.452
Hist.: PH 25-2004, f. & cert. ef. 7-16-04; PH 8-2008, f. & cert. ef. 5-5-08

Emergency Health Care Services

333-003-0100
Scope

The rules in OAR 333-003-0100 to 333-003-0210 pertain to the registration and deployment of health care providers to perform emergency health care services during a declared emergency and to the designation of emergency health care centers under ORS 401.651 to 401.670 during a declared emergency.

Stat. Auth.: ORS 401.651 - 401.670
Stats. Implemented: ORS 401.651 - 401.670
Hist.: PH 26-2004, f. & cert. ef. 7-30-04; PH 17-2010, f. & cert. ef. 8-12-10

333-003-0105
Definitions

For purposes of OAR 333-003-0100 through 333-003-0140, the following definitions apply:

(1) "Cooperative Agreement" means an agreement between the Division and a local public health authority under ORS 401.657.

(2) "Credentialing" means granting privileges or permission, including any limitations or limits on the privileges or permission, authorizing a health care provider to provide health care services at a health care facility.

(3) "Credentialing plan" means the procedures established by an emergency health care center for credentialing registrants and volunteers, including but not limited to a plan for verifying that a health care provider is in good standing.

(4) "Declaration" or "declared emergency" means the Governor has declared a state of emergency to exist under ORS 401.055 or 433.441

(5) "Division" means Oregon Health Authority, Public Health Division.

(6) "Emergency health care center" means a health care facility, or any portion thereof designated by the Division or by a local public health authority or any other location designated by the Division or by a local public health authority in accordance with OAR 333-003-0130.

(7) "Emergency health care services" means health care services rendered by a registrant or volunteer during a declared emergency.

(8) "Emergency Support Function 8 (ESF-8)" means the Public Health and Medical Services response for the State of Oregon during a declared emergency.

(9) "Health care facility" means a health care facility as defined in ORS 442.015 that has been licensed under ORS Chapter 441.

(10) "Health care provider" means:

(a) An individual licensed, certified or otherwise authorized or permitted by the laws of this state or another state to administer health care services in the ordinary course of business or practice of a profession; and

(b) A person entered in the emergency health care provider registry under Oregon Laws 2011, chapter 89 and OAR 333-003-0117.

(11) "Health professional regulatory board" has the meaning given that term in ORS 676.160.

(12) "Incident Command System (ICS)" means a standardized on-scene emergency management system that enables multiple agencies and jurisdictions to respond to single or multiple incidents using an integrated organizational structure.

(13)(a) "In good standing" means that:

(A) A health care provider is currently certified, registered or licensed, does not have any disciplinary restrictions placed on any certificate, registration or license, and who is not suspended or on probation with any certifying, registering or licensing agency that issued a certificate, registration or license for any reason; or

(B) At the time the health care provider was last certified, registered or licensed the health care provider:

(i) Did not have any disciplinary restrictions placed on a certificate, registration or license; and

(ii) Was not on probation or did not have a certificate, registration or license revoked or suspended by the certifying, registering or licensing agency that issued the certificate, registration or license, for any reason.

(b) An individual is not in good standing if he or she voluntarily surrendered a certificate, registration or license while under investigation by a certifying, registering, or licensing board or surrendered a certificate, registration or license in lieu of discipline.

(14) "Local public health authority" has the meaning provided in ORS 431.260.

(15) "Registrant" means a health care provider listed on the Registry.

(16) "Registry" means the Health Care Provider Registry established by the Division.

(17) "Volunteer" means a health care provider who is not a registrant or is a registrant but is not deployed by the Registry, who provides emergency health care services at an emergency health care center.

Stat. Auth.: ORS 401.651 - 401.670
Stats. Implemented: ORS 401.651 - 401.670
Hist.: PH 26-2004, f. & cert. ef. 7-30-04; PH 8-2008, f. & cert. ef. 5-5-08; PH 17-2010, f. & cert. ef. 8-12-10; PH 6-2012, f. 3-30-12, cert. ef. 4-1-12

333-003-0110
The Health Care Provider Registry

(1) Under ORS 431.654 the Division is authorized to maintain a registry of health care providers who may, during a declared emergency, be deployed by the Division to provide emergency health care services. The Division shall include the following minimum information in the Registry concerning each registrant:

(a) Name;

(b) Contact information;

(c) Current license, registration or other certification, or previous license, registration or certification; and

(d) Information about the registrant's usual or former practice or specialty, if that information is available and the Division determines it is necessary to include in the Registry.

(2) Health care providers that may be registered include but are not limited to individuals currently or previously within the last 10 years licensed, registered or certified by the:

(a) State Board of Examiners for Speech-Language Pathology and Audiology;

(b) State Board of Chiropractic Examiners;

(c) State Board of Licensed Social Workers;

(d) Oregon Board of Licensed Professional Counselors and Therapists;

(e) Oregon Board of Dentistry;

(f) Board of Examiners of Licensed Dietitians;

(g) State Board of Massage Therapists;

(h) Oregon Board of Naturopathic Medicine;

(i) Oregon State Board of Nursing;

(j) Oregon Board of Optometry;

(k) State Board of Pharmacy;

(l) Oregon Medical Board;

(m) Occupational Therapy Licensing Board;

(n) Physical Therapist Licensing Board;

(o) State Board of Psychologist Examiners;

(p) Board of Medical Imaging;

(q) State Board of Direct Entry Midwifery;

(r) State Board of Denture Technology;

(s) Respiratory Therapist Licensing Board; or

(t) Oregon Health Authority, to the extent that the Authority certifies emergency medical technicians.

(3) The Division may share information about registrants with state and local emergency management departments, local public health authorities, and other state or federal agencies and health care facilities as necessary, for emergency response purposes. Nothing in this section prohibits the Division from sharing registry information for any lawful purpose.

Stat. Auth.: ORS 401.651 - 401.670
Stats. Implemented: ORS 401.651 - 401.670
Hist.: PH 26-2004, f. & cert. ef. 7-30-04; PH 8-2008, f. & cert. ef. 5-5-08; PH 17-2010, f. & cert. ef. 8-12-10; PH 6-2012, f. 3-30-12, cert. ef. 4-1-12

333-003-0115
Registration of Currently Licensed Health Care Providers; Renewal

(1) A health care provider who is currently licensed, registered or certified may apply to the Division to be registered as a health care provider to provide emergency health care services during an emergency.

(2) A health care provider shall apply by completing a form prescribed by the Division and submitting the form in the manner prescribed by the Division.

(3) The Division shall verify that an applicant is in good standing.

(4) The Division may request additional information from an applicant if the application is incomplete or questions arise about the applicant during the Division's verification process.

(5) The Division may require that an applicant undergo a criminal background check if during the application process the Division learns of issues related to the applicant's history that reasonably raises questions about the ability of the applicant to safely provide emergency health care services. If the Division does require a criminal background check an applicant must sign any necessary authorizations for the criminal background check, provide fingerprints if requested and pay any necessary fees to cover the costs for the background check.

(6) The Division shall notify an applicant, in writing, if he or she has been accepted as a registrant and if not, why not.

(7) If an applicant has been accepted, the Division shall also provide the registrant information described in OAR 333-003-0118.

(8) The Division shall issue a registrant a registry identification card once the registrant has completed the orientation and training required in OAR 333-018-0118. The identification card shall:

(a) Identify the registrant;

(b) Indicate that the registrant is registered as an emergency health care provider;

(c) Identify the license or certification held by the registrant; and

(d) Identify the registrant's usual area of practice if that information is available and the authority determines that it is appropriate to provide that information.

(9) The Division shall require each registrant to update his or her registration information every two years, or when changes occur, and a registrant shall be required to sign a form, prescribed by the Division, that indicates the registrant is willing and able to remain on the Registry.

(10) A registrant identification card shall be renewed and provided to a registrant who fulfills the requirements in section (9) of this rule.

(11) The Division may remove a registrant from the Registry if the Division:

(a) Is notified or learns that a registrant is not in good standing with his or her licensing board or certifying agency;

(b) Determines that a registrant is not capable of providing emergency health care services;

(c) Determines that a registrant has a personal or criminal history that calls into question the ability of the registrant to safely provide emergency health care services; or

(d) Determines that a registrant is not complying with these rules.

(12) A registrant removed from the Registry may reapply at any time but must include with his or her application an explanation that describes how the issue that led to removal has been addressed.

(13) The Division may require a registrant to undergo a criminal background check if at any time the Division learns of issues related to the registrant's history that reasonably raises questions about the ability of the applicant to safely provide emergency health care services. If the Division does require a criminal background check a registrant must sign any necessary authorizations for the criminal background check, provide fingerprints if requested and pay any necessary fees to cover the costs for the background check.

Stat. Auth.: ORS 401.651 - 401.670
Stats. Implemented: ORS 401.651 - 401.670
Hist.: PH 26-2004, f. & cert. ef. 7-30-04; PH 8-2008, f. & cert. ef. 5-5-08; PH 17-2010, f. & cert. ef. 8-12-10; PH 6-2012, f. 3-30-12, cert. ef. 4-1-12

333-003-0116
Out-of-State Health Care Providers

(1) The Division may enter into agreements with other states to facilitate the registry of out-of-state health care providers in the Registry established under these rules.

(2) During a state of emergency declared under ORS 401.165 or a state of public health emergency proclaimed under 433.441, a health care provider who is licensed, certified or otherwise authorized or permitted by the laws of another state to administer health care services and who is registered under these rules may administer health care services in this state as if the health care provider were licensed in this state.

Stat. Auth.: ORS 401.670
Stats. Implemented: ORS 401.655
Hist.: PH 17-2010, f. & cert. ef. 8-12-10

333-003-0117
Registration of Formerly Licensed Health Care Providers; Renewal

(1) A person who was licensed, certified or otherwise authorized to provide health care services not more than 10 years prior to the date of application, may apply to the Division to be registered as a health care provider to provide emergency health care services during an emergency.

(2) A person described in section (1) of this rule shall apply by completing a form prescribed by the Division and submitting the form in the manner prescribed by the Division.

(3) An applicant shall provide evidence from the entity that licensed, certified, or otherwise authorized the applicant to previously provide health care services that verifies that the applicant was in good standing at the time the applicant surrendered his or her license, certification or authorization to provide health care services.

(4) The Division may request additional information from an applicant if the application is incomplete or questions arise about the applicant during the Division's verification process.

(5) An applicant shall undergo a criminal background check and shall sign any necessary authorizations and pay any necessary fees for the criminal background check.

(6) The Division shall notify an applicant, in writing, if he or she has been accepted as a registrant and if not, why not.

(7) If an applicant has been accepted, the Division shall also provide the registrant information described in OAR 333-003-0118.

(8) The Division shall issue a registrant a registry identification card once the registrant has completed the orientation and training required in OAR 333-018-0118. The identification card shall:

(a) Identify the registrant;

(b) Indicate that the registrant is registered as an emergency health care provider;

(c) Identify the license or certification previously held by the registrant; and

(d) Identify the registrant's former area of practice if that information is available and the Division determines that it is appropriate to provide that information.

(9) The Division shall require each registrant to update his or her registration information every two years, or when changes occur, and a registrant shall be required to sign a form, prescribed by the Division, that indicates the registrant is willing and able to remain on the Registry. A registrant shall provide documentation of completed continuing education credits with the renewal form.

(10) The Division shall conduct a criminal background check on registrants registered under this rule every five years. A registrant is responsible for signing any necessary authorizations and paying any necessary fees.

(11) A registrant identification card shall be renewed and provided to a registrant who fulfills the requirements in section (9) and (10) of this rule.

(12) The Division may remove a registrant from the Registry if the Division:

(a) Is notified or learns that a registrant is not in good standing with his or her licensing board or certifying agency;

(b) Determines that a registrant is not capable of providing emergency health care services;

(c) Determines that a registrant has a personal or criminal history that calls into question the ability of the registrant to safely provide emergency health care services; or

(d) Determines that a registrant is not complying with these rules.

(13) A registrant removed from the Registry may reapply at any time if the registrant meets the criteria in section (1) of this rule but must include with his or her application an explanation that describes how the issue that led to removal has been addressed.

Stat. Auth.: ORS 401.651 - 401.670
Stats. Implemented: ORS 401.651 - 401.670
Hist.: PH 6-2012, f. 3-30-12, cert. ef. 4-1-12

333-003-0118
Duties of Registrants

(1) A registrant is required to complete an orientation session offered or approved by the Division and complete mandatory training offered or approved by the Division including but not limited to ICS training, prior to receiving an identification card.

(2) A registrant has one year from the date the registrant is notified of acceptance into the Registry to complete the orientation and required training or the Division shall remove the registrant's name from the Registry.

(3) If the Division notifies a registrant of an activation, the registrant shall respond to the Division within 24 hours whether or not the registrant is willing to be activated and deployed in accordance with OAR 333-003-0125.

(4) A registrant is required to notify the Division, as soon as practicable, but within 30 days, of the following:

(a) A change in mailing address, phone number, or electronic mail address;

(b) A change in licensure status, certification or registration status; and

(c) A change in mental or physical health that renders a registrant unable to perform emergency health care services.

(5) A registrant shall immediately notify the Division if a registrant's identification card is lost or stolen. The Division shall replace a lost or stolen identification card and may charge a fee for the replacement card.

(6) A registrant may request removal from the Registry at any time by notifying the Division, in writing, of the request, and by returning the identification card described in OAR 333-003-0115. Upon receipt of such request and verification that it came from the registrant, the Division shall remove the registrant from the Registry.

(7) If at any time a registrant is notified by the Division that the registrant has been removed from the Registry, the registrant shall return the identification card described in OAR 333-003-0115 to the Division within 10 days of the date the notification was mailed or electronically mailed. Removed registrants may re-apply at a later date subject to Division approval.

(8) A registrant may only provide health care services during an emergency that the registrant is competent to perform.

Stat. Auth.: ORS 401.670
Stats. Implemented: ORS 401.654
Hist.: PH 17-2010, f. & cert. ef. 8-12-10; PH 6-2012, f. 3-30-12, cert. ef. 4-1-12

333-003-0119
Criminal Background Checks

The Division shall perform criminal background checks in accordance with OAR chapter 943, division 7, or through the Oregon State Police.

Stat. Auth.: ORS 401.670
Stats. Implemented: ORS 401.654
Hist.: PH 6-2012, f. 3-30-12, cert. ef. 4-1-12

333-003-0120
Health Care Providers Not Included in the Registry

A volunteer may provide emergency health care services at a designated emergency health care center if authorized to do so pur-

suant to the designated emergency health care center's emergency operations plan and credentialing plan.

Stat. Auth.: ORS 401.651 - 401.670
Stats. Implemented: ORS 401.651 - 401.670
Hist.: PH 26-2004, f. & cert. ef. 7-30-04; PH 17-2010, f. & cert. ef. 8-12-10

333-003-0125
Activation of Registrants

(1) The Division may activate the Registry in the event of a declaration and direct registrants willing to provide emergency health care services to proceed to any place in Oregon where emergency health care services are required by reason of the emergency or crisis.

(2) The Division may also activate the Registry pursuant to the Emergency Management Assistance Compact and the Pacific Northwest Emergency Management Arrangement and direct registrants willing to provide emergency health care services to proceed to another state where emergency health care services are required by reason of the emergency or crisis in that state.

(3) The activation of the Registry may be used to support the state Emergency Coordination Center, the State Emergency Management Plan and to implement ESF 8 plans, protocols, and procedures to integrate registrants into the state and local emergency response.

(4) The Division shall notify registrants of activation by phone, electronic mail, or any other means of communications.

(5) The Division shall provide, at a minimum, the following to a registrant willing to be deployed:

(a) A mission order;

(b) A description of items needed during the deployment; and

(c) If applicable, items that will be provided to a registrant.

(6) A registrant willing to be deployed shall bring his or her registry identification card and driver's license to the deployment site.

(7) A registrant may decline to be deployed at the time the registrant is notified of the activation. A registrant shall remain on the Registry whether or not the registrant agrees to be deployed unless the registrant notifies the Division in accordance with OAR 333-003-0118 that he or she wants to be removed from the Registry.

(8) If a registrant deployed under these rules provides emergency health care services at a designated emergency health care center the registrant must provide those services in accordance with the emergency operations plan and credentialing plan adopted by the designated emergency health care center.

(9) In anticipation of a declaration of emergency or during a declared emergency the Division may register health care providers without complying with OAR 333-003-0115 and provide just-in-time orientation and training. Under this section the Division shall verify licensure status as quickly as possible and shall issue the health care provider a temporary identification card.

Stat. Auth.: ORS 401.651 - 401.670
Stats. Implemented: ORS 401.651 - 401.670
Hist.: PH 26-2004, f. & cert. ef. 7-30-04; PH 8-2008, f. & cert. ef. 5-5-08; PH 17-2010, f. & cert. ef. 8-12-10; PH 6-2012, f. 3-30-12, cert. ef. 4-1-12

333-003-0130
Designation of Emergency Health Care Centers

(1) The Division may designate a health care facility, a portion thereof, or any location as an emergency health care center.

(2) During a declared emergency a designated emergency health care center may be used for:

(a) Evaluation and referral of individuals affected by the emergency;

(b) Provision of health care services; and

(c) Preparation of patients for transportation.

(3) A local public health authority may designate a health care facility, a portion thereof, or any location as an emergency health care center if authorized to do so in a cooperative agreement executed by the Division and the local public health authority.

(4) In order to be designated as an emergency health care center a health care facility is required to have an emergency operations plan that includes but is not limited to:

(a) An ICS structure;

(b) Procedures for increasing staff during an emergency;

(c) A credentialing plan that:

(A) Governs the use of registrants and volunteers;

(B) Provides for emergency privileges to be granted upon presentation of any of the following:

(i) A current picture hospital ID card;

(ii) A current license to practice and a valid picture ID; issued by a state, federal or regulatory agency;

(iii) Identification indicating that the individual is a member of Oregon Disaster Medical Assistance Team (ODMT);

(iv) Identification indicating that the individual has been granted authority to render patient care in emergency circumstances, such authority having been granted by federal, state, or municipal entity; or

(v) Presentation by current hospital or medical staff members(s) with personal knowledge regarding practitioner's identity.

(d) A description of individual(s) responsible for granting emergency privileges;

(e) A process for making decisions about whether to grant privileges to registrants or volunteers on a case-by-case basis and at the discretion of the individual(s) responsible for granting emergency privileges;

(f) A mechanism to readily identify the emergency-privileged individuals; and

(g) A process, to begin as soon as the situation that gave rise to the declaration allows, for verifying the license and any other information relevant to a registrant or volunteer who is granted emergency privileges under the credentialing plan.

(5) If the Division designates a location other than a health care facility as an emergency health care center the Division shall utilize its own emergency operations plan or ensure that the location is operated using a plan that includes the provisions described in section (4) of this rule.

(6) The Division shall consider the following in making a decision to designate a facility or another location as an emergency health care center:

(a) Whether the existing health care system is overwhelmed or incapacitated;

(b) Whether patients with a particular communicable disease need to be concentrated at particular locations or one location;

(c) Whether registrants are being activated to provide care at particular health care facilities or whether registrants or volunteers are needed to provide emergency health care services;

(d) Whether it is necessary for the state to direct activities at a health care facility or other location where emergency health care services are to be provided; or

(e) Whether a health care facility is being asked to perform services outside of the general scope of services it customarily provides.

(7) In order to facilitate the designation process during a declared emergency, the Division shall make every effort to pre-designate health care facilities, a portion thereof, or any location as an emergency health care center. Pre-designation shall include review and approval of the facility's emergency operations plan. For a location that is not a health care facility, the Division shall review the operations plan that would be utilized at that location.

(8) A facility or location that has been pre-designated does not automatically become a designated emergency health center upon a declaration. Designation shall be made in accordance with section (9) of this rule.

(9) If a facility or location is designated as an emergency health care center the Division shall notify the person in charge of a facility or location in writing and shall issue orders to the emergency health care center that identify the emergency response required by the Division and the time period that the designation is in effect. The liability protection described in OAR 333-003-0210 only extends to activities undertaken by a designated emergency health care center that are directed by the Division.

(10) To the extent practicable, the Division shall request that a facility accept the designation as an emergency health care center.

However, acceptance of a designation is not required for the Division to exercise its authority under ORS 401.657.

(11) If the Division pre-designates a facility, portion thereof, or another location in accordance with section (7) of this rule, the Division shall review the applicable emergency operations plan every two years to ensure it remains acceptable.

(12) A designated emergency health care center may determine the services to be provided by a registrant or volunteer deployed under these rules.

Stat. Auth.: ORS 401.651 - 401.670
Stats. Implemented: ORS 401.651 - 401.670
Hist.: PH 26-2004, f. & cert. ef. 7-30-04; PH 8-2008, f. & cert. ef. 5-5-08; PH 17-2010, f. & cert. ef. 8-12-10

333-003-0140
Training

(1) The Division may require or otherwise make available to registrants training that the Division determines necessary or beneficial to the provision of emergency health care services that may be rendered by registrants pursuant to ORS 401.651 through 401.670 and these rules, including but not limited to training in the emergency response system structure, operations, emergency preparedness and table top or other emergency response exercises. The Division shall not require training that is related to a registrant's professional license.

(2) A person who is registered in accordance with OAR 333-003-0117 shall:

(a) Prior to being eligible for activation, and thereafter every three years, complete the following training and provide documentation of completion to the Division.

(A) First Aid that includes CPR and AED use;

(B) Basic Disaster Life Support;

(C) Triage; and

(D) Psychological First Aid.

(b) Complete at least a total of six hours of continuing education credits every two years on the following subjects or substantially similar subjects:

(A) Disaster medicine;

(B) Psychological first aid;

(C) Disaster life support; and

(D) Wilderness first aid or medicine.

Stat. Auth.: ORS 401.651 - 401.670
Stats. Implemented: ORS 401.651 - 401.670
Hist.: PH 26-2004, f. & cert. ef. 7-30-04; PH 17-2010, f. & cert. ef. 8-12-10; PH 6-2012, f. 3-30-12, cert. ef. 4-1-12

333-003-0200
Public Health Emergency Plans

The Public Health Director and local public health authorities shall use an incident command system framework in their respective public health emergency plans.

Stat. Auth.: ORS 431.266
Stats. Implemented: ORS 431.266
Hist.: PH 8-2008, f. & cert. ef. 5-5-08

333-003-0210
Liability Protection; Workers' Compensation

(1) Registrants and volunteers who perform emergency health care services in accordance with ORS 401.651 through 401.670 and these rules are agents of the state under 30.260 through 30.300 for the purposes of any claims arising out of services that are provided under 401.651 through 401.670 and these rules pursuant to directions from a public body and that are within the course and scope of the registrant's or volunteer's duties, without regard to whether the registrant or volunteer is compensated for the services.

(2) If the Governor declares an emergency a designated emergency health care center and persons operating a designated emergency health care center are agents of the state under ORS 30.260 through 30.300 for the purposes of any claims arising out of services that are provided through the designated emergency health care center pursuant to directions from a public body and that are within the course and scope of the duties of the health care facility or other person, without regard to whether the health care facility or other person is compensated for the services.

(3) A registrant participating in training authorized by Oregon Health Authority under ORS 401.651 through 401.670 and OAR 333-003-0140 is an agent of the state under ORS 30.260 through 30.300 for the purposes of any claims arising out of that training.

(4) The provisions of section (2) of this rule apply only to a designated emergency health care center that has adopted an emergency operations plan and credentialing plan that governs the use of registrants and volunteers. An emergency operations plan and a credentialing plan must comply with these rules.

(5) A registrant shall also be considered a qualified emergency services volunteer under ORS 401.358 through 401.368 for the purpose of receiving workers' compensation coverage if injured in the course and scope of providing emergency health care services.

(6) A volunteer must meet the definition of a qualified emergency services volunteer under ORS 401.358 in order to receive workers' compensation coverage under 401.358 through 401.368.

Stat. Auth.: ORS 401.670
Stats. Implemented: ORS 401.667
Hist.: PH 17-2010, f. & cert. ef. 8-12-10; PH 6-2012, f. 3-30-12, cert. ef. 4-1-12

DIVISION 4

OREGON CONTRACEPTIVE CARE

333-004-0000
Description of OregonContraceptiveCare

OregonContraceptiveCare (CCare) is a Medicaid waiver demonstration project approved by the Centers for Medicare and Medicaid Services (CMS) to provide comprehensive contraceptive management services to eligible low-income Oregon residents statewide. OregonContraceptiveCare extends Medicaid coverage for contraceptive management services to Oregon residents with family incomes at or below 250 percent of the Federal Poverty Level (FPL) through a contract network of qualified agencies. The administrative rules set forth for this project apply only to agencies with an approved medical services agreement (MSA) to provide contraceptive management services through this project. Other reproductive health services and reimbursement covered by Medicaid are governed by Oregon Health Authority, Division of Medical Assistance Program's administrative rules and federal guidelines.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.032
Hist.: PH 4-2005, f. & cert. ef. 2-18-05; PH 5-2007, f. 4-9-07, cert. ef. 4-23-07; PH 19-2012, f. & cert. ef. 12-26-12

333-004-0010
Definitions

(1) "Acquisition cost" means the net amount paid per invoice line item to a pharmaceutical manufacturer, supplier or distributor for a contraceptive supply, plus any shipping and handling that is supported by the invoice.

(2) "Agency" means an entity enrolled by the Reproductive Health Program (RH) to provide CCare covered services at clinic site(s) to clients.

(3) "Authority" means the Oregon Health Authority.

(4) "CCare Eligibility Database" means the web-based database designed and managed by the Center for Prevention and Health Promotion (Center) for the statewide collection, tracking and storage of CCare client eligibility information.

(5) "Center" means the Center for Prevention and Health Promotion, within Public Health Division, Oregon Health Authority.

(6) "Citizenship verification" means confirming a client's claim of U.S. citizenship through documentation of a certified birth record, passport or other document(s) deemed acceptable proof of U.S. citizenship verification by the federal government.

(7) "CLIA" means the Clinical Laboratory Improvement Amendments of 1988, which establishes quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results, and allows for certification of clinical laboratories operating in accordance with these federal amendments.

(8) "Client" means a person of any age or gender who is enrolled in and receives contraceptive management services from CCare.

(9) "Clinic" means a site within an agency that provides CCare billable services to eligible clients.

(10) "Clinic Visit Record" or "CVR" means the form or set of information that is completed for each client visit, and that is used as a data collection instrument and a billing claim form for CCare.

(11) "CMS" means the Centers for Medicare and Medicaid Services, located within the federal Department of Health and Human Services.

(12) "Contraceptive management" means a limited scope of reproductive health services as described in OAR 333-004-0040.

(13) "Established client," for the purpose of mail ordered supplies, means a person who has been obtaining contraceptive services/supplies from the prescribing clinic for a minimum of three consecutive months.

(14) "FPL" means the federal poverty level guidelines established each year by the Department of Health and Human Services, used to determine eligibility for CCare other federally funded programs.

(15) "Individual" means a person who has applied for CCare, but has not yet been verified as eligible for services.

(16) "Lawful Permanent Resident" or "LPR" means a person who, notwithstanding other eligibility requirements, is a qualified non-citizen as described in OAR 461-120-0125(14).

(17) "Medical Services Agreement" or "MSA" means an agreement that sets forth the relationship between the Center and the enrolling agency regarding payment by the Center for contraceptive management services, supplies, or devices.

(18) "Nationally-recognized standard of care" means a diagnostic, screening, or treatment process recognized by a national organization, including but not limited to the American Cancer Society (ACS), American College of Obstetrics and Gynecologists (ACOG), U.S. Preventative Services Task Force (USPSTF), or the U.S. Medical Eligibility Criteria (USMEC).

(19) "OregonContraceptiveCare" or "CCare" means the Medicaid waiver program that provides statewide reproductive health services to eligible clients that is administered by the Reproductive Health Program within the Authority.

(20) "Project number" means the administrative number assigned by the RH to an agency.

(21) "Provider" means a licensed health care professional operating within a scope of practice, who works for an agency that is authorized by the Authority to bill for contraceptive management services for eligible CCare clients.

(22) "Refugee/Asylee" means a person admitted to the United States because of a well-founded fear of persecution in their homeland due to race, religion or political opinion, as determined by the United States Citizenship and Immigration Services.

(23) "Reproductive Health Program" or "RH" means the program within the Center for Prevention and Health Promotion that administers CCare.

(24) "Reproductive health services" means comprehensive family planning and related preventive health services provided to clients, including but not limited to:

(a) Patient education and counseling;

(b) Breast and pelvic examinations;

(c) Breast and cervical cancer screening;

(d) Sexually transmitted disease (STD) prevention education, counseling, testing and referral; and

(e) Pregnancy diagnosis and counseling.

(25) "RH program manual" means the reference guide provided by RH to agencies, outlining the scope and policies of the CCare program. This manual is available online by selecting "Program Manuals" at www.healthoregon.org/rhmaterials.

(26) "School-Based Health Center" means a health center certified by the School-Based Health Center Program located within the Center for Prevention and Health Promotion.

(27) "Site number" means the administrative number assigned by RH to each clinic within a participating CCare agency.

Stat. Auth.: ORS 413.042

Stats. Implemented: ORS 413.032

Hist.: PH 4-2005, f. & cert. ef. 2-18-05; PH 3-2007(Temp), f. 2-23-07, cert. ef. 4-1-07 thru 9-28-07; PH 5-2007, f. 4-9-07, cert. ef. 4-23-07; PH 2-2009, f. & cert. ef. 3-2-09; PH 10-2010, f. & cert. ef. 6-30-10; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 11-2011, f. & cert. ef. 10-27-11; PH 19-2012, f. & cert. ef. 12-26-12

333-004-0020
Client Eligibility

(1) In order to be eligible for CCare, an individual must:

(a) Have a household income and size at or below 250 percent of the FPL;

(b) Reside in Oregon;

(c) Not be sterile, have an unconfirmed sterilization status, or have been sterilized less than six months prior to eligibility determination;

(d) If female, be less than 60 years of age;

(e) Provide a valid Social Security Number (SSN) as required by 42 USC 1320b-7; and

(f) Be a citizen of the United States, with acceptable proof of citizenship verification and identity; or

(g) Meet the definition of Lawful Permanent Resident as described in OAR 333-004-0010; or

(h) Meet the definition of refugee/asylee as described in OAR 333-004-0010 and provide acceptable proof of refugee/asylee status.

(2) An individual who is in the custody of a law enforcement agency or is an inmate of a public institution, including a juvenile detention facility, is not eligible for CCare.

(3) An individual who receives or who is eligible for the Citizen/Alien-Waived Emergency Medical benefit package under Title XIX is not eligible for CCare.

(4) An individual enrolled in another Medicaid program that provides family planning benefits is not eligible for CCare.

(5) Eligibility for CCare does not constitute eligibility for any other medical assistance program. Eligibility for reproductive health services, including contraceptive management, as part of any other medical program is determined by the eligibility requirements for that specific program.

Stat. Auth.: ORS 413.042

Stats. Implemented: ORS 413.032

Hist.: PH 4-2005, f. & cert. ef. 2-18-05; PH 5-2007, f. 4-9-07, cert. ef. 4-23-07; PH 2-2009, f. & cert. ef. 3-2-09; PH 19-2012, f. & cert. ef. 12-26-12

333-004-0030
Client Enrollment

(1) An individual is considered eligible for CCare upon submission of the following items to the CCare agency:

(a) A signed, completed, and dated CCare enrollment form that includes SSN and appropriate residency and income information; applicants under age 20 can be enrolled based on their own income, whether living at home or on their own; and

(b) If the individual claims U.S. citizenship, acceptable proof of U.S. citizenship verification and identity.

(2) All CCare client eligibility information must be recorded in the CCare Eligibility Database by the enrolling CCare agency.

(3) Final determination of eligibility and enrollment into CCare is made by RH based on the information recorded in the CCare Eligibility Database.

(a) An individual's enrollment in CCare shall be suspended by RH if it determines that the individual's SSN is invalid or income is above the eligibility threshold.

(b) An individual shall have 45 days to submit a valid SSN and income information to the CCare agency or the individual's enrollment in CCare shall be terminated by RH.

(4) An enrolling CCare agency must retain a current, signed enrollment form and a copy of any citizenship and identity documents provided by the client as described in OAR 333-004-0120(3).

(5) If a CCare agency enrolls an individual who is deemed ineligible by RH, the individual's eligibility shall be terminated by RH.

(6) A client's eligibility is effective for one year from the date of enrollment. The date of enrollment must be on or before the first date of service.

(7) CCare enrollment forms may not be backdated. An individual or enrolling agency that backdates a form shall be considered by RH to have committed fraud.

(8) An individual who meets all eligibility criteria apart from acceptable proof of U.S. citizenship verification may be granted by RH a reasonable opportunity period (ROP) of 45 days during which time the individual may receive services. An individual must have U.S. citizenship verified before he or she can be enrolled in CCare.

Stat. Auth.: ORS 413.042

Stats. Implemented: ORS 413.032

Hist.: PH 4-2005, f. & cert. ef. 2-18-05; PH 5-2007, f. 4-9-07, cert. ef. 4-23-07; PH 2-2009, f. & cert. ef. 3-2-09; PH 19-2012, f. & cert. ef. 12-26-12

333-004-0040

Covered Services

(1) CCare covers contraceptive management services that are a limited scope of reproductive health services directly related to initiating or obtaining a contraceptive method and maintaining effective use of that method. CCare agencies shall only be reimbursed for visits at which the primary service is contraceptive initiation or management, and not for excluded services described in OAR 333-004-0050.

(2) Contraceptive management services based on a nationally-recognized standard of care include:

(a) An annual exam payable once each year;

(b) Clinically indicated follow-up visits to evaluate effectiveness of a contraceptive method;

(c) Management of side effects related to a contraceptive method;

(d) Changing a contraceptive method if medically necessary or requested by the client;

(e) Reproductive health counseling and education; and

(f) Laboratory tests, medical procedures (including vasectomy), and pharmaceutical supplies and devices directly related to contraceptive management as documented in clinic protocol.

(3) Each client may receive up to a one-year supply of contraceptives from the CCare agency.

Stat. Auth.: ORS 413.042

Stats. Implemented: ORS 413.032

Hist.: PH 4-2005, f. & cert. ef. 2-18-05; PH 5-2007, f. 4-9-07, cert. ef. 4-23-07; PH 2-2009, f. & cert. ef. 3-2-09; PH 19-2012, f. & cert. ef. 12-26-12

333-004-0050

Excluded Services

(1) Services and laboratory tests not described in OAR 333-004-0040 are not covered by CCare for any eligible client. If a client accepts financial responsibility for a non-covered service that is received during a visit, payment arrangements are between the agency and the client.

(2) RH shall not pay for any expense incurred for any of the following services or items:

(a) Sterilizations for female clients;

(b) Treatment for infections;

(c) Prenatal care, including pregnancy confirmations;

(d) Repeat pap smears not associated with contraceptive management services;

(e) Hysterectomies or abortions;

(f) Transportation to or from a clinic appointment;

(g) Procedures performed for medical reasons, whether or not the procedure results in preventing or delaying pregnancy or restoring fertility;

(h) Any other medical service or laboratory test that is not described in OAR 333-004-0060(6) and whose primary purpose is other than contraceptive management; and

(i) A clinic visit that has the purpose of ensuring or reinforcing the client's effective use of a contraceptive method and where no medical decision-making is required (behavior modification visit).

Stat. Auth.: ORS 413.042

Stats. Implemented: ORS 413.032

Hist.: PH 4-2005, f. & cert. ef. 2-18-05; PH 5-2007, f. 4-9-07, cert. ef. 4-23-07; PH 2-2009, f. & cert. ef. 3-2-09; PH 19-2012, f. & cert. ef. 12-26-12

333-004-0060

Standards of Care for Contraceptive Management Services

Participating CCare agencies shall provide contraceptive management services according to the following standards.

(1) Informed Consent. The client's decision to participate in and consent to receive contraceptive management services must be voluntary and without bias or coercion.

(a) The informed consent process, provided verbally and supplemented with written materials, must be presented in a language the client understands.

(b) A signed consent must be obtained from the client receiving contraceptive management services.

(c) A separate, signed contraceptive method-specific consent must be obtained from the client for each prescription contraceptive method received.

(2) Confidentiality. Services must be provided in a manner that respects the client's privacy and dignity in accordance with OAR 333-004-0060(7)(b).

(a) Clients must be assured of the confidentiality of services and of their medical and legal records.

(b) Records cannot be released without written client consent, except as may be required by law, or otherwise permitted by the Health Insurance Portability and Accountability Act (HIPAA).

(3) Availability of Contraceptive Services. A broad range of Federal Drug Administration (FDA)-approved contraceptive methods and their applications, consistent with recognized medical practice standards, as well as fertility awareness methods must be available on-site at the clinic for dispensing to the client at the time of the visit.

(a) If the agency's clinical staff lack the specialized skills to provide vasectomies, intra-uterine devices (IUDs) or subdermal contraceptives, or if there is insufficient volume to ensure and maintain high skill level for these procedures, clients must be referred to another qualified provider for these procedures.

(b) Clients shall be able to get their first choice of contraceptive method during their visits unless there are specific contraindications.

(c) Contraceptive methods, including emergency contraception, must be available at the clinic site and available to the client at the time of service, except as provided in OAR 333-004-0060(8)(a).

(4) Linguistic and Cultural Competence. All services, support and other assistance must be provided in a manner that is responsive to the beliefs, interpersonal styles, attitudes, language

and behaviors of the client receiving services, and in a manner that has the greatest likelihood of ensuring maximum program participation.

(a) The agency shall employ bilingual or bicultural staff, personnel or volunteers skilled or certified in the provision of medical and clinical interpretation during all clinic encounters for clients with limited English proficiency or who otherwise need this level of assistance. All persons providing interpretation services must adhere to confidentiality guidelines.

(b) The agency must assure the competency of language assistance provided to limited English proficiency clients by interpreters and bilingual staff. Family and friends shall not be used to provide interpretation services, unless requested by the client.

(c) The agency must make interpretation services available to all clients needing or requesting such assistance at no cost to the client. The agency must notify clients in need of interpretation services of the availability of such services in accordance with the Civil Rights Act of 1964.

(d) The agency shall make easily understandable print materials available to clients and post signage in the languages of groups represented or commonly encountered in the service area.

(e) All print, electronic and audiovisual materials shall be appropriate in terms of the client's language and literacy level. A client's need for alternate formats must be accommodated.

(5) Access to Care. Services covered by CCare must be provided without cost to eligible clients. Clients must be informed of the scope of services available through the program.

(a) Appointments for established clients shall be available within a reasonable time period, generally less than two weeks. New clients who cannot be seen within this time period shall be referred to other qualified provider agencies in the area.

(b) Clinics with the appropriate license from the Oregon Board of Pharmacy may offer established clients the option of receiving their contraceptive methods by mail.

(A) Use of this option is at the discretion of the client; it cannot be offered as the only way in which to receive contraceptive methods.

(B) Contraceptive methods that require a written prescription may only be mailed to established clients who have been using the method(s) for at least three months, with no problems or contraindications.

(C) Non-prescription methods may be mailed to any established client, regardless of the client's previous use of the method(s).

(D) Clients must not incur any cost for the option of receiving contraceptive methods through the mail.

(E) Clinics must package and mail supplies in a manner that ensures the integrity of contraceptive packaging and effectiveness of the method upon delivery.

(c) Although not covered by CCare, treatment and supplies for sexually transmitted infections must be available at the clinic site, or by referral.

(d) Clients in need of additional medical or psychosocial services beyond the scope of the agency must be provided with information about available local resources, including domestic violence and substance abuse related services. Clients must also be given a brochure listing locations of free or low-cost primary care services in the area.

(e) All services must be provided to eligible clients without regard to age, marital status, race, parity, disability, gender identity, or sexual orientation.

(f) All counseling and referral-to-care options appropriate to a positive or negative pregnancy test result during authorized contraceptive services must be provided in an unbiased manner, allowing the client full freedom of choice between prenatal care, adoption counseling or pregnancy termination services.

(6) Clinical and Preventive Services.

(a) The scope of contraceptive management services offered to women and female-bodied clients at each CCare clinic site must include:

(A) A comprehensive health history, including health risk behaviors and a complete obstetrical, gynecological, contraceptive, personal and family medical history; and a sexual health history, in conjunction with contraceptive counseling;

(B) An initial physical examination including cervical cancer screening as indicated, that follows a nationally-recognized standard of care.

(C) Routine laboratory tests related to the decision-making process for contraceptive choices;

(D) Provision of a broad range of FDA-approved contraceptive methods, devices, supplies, and procedures, including emergency contraception;

(E) Follow-up care for maintenance of a client's contraceptive method or for change of method;

(F) Information about providers available for meeting primary care needs and direct referral for needed medical services not covered by CCare, including management of high-risk conditions and specialty consultation if needed; and

(G) Preventive and control services for communicable diseases, provided within the context of a contraceptive management visit, including:

(i) Testing and diagnosis for sexually transmitted infections (STIs) as indicated; and

(ii) Reporting of STIs, as required, to appropriate public health agencies for contact management, prevention, and control.

(b) The scope of contraceptive management and clinical preventative services offered to men and male-bodied clients must include:

(A) A health history, including health risk behaviors and a sexual health history, in conjunction with contraceptive counseling and provision of contraceptive barrier methods;

(B) Vasectomy or referral for vasectomy, as appropriate;

(C) Vasectomy counseling, including a comprehensive health history that includes health risk behaviors and a complete contraceptive, personal and family medical history; and a sexual health history;

(D) Physical examination if indicated within the context of a contraceptive management visit;

(E) Information about providers available for meeting primary care needs and direct referral for needed medical services not covered by CCare, including management of high-risk conditions and specialty consultation if needed; and

(F) Preventive and control services for communicable diseases, provided within the context of a contraceptive management visit, including:

(i) Testing and diagnosis for sexually transmitted infections (STIs) as indicated; and

(ii) Reporting of sexually transmitted infections (STI), as required, to appropriate public health agencies for contact management, prevention, and control.

(c) All services must be documented in the client's medical record.

(7) Education and Counseling Services. The following elements comprise the required education and counseling services that must be provided to all contraceptive management clients:

(a) Initial clinical assessment and re-assessment as needed, of the client's contraceptive management educational needs and knowledge about reproductive health, including:

(A) Counseling and education about a broad range of FDA-approved contraceptive methods, devices, supplies, and procedures, including emergency contraception;

(B) A description of services and clinic procedures;

(C) Relevant reproductive anatomy and physiology;

(D) Preventive health care, nutrition, preconception health maintenance, pregnancy plans, and STI and Human Immunodeficiency Virus (HIV) prevention;

(E) Psychosocial issues, such as partner relationship and communication, risk-taking, and decision-making; and

(F) An explanation of how to locate and access primary care services not covered by CCare.

(b) Initial and all subsequent education and counseling sessions must be provided in a way that is understandable to the client and conducted in a manner that respects the dignity and

privacy of the client and facilitates the client's ability to make informed decisions about reproductive health behaviors and goals, and must include:

(A) An explanation of the results of the physical examination and the laboratory tests;

(B) Information on where to obtain 24-hour emergency care services;

(C) The option of including a client's partner in the education/counseling session, and other services at the client's discretion; and

(D) Effective educational information that takes into account diverse cultural and socioeconomic factors of the client and the psychosocial aspects of reproductive health.

(c) Each client must be provided with adequate information to make an informed choice about contraceptive management methods, including:

(A) A general verbal or written review of all FDA-approved contraceptive methods, including sterilizations and emergency contraception, along with the opportunity for the client to ask questions. Documentation of this method education must be maintained in the client record;

(B) A description of the implications and consequences of sterilization procedures, if provided;

(C) Specific instructions for care, use, and possible danger signs for the selected method. Documentation of method-specific information must be maintained in the client record;

(D) The opportunity for questions concerning procedures or methods; and

(E) Written information about how to obtain services for contraceptive management related complications or emergencies.

(d) Clinicians and other agency staff persons providing education and counseling must be knowledgeable about the psychosocial and medical aspects of reproductive health, and trained in client-centered counseling techniques. Agency staff must make referrals for more intensive counseling as indicated.

(8) Exceptions:

(a) School-Based Health Centers are exempt from the requirement to make contraceptive methods available for on-site dispensing described in section (3) and subsection (5)(b) of this rule. Because some school boards prohibit dispensing contraceptives on school grounds, School-Based Health Centers may offer contraceptive methods to clients either on-site or by referral. When offered by referral, School-Based Health Centers must have an established referral agreement in place, preferably with another CCare clinic. RH must be notified of the parties involved in order to ensure proper billing and audit practices. When the referral clinic participates in CCare, that clinic may submit claims directly to CCare for reimbursement of the dispensed supplies. When referral clinics do not participate in CCare, payment arrangements must be made between the referring and receiving clinics. Dispensing by any provider must not result in a charge to the client.

(b) Non-School-Based Health Center sites:

(A) Agencies may bill CCare for client counseling and education services conducted at a school site, grade 12 and under, if the site meets the following criteria:

(i) The school site must have no established School-Based Health Center;

(ii) The school site must be within a RH-approved distance from the enrolled CCare agency to ensure adequate access to client contraceptive method of choice; and

(iii) The school site must have a dedicated, private room(s) for services to be conducted.

(B) Agencies that wish to bill CCare for client counseling and education services conducted at secondary school sites must adhere to the following standards:

(i) The agency must notify RH of the school site to be enrolled and must request from RH a unique site number for the school site;

(ii) The agency must receive written approval from the school site to conduct services;

(iii) For newly enrolling clients, the agency must ensure that clients meet all eligibility criteria described in OAR 333-004-0020 and are enrolled according to 333-004-0030 at the school site;

(iv) For clients already enrolled in CCare, the agency must ensure that clients have active eligibility;

(v) The agency must follow all standards of care for contraceptive management services described in OAR 333-004-0060 with the exception of 333-004-0060(3) (supplies dispensed on-site) and 333-004-0060(6) (clinical and preventive services);

(vi) The agency must offer clients a written referral to the enrolled CCare clinic for supply pick-up and full array of clinical services; and

(vii) The agency must submit claims for services conducted at the school site using the assigned project and site number of the school site.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.032
Hist.: PH 4-2005, f. & cert. ef. 2-18-05; PH 5-2007, f. 4-9-07, cert. ef. 4-23-07; PH 2-2009, f. & cert. ef. 3-2-09; PH 10-2010, f. & cert. ef. 6-30-10; PH 19-2012, f. & cert. ef. 12-26-12

333-004-0070
Provider Enrollment

(1) An agency and its providers must meet applicable licensing or regulatory requirements set forth by federal and state statutes, regulations, and rules to be enrolled and to bill as an agency. In addition, all agencies and its providers within the state of Oregon must have a valid Oregon business license if such a license is a requirement of the state, federal, county or city government to operate a business or to provide services.

(2) Signing a MSA constitutes agreement by agencies to comply with all applicable rules of RH, the Division of Medical Assistance Programs, and federal and state laws and regulations.

(3) Signing a MSA constitutes agreement by agencies to serve both CCare and Oregon Health Plan covered clients.

(4) An agency or any of its providers that are currently subject to sanctions by the Authority or the federal government is not eligible for enrollment as a CCare agency.

(5) A CCare project number and site number shall be issued to an agency and any applicable clinics upon:

(a) Completion of the MSA and submission of the required documents;

(b) The signing of the MSA and related forms by the person authorized by the agency to bind the agency and its providers to compliance with these rules;

(c) Verification of licensing or certification; and

(d) Approval of the application by RH and the Division of Medical Assistance Programs.

(6) An agency must notify RH within 30 days of a change in address, business affiliation, licensure, ownership, certification, billing agents or Federal Tax Identification Number (TIN). Failure to notify RH of a change of Federal Tax Identification Number may result in a sanction. Changes in business affiliation, ownership, and Federal Tax Identification Number may require the submission of a new application. In the event of bankruptcy proceedings, the agency must immediately notify RH in writing. RH may recover payments made to agencies who have not notified RH of changes as required by this section.

(7) Agencies outside the state of Oregon may be enrolled under the following conditions:

(a) The agency is appropriately licensed or certified and meets standards established within the provider's state for participation in Medicaid; and

(b) The agency is located in a state contiguous to Oregon, and is within 75 miles of the Oregon border.

(8) Agency termination:

(a) An agency may terminate enrollment at any time. The notice must be made to RH in writing, via certified mail, return-receipt requested. The notice shall specify the provider number to be terminated and the effective date of termination. Termination of agency enrollment does not terminate any obligations of the

agency for dates of services during which the enrollment was in effect.

(b) RH may terminate CCare agency enrollment due to inactivity. After 12 months of no claims activity, agencies may be contacted by RH with a written notice by certified mail, return-receipt requested, regarding inactivity and pending termination of agency enrollment. The notice shall specify the effective date of termination unless the agency notifies RH within 30 days upon receipt of notice of intention to resume claims activity.

(9) Agency responsibilities:

(a) An agency performs all services, or provides all items, as an independent contractor. The agency is not an officer, employee, or agent of RH.

(b) The agency is responsible for its employees, and for providing employment-related benefits and deductions that are required by law. The agency is solely responsible for its acts or omissions, including the acts or omissions of its own officers, employees or agents. RH's responsibility is limited to its authorization and payment obligations for covered services or items provided in accordance with OAR 333-004-0000 through 333-004-0230.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.032
Hist.: PH 4-2005, f. & cert. ef. 2-18-05; PH 5-2007, f. 4-9-07, cert. ef. 4-23-07; PH 2-2009, f. & cert. ef. 3-2-09; PH 10-2010, f. & cert. ef. 6-30-10; PH 19-2012, f. & cert. ef. 12-26-12

333-004-0080
Billing and Claims

(1) Only clinics providing contraceptive management services pursuant to an approved MSA, and who have been assigned a project number and site number may submit claims for CCare services.

(2) An agency may bill for contraceptive management services by submitting CVR data or by submitting the CVR form to RH. A claim is considered valid only if all required data are submitted.

(3) An agency may bill RH for supplies through the CVR at actual acquisition cost; that is, the amount or unit cost of the contraceptive supply the agency actually pays to the pharmaceutical manufacturer, supplier or distributor for the contraceptive supplies, after applying any discounts, promotions or other reductions. Shipping and handling may be included in the acquisition cost only if supported by an invoice.

(4) An agency shall include a primary diagnosis code on all claims. All billings must be coded with the most recent and appropriate International Classification of Diseases. All billings must be coded with the diagnosis codes in the Z30 Contraceptive Management series to the highest level of specificity. No other primary diagnosis code can be billed.

(5) An agency may bill RH for laboratory services related to contraceptive management through a fixed rate that includes clinical and laboratory services. The exception to this is the combined gonorrhea/Chlamydia (GC/CT) test occurring in the context of a CCare contraceptive initiation management visit. The combined GC/CT test shall be reimbursed separately from the fixed rate only if the appropriate medical service is indicated on the CVR.

(6) Birth control supplies billable to CCare must be approved by the Authority, be FDA approved, and may include intrauterine devices, cervical caps, oral contraceptives, subdermal implants, condoms, diaphragms, spermicides, patches, rings, injectibles, and emergency contraception.

(7) An agency must ensure that all laboratory tests done at the clinic site or by an outside clinic are conducted by CLIA certified laboratories.

(8) An agency enrolled with CCare must not seek payment from an eligible client, or from a financially responsible relative or representative of that client, for any services covered by CCare. The agency shall accept RH reimbursement for any CCare-covered services, pharmaceuticals, devices, or supplies as payment in full.

(a) If an agency has misrepresented client eligibility for services, the agency must assume responsibility for the full cost of services provided.

(b) A client may be billed for services that are not covered by CCare as outlined in the CCare enrollment form.

(9) Upon submission of a claim to RH for payment, the agency attests that it has complied with all rules of CCare.

(a) Except for services performed by a CLIA certified laboratory outside of the clinic, all billings must be for services provided within the agency and its provider's licensure or certification.

(b) It is the responsibility of an agency to submit true and accurate information when billing CCare.

(c) A claim may not be submitted prior to providing services.

(10) No agency shall submit to RH:

(a) Any false claim for payment;

(b) Any claim altered in such a way as to result in a payment for a service that has already been paid; or

(c) Any claim upon which payment has been made by another source unless the amount paid is clearly entered on the claim form.

(11) An agency is required to correct the billing error or to refund the amount of the overpayment, on any claim where the agency identifies an overpayment made by RH.

(12) An agency that, after having been previously warned in writing by the Authority or the Department of Justice regarding findings of improper billing practices as described in OAR 333-004-0140, is found to have continued such improper billing practices and has had an opportunity for a contested case hearing, shall be liable to RH for up to triple the amount of the established overpayment received as a result of such violation.

(13) Third Party Resources. The following subsections apply only to clients with private insurance coverage.

(a) Federal law requires that all reasonable efforts be taken to ensure that CCare is the payor of last resort, unless a client requests special confidentiality which must be documented on the CCare enrollment form. A client's request for special confidentiality ensures that the agency must not bill third party resources, but instead must bill CCare directly.

(b) An agency must make reasonable efforts to obtain payment from other resources before billing CCare. For the purposes of this rule "reasonable efforts" include:

(A) Determining the existence of insurance or other resource by asking the client.

(B) When third party coverage is known to the agency, prior to billing CCare:

(i) The agency must bill the third party resource; and

(ii) Resubmit a denied claim when the service is payable in whole or in part by an insurer.

(c) If the client has private insurance that has been billed for CCare services and the reimbursement from the insurance does not cover the entire cost of the services, the balance may be billed to CCare.

(d) An agency must report the reimbursement received from insurance, including both services and supplies, on box 17A, 2 of the CVR. The exact amount received from the insurance company must be reported in total.

(e) The CCare payment to the agency after the agency has received third party payment may not exceed the total of what CCare would pay for both services and supplies. The total amount of service and supply minus the amount paid by the primary insurance is the amount the agency shall be reimbursed.

(f) If third-party payment is received after CCare has been billed, agencies are required to submit a billing correction showing the amount of the third party payment or to refund the amount received from another source within 30 days of the date the payment is received. Failure to submit a billing correction within 30 days of receipt of the third party payment or to refund the appropriate amount within this time frame is considered concealment of material facts and grounds for recovery or sanction.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.032
Hist.: PH 4-2005, f. & cert. ef. 2-18-05; PH 3-2007(Temp), f. 2-23-07, cert. ef. 4-1-07 thru 9-28-07; PH 5-2007, f. 4-9-07, cert. ef. 4-23-07; PH 2-2009, f. & cert. ef. 3-2-09; PH 19-2012, f. & cert. ef. 12-26-12; PH 17-2015, f. 9-30-15, cert. ef. 10-1-15

333-004-0100
Timely Submission of Claims

(1) CCare claims are processed once a month, on or near the 15th of the month. To be included in a given month's processing, an agency must submit a claim to RH and RH must receive the claim by the Thursday before the 15th of each month.

(2) RH shall pay CCare claims within 12 months of the date of service. Claims submitted more than 12 months after the date of service shall be rejected.

(3) Errors causing rejection of any claim must be resolved by the agency within 12 months of the date of service. Claims older than 12 months submitted by the agency to RH shall not be paid, except when RH has made an error that caused the agency not to be able to bill within 12 months of the date of service. The error must be confirmed by RH before the claim shall be paid.

(4) Client data not related to payment of the claim may be corrected by the agency at any time after the date of service.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.032
Hist.: PH 4-2005, f. & cert. ef. 2-18-05; PH 5-2007, f. 4-9-07, cert. ef. 4-23-07; PH 2-2009, f. & cert. ef. 3-2-09; PH 19-2012, f. & cert. ef. 12-26-12

333-004-0110
Payment

(1) RH shall make payment only to an enrolled agency that actually performs the services for eligible clients.

(2) The reimbursement rates for CCare visits are set by RH and are available online at www.healthoregon.org/rhmaterials by selecting "Program Manuals," and then selecting "Section C, Exhibit 8." Claims are reimbursed at the rates in effect on the date of service.

(3) Contraceptive pharmaceuticals, devices and supplies are separately reimbursed at acquisition cost as described in OAR 333-004-0080(3), up to a set maximum amount, and are available online at www.healthoregon.org/rhmaterials by selecting "Program Manuals," and then selecting "Section C, Exhibit 8."

(4) The combined gonorrhea/Chlamydia test is reimbursed separately from the visit.

(5) RH may not make payment on claims that have been assigned, sold, or otherwise transferred, or on which an agency of billing services receives a percentage of the amount billed or payment authorized. This includes, but is not limited to, transfer to a collection agency or party who advances money to an agency for accounts receivable.

(6) RH shall only pay for services that are adequately documented and for contraceptive supply costs that are supported by invoice.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.032
Hist.: PH 4-2005, f. & cert. ef. 2-18-05; PH 3-2007(Temp), f. 2-23-07, cert. ef. 4-1-07 thru 9-28-07; PH 5-2007, f. 4-9-07, cert. ef. 4-23-07; PH 2-2009, f. & cert. ef. 3-2-09; PH 19-2012, f. & cert. ef. 12-26-12

333-004-0120
Requirements for Financial, Clinical and Other Records

(1) RH is responsible for analyzing and monitoring the operation of CCare and for auditing and verifying the accuracy and appropriateness of payment, utilization of services, the quality of care, and access to care. An agency shall:

(a) Develop and maintain adequate financial and clinical records and other documentation that supports the services for which payment has been requested.

(b) Document the service provided, primary diagnosis code for the services, the date on which the service was provided, and the agency staff who provided the services in every medical record. Client account and financial records must also include documentation of charges, identification of other payment resources pursued, the date and amount of all debit or credit billing actions, and support the appropriateness of the amount billed and paid. The records must be accurate and in sufficient detail to substantiate the data reported.

(c) Sufficiently document that the client's purpose of visit was primarily for contraceptive management services. The client's record must be annotated each time a service is provided and signed or initialed by the agency staff that provided the service or must clearly indicate the agency staff that provided the service. Information contained in the record must meet the standards of care for contraceptive management services as described in OAR 333-004-0060, and must be appropriate in quality and quantity to meet the professional standards applicable to the provider and any additional standards for documentation found in this rule.

(2) An agency must have policies and procedures to ensure the maintenance of the confidentiality of medical record information. These procedures must ensure that the agency may release such information in accordance with federal and state statutes, including but not limited to ORS 179.505 through 179.507, 413.175, 42 CFR part 2, if applicable, 42 CFR subpart F, and ORS 433.045 with respect to HIV test information.

(3) An agency must retain clinical records for seven years and financial and other records described in this rule for at least five years from the date of service. Original enrollment records must be retained for seven years.

(4) Upon written request from RH, the Division of Medical Assistance Programs, the Authority, the Oregon Department of Justice Medicaid Fraud Unit, the Oregon Secretary of State or their authorized representatives (requestor), an agency must furnish requested documentation, without charge, immediately or within the time-frame specified in the written request.

(5) If an agency fails to comply with requests for records within the specified timeframes it may result in the Authority deeming those records not to exist for purposes of verifying appropriateness of payment, medical appropriateness, the quality of care, and the access to care in an audit or overpayment determination, and accordingly subjects the agency to possible denial or recovery of payments made by the Authority, or to sanctions.

(6) The agency, and any officers, employees, agents, and subcontractors of the agency shall comply with the following requirements for the CCare Eligibility Database:

(a) Implement security measures that reasonably and appropriately provide administrative, physical and technical safeguards that protect the confidentiality, integrity and availability of the CCare Eligibility Database. The agency's security measures must be documented in writing and be available for review by RH upon request. RH review of the reasonableness of security measures, as well as the agency's compliance with RH assigned access control or security requirements, shall take into account the agency's physical, administrative, and technical capabilities related to security measures and the potential risk of unauthorized use or disclosure of the CCare Eligibility Database by the agency, its officers, employees, agents or subcontractors;

(b) Prevent any unauthorized access to or disclosure of information from the CCare Eligibility Database;

(c) Take necessary actions to comply with RH determinations of the level of access that may be granted, as well as changes in level of access, or suspension or termination of access as determined by RH;

(d) Keep any RH-assigned access control requirements such as identification of authorized user(s) and access-control information in a secure location until access is terminated; monitor and securely maintain access by the agency and its agents or subcontractors in accordance with security requirements or access controls assigned by RH; and make available to RH upon request all information about the agency's use or application of the CCare Eligibility Database.

(e) Report any privacy or security incidents by the agency, its officers, employees, agents or subcontractors that compromise, damage, or cause a loss of protection to the CCare Eligibility Database, as follows:

(A) Report to RH in writing within five business days of the date on which the agency becomes aware of such incident; and

(B) Provide RH the results of the incident assessment findings and resolution strategies.

(7) The agency must comply with RH requests for corrective action concerning a privacy or security incident, and with laws

requiring mitigation of harm caused by the unauthorized use or disclosure of confidential information, if any.

(8) If RH determines that the agency's security measures or actions required under section (7) of this rule are inadequate to address the security requirements, RH shall notify the agency. RH and the agency may meet to discuss appropriate security measures or action. If security measures or corrective actions acceptable to RH cannot be agreed upon, RH reserves the right to take such actions as it determines appropriate under the circumstances. Actions may include, but are not limited to, restricting access, or amending or terminating the agency agreement.

(9) RH reserves the right to request additional information from the agency related to security measures, and to change, suspend or terminate access to or use of the CCare Eligibility Database by the agency, its officers, employees, agents or subcontractors.

(10) Wrongful use or disclosure of the CCare Eligibility Database by the agency, officers, its employees, agents or its subcontractors may cause the immediate suspension or revocation of any access granted, in the sole discretion of RH. RH may also pursue any other legal remedies provided under the law.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.032
Hist.: PH 4-2005, f. & cert. ef. 2-18-05; PH 5-2007, f. 4-9-07, cert. ef. 4-23-07; PH 2-2009, f. & cert. ef. 3-2-09; PH 19-2012, f. & cert. ef. 12-26-12

333-004-0130
Compliance with Federal and State Statutes

(1) Submission of a claim for medical services or supplies provided to a CCare client shall be deemed a representation by the agency to RH of the agency's compliance with the applicable sections of the federal and state statutes referenced in this rule:

(a) 45 CFR Part 84 that implements Title V, Section 504 of the Rehabilitation Act of 1973;

(b) Title II and Title III of the Americans with Disabilities Act of 1991;

(c) Title VI of the Civil Rights Act of 1964; and

(d) 42 CFR Part 493 Laboratory Requirements and ORS Chapter 438 (Clinical Laboratories).

(2) Agencies are required to comply with the "Health Insurance Portability and Accountability Act" (HIPAA) regarding the confidentiality of client records.

(3) Providers described in ORS Chapter 419B are required to report suspected child abuse to their local child welfare office of the Department of Human Services or police, in the manner described in ORS Chapter 419B.

(4) The Clinical Laboratory Improvement Act (CLIA), requires all entities that perform even one laboratory test, including waived tests on, "materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings" to meet certain federal requirements. If an entity performs tests for these purposes, it is considered under CLIA to be a laboratory.

(5) Clinics that dispense contraceptive methods on-site must be licensed by the Oregon Board of Pharmacy as described in OAR 855-043-0001 through 855-043-0310.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.032
Hist.: PH 4-2005, f. & cert. ef. 2-18-05; PH 5-2007, f. 4-9-07, cert. ef. 4-23-07; PH 19-2012, f. & cert. ef. 12-26-12

333-004-0140
Review or Audit of Claims

(1) RH staff, contractor or auditor may review a claim for assurance that the specific medical service or contraceptive device or supply was provided by an agency in accordance with OAR 333-004-0000 through 333-004-0230 and the Standards of Care for Contraceptive Management Services set forth in 333-004-0060.

(2) To determine the number of inappropriate claims, and subsequently the overpayment amount, RH may review a statistically valid random sample of claims with sufficient sample size for a confidence interval of 95 percent.

(3) RH may deny payment or seek recovery or payment if a review or audit determines the service does not meet RH rules or the Standards of Care for Contraceptive Management Services set forth in OAR 333-004-0060.

(4) RH shall notify the agency, in writing, of the improper billing findings and subsequent actions to be taken by the agency to correct the identified findings and any sanctions that may be imposed by RH.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042
Hist.: PH 4-2005, f. & cert. ef. 2-18-05; PH 5-2007, f. 4-9-07, cert. ef. 4-23-07; PH 2-2009, f. & cert. ef. 3-2-09; PH 19-2012, f. & cert. ef. 12-26-12

333-004-0150
Recovery of Overpayments to Agencies Resulting from Review or Audit

(1) When RH determines that an overpayment has been made to an agency, the amount of overpayment is subject to recovery.

(a) If RH determines an overpayment amount by the random sampling method set forth in OAR 333-004-0140(2), an agency may request a 100 percent audit of all billings submitted to CCare for contraceptive management services provided during the period in question.

(b) If an agency requests a 100 percent audit:

(A) The agency is responsible for payment and arrangement; and

(B) The audit must be conducted by a certified public accountant who is knowledgeable with the Oregon Administrative Rules covering the payments in question, and must be conducted within 120 calendar days of the request to use such audit in lieu of RH's random sample.

(2) The amount of the review or audit overpayment to be recovered:

(a) Is the entire amount determined by RH or the amount agreed to by RH and the agency;

(b) Is not limited to amounts determined by criminal or civil proceedings; and

(c) Includes interest charged at allowable state rates.

(3) RH shall deliver to an agency by registered or certified mail or in person a request for repayment of the overpayment and the documentation to support the overpayment amount.

(4) The overpayment is due and payable 30 calendar days from the date of the decision by RH:

(a) An agency may request an additional 30-day grace period from RH.

(b) A request for a hearing does not change the date the repayment of the overpayment is due.

(5) RH may extend the reimbursement period for an agency or accept an offer of repayment terms from an agency. Any change in reimbursement period or terms must be made in writing by the RH.

(6) If the agency refuses to reimburse the overpayment or does not adhere to an agreed upon payment schedule, RH may:

(a) Recoup future agency payments up to the amount of the overpayment;

(b) Suspend or terminate the agency's enrollment in CCare; or

(c) Pursue civil action to recover the overpayment.

(7) RH may, at any time, change the amount of the overpayment upon receipt of additional information. RH shall notify an agency in writing of any changes. Any monies paid to RH by an agency that exceed an overpayment shall be refunded to the agency.

(8) If an agency is terminated or sanctioned for any reason, RH may pursue civil action to recover any amounts due and payable to CCare.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.032
Hist.: PH 4-2005, f. & cert. ef. 2-18-05; PH 5-2007, f. 4-9-07, cert. ef. 4-23-07; PH 2-2009, f. & cert. ef. 3-2-09; PH 19-2012, f. & cert. ef. 12-26-12

333-004-0160
Provider Sanctions

The following are conditions that may result in the imposition of a sanction on an agency.

(1) Basis for sanction:

(a) Conviction of a provider of a felony or misdemeanor related to a crime or violation of Title XVIII, XIX, or XX of the Social Security Act or related state laws (or entered a plea of nolo contendere);

(b) Conviction of fraud related to any federal, state, or locally financed health care program or commission of an act that is subject to criminal or civil penalties under Medicaid statutes;

(c) Conviction of interference with the investigation of health care fraud;

(d) Conviction of unlawfully manufacturing, distributing, prescribing, or dispensing a controlled substance;

(e) Failure to comply with the state and federal statutory requirements set forth in OAR 333-004-0130;

(f) An action by a state licensing authority relating to a provider's professional competence, professional conduct, or financial integrity, that results in the provider either:

(A) Having his or her license suspended or revoked; or

(B) Surrendering the license while a formal disciplinary proceeding was pending before a licensing authority.

(g) Suspension or exclusion from participation in a federal or state-administered health care program for reasons related to professional competence, professional performance, or other reason;

(h) Improper billing practices, including billing for excessive charges or visits, furnishing items or services substantially in excess of the patient's contraceptive management needs, or of a quality that fails to meet professionally recognized standards;

(i) Failure to furnish services as required by law or contract with the RH;

(j) Failure to supply requested information on subcontractors and suppliers of goods or services;

(k) Failure to supply requested payment information;

(l) Failure to grant access or to furnish as requested, records, or to grant access to facilities upon request of RH or a designated requestor;

(m) Receiving payments for services provided to persons who were not eligible;

(n) Establishing multiple claims using procedure codes that overstate or misrepresent the level, amount or type of health care provided;

(o) Failure to develop, maintain, and retain in accordance with relevant rules and standards adequate clinical or other records that document the medical appropriateness, nature, and extent of the health care provided;

(p) Failure to develop, maintain, and retain in accordance with relevant rules and standards adequate financial records that document charges incurred by a client and payments received from any source;

(q) Failure to follow generally accepted accounting principles or accounting standards or cost principles required by federal or state laws, rule, or regulation;

(r) Submission of claims or written orders contrary to generally accepted standards of medical practice;

(s) Submission of claims for services that exceed that requested or agreed to by the client or the responsible relative or guardian or requested by another medical practitioner;

(t) Breach of the terms of the medical services agreement;

(u) Failure to correct deficiencies in operations after receiving written notice of the deficiencies from RH;

(v) Submission of any claim for payment for which payment has already been made by RH;

(w) Provision of or billing for services provided by ineligible or unsupervised staff; or

(x) Alteration of clinical or billing records that have been requested by RH or a designated requestor.

(2) An agency or any of its providers who have been suspended, terminated, or excluded from participation in a federal or state-administered medical program, such as Medicare or Medicaid, or whose license to practice has been suspended or revoked by a state licensing board, shall not submit claims for payment, either personally or through claims submitted by any billing agency or other agency, for any services or supplies provided under CCare, except those services or supplies provided prior to the date of suspension or termination.

(3) No agency shall submit claims for payment to RH for any services or supplies provided by a person or agency that has been suspended or terminated from participation in a federal or state-administered medical program, such as Medicare or Medicaid, or whose license to practice has been suspended or revoked by a state licensing board, except for those services or supplies provided prior to the date of suspension or termination.

(4) When the provisions of sections (2) or (3) of this rule are violated, RH may suspend or terminate the agency who is responsible for the violation.

(5) Agency sanctions shall be imposed at the discretion of RH or the director of the office whose budget includes payment for the services involved. RH shall notify an agency in writing of any sanction proposed to be imposed that shall explain the agency's appeal rights in accordance with OAR 333-004-0200 through 333-004-0230.

(6) RH shall consider the following factors in determining the sanction(s) to be imposed (this list includes but is not limited to these factors):

(a) Seriousness of the offenses(s);

(b) Extent of violations by the agency;

(c) History of prior violations by the agency;

(d) Prior imposition of sanctions;

(e) Prior agency education; and

(f) Agency willingness to comply with RH rules.

(7) The Division of Medical Assistance Programs shall be notified whenever a sanction is imposed on an agency.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.032
Hist.: PH 4-2005, f. & cert. ef. 2-18-05; PH 5-2007, f. 4-9-07, cert. ef. 4-23-07; PH 2-2009, f. & cert. ef. 3-2-09; PH 19-2012, f. & cert. ef. 12-26-12

333-004-0200
Agency Appeals

(1) An agency may appeal a RH decision in which the agency is directly adversely affected such as the following:

(a) A denial or limitation of payment allowed for services or items provided;

(b) A denial of an application for new or continued participation in CCare;

(c) Sanctions imposed, or intended to be imposed, by RH on an agency; or

(d) RH overpayment determinations made under OAR 333-004-0150.

(2) An agency appeal is initiated by filing a timely request in writing for review with RH.

(a) An agency appeal request is not required to follow a specific format as long as it provides a clear written expression from an agency expressing disagreement with a RH decision.

(b) The request must identify the decision made by RH that is being appealed and the reason the agency disagrees with that decision.

(c) An agency appeal request is timely if it is received by RH within 60 calendar days of the date of RH's decision.

(3) Types and methods for agency appeals are as follows:

(a) A RH denial of or limitation of payment allowed, RH claim decision, or RH overpayment determination for services or items provided to a client must be appealed as claim re-determinations under OAR 333-004-0210.

(b) A notice of sanctions imposed, or intended to be imposed, the effect of the notice of sanction is, or will be, to deny, suspend or revoke an agency's project number necessary to participate in CCare is entitled to appeal under OAR 333-004-0230. An agency that is entitled to appeal a notice of sanction as a contested case may request administrative review instead of a contested case hearing if the agency submits a written request for administrative review of the notice of sanction and agrees in writing to waive the right to a contested case hearing, and RH agrees to review the appeal of the notice of sanction as an administrative review.

(c) All agency appeals of RH decisions not described in subsections (3)(a) or (b) of this rule are handled as administrative reviews in accordance with OAR 333-004-0220 unless RH issues an order granting a contested case hearing.

(4) In the event an agency's request for appeal is not timely, RH shall determine whether the failure to file the request was caused by circumstances beyond the control of the agency. In determining whether to accept a late request for review, RH requires the request to be supported by a written statement that explains why the request for review is late. RH may conduct such further inquiry as RH deems appropriate. In determining timeliness of filing a request for review, the amount of time RH determines accounts for circumstances beyond the control of the provider is not counted.

(5) The burden of presenting evidence to support an agency appeal is on the agency.

(a) Consistent with OAR 333-004-0110, payment on a claim shall only be made for services that are adequately documented and billed in accordance with 333-004-0080 and all applicable administrative rules related to covered services for clients and establishing the conditions under which services, supplies or items are covered.

(b) Eligibility for enrollment and for continued enrollment is based on compliance with applicable rules, the information submitted or required to be submitted with the application for enrollment and the enrollment agreement, and the documentation required to be produced or maintained in accordance with OAR 333-004-0120.

(6) Agency appeal proceedings, if any, shall be held in Portland, unless otherwise stipulated to by all parties and agreed to by RH.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.032
Hist.: PH 19-2012, f. & cert. ef. 12-26-12

333-004-0210
Claim Re-Determination

(1) If an agency disagrees with an initial claim determination, it may request a review for re-determination of the denied claim payment. The request to open an initial claim determination for a re-determination review must be made through RH in writing, within 60 days from the date of the RH original claim adjudication date.

(2) All requests must contain a detailed letter of explanation identifying the specific re-determination denial issue and alleged error. This information must be submitted to RH at the time of the request.

(3) At the time the request for re-determination is made an agency is responsible for providing the information needed to adjudicate its claim, including relevant medical records and evidence-based practice data to support the position being asserted on review. RH may request additional information that it finds relevant to the review. An agency requesting a re-determination review must include the following:

(a) The specific service, supply or item being denied, and include all relevant codes and a detailed justification for the re-determination of the denied service;

(b) A copy of the original claim and a copy of the original denial notice or remittance advice that describes the basis for the claim denial under re-determination; and

(c) Any information or medical documentation pertinent to support the request and to obtain a resolution of the re-determination review dispute.

(4) A re-determination review is based on RH review of documentation and applicable law. RH does not provide a face-to-face meeting with an agency as part of the re-determination process.

(a) The agency is responsible for the timely submission of review request and all information pertinent to conducting the review and consistent with the requirements of this rule.

(b) RH shall notify an agency requesting review that the re-determination request has been denied if:

(A) The agency did not submit a timely request;

(B) The required information is not provided at the same time the request is submitted; or

(C) The agency fails to submit any additional requested information within 14 business days of request.

(5) RH's final decision under this rule is the final decision on appeal. Under ORS 183.484, this decision is an order in other than a contested case. ORS 183.484 and the procedures in OAR 137-004-0080 through 137-004-0092 apply to RH's final decision under this rule.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.032
Hist.: PH 19-2012, f. & cert. ef. 12-26-12

333-004-0220
Agency Appeals — Administrative Review

(1) An administrative review is an agency appeal process that allows an opportunity for the Center administrator or designee to review a RH decision affecting the agency, where administrative review is appropriate and consistent with OAR 333-004-0200, Agency Appeals.

(2) Administrative review is an appeal process under OAR 333-004-0200 that addresses primarily legal or policy issues that may arise in the context of a RH decision that adversely affects the agency and that is not otherwise reviewed as a claim re-determination, a contested case, or client appeal.

(a) If RH finds that the appeal shall be handled as a different form of agency appeal the Center administrator or designee shall notify the agency of this determination.

(b) Within the time limits established by RH in the administrative review, the agency must provide RH with a copy of all relevant records, the RH decision, and other materials relevant to the appeal.

(3) If the Center administrator or designee decides that a meeting between the agency and RH staff shall assist the review, the Center administrator or designee shall notify the agency requesting the review of the date, time, and place the meeting is scheduled.

(4) The review meeting shall be conducted in the following manner:

(a) It shall be conducted by the Center administrator or designee;

(b) No minutes or transcript of the review shall be made;

(c) The agency requesting the review does not have to be represented by counsel during an administrative review meeting and shall be given ample opportunity to present relevant information;

(d) RH staff shall not be available for cross-examination but RH staff may attend and participate in the review meeting;

(e) Failure to appear without good cause constitutes acceptance of RH's determination;

(f) The Center administrator may combine similar administrative review proceedings, including the meeting, if the Center administrator determines that joint proceedings may facilitate the review; and

(g) The Center administrator or designee may request the agency making the appeal to submit, in writing, new information that has been presented orally. In such an instance, a specific date for receiving such information shall be established.

(5) The results of the administrative review shall be sent to the agency, in writing, within 30 calendar days of the conclusion of the administrative review proceeding, or such time as may be agreed to by the agency and RH.

(6) RH's final decision on administrative review is the final decision on appeal and binding on the parties. Under ORS 183.484, this decision is an order in other than a contested case. ORS 183.484 and the procedures in OAR 137-004-0080 through 137-004-0092 apply to the Authority's final decision on administrative review.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.032
Hist.: PH 19-2012, f. & cert. ef. 12-26-12

333-004-0230
Agency Appeals — Contested Case Hearings

(1) A contested case procedure is a hearing that is conducted by the Office of Administrative Hearings where a contested case is

appropriate and consistent with OAR 333-004-0200, Agency Appeals. If the request for contested case hearing was timely filed but should have been filed as a claim re-determination, administrative review, or client appeal, RH shall refer the request to the proper appeal procedure and notify the agency.

(2) Contested case hearings are conducted in accordance with the Attorney General's Model Rules, OAR 137-003-0501 through 137-003-0700.

(3) The party to an agency contested case hearing is the agency who requested the appeal. An agency that is a corporation may be represented by any of the persons identified in ORS 413.041.

(4) Informal conference. RH may notify the agency of the time and place of an informal conference, without the presence of the Administrative Law Judge (ALJ). The purposes of the informal conference are:

(a) To provide an opportunity to settle the matter;

(b) To make sure the agency and RH understand the specific reason for the action of the hearing request;

(c) To give the agency and RH an opportunity to review the information that is the basis for action; and

(d) To give the agency and RH the chance to correct any misunderstanding of the facts.

(5) The agency may, at any time prior to the hearing date, request an additional informal conference with RH that may be granted if RH finds, at its sole discretion, the additional informal conference shall facilitate the contested case hearing process or resolution of disputed issues.

(6) Contested case hearing. The ALJ shall conduct the contested case hearing using the Attorney General's Model Rules, OAR 137-003-0501 through 137-003-0700.

(a) The burden of presenting evidence to support an agency appeal is on the agency that requested the appeal. Consistent with OAR 333-004-0110, payment on a claim shall only be made for services that are adequately documented and billed in accordance with OAR 333-004-0080 and all applicable administrative rules related to covered services for the client.

(b) Subject to RH approval under OAR 137-003-0525, the ALJ shall determine the location of the contested case hearings.

(7) Proposed and final orders. The ALJ is authorized to serve a proposed order on all parties and the RH unless, prior to the hearing, RH notifies the ALJ that a final order may be served by the ALJ.

(a) If the ALJ issues a proposed order, and the proposed order is adverse to a party, the party may file written exceptions to the proposed order to be considered by RH, or the ALJ when the ALJ is authorized to issue the final order. The exceptions must be in writing and received by RH or the ALJ, when the ALJ is authorized to issue the final order, not later than 10 calendar days after the date the proposed order is issued by the ALJ. No additional evidence may be submitted without prior approval of RH.

(b) The proposed order issued by the ALJ shall become a final order if no exceptions are filed within the time specified in subsection (a) of this section, unless RH notifies the parties and the ALJ that RH shall issue the final order. After receiving the exceptions or argument, if any, RH may adopt the proposed order as the final order or may prepare a new order. Prior to issuing the final order, RH may issue an amended proposed order.

(c) Procedures applicable to default orders for withdrawal of a hearing request, failure to timely request a hearing, failure to appear at a hearing, or other default, are governed by the Attorney General's Model Rules, OAR 137-003-0670 through 137-003-0672.

(d) The final order is effective immediately upon being signed or as otherwise provided in the order.

(8) All contested case hearing decisions are subject to the procedures established in OAR 137-003-0675 through 137-003-0700 and to judicial review under ORS 183.482 in the Court of Appeals.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.032
Hist.: PH 19-2012, f. & cert. ef. 12-26-12

DIVISION 7

MARIJUANA LABELING, CONCENTRATION LIMITS, AND TESTING

Labeling

333-007-0010
Purpose, Scope and Effective Date

(1) The purpose of OAR 333-007-0010 through 333-007-0100 is to set the minimum standards for the labeling of marijuana items that are sold to a consumer, patient or designated primary caregiver. These minimum standards are applicable to:

(a) A Commission licensee as that is defined in OAR 845-025-1015; and

(b) A person registered with the Authority under ORS 475B.400 to 475B.525 who is not exempt from the labeling requirements as described in section (2) of this rule.

(2) The labeling requirements in these rules do not apply to:

(a) A grower if the grower is transferring usable marijuana or an immature marijuana plant to:

(A) A patient who designated the grower to grow marijuana for the patient; or

(B) A designated primary caregiver of the patient who designated the grower to grow marijuana for the patient.

(b) A designated primary caregiver of a patient if the caregiver is transferring a marijuana item to a patient of the designated primary caregiver.

(3) Nothing in these rules prohibits the Commission or the Authority from:

(a) Imposing additional labeling requirements in their respective rules governing licensees and registrants as long as those additional labeling requirements are not inconsistent with these rules; or

(b) Requiring licensees or registrants to provide informational material to a consumer, patient or designated primary caregiver at the point of sale.

(4) A person licensed by the Commission must comply with these rules at all times.

(5) On and after October 1, 2016:

(a) A marijuana item received or transferred by a dispensary must meet the labeling requirements in these rules; and

(b) A dispensary may not transfer a marijuana item that does not meet the labeling requirements in these rules.

(6) By October 1, 2016, a dispensary must:

(a) Transfer marijuana items that do not meet the labeling requirements in these rules to a patient or caregiver;

(b) Return any marijuana item that does not meet labeling requirements in these rules to the individual who transferred the item to the dispensary, and document who the item was returned to, what was returned and the date of the return; or

(c) Dispose of any marijuana item that does not meet labeling requirements and that cannot be returned in accordance with subsection (b) of this section, in a manner specified by the Authority.

(7) A marijuana item that was transferred to a registered dispensary prior to October 1, 2016 is not required to:

(a) Have a label with a harvest date, harvest lot number, date the product was made or the process lot number if that information is not known by the dispensary.

(b) Have gone through the Commission's pre-approval process for packaging and labeling, but still must meet the labeling requirements in OAR 333-007-0010 to 333-007-0100 and the packaging requirements in OAR 845-025-7000 to 845-025-7020 and 845-025-7060.

Stat. Auth.: ORS 475B.605
Stats. Implemented: ORS 475B.605
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 4-2016(Temp), f. & cert. ef. 2-8-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16; PH 27-2016(Temp), f. & cert. ef. 9-30-16 thru 3-1-17

333-007-0020
Definitions

For the purposes of OAR 333-007-0100 through 333-007-0100, unless otherwise specified:

(1) "Activation time" means the amount of time it is likely to take for an individual to begin to feel the effects of ingesting or inhaling a marijuana item.

(2) "Authority" means the Oregon Health Authority.

(3) "Cannabinoid concentrate or extract" means a substance obtained by separating cannabinoids from marijuana by a mechanical, chemical or other process.

(4)(a) "Cannabinoid edible" means:

(A) Food or potable liquid into which a cannabinoid concentrate or extract or the dried leaves or flowers of marijuana have been incorporated; or

(B) For purposes of labeling, includes any cannabinoid concentrate, extract or cannabinoid product that is intended for human consumption or marketed in a manner that implies the item is for human consumption.

(b) For purposes of labeling "cannabinoid edible" does not include a cannabinoid tincture.

(5)(a) "Cannabinoid product" means a cannabinoid edible or any other product intended for human consumption or use, including a product intended to be applied to a person's skin or hair, that contains cannabinoids or the dried leaves or flowers of marijuana.

(b) "Cannabinoid product" does not include:

(A) Usable marijuana by itself;

(B) A cannabinoid concentrate or extract by itself; or

(C) Industrial hemp, as defined in ORS 571.300.

(6) "Cannabinoid tincture" means a solution of alcohol, cannabinoid concentrate or extract, and perhaps other ingredients intended for human consumption or ingestion, and that is exempt from the Liquor Control Act under ORS 471.035.

(7) "Cannabinoid topical" means a cannabinoid product intended to be applied to skin or hair.

(8) "CBD" means cannabidiol.

(9) "Commission" means the Oregon Liquor Control Commission.

(10) "Consumer" has the meaning given that term in ORS 475B.015 and does not include a patient or designated primary caregiver.

(11) "Container"

(a) Means a sealed, hard or soft-bodied receptacle in which a marijuana item is placed.

(b) Does not mean inner wrapping or packaging that is not intended to display the marijuana item for sale to a consumer.

(12) "Date of harvest" means the date the mature marijuana plants in a harvest lot were removed from the soil or other growing media. If the harvest occurred on more than one day, the "date of harvest" is the day the last mature marijuana plant in the harvest lot was removed from the soil or other growing media.

(13) "Delta-9 THC" is the principal psychoactive constituent (the principal cannabinoid) of cannabis.

(14)(a) "Designated primary caregiver" means an individual:

(A) Who is 18 years of age or older;

(B) Who has significant responsibility for managing the well-being of a person who has been diagnosed with a debilitating medical condition; and

(C) Who is designated as the person responsible for managing the well-being of a person who has been diagnosed with a debilitating medical condition on that person's application for a registry identification card or in other written notification submitted to the Authority.

(b) "Designated primary caregiver" does not include a person's attending physician.

(15) "Food" means a raw, cooked, or processed edible substance, or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum.

(16) "Grower" has the same meaning as "person responsible for a marijuana grow site."

(17) "Harvest lot" means marijuana that is uniform in strain, cultivated utilizing the same growing practices and harvested at the same time.

(18) "Human consumption" means to ingest, generally through the mouth, food, drink or other substances such that the substance enters the human body but does not include inhalation.

(19) "Licensee" has the meaning given that term in ORS 475B.015.

(20) "Major food allergen" means an ingredient that is one of the five foods listed in subsections (a) to (e) of this section, or from one of the three food groups listed in subsections (f) to (h) of this section, or is an ingredient that contains protein derived from one of the following:

(a) Milk;

(b) Egg;

(c) Fish;

(d) Crustacean shellfish;

(e) Tree nuts;

(f) Wheat;

(g) Peanuts; and

(h) Soybeans.

(21)(a) "Marijuana" means the plant Cannabis family Cannabaceae, any part of the plant Cannabis family Cannabaceae and the seeds of the plant Cannabis family Cannabaceae.

(b) "Marijuana" does not include industrial hemp, as defined in ORS 571.300.

(22) "Marijuana item" means marijuana, usable marijuana, a cannabinoid product, or a cannabinoid concentrate or extract.

(23) "Medical grade cannabinoid product, cannabinoid concentrate or cannabinoid extract" means a cannabinoid product, cannabinoid concentrate or cannabinoid extract that has a concentration of THC that is permitted under ORS 475B.625 in a single serving of the cannabinoid product, cannabinoid concentrate or cannabinoid extract for a patient.

(24) "Medical grade symbol" means the image established by the Authority and made available to licensees indicating the cannabinoid product, concentrate or extract may only be sold or transferred to a designated primary caregiver or patient, for use only by a patient.

(25) "Medical marijuana dispensary" means a facility registered under ORS 475B.450.

(26) "Net weight" means the gross weight minus the tare weight of the packaging.

(27) "Package unique identification number" mean the unique identification number that was generated by the Commission's seed to sale tracking system at the time the marijuana item was packaged and labeled for sale to the consumer, patient, or designated primary caregiver.

(28) "Patient" has the same meaning as "registry identification cardholder."

(29) "Person responsible for a marijuana grow site" means a person who has been selected by a patient to produce medical marijuana for the patient, and who has been registered by the Authority for this purpose and has the same meaning as "grower."

(30) "Place of address" means the name, mailing address, city, state and zip code of the processor who made the cannabinoid edible.

(31) "Principal display panel" means the part of a label on a package or container that is most likely to be displayed, presented, shown or seen under customary conditions of display for sale or transfer.

(32) "Processor" means a person:

(a) Licensed by the Commission to process marijuana under ORS 475B.090; or

(b) Registered with the Authority under ORS 475B.435 as a processing site and who is not exempt from labeling requirements under ORS 475B.605

(33) "Process lot" means:

(a) Any amount of cannabinoid concentrate or extract of the same type and processed at the same time using the same extraction methods, standard operating procedures and batches from the same or different harvest lots; or

(b) Any amount of cannabinoid products of the same type and processed at the same time using the same ingredients, standard

operating procedures and batches from the same or different harvest lots or process lots of cannabinoid concentrate or extract.

(34) "Producer" means a person:

(a) Licensed by the Commission to produce marijuana under ORS 475B.070; and

(b) Registered with the Authority under ORS 475B.420 as a grower and who is not exempt from labeling requirements under ORS 475B.605.

(35) "Product identity" means a truthful or common name of the product that is contained in the package.

(36) "Registrant" means a person registered with the Authority under ORS 475B.400 to 475B.525.

(37) "Registry identification cardholder" means a person to whom a registration card has been issued under ORS 475B.415.

(38)(a) "Test batch" means a group of test samples that are collectively submitted to a laboratory for testing purposes.

(b) "Test batch" does not mean a combination of marijuana flowers, marijuana leaves, cannabinoid products, or cannabinoid concentrate or extract.

(39) "Test sample" means anything collected by an individual authorized by the Authority to collect a sample from a licensee or registrant that is provided to a laboratory for testing, including but not limited to marijuana items, soil, growing medium, water, solvent or swab of a counter or equipment.

(40) "THC" means tetrahydrocannabinol and has the same meaning as delta-9 THC.

(41) "These rules" means OAR 333-007-0010 through 333-007-0100.

(42) "Universal symbol" means the image, established by the Authority and made available to licensees and registrants, indicating the marijuana item contains marijuana.

(43)(a) "Usable marijuana" means the dried leaves and flowers of marijuana.

(b) "Usable marijuana" does not include:

(A) The seeds, stalks and roots of marijuana; or

(B) Waste material that is a by-product of producing or processing marijuana.

Stat. Auth.: ORS 475B.605
Stats. Implemented: ORS 475B.605
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0030
Marijuana Plant Labeling Requirements

Prior to a marijuana plant being sold or transferred to a consumer, patient or designated primary caregiver a tag or label must be affixed to the plant or plant container that has the following information:

(1) Producer's business or trade name and licensee or registrant number;

(2) Business or trade name of licensee or registrant that packaged or distributed the product, if different from the producer;

(3) Name of the strain; and

(4) Universal symbol.

Stat. Auth.: ORS 475B.605
Stats. Implemented: ORS 475B.605
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0040
Marijuana Seed Labeling Requirements

Prior to marijuana seeds being sold or transferred to a consumer, patient or designated primary caregiver the container holding the seeds must have a label that has the following information:

(1) Producer's business or trade name and licensee or registrant number;

(2) Business or trade name of licensee or registrant that packaged or distributed the product, if different from the producer;

(3) Name of the strain of seed;

(4) Date of harvest;

(5) Number of seeds or net weight in U.S. customary and metric units as appropriate; and

(6) Universal symbol.

Stat. Auth.: ORS 475B.605
Stats. Implemented: ORS 475B.605
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0050
Usable Marijuana Labeling Requirements

Prior to usable marijuana being sold or transferred to a consumer, patient or designated primary caregiver the container holding the usable marijuana must have a label that has the following information:

(1) Producer's business or trade name and licensee or registrant number;

(2) Business or trade name of licensee or registrant that packaged or distributed the product, if different from the producer;

(3) For licensees, package unique identification number and for registrants, harvest lot number;

(4) Date of harvest;

(5) Name of strain;

(6) Net weight in U.S. customary and metric units;

(7) Concentration of THC and CBD, as calculated under OAR 333-064-0100;

(8) Activation time expressed in words or through a pictogram;

(9) Name of the lab that performed any test, any associated test batch number and any test analysis date;

(10) Universal symbol;

(11) For usable marijuana for sale to a consumer warnings that state:

(a) "For use by adults 21 and older. Keep out of reach of children."

(b) "It is illegal to drive a motor vehicle while under the influence of marijuana."

(12) For usable marijuana for use by a patient warnings that state:

(a) "For use by OMMP patients only. Keep out of reach of children."

(b) "It is illegal to drive a motor vehicle while under the influence of marijuana."

Stat. Auth.: ORS 475B.605
Stats. Implemented: ORS 475B.605
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0060
Cannabinoid Topical Labeling Requirements

Prior to a cannabinoid topical product being sold or transferred to a consumer, patient or designated primary caregiver the container holding the cannabinoid product must have a label that has the following information:

(1) Processor's business or trade name and licensee or registrant number;

(2) Business or trade name of licensee or registrant that packaged or distributed the product, if different from the processor;

(3) For licensees, package unique identification number and for registrants, process lot number;

(4) Product identity (common or usual name);

(5) Date the product was made;

(6) Net weight or volume in U.S. customary and metric units;

(7) Amount suggested for use by the consumer or patient at any one time;

(8) Concentration or amount by weight or volume of THC and CBD in the container;

(9) List of ingredients in descending order or predominance by weight or volume used to process the cannabinoid topical;

(10) Activation time, expressed in words or through a pictogram;

(11) Name of the lab that performed any test, any associated test batch number and any test analysis date;

(12) Universal symbol;

(13) For licensees, a medical grade symbol if applicable;

(14) A statement that reads: "This product is not approved by the FDA to treat, cure, or prevent any disease";

(15) For cannabinoid topicals for sale to a consumer warnings that state:

(a) "For use only by adults 21 and older. Keep out of reach of children."

(b) "DO NOT EAT" in bold, capital letters.

(16) For cannabinoid topicals for use by a patient warnings that state:

(a) "For use by OMMP patients only. Keep out of reach of children."

(b) "DO NOT EAT" in bold, capital letters.

Stat. Auth.: ORS 475B.605
Stats. Implemented: ORS 475B.605
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0070
Cannabinoid Edible Labeling Requirements

Prior to a cannabinoid edible being sold or transferred to a consumer, patient or designated primary caregiver the container holding the edible must have a label that has the following information:

(1) Processor's business or trade name, place of address, and licensee or registrant number;

(2) Business or trade name and place of address of licensee or registrant that packaged or distributed the product, if different from the processor;

(3) Product identity (common or usual name);

(4) For licensees, package unique identification number and for registrants, process lot number;

(5) Date the edible was made;

(6) Net weight or volume in U.S. customary and metric units;

(7) Serving size and number of servings per container;

(8) Concentration or amount by weight or volume of THC and CBD in each serving and in each container;

(9) List of all ingredients in descending order of predominance by weight or volume used to process the cannabinoid edible;

(10) List of potential major food allergens:

(a) Using a "contains" statement to summarize the major food allergen information at the end of or immediately adjacent to the ingredient list; or

(b) Placing the term for the appropriate major food allergen in parenthesis within the ingredient list after the common or usual name of the ingredient derived from that major food allergen;

(11) The amount, in grams, of sodium, sugar, carbohydrates and total fat per serving;

(12) If the edible is perishable, a statement that the edible must be refrigerated or kept frozen;

(13) Name of the lab that performed any test, any associated test batch number and any test analysis date;

(14) Activation time, expressed in words or through a pictogram;

(15) Universal symbol;

(16) For licensees, a medical grade symbol if applicable;

(17) A statement that reads: "This product is not approved by the FDA to treat, cure, or prevent any disease";

(18) For cannabinoid edibles for sale to a consumer warnings that state:

(a) "For use only by adults 21 and older. Keep out of reach of children."

(b) "It is illegal to drive a motor vehicle while under the influence of marijuana."

(c) "BE CAUTIOUS" in bold, capital letters, followed by "Cannabinoid edibles can take up to 2 hours or more to take effect."

(19) For cannabinoid edibles for use by a patient warnings that state:

(a) "For use by OMMP patients only. Keep out of reach of children."

(b) "It is illegal to drive a motor vehicle while under the influence of marijuana."

(c) "BE CAUTIOUS" in bold, capital letters, followed by "Cannabinoid edibles can take up to 2 hours or more to take effect."

Stat. Auth.: ORS 475B.605
Stats. Implemented: ORS 475B.605
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0080
Labeling Requirements for Cannabinoid Concentrates and Extracts

Prior to a cannabinoid concentrate or extract being sold or transferred to a consumer, patient or designated primary caregiver the container holding the concentrate or extract must have a label that has the following information:

(1) Processor's business or trade name and licensee or registrant number;

(2) Business or trade name of licensee or registrant that packaged or distributed the product, if different from the processor;

(3) For licensees, package unique identification number and for registrants, process lot number;

(4) Product identity (concentrate or extract);

(5) Date the concentrate or extract was made;

(6) Net weight or volume in U.S. customary and metric units;

(7) If applicable, serving size and number of servings per container or amount suggested for use by the consumer or patient at any one time;

(8) Concentration or amount by weight or volume of THC and CBD in each amount suggested for use and in the container;

(9) Activation time, expressed in words or through a pictogram;

(10) Name of the lab that performed any test, any associated test batch number and any test analysis date;

(11) Universal symbol;

(12) For licensees, a medical grade symbol if applicable;

(13) A statement that reads: "This product is not approved by the FDA to treat, cure, or prevent any disease";

(14) For cannabinoid concentrates and extracts for sale to a consumer warnings that state:

(a) "For use only by adults 21 and older. Keep out of reach of children."

(b) "It is illegal to drive a motor vehicle while under the influence of marijuana."

(c) "DO NOT EAT" in bold, capital letters.

(15) For cannabinoid concentrates and extracts for use by a patient warnings that state:

(a) "For use by OMMP patients only. Keep out of reach of children."

(b) "It is illegal to drive a motor vehicle while under the influence of marijuana."

(c) "DO NOT EAT" in bold, capital letters.

Stat. Auth.: ORS 475B.605
Stats. Implemented: ORS 475B.605
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0083
Cannabinoid Tincture Labeling Requirements

Prior to a cannabinoid tincture being sold or transferred to a consumer, patient or designated primary caregiver the container holding the tincture must have a label that has the following information:

(1) Processor's business or trade name, place of address and licensee or registrant number;

(2) Business or trade name and place of address of licensee or registrant that packaged or distributed the product, if different from the processor;

(3) Product identity (common or usual name);

(4) For licensees, package unique identification number and for registrants, process lot number;

(5) Date the tincture was made;

(6) Net weight or volume in U.S. customary and metric units;

(7) Serving size and number of servings per container;

(8) Concentration or amount by weight or volume of THC and CBD in each serving and in each container;

(9) List of all ingredients in descending order of predominance by weight or volume used to process the cannabinoid tincture;

(10) Name of the lab that performed any test, any associated test batch number and any test analysis date;

(11) Universal symbol;

(12) For licensees, a medical grade symbol if applicable;

(13) Activation time expressed in words or through a pictogram;

(14) A statement that reads: "This product is not approved by the FDA to treat, cure, or prevent any disease";

(15) For cannabinoid tinctures for sale to a consumer warnings that state:

(a) "For use only by adults 21 and older. Keep out of reach of children."

(b) "It is illegal to drive a motor vehicle while under the influence of marijuana."

(16) For cannabinoid tinctures for use by a patient warnings that state:

(a) "For use by OMMP patients only. Keep out of reach of children."

(b) "It is illegal to drive a motor vehicle while under the influence of marijuana."

Stat. Auth.: ORS 475B.605
Stats. Implemented: ORS 475B.605
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0085
Cannabinoid Products Other than Cannabinoid Edibles, Topicals, or Tinctures

Prior to a cannabinoid product other than a cannabinoid edible, topical or tincture being sold or transferred to a consumer, patient or designated primary caregiver the container holding the product must have a label that has the following information:

(1) Processor's business or trade name and licensee or registrant number;

(2) Business or trade name of licensee or registrant that packaged or distributed the product, if different from the processor;

(3) Place of address for the processor and packager, if applicable;

(4) Product identity (common or usual name);

(5) For licensees, package unique identification number and for registrants, process lot number;

(6) Date the product was made;

(7) Net weight or volume in U.S. customary and metric units;

(8) Serving size and number of servings per container;

(9) Concentration or amount by weight or volume of THC and CBD in each serving and in each container;

(10) List of all ingredients in descending order of predominance by weight or volume used to process the cannabinoid product;

(11) Name of the lab that performed any test, any associated test batch number and any test analysis date;

(12) Universal symbol;

(13) For licensees, a medical grade symbol if applicable;

(14) Activation time expressed in words or through a pictogram;

(15) A statement that reads: "This product is not approved by the FDA to treat, cure, or prevent any disease";

(16) For cannabinoid products for sale to a consumer warnings that state:

(a) "For use only by adults 21 and older. Keep out of reach of children."

(b) "It is illegal to drive a motor vehicle while under the influence of marijuana."

(17) For cannabinoid products for use by a patient warnings that state:

(a) "For use by OMMP patients only. Keep out of reach of children."

(b) "It is illegal to drive a motor vehicle while under the influence of marijuana."

Stat. Auth.: ORS 475B.605
Stats. Implemented: ORS 475B.605
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0090
General Label Requirements; Prohibitions; Exceptions

(1) Principal Display Panel.

(a) Every container that contains a marijuana item for sale or transfer to a consumer, patient or designated primary caregiver must have a principal display panel, as that term is defined in OAR 333-007-0020.

(b) If a container is placed within packaging for purposes of displaying the marijuana item for sale or transfer to a consumer, patient or designated primary caregiver, the packaging must have a principal display panel as that term is defined in OAR 333-007-0020.

(c) The principal display panel must contain the product identity, net weight, and universal symbol, if applicable.

(d) If the product is a medical grade cannabinoid product, concentrate or extract processed by a licensee the principal display panel must include the medical grade symbol.

(2) A label required by these rules must:

(a) Be placed on the container and on any packaging that is used to display the marijuana item for sale or transfer to a consumer, patient or designated primary caregiver.

(b) Comply with the National Institute of Standards and Technology (NIST) Handbook 130 (2016), Uniform Packaging and Labeling Regulation, incorporated by reference.

(c) Be in no smaller than 8 point Times New Roman, Helvetica or Arial font;

(d) Be in English, though it can be in other languages; and

(e) Be unobstructed and conspicuous.

(3) A marijuana item may have one or more labels affixed to the container or packaging.

(4) A marijuana item that is in a container that because of its size does not have sufficient space for a label that contains all the information required for compliance with these rules:

(a) May have a label on the container that contains a marijuana item and on any packaging that is used to display the marijuana item for sale or transfer to a consumer, patient or designated primary caregiver that includes at least the following:

(A) Information required on a principal display panel, if applicable for the type of marijuana item;

(B) Licensee or registrant business or trade name and licensee or registrant number;

(C) For licensees, package unique identification number and for registrants, batch or process lot number;

(D) Concentration of THC and CBD; and

(E) Required warnings; and

(b) Must include all other required label information not listed in subsection (4)(a) of this rule on an outer container or package, or on a leaflet that accompanies the marijuana item.

(5) A marijuana item in a container that is placed in packaging that is used to display the marijuana item for sale or transfer to a consumer, patient, or designated primary caregiver must comply with the labeling requirements in these rules, even if the container qualifies for the exception under section (4) of this rule.

(6) The universal symbol:

(a) Must be at least 0.48 inches wide by 0.35 inches high.

(b) May only be used by licensees or registrants.

(c) May be downloaded at www.healthoregon.org/marijuana.

(7) Medical grade symbol. The medical grade symbol must be at least 0.35 inches in diameter.

(8) A label may not:

(a) Contain any untruthful or misleading statements including, but not limited to, a health claim that is not supported by the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), and for which there is significant scientific agreement, among

experts qualified by scientific training and experience to evaluate such claims; or

(b) Be attractive to minors, as that is defined in OAR 845-025-7000.

(9) A marijuana item that falls within more than one category, for example a product that is both a cannabinoid concentrate and cannabinoid edible, must comply with the labeling requirements that apply to both categories, with the exception of the "DO NOT EAT" warning if the product is intended for human consumption or the "BE CAUTIOUS" warning if the effects of the product are customarily felt immediately.

(10) The THC and CBD amount required to be on a label must be the value calculated by the laboratory that did the testing in accordance with OAR 333-064-0100.

(11) If a marijuana item has more than one test batch number, laboratory, or test analysis date associated with the marijuana item that is being sold or transferred, each test batch number, laboratory and test analysis date must be included on a label.

(12) If a marijuana item is placed in a package that is being reused, the old label or labels must be removed and it must have a new label or labels.

(13) A licensee or registrant must have documentation that demonstrates the validity of the calculation of the amount of sodium, sugar, carbohydrates and total fat in a cannabinoid edible and must make that documentation available to the Commission or the Authority upon request.

(14) Exit packaging must contain a label that reads: "Keep out of the reach of children."

Stat. Auth.: ORS 475B.605
Stats. Implemented: ORS 475B.605
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0100
Pre-Approval of Labels

(1) A registrant must submit labels for pre-approval in accordance with OAR 845-025-7060 and must keep all records related to the pre-approval process and provide those records at the request of the Authority.

(2) On and after October 1, 2016, a registrant may not transfer a marijuana item unless the label has been pre-approved in accordance with OAR 845-025-7060, unless pre-approval is not required under OAR 845-025-7060(9) to (12).

(3) A marijuana item that was transferred to a registered dispensary prior to October 1, 2016 is not required to have a label that was pre-approved by the Commission, but must meet the labeling requirements in these rules.

Stat. Auth.: ORS 475B.610
Stats. Implemented: ORS 475B.610
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16; PH 27-2016(Temp), f. & cert. ef. 9-30-16 thru 3-1-17

Concentration and Serving Size Limits

333-007-0200
Definitions, Purpose, Scope, Effective Date

(1) In accordance with ORS 475B.625, the Authority must establish, for marijuana items sold or transferred to a consumer, patient or designated primary caregiver through a Commission licensed marijuana retailer or medical marijuana dispensary:

(a) The maximum concentration of THC permitted in a single serving of a cannabinoid product or cannabinoid concentrate or extract; and

(b) The number of servings permitted in a cannabinoid product container or cannabinoid concentrate or extract container.

(2) The concentration of THC permitted under OAR 333-007-0210 through 333-007-0220 must take into account both the amount of Delta-9 THC in the cannabinoid product or cannabinoid concentrate or extract and the amount of tetrahydrocannabinolic acid (THCA) in the cannabinoid product or cannabinoid concentrate or extract that if heated would convert THCA to THC. A cannabinoid product or cannabinoid concentrate or extract that contains a high amount of THCA must meet the concentration limits established in OAR 333-007-0200 through 333-007-0220 even if heated.

(3) The amounts of THC listed on a label are based on an average from samples taken from a harvest or process lot and may not represent the exact amount of THC in a marijuana item purchased by a consumer, patient or designated primary caregiver.

(4) On and after October 1, 2016:

(a) A marijuana item received or transferred by a dispensary must meet the concentration and serving size limits in OAR 333-007-0210 or 333-007-0220, depending on whether the marijuana is available for sale or transfer to a consumer, patient or designated primary caregiver; and

(b) A dispensary may not receive or transfer a marijuana item that does not meet the concentration and serving size limits in OAR 333-007-0210 or 333-007-0220, as applicable.

(5) By October 1, 2016, a dispensary must have either transferred marijuana items that do not meet the concentration and serving size limits in OAR 333-007-0210 or 333-007-0220 to a patient or caregiver or must have returned any marijuana item that does not meet the requirements to the individual who transferred the item to the dispensary, and must document who the item was returned to, what was returned and the amount, and the date of the return.

(6) For purposes of OAR 333-007-0200 through 333-007-0220:

(a) The definitions in OAR 333-007-0020 apply unless otherwise specified.

(b) "Cannabinoid capsule" means a small soluble container, usually made of gelatin, that encloses a dose of a cannabinoid product, concentrate or extract intended for human ingestion.

(c) "Cannabinoid edible" means a food or potable liquid into which a cannabinoid concentrate or extract or the dried leaves or flowers of marijuana have been incorporated.

(d) "Cannabinoid suppository" means a small soluble container designed to melt at body temperature within a body cavity other than the mouth, especially the rectum or vagina containing a cannabinoid product, concentrate or extract.

(e) "Cannabinoid transdermal patch" means an adhesive substance applied to human skin that contains a cannabinoid product, concentrate or extract for absorption into the bloodstream.

(f) "Medical marijuana item" is a marijuana item for sale or transfer to a patient or designated primary caregiver and includes medical grade cannabinoid products, cannabinoid concentrates and cannabinoid extracts.

(g) "Retail adult use marijuana item" is a marijuana item for sale to a consumer.

(h) "Scored" means to physically demark a cannabinoid edible in a way that enables a reasonable person to:

(A) Intuitively determine how much of the product constitutes a single serving; and

(B) Easily physically separate the edible into single servings either by hand or with a common utensil, such as a knife.

Stat. Auth.: ORS 475B.625
Stats. Implemented: ORS 475B.625
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0210
Retail Marijuana Item Concentration and Serving Size Limits

(1) The maximum concentration or amount of THC permitted in a container and the maximum concentration or amount of THC permitted in a serving of a retail adult use marijuana item is listed in Table 1. [Table not included. See ED. NOTE.]

(2) A cannabinoid edible must be scored unless it is not capable of being scored because it is not solid at room temperature in which case the cannabinoid edible must be:

(a) Sold and packaged with a measuring device that measures single servings; or

(b) Placed in packaging that clearly enables a consumer to determine when a single serving has been consumed.

(3) Serving size is as determined by the processor.

(4) A retail adult use marijuana item that does not fall within a category in Table 1 such as cannabinoid suppositories and transdermal patches must meet the concentration and serving size limits applicable to a cannabinoid edible in Table 1.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: Sec. 105, ch. 614, OL 2015

Stats. Implemented: Sec. 105, ch. 614, OL 2015

Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0220
Medical Marijuana Item Concentration Limits

(1) The maximum concentration or amount of THC permitted in a container and the maximum concentration or amount of THC permitted in a serving of a medical marijuana item is listed in Table 2. [Table not included. See ED. NOTE.]

(2) A cannabinoid edible must be scored unless it is not capable of being scored because of its form or because it is not solid at room temperature in which case the cannabinoid edible must be:

(a) Sold and packaged with a measuring device that measures single servings; or

(b) Placed in packaging that clearly enables a patient to determine when a single serving has been consumed, as that serving size is determined by the processor.

(3) Serving size is as determined by the processor.

(4) A medical marijuana item that does not fall within a category in Table 2 must meet the concentration and serving size limits applicable to a cannabinoid edible in Table 2.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: Sec 105, ch 614, OL 2015

Stats. Implemented: Sec 105, ch 614, OL 2015

Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

Marijuana Testing

333-007-0300
Purpose and Effective Date

(1) The purpose of these rules is to establish the minimum testing standards for marijuana items. These rules are applicable to:

(a) A licensee; and

(b) A registrant who is not exempt from the testing requirements.

(2) The testing requirements do not apply to:

(a) A grower if the person is transferring usable marijuana or an immature marijuana plant to:

(A) A patient who designated the grower to grow marijuana for the patient; or

(B) A designated primary caregiver of the patient who designated the grower to grow marijuana for the patient; or

(b) A designated primary caregiver of a patient if the caregiver is transferring a marijuana item to a patient of the designated primary caregiver.

(3) A person registered with the Authority under ORS 475B.400 to 475B.525 who is subject to these rules may not:

(a) Transfer a marijuana item on or after October 1, 2016, that is not sampled and tested in accordance with these rules; or

(b) Accept the transfer of a marijuana item on or after October 1, 2016, that is not sampled and tested in accordance with these rules.

(4) A person licensed by the Commission must comply with these rules at all times.

(5) Notwithstanding section (3)(a) of this rule, until January 1, 2017, a dispensary may transfer a marijuana item to a patient or caregiver that was transferred to the dispensary before October 1, 2016, and that was not sampled and tested in accordance with these rules if the item contains a label placed on the package where it can easily be seen by the patient or caregiver that reads "DOES NOT MEET NEW TESTING REQUIREMENTS" in 12 point font, and in bold, capital letters.

(6) Nothing in these rules prevents a registrant from having marijuana items sampled and tested in accordance with these rules by an accredited and licensed laboratory prior to October 1, 2016.

(7) Prior to October 1, 2016, an accredited laboratory performing sampling or testing for a registrant may comply with this rule or OAR 333-008-1190 but the laboratory must identify on the test result which rule the results are compliant with.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0310
Definitions

For purposes of OAR 333-007-0300 through 333-007-0490:

(1) "Authority" means the Oregon Health Authority.

(2) "Batch" means:

(a) A quantity of usable marijuana from a harvest lot; or

(b) A quantity of cannabinoid concentrate or extract or cannabinoid product from a process lot.

(3) "Cannabinoid" means any of the chemical compounds that are the active constituents of marijuana.

(4) "Cannabinoid concentrate or extract" means a substance obtained by separating cannabinoids from marijuana by a mechanical, chemical or other process.

(5) "Cannabinoid edible" means food or potable liquid into which a cannabinoid concentrate or extract or the dried leaves or flowers of marijuana have been incorporated.

(6)(a) "Cannabinoid product" means a cannabinoid edible or any other product intended for human consumption or use, including a product intended to be applied to a person's skin or hair, that contains cannabinoids or the dried leaves or flowers of marijuana.

(b) "Cannabinoid product" does not include:

(A) Usable marijuana by itself;

(B) A cannabinoid concentrate or extract by itself; or

(C) Industrial hemp, as defined in ORS 571.300.

(7) "Cannabinoid capsule":

(a) Means a small soluble container, usually made of gelatin that encloses a dose of a cannabinoid product, concentrate or extract intended for human ingestion.

(b) Does not mean a cannabinoid suppository.

(8) "Cannabinoid suppository" means a small soluble container designed to melt at body temperature within a body cavity other than the mouth, especially the rectum or vagina containing a cannabinoid product, concentrate or extract.

(9) "Cannabinoid tincture" means a solution of alcohol, cannabinoid concentrate or extract, and perhaps other ingredients intended for human consumption or ingestion, and that is exempt from the Liquor Control Act under ORS 471.035.

(10) "Cannabinoid topical" means a cannabinoid product intended to be applied to skin or hair and for purposes of testing includes transdermal patches.

(11) Cannabinoid Transdermal patch" means an adhesive substance applied to human skin that contains a cannabinoid product, concentrate or extract for absorption into the bloodstream.

(12) "CBD" means cannabidiol, Chemical Abstracts Service Number 13956-29-1.

(13) "CBDA" means cannabidiolic acid, Chemical Abstracts Service Number 1244-58-2.

(14) "Chain of custody procedures" means procedures employed by laboratory personnel using a chain of custody form to record the possession of samples from the time of sampling through the retention time specified by the Authority or Commission.

(15) "Chain of custody form" means a form completed by laboratory personnel that documents the collection, transport, and receipt of samples by the laboratory.

(16) "Commission" means the Oregon Liquor Control Commission.

(17) "Consumer" has the meaning given that term in ORS 475B.015 and does not include a patient or designated primary caregiver.

(18) "Delta-9 THC" is the principal psychoactive constituent (the principal cannabinoid) of cannabis, Chemical Abstracts Service Number 1972-08-3.

(19)(a) "Designated primary caregiver" means an individual 18 years of age or older who has significant responsibility for managing the well-being of a person who has been diagnosed with a debilitating medical condition, who is designated as such on that person's application for a registry identification card or in other written notification to the Authority, and who has been issued an identification card by the Authority under ORS 475B.415(5)(b).

(b) "Designated primary caregiver" does not include the person's attending physician.

(20) "Field duplicate sample" means a sample taken in an identical manner from and representative of the same marijuana item being sampled that is analyzed separately, that is used for quality control only.

(21) "Food" means a raw, cooked, or processed edible substance, or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum.

(22) "Grower" has the same meaning as "person responsible for a marijuana grow site."

(23) "Grow site" means a specific location registered by the Authority and used by the grower to produce marijuana for medical use by a specific patient under ORS 475B.420.

(24) "Harvest lot " means a specifically identified quantity of marijuana that is uniform in strain, cultivated utilizing the same growing practices, harvested at the same time at the same location and cured under uniform conditions.

(25) "Homogeneous" means a cannabinoid product, concentrate or extract has uniform composition and properties throughout each process lot.

(26) "Human consumption or human ingestion" means to ingest, generally through the mouth, food, drink or other substances such that the substance enters the human body but does not include inhalation.

(27) "Laboratory" means a laboratory that is accredited under ORS 438.605 to 438.620 to sample or conduct tests on marijuana items and licensed by the Oregon Liquor Control Commission under ORS 475B.560.

(28) "Licensee" has the meaning given that term in ORS 475B.015.

(29)(a) "Marijuana" means the plant Cannabis family Cannabaceae, any part of the plant Cannabis family Cannabaceae and the seeds of the plant Cannabis family Cannabaceae.

(b) "Marijuana" does not include industrial hemp, as defined in ORS 571.300.

(30) "Marijuana item" means marijuana, usable marijuana, a cannabinoid product or a cannabinoid concentrate or extract.

(31) "Marijuana processing site" means a marijuana processing site registered under ORS 475B.435.

(32) "Medical marijuana dispensary" or "dispensary" means a medical marijuana dispensary registered under ORS 475B.450.

(33) "ORELAP" means the Oregon Environmental Laboratory Accreditation Program administered by the Authority pursuant to ORS 438.605 to 438.620.

(34) "Patient" has the same meaning as "registry identification cardholder."

(35) "Person responsible for a marijuana grow site" has the same meaning as "grower" and means a person who has been selected by a patient to produce medical marijuana for the patient and who has been registered by the Authority for this purpose under ORS 475B.420.

(36) "Process lot" means:

(a) Any amount of cannabinoid concentrate or extract of the same type and processed using the same extraction methods, standard operating procedures and batches from the same or a different harvest lot; or

(b) Any amount of a cannabinoid product of the same type and processed using the same ingredients, standard operating procedures and batches from the same or a different harvest lot or process lot of cannabinoid concentrate or extract as defined in subsection (a) of this section.

(37) "Process validation" means a study performed on products or matrices of unknown homogeneity to assure required uniformity of product accomplished through a series of sampling and testing from three consecutive process lots as described in OAR 333-007-0440.

(38) "Processing" means the compounding or conversion of marijuana into cannabinoid products or cannabinoid concentrates or extracts.

(39) "Processing site" means a processor registered with Authority under ORS 475B.435.

(40) "Processor" has the meaning given that term in OAR 845-025-1015.

(41) "Producer" has the meaning given that term in OAR 845-025-1015.

(42) "Producing" means:

(a) Planting, cultivating, growing, trimming or harvesting marijuana; or

(b) Drying marijuana leaves and flowers.

(43) "Registrant" means a grower, marijuana processing site, or a medical marijuana dispensary registered with the Authority under ORS 475B.420, 475B.435 or 475B.450.

(44) "Registry identification cardholder" means a person who has been diagnosed by an attending physician with a debilitating medical condition and for whom the use of medical marijuana may mitigate the symptoms or effects of the person's debilitating medical condition, and who has been issued a registry identification card by the Authority under ORS 475B.415(5)(a).

(45) "Relative percentage difference" or "RPD" means the comparison of two quantities while taking into account the size of what is being compared as calculated under OAR 333-064-0100.

(46) "Relative standard deviation" or "RSD" means the standard deviation expressed as a percentage of the mean recovery as calculated under OAR 333-064-0100.

(47) "Sample" means an amount of a marijuana item collected by laboratory personnel from a registrant or licensee and provided to a laboratory for testing.

(48) "Sterilization" means the removal of all microorganisms and other pathogens from a marijuana item by treating it with approved chemicals or subjecting it to high heat.

(49) "Test batch" means a group of samples from a batch submitted collectively to a laboratory for testing purposes.

(50) "THC" means tetrahydrocannabinol and has the same Chemical Abstracts Service Number as delta-9 THC.

(51) "THCA" means tetrahydrocannabinolic acid, Chemical Abstracts Service Number 23978-85-0.

(52) "These rules" means OAR 333-007-0300 through 333-007-0490.

(53) "TNI" means The NELAC (National Environmental Laboratory Accreditation Conference) Institute, a voluntary organization of state and federal environmental officials and interest groups purposed primarily to establish consensus standards for accrediting environmental laboratories.

(54) "TNI EL Standards" means the adopted 2009 TNI Environmental Lab Standards (© 2009 The NELAC Institute), which describe the elements of laboratory accreditation developed and established by the consensus principles of TNI and that meet the approval requirements of TNI procedures and policies.

(55) "Total THC" means the molar sum of THC and THCA.

(56)(a) "Usable marijuana" means the dried leaves and flowers of marijuana.

(b) "Usable marijuana" does not include:

(A) The seeds, stalks and roots of marijuana; or

(B) Waste material that is a by-product of producing or processing marijuana.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0315
Ordering Tests

A registrant or licensee must provide a laboratory, prior to laboratory taking samples, with the following:

(1) A written request of analysis for each test the laboratory is being requested to conduct.

(2) Notification of whether the batch is being re-sampled because of a failed test and the failed test results.

(3) Certification of successful process validation, if applicable, on a form prescribed by the Authority.

(4) Proof of a waiver under OAR 333-007-0490, if applicable.

Stat. Auth.: ORS 475B.555
Stats. Implemented: ORS 475B.555
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0320
Testing Requirements for Marijuana or Usable Marijuana

(1) A producer or grower must test every harvest lot of marijuana or usable marijuana intended for use by a consumer or patient prior to selling or transferring the marijuana or usable marijuana for the following:

(a) Pesticides in accordance with OAR 333-007-0400.

(b) Water activity and moisture content in accordance with OAR 333-007-0420.

(c) THC and CBD concentration in accordance with OAR 333-007-0430.

(2) A producer or grower must test every harvest lot of marijuana or usable marijuana intended for use by a processor or processing site for water activity and moisture content in accordance with OAR 333-007-0420 unless the processor or processing site uses a method of processing that results in effective sterilization.

(3) A producer or grower must test a harvest lot of marijuana or usable marijuana for microbiological contaminants in accordance with OAR 333-007-0390, upon written request by the Authority or the Commission.

(4) In lieu of ordering and arranging for the sampling and testing required in this rule a producer may transport batches of marijuana or usable marijuana to a wholesaler licensed by the Commission under ORS 475B.100 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.

Stat. Auth.: ORS 475B.555
Stats. Implemented: ORS 475B.555
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0330
Testing Requirements for Cannabinoid Concentrates and Extracts

(1) A processor or processing site must test every process lot of cannabinoid concentrate or extract for use by a consumer or patient prior to selling or transferring the cannabinoid concentrate or extract for the following:

(a) Pesticides in accordance with OAR 333-007-0400.

(b) Solvents in accordance with OAR 333-007-0410.

(c) THC and CBD concentration in accordance with OAR 333-007-0430.

(2) A processor or processing site must test every process lot of a cannabinoid concentrate or extract intended for use by a processor or processing site to make a cannabinoid product for the following:

(a) Pesticides in accordance with OAR 333-007-0400.

(b) Solvents in accordance with OAR 333-007-0410.

(3) A processor or processing site is exempt from testing for solvents under this rule if the processor or processing site:

(a) Did not use any solvent listed in OAR 333-007-0410, Table 4; and

(b) Only used a mechanical extraction process to separate cannabinoids from the marijuana; or

(c) Used only water, animal fat or vegetable oil as a solvent to separate the cannabinoids from the marijuana.

(4) A processor or processing site must test a process lot of a cannabinoid concentrate or extract for microbiological contaminants in accordance with OAR 333-007-0390, upon written request by the Authority or the Commission.

(5) In lieu of ordering and arranging for the sampling and testing required in this rule a processor may transport batches of cannabinoid concentrates or extracts to a wholesaler licensed by the Commission under ORS 475B.100 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.

Stat. Auth.: ORS 475B.555
Stats. Implemented: ORS 475B.555
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0340
Testing Requirements for Cannabinoid Products Intended for Human Consumption or Ingestion and Cannabinoid Suppositories

(1) A processor or processing site must test every process lot of a cannabinoid product intended for human consumption or ingestion, including cannabinoid edibles, capsules, and tinctures, and cannabinoid suppositories for use by a consumer or patient prior to selling or transferring the cannabinoid product for THC and CBD concentration in accordance with OAR 333-007-0430.

(2) A processor or processing site must test a process lot for microbiological contaminants in accordance with OAR 333-007-0390, upon written request by the Authority or the Commission.

(3) In lieu of ordering and arranging for the sampling and testing required in this rule a processor may transport batches of cannabinoid products references in section (1) of this rule to a wholesaler licensed by the Commission under ORS 475B.100 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.

Stat. Auth.: ORS 475B.555
Stats. Implemented: ORS 475B.555
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0345
Testing Requirements for Cannabinoid Topicals and Cannabinoid Transdermal Patches

(1) A processor or processing site must test every process lot of a cannabinoid topical or transdermal patch for use by a consumer or patient prior to selling or transferring the cannabinoid product for THC and CBD concentration in accordance with OAR 333-007-0430.

(2) A processor or processing site must test a process lot of a cannabinoid topical or transdermal patch for microbiological contaminants in accordance with OAR 333-007-0390, upon written request by the Authority or the Commission.

(3) In lieu of ordering and arranging for the sampling and testing required in this rule a processor may transport batches of cannabinoid products references in section (1) of this rule to a wholesaler licensed by the Commission under ORS 475B.100 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.

Stat. Auth.: ORS 475B.555
Stats. Implemented: ORS 475B.555
Hist.: PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0350
Batch Requirements

(1) Usable marijuana.

(a) A producer or grower must separate each harvest lot into no larger than 10 pound batches.

(b) Notwithstanding subsection (1)(a) of this rule, a producer or grower may combine harvest lots together for purposes of having a batch sampled if each batch is intended for use by a pro-

cessor or processing site to make a cannabinoid concentrate or extract and each harvest lot was:

(A) Cultivated utilizing the same growing practices and grown in close proximity on the licensed or registered premises;

(B) Harvested at the same time; and

(C) If cured prior to sampling, cured under uniform conditions.

(c) A producer or grower may not combine harvest lots into a batch for purposes of sampling and testing for THC or CBD.

(d) If harvest lots are combined in accordance with subsection (1)(b) of this rule the batch must be labeled so that it identifies the different harvest lots that were combined.

(2) Cannabinoid concentrates and extracts and cannabinoid products. A process lot is considered a batch.

(3) A grower and processing site must assign each batch a unique batch number and that unique batch number must be:

(a) Documented and maintained in the grower and processing site records for at least two years and available to the Authority upon request;

(b) Provided to the individual responsible for taking samples; and

(c) Included on the batch label as required in OAR 333-007-0380.

(4) A grower and processing site may not reuse a unique batch number.

Stat. Auth.: ORS 475B.555
Stats. Implemented: ORS 475B.555
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0360
Sampling and Sample Size

(1) Usable marijuana.

(a) Usable marijuana may only be sampled after it is cured, unless the usable marijuana is intended for sale or transfer to a processor or processing site to make a cannabinoid concentrate or extract.

(b) Samples taken must in total represent a minimum of 0.5 percent of the batch, consistent with the laboratory's accredited sampling policies and procedures, described in OAR 333-064-0100(2).

(2) Cannabinoid concentrates, extracts and products.

(a) Unless a cannabinoid concentrate, extract or product has successfully passed process validation, enough samples from a batch must be taken to ensure that the required attributes in the batch to be tested are homogenous and consistent with the laboratory's accredited sampling policies and procedures described in OR 333-064-0100(2).

(b) If a cannabinoid concentrate, extract or product has successfully passed process validation only a primary sample and field duplicate sample must be taken from a batch in accordance with the laboratory's accredited sampling policies and procedures described in OAR 333-064-0100(2).

Stat. Auth.: ORS 475B.555
Stats. Implemented: ORS 475B.555
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0370
Sampling Personnel Requirements; Sampling Recordkeeping

(1) Only individuals employed by a laboratory with an ORELAP accredited scope item for sampling under these rules may take samples.

(2) Sampling may be conducted at a licensee's or registrant's premises or the licensee or registrant may transport the batch to a laboratory with an ORELAP accredited scope item for sampling under these rules.

(3) Laboratory personnel that perform sampling must:

(a) Follow the laboratory's accredited sampling policies and procedures;

(b) Follow chain of custody procedures consistent with TNI EL Standard V1M2 5.7 and 5.8; and

(c) After taking samples document the samples in accordance with OAR 333-064-0100(2) and if sampling for a licensee record the sampling and transfer information in the Commission's seed to sale system, as required by the Commission.

(4) A laboratory must maintain the documentation required in these rules for at least two years and must provide that information to the Authority upon request.

Stat. Auth.: ORS 475B.555
Stats. Implemented: ORS 475B.555
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0380
Grower and Processing Site Requirements for Labeling, Storing, and Securing Pre-Tested Marijuana Items; Recordkeeping

(1) Following samples being taken from a harvest or process lot batch a grower or processing site must:

(a) Label the batch with the following information:

(A) The registrant's registration number;

(B) The harvest or process lot unique identification number;

(C) The name and accreditation number of the laboratory that took samples and the name and accreditation number of the laboratory responsible for the testing, if different;

(D) The test batch or sample unique identification numbers supplied by the laboratory personnel;

(E) The date the samples were taken; and

(F) In bold, capital letters, no smaller than 12 point font, "PRODUCT NOT TESTED."

(b) Store and secure the batch in a manner that prevents the product from being tampered with or transferred prior to test results being reported.

(c) Be able to easily locate a batch stored and secured under section (1)(b) of this rule and provide that location to the Authority or a laboratory upon request.

(2) If the samples pass testing the product may be sold or transferred in accordance with the applicable Authority rules.

(3) If the samples do not pass testing the grower or processing site must comply with OAR 333-007-0450.

Stat. Auth.: ORS 475B.555
Stats. Implemented: ORS 475B.555
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0390
Standards for Testing Microbiological Contaminants

(1) A marijuana item required to be tested for microbiological contaminants must be sampled using appropriate aseptic technique and tested by a laboratory for total coliform count.

(2) If a laboratory detects the presence of any coliforms the sample must be assessed for Escherichia coli (E. coli).

(3) A batch fails microbiological contaminant testing if the laboratory detects the presence of E. coli at more than 100 colony forming units per gram in a sample:

(a) During an initial test where no reanalysis is requested; or

(b) Upon reanalysis as described in OAR 333-007-0450(1).

Stat. Auth.: ORS 475B.555
Stats. Implemented: ORS 475B.555
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0400
Standards for Testing Pesticides

(1) A marijuana item required to be tested for pesticides must be tested by a laboratory for the analytes listed in Exhibit A, Table 3, incorporated by reference. [Table not included. See ED. NOTE.]

(2) A batch fails pesticide testing if a laboratory detects the presence of a pesticide above the action levels listed in Exhibit A, Table 3 in a sample:

(a) During an initial test where no reanalysis is requested; or

(b) Upon reanalysis as described in OAR 333-007-0450(1). [Table not included. See ED. NOTE.]

(3) The Authority will review and update, if necessary, the analytes listed in Exhibit A, Table 3, at least every two years.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0410

Standards for Testing Solvents

(1) A marijuana item required to be tested for solvents must be tested by a laboratory for the analytes listed in Exhibit A, Table 4 incorporated by reference. [Table not included. See ED. NOTE.]

(2) A batch fails solvent testing if a laboratory, during an initial test where no reanalysis is requested or upon reanalysis as described in OAR 333-007-0450(1):

(a) Detects the presence of a solvent above the action level listed in Exhibit A, Table 4 in a sample; or [Table not included. See ED. NOTE.]

(b) Calculates a RPD of more than 20 percent between the field primary result of the sample and the field duplicate result.

(3) The Authority will review and update, if necessary, the analytes listed in Exhibit A, Table 4, at least every two years. [Table not included. See ED. NOTE.]

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0420

Standards for Testing Water Activity and Moisture Content

(1) Usable marijuana must be tested by a laboratory for:

(a) Water activity; and

(b) Moisture content.

(2) If a sample has a water activity rate of more than 0.65 Aw the sample fails.

(3) If a sample has a moisture content of more than 15 percent the result must be reported to the licensee but the sample does not fail.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0430

Standards for THC and CBD Testing

(1) A laboratory must test for the following when testing a marijuana item for potency:

(a) THC.

(b) THCA.

(c) CBD.

(d) CBDA.

(2) A process lot of a cannabinoid concentrate, extract or product that has not successfully completed process validation fails potency testing if, based on an initial test where no reanalysis is requested or upon reanalysis as described in OAR 333-007-0450(1):

(a) The amount of THC, as calculated pursuant to OAR 333-064-0100, between samples taken from the batch exceeds 30 percent RSD; or

(b) The amount or percentage of THC, as calculated pursuant to OAR 333-064-0100, exceeds the maximum concentration limits permitted in package as specified in OAR 333-007-0200 to 333-007-0220, as applicable.

(3) A process lot of a cannabinoid concentrate, extract or product that has successfully completed process validation fails potency testing if, based on an initial test where no reanalysis is requested or upon reanalysis as described in OAR 333-007-0450(1):

(a) The amount of THC, as calculated pursuant to OAR 333-064-0100, between the sample and the field duplicate exceeds 20 percent RPD; or

(b) The amount or percentage of THC, as calculated pursuant to OAR 333-064-0100, exceeds the maximum concentration limits permitted in a package as specified in OAR 333-007-0200 to 333-007-0220, as applicable.

(4) A sample cannot fail CBD testing.

(5) Notwithstanding section (2)(a) and (3)(a) of this rule, a sample that has less than 5 mg of THC as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RSD or RPD as described in section (2)(a) or (3)(a) of this rule.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0440

Process Validation

(1) A laboratory may perform process validation tests on three consecutive process lots of cannabinoid concentrates, extracts or products for a processor or processing site if the processor or processing site informs the laboratory, in writing:

(a) That sampling and testing is for the purposes of process validation; and

(b) For cannabinoid products, the expected THC range for the product.

(2) Samples taken for purposes of process validation testing may not be combined.

(3) Samples of cannabinoid concentrate and extracts must be tested for:

(a) Pesticides in accordance with OAR 333-007-0400,

(b) Solvents in accordance with OAR 333-007-0410.

(4) Samples of cannabinoid products must be tested for THC concentration in accordance with OAR 333-007-0430, as calculated pursuant to OAR 333-064-0100.

(5) During process validation a batch passes:

(a) Pesticide testing if each sample is below the action limit established in OAR 333-007-0400.

(b) Solvent testing if:

(A) Each sample is below the action limit established in OAR 333-007-0410; and

(B) The results above the LOQ are not greater than 30 percent RSD between samples.

(c) THC concentration testing if:

(A) The amount of THC, as calculated pursuant to OAR 333-064-0100, between samples taken from the batch does not exceed 30 percent RSD; and

(B) The amount or percentage of THC as calculated pursuant to OAR 333-064-0100, does not exceed the maximum concentration limit permitted in a package as specified in OAR 333-007-0200 to 333-007-0220, as applicable.

(6) A laboratory must identify on a form prescribed by the Authority if a batch undergoing process validation has passed for any of the following:

(a) Pesticides, if applicable.

(b) Solvents, if applicable.

(c) THC concentration as calculated pursuant to OAR 333-064-0100, if applicable.

(7) A process lot sampled and tested for purposes of process validation may be sold or transferred if the samples pass all the required tests.

(8) A processor or processing site must undergo process validation for a product again or must have batches sampled and tested as if the product had not undergone process validation if:

(a) There are any changes to the standard operating procedures for that product.

(b) There are any changes in the type of ingredient in the product, except for a difference in the strain of usable marijuana, or the purity of an ingredient.

(9) Process validation is only valid for two years.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0450

Failed Test Samples

(1) If a sample fails any initial test the laboratory that did the testing may reanalyze the sample. If the sample passes, another laboratory must resample the batch and confirm that result in order for the batch to pass testing.

(2) If a sample fails a test or a reanalysis under section (1) of this rule the batch:

(a) May be remediated or sterilized in accordance with this rule; or

(b) If it is not or cannot be remediated or sterilized under this rule, must be destroyed in a manner specified by the Authority or the Commission.

(3) If a licensee or registrant is permitted under this rule to sell or transfer a batch that has failed a test, the licensee or registrant must notify the licensee or registrant to whom the batch is sold or transferred of the failed test.

(4) Failed microbiological contaminant testing.

(a) If a sample from a batch of usable marijuana fails microbiological contaminant testing the batch may be used to make a cannabinoid concentrate or extract if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon based solvent or a CO2 closed loop system.

(b) If a sample from a batch of a cannabinoid concentrate or extract fails microbiological contaminant testing the batch may be further processed if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon based solvent or a CO2 closed loop system.

(c) A batch that is sterilized in accordance with subsection (a) or (b) of this section must be sampled and tested in accordance with these rules and must be tested if not otherwise required for that product, for microbiological contaminants, solvents and pesticides.

(d) A batch that fails microbiological contaminant testing after undergoing a sterilization process in accordance with subsection (a) or (b) of this section must be destroyed in a manner specified by the Authority or the Commission.

(5) Failed solvent testing.

(a) If a sample from a batch fails solvent testing the batch may be remediated using procedures that would reduce the concentration of solvents to less than the action level.

(b) A batch that is remediated in accordance with subsection (a) of this section must be sampled and tested in accordance with these rules and must be tested if not otherwise required for that product under these rules, for solvents and pesticides.

(c) A batch that fails solvent testing that is not remediated or that if remediated fails testing must be destroyed in a manner specified by the Authority or the Commission.

(6) Failed water activity testing.

(a) If a sample from a batch of usable marijuana fails for water activity the batch from which the sample was taken may:

(A) Be used to make a cannabinoid concentrate or extract; or

(B) Continue to dry or cure.

(b) A batch that undergoes additional drying or curing as described in paragraph (a)(B) of this section must be sampled and tested in accordance with these rules.

(7) Failed pesticide testing.

(a) If a sample from a batch fails pesticide testing the batch may not be remediated and must be destroyed in a manner approved by the Authority or the Commission.

(b) The Authority must report to the Oregon Department of Agriculture all test results that show that a sample failed a pesticide test.

(8) Failed potency testing.

(a) A marijuana item that fails potency testing under OAR 333-007-0430(2)(a) or (3)(a) may be repackaged in a manner that enables the item to meet the standard in OAR 333-007-0430(2)(a) or (3)(a).

(b) A marijuana item that is repackaged in accordance with this section must be sampled and tested in accordance with these rules.

(9) If a sample fails a test after undergoing remediation or sterilization as permitted under this rule the batch must be destroyed in a manner approved by the Authority or the Commission.

(10) An Authority representative must witness the destruction of a batch if destruction is required by this rule.

(11) A registrant must inform a laboratory prior to samples being taken that the batch has failed a test and is being retested after undergoing remediation or sterilization.

(12) A registrant must, as applicable:

(a) Have detailed procedures for sterilization processes to remove microbiological contaminants and for reducing the concentration of solvents.

(b) Document all sampling, testing, sterilization, remediation and destruction that are a result of failing a test under these rules.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0470

Tentative Identification of Compounds

(1) Tentatively Identified Compounds (TICs) are compounds detected in a sample using gas chromatography mass spectrometry that are not among the target analytes for the residual solvent analysis.

(2) The Authority may initiate an investigation of a registrant upon receipt of a TICS report from a laboratory and may require a registrant to submit samples for additional testing, including testing for analytes that are not required by these rules, at the registrant's expense.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0480
Audit and Random Testing

(1) The Authority may require a registrant to submit samples identified by the Authority to a laboratory of the registrant's choosing to be tested in order to determine whether a registrant is in compliance with OAR 333-007-0300 through 333-007-0490, and may require additional testing that is not required by these rules.

(2) A laboratory doing audit testing must comply with these rules, to the extent they are applicable, and if conducting testing not required by these rules, may only use Authority approved methods.

(3) The Authority must establish a process for the random testing of marijuana items for microbiological contaminants that ensures each registrant tests every product for microbiological contaminants at least once a year.

Stat. Auth.: ORS 475B.555
Stats. Implemented: ORS 475B.555
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-0490
Waiver of Sampling and Testing Requirements

(1) Solvent testing.

(a) The Commission or the Authority may, upon receipt of a written request from a licensee or registrant, waive a requirement that every batch of a process lot be tested for solvents, if the licensee or registrant can demonstrate that none of the batches from any of the previous four process lots tested failed a solvent test.

(b) In order to qualify for a waiver under this section the fourth process lot must be processed at least 30 days after the first.

(c) If the waiver is granted the Commission or Authority must provide notice, in writing, to the registrant or licensee of the waiver and how long the waiver will be in effect.

(d) If the Commission or the Authority waives the testing requirement the licensee or registrant is subject to random testing and the Commission or the Authority shall notify the licensee or registrant when a process lot must be tested in accordance with these rules.

(2) Sampling.

(a) The Commission or the Authority may, upon receipt of a written request from a processor or processing site waive the sampling requirements in OAR 333-007-0360(2)(a) for a particular product if the processor processing site:

(A) Can demonstrate that none of the batches from any of the previous four process lots tested failed any test;

(B) Submits to the Commission or the Authority detailed processing standard operating procedures that demonstrate the product is uniform and uniform from process lot to process lot;

(C) Can demonstrate that it has and follows quality control measures; and

(D) Can demonstrate that subjecting a product to process validation under OAR 333-007-0440 is cost prohibitive.

(b) In order to qualify for a waiver under this section the fourth process lot must be processed at least 30 days after the first.

(c) If the waiver is granted the Commission or Authority must provide notice, in writing, to the registrant or licensee of the waiver, how long the waiver will be in effect, and the sampling that is required of the product for which the waiver was approved.

Stat. Auth.: ORS 475B.555
Stats. Implemented: ORS 475B.555
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-007-1000
Temporary OLCC Licensee Pesticide Testing Requirements

(1) Notwithstanding OAR 333-007-0300 to 333-007-0490 and 333-064-0100, until March 1, 2017, if the Commission finds there is insufficient laboratory capacity for the testing of pesticides, the Commission may permit randomly chosen samples from batches of usable marijuana to be tested for pesticides by a licensed laboratory rather than requiring every batch of usable marijuana from a harvest lot to be tested for pesticides.

(2) The Commission must ensure that samples from at least one batch of every harvest lot are tested for pesticides.

(3) If any one of the randomly chosen samples from a batch of a producer licensee's harvest lot fails a pesticide test every batch from the harvest lot must be tested for pesticides.

(4) If the randomly chosen samples from batches of usable marijuana that are tested for pesticides all pass, the entire harvest lot is considered to have passed pesticide testing and may be transferred or sold.

Stat. Auth.: ORS 475B.555
Stats. Implemented: ORS 475B.555
Hist.; PH 27-2016(Temp), f. & cert. ef. 9-30-16 thru 3-1-17

DIVISION 8

MEDICAL MARIJUANA

333-008-0010
Definitions

For the purposes of OAR chapter 333, division 8 the following definitions apply unless otherwise indicated:

(1) "Advertising" means publicizing the trade name of a PRMG, registered processing site or dispensary together with words or symbols referring to marijuana or publicizing the brand name of marijuana or a medical cannabinoid product, concentrate or extract in any medium.

(2) "Applicant" means, as applicable to the registration being applied for:

(a) An individual applying for a registry identification card under ORS 475B.415.

(b) An individual applying for a grow site registration under ORS 475B.420.

(c) A person applying for a marijuana processing site registration under ORS 475B.435.

(d) A person applying for a medical marijuana dispensary registration under ORS 475B.450.

(3) "Attending physician" means a Doctor of Medicine (MD) or Doctor of Osteopathy (DO), licensed under ORS chapter 677, who has primary responsibility for the care and treatment of a person diagnosed with a debilitating medical condition.

(4) "Attending physician statement" or "APS" means the form, prescribed by the Authority and signed by an attending physician, that states the individual has been diagnosed with a debilitating medical condition and that the medical use of marijuana may mitigate the symptoms or effects of the individual's debilitating medical condition.

(5) "Authority" means the Oregon Health Authority.

(6) "Business day" means Monday through Friday excluding legal holidays.

(7) "CBD" means cannabidiol.

(8) "Cannabinoid" means any of the chemical compounds that are the active constituents of marijuana.

(9) "Cannabinoid concentrate" means a substance obtained by separating cannabinoids from marijuana by:

(a) A mechanical extraction process;

(b) A chemical extraction process using a nonhydrocarbon-based solvent, such as vegetable glycerin, vegetable oils, animal fats, isopropyl alcohol or ethanol;

(c) A chemical extraction process using the hydrocarbon-based solvent carbon dioxide, provided that the process does not involve the use of high heat or pressure; or

(d) Any other process authorized in these rules.

(10) "Cannabinoid edible" means food or potable liquid into which a cannabinoid concentrate, cannabinoid extract or dried leaves or flowers of marijuana have been incorporated.

(11) "Cannabinoid extract" means a substance obtained by separating cannabinoids from marijuana by:

(a) A chemical extraction process using a hydrocarbon-based solvent, such as butane, hexane or propane; or

(b) A chemical extraction process using the hydrocarbon-based solvent carbon dioxide, if the process uses high heat or pressure.

(12) "Cartoon" means any drawing or other depiction of an object, person, animal, creature or any similar caricature that satisfies any of the following criteria:

(a) The use of comically exaggerated features;

(b) The attribution of human characteristics to animals, plants or other objects, or the similar use of anthropomorphic technique; or

(c) The attribution of unnatural or extra-human abilities, such as imperviousness to pain or injury, X-ray vision, tunneling at very high speeds or transformation.

(13) "Commission" means the Oregon Liquor Control Commission.

(14) "Conviction" means an adjudication of guilt upon a verdict or finding entered in a criminal proceeding in a court of competent jurisdiction.

(15) "Database" means the electronic system established pursuant to ORS 475B.458, in which the Authority stores the information PRMGs, registered processing sites and dispensaries are required to submit under these rules.

(16) "Debilitating medical condition" means:

(a) Cancer, glaucoma, a degenerative or pervasive neurological condition, positive status for human immunodeficiency virus or acquired immune deficiency syndrome, or a side effect related to the treatment of those medical conditions;

(b) A medical condition or treatment for a medical condition that produces, for a specific patient, one or more of the following:

(A) Cachexia;

(B) Severe pain;

(C) Severe nausea;

(D) Seizures, including but not limited to seizures caused by epilepsy; or

(E) Persistent muscle spasms, including but not limited to spasms caused by multiple sclerosis;

(c) Post-traumatic stress disorder; or

(d) Any other medical condition or side effect related to the treatment of a medical condition adopted by the Authority by rule or approved by the Authority pursuant to a petition filed under OAR 333-008-0090.

(17) "Delivery" has the meaning given that term in ORS 475B.410.

(18)(a) "Designated primary caregiver" means an individual who:

(A) Is 18 years of age or older;

(B) Has significant responsibility for managing the well-being of a person who has been diagnosed with a debilitating medical condition; and

(C) Is designated as the person responsible for managing the well-being of a person who has been diagnosed with a debilitating medical condition on that person's application for a registry identification card or in other written notification submitted to the Authority.

(b) "Designated primary caregiver" does not include a person's attending physician.

(19) "Direct interest" means an interest that is held in the name of the individual.

(20) "Domicile" means the place an individual intends as his or her fixed place of abode or habitation where he or she intends to remain and to which, if absent, the individual intends to return.

(21) "Elementary school" means a learning institution containing any combination of grades Kindergarten through 8.

(22) "Employee":

(a) Means any individual, including an alien, employed for remuneration or under a contract of hire, written or oral, express or implied, by an employer.

(b) Does not mean an individual who volunteers or donates services performed for no remuneration or without expectation or contemplation of remuneration as adequate consideration for the services performed for a religious or charitable institution or a governmental entity.

(23) "Food stamps" means the Supplemental Nutrition Assistance Program as defined and governed by ORS 411.806 through 411.845.

(24) "Grandfathered grow site" means a grow site registered by the Authority that has been approved by the Authority under OAR 333-008-0520 that can have up to:

(a) 24 mature marijuana plants if the location is within city limits and zoned residential; or

(b) 96 mature marijuana plants if the location is within city limits but not zoned residential or not within city limits.

(25) "Grow site" means a location registered under ORS 475B.420 where marijuana is produced for use by a patient or, with permission from a patient, for transfer to a registered processing site or dispensary.

(26) "Grow site registration card" means a card issued by the Authority that identifies the address of a marijuana grow site and the PRMG.

(27) "Immature marijuana plant" means a marijuana plant that is not flowering.

(28) "Indirect interest" means:

(a) An interest that is owned by a business entity that is owned, in whole or in part and either directly or indirectly, through one or more other intermediate business entities, by the individual; or

(b) An interest held in the name of another but the benefits of ownership of which, the individual is entitled to receive.

(29) "Individual who has a financial interest" in a business entity that owns a processing site or dispensary means:

(a) If the business entity is a corporation:

(A) Stockholders: Any individual who owns, directly or indirectly, 10 percent or more of the outstanding stock of such corporation.

(B) Directors: Any director of the corporation who receives compensation for acting in that capacity or who owns, directly or indirectly, 5 percent or more of the outstanding stock of such corporation.

(C) Officers: Any officer of the corporation who receives compensation for acting in that capacity or who owns, directly or indirectly, 5 percent or more of the outstanding stock of such corporation.

(b) If the business entity is a trust:

(A) Trustees: Any individual who is a trustee of the trust and who receives compensation for acting in that capacity and any individual who owns, directly or indirectly, 10 percent or more of the ownership interests of a business entity that is a trustee of the trust and that receives compensation for acting in that capacity.

(B) Beneficiaries: Any individual who is entitled to receive, directly or indirectly, income or benefit from the trust.

(c) If the business entity is a partnership:

(A) General Partners: Any individual who is a general partner of the partnership and who receives compensation for acting in that capacity or who owns 5 percent or more of the ownership interests of the partnership and any individual who owns, directly or indirectly, 10 percent or more of the ownership interests of a business entity that is a general partner of the partnership and that receives compensation for acting in that capacity or owns 5 percent or more of the ownership interests of the partnership.

(B) Limited Partners: Any individual who is a limited partner of the partnership and who owns 10 percent or more of the ownership interests of the partnership and any individual who owns, directly or indirectly, 10 percent or more of the ownership interests of a business entity that is a limited partner of the partnership and that owns 10 percent or more the ownership interests of the partnership.

(d) If the business entity is a joint venture: Any individual who is entitled to receive, directly or indirectly, income or benefit from the joint venture.

(e) If the business entity is a limited liability company:

(A) Managers: Any individual who is a manager of the limited liability company and who receives compensation for acting in that capacity or who owns 5 percent or more of the ownership interests of the limited liability company and any individual who owns, directly or indirectly, 10 percent or more of the ownership interests of a business entity that is a manager of the limited liability company and that receives compensation for acting in that capacity or owns 5 percent or more of the ownership interests of the limited liability company.

(B) Members: Any individual who is a member of the limited liability company and who owns 10 percent or more of the ownership interests of the limited liability company and any individual who owns, directly or indirectly, 10 percent or more of the ownership interests of a business entity that is a member of the limited liability company and that owns 10 percent or more of the ownership interests of the limited liability company.

(f) Immediate family members: Any person, 18 years of age or older, involved in a marijuana processing site or dispensary, in any capacity, who is a member of the immediate family of any individual who otherwise has a financial interest in the business entity that owns the marijuana processing site or dispensary. A person is a member of the immediate family of the individual if the person receives more than 50 percent of his or her financial support from that individual.

(g) Landlord: Any individual who is a landlord of a processing site or dispensary and who is entitled to receive 40 percent or more of the proceeds from the marijuana processing site or dispensary as a part of lease payments or rent, any individual who owns, directly or indirectly, 10 percent or more of the ownership interests of a business entity that is a landlord of a processing site or dispensary and that is entitled to receive 40 percent or more of the proceeds from the marijuana processing site or dispensary as part of lease payments or rent, and any individual who the Authority finds, based on reasonably reliable information, exerts influence over the operation of the marijuana processing site or dispensary through a landlord-tenant relationship and receives a portion of the proceeds from that marijuana processing site or dispensary.

(h) Other forms of business organization: If the form of business entity is not expressly addressed in subsections (a) to (g) of this section, the Authority will, in determining individuals who have a financial interest in the business entity, apply the portions of this definition applicable to the business entity that are most similar to the subject business entity, interpreting the terminology and concepts of this definition in the context of the subject business entity as necessary or appropriate.

(30) "Indoor production" for purposes of OAR 333-008-0580 means producing marijuana in any manner:

(a) Utilizing artificial lighting on mature marijuana plants; or

(b) Other than "outdoor production" as that is defined in this rule.

(31) "Limited access area" means:

(a) For a dispensary a building, room, or other contiguous area on a dispensary premises where a marijuana item is present but does not include the area where marijuana items are transferred to a patient or designated primary caregiver.

(b) For a processing site a building, room, or other contiguous area on a processing site premises where a marijuana item is present.

(32)(a) "Marijuana" means the plant Cannabis family Cannabaceae, any part of the plant Cannabis family Cannabaceae and the seeds of the plant Cannabis family Cannabaceae.

(b) "Marijuana" does not include industrial hemp, as defined in ORS 571.300.

(33) "Marijuana item" means marijuana, cannabinoid concentrates, cannabinoid extracts, medical cannabinoid products, and immature marijuana plants.

(34) "Marijuana processing site" or "processing site" means a marijuana processing site registered under ORS 475B.435 or a site for which an applicant has submitted an application for registration under ORS 475B.435.

(35) "Mature marijuana plant" means a marijuana plant that is not an immature marijuana plant.

(36)(a) "Medical cannabinoid product" means a cannabinoid edible and any other product intended for human consumption or use, including a product intended to be applied to a person's skin or hair, that contains cannabinoids or dried leaves or flowers of marijuana.

(b) "Medical cannabinoid product" does not include:

(A) Usable marijuana by itself;

(B) A cannabinoid concentrate by itself;

(C) A cannabinoid extract by itself; or

(D) Industrial hemp, as defined in ORS 571.300.

(37) "Medical marijuana dispensary" means a medical marijuana dispensary registered under ORS 475B.450 or a site for which an applicant has submitted an application for registration under ORS 475B.450.

(38) "Medical use of marijuana" means the production, processing, possession, delivery, or administration of marijuana, or use of paraphernalia used to administer marijuana to mitigate the symptoms or effects of a debilitating medical condition.

(39) "Minor" means an individual under the age of 18.

(40) "Oregon Health Plan (OHP)" means the medical assistance program administered by the Authority under ORS chapter 414.

(41) "OMMP" means the section within the Authority that administers the provisions of ORS 475B.400 to 475B.525, the applicable provisions of 475B.550 to 475B.590, 475B.600 to 475B.655, and the rules in OAR chapter 333, divisions 7 and 8.

(42) "Outdoor production" for purposes of OAR 333-008-0580 means producing marijuana:

(a) In an expanse of open or cleared ground open to the air; or

(b) In a greenhouse, hoop house or similar non-rigid structure that does not utilize any artificial lighting on mature marijuana plants, including but not limited to electrical lighting sources.

(43) "Parent or legal guardian" means the custodial parent or legal guardian with responsibility for health care decisions for the person under 18 years of age.

(44) "Patient" has the same meaning as "registry identification cardholder."

(45) "Person designated to produce marijuana by a registry identification cardholder" or "person designated to produce marijuana by a patient" mean a person designated to produce marijuana by a patient under ORS 475B.420 who produces marijuana for that patient at an address:

(a) Other than the address where the patient resides; or

(b) Where more than 12 mature marijuana plants are produced.

(46) "Person responsible for a marijuana grow site," or "PRMG" mean any individual designated by a patient to produce marijuana for the patient, including a patient who identifies him or herself as a person responsible for the marijuana grow site.

(47) "Personal agreement" means a document, as described in ORS 475B.425 signed and dated by a patient, assigning a patient's right to possess seeds, immature marijuana plants and usable marijuana to a PRMG.

(48) "Point of sale" means a specific location within a point of sale area at which the transfer of a marijuana item occurs.

(49) "Point of sale area" means a secure area where a registered dispensary transfers a marijuana item to a patient or caregiver.

(50) "Premises" means a location registered by the Authority as a processing site or dispensary under these rules and includes all areas at the location that are used in the business operated at the location, including offices, kitchens, rest rooms and storerooms, including all public and private areas where individuals are permitted to be present.

(51) "Primary responsibility" as that term is used in relation to an attending physician means that the physician:

(a) Provides primary health care to the patient; or

(b) Provides medical specialty care and treatment to the patient as recognized by the American Board of Medical Specialties; or

(c) Is a consultant who has been asked to examine and treat the patient by the patient's primary care physician licensed under ORS chapter 677, the patient's physician assistant licensed under ORS chapter 677, or the patient's nurse practitioner licensed under ORS chapter 678; and

(d) Has reviewed a patient's medical records at the patient's request and has conducted a thorough physical examination of the patient, has provided or planned follow-up care, and has documented these activities in the patient's medical record.

(52) "Process" means the compounding or conversion of marijuana into medical cannabinoid products, cannabinoid concentrates or cannabinoid extracts.

(53) "Production" or "growing" means:

(a) Planting, cultivating, growing, trimming or harvesting marijuana; or

(b) Drying marijuana leaves or flowers.

(54) "Registry identification card" means a document issued by the Authority under ORS 475B.415 that identifies a person authorized to engage in the medical use of marijuana, and, if the person has a designated primary caregiver under ORS 475B.418, the person's designated primary caregiver.

(55) "Registry identification cardholder" means a person to whom a registry identification

card has been issued under ORS 475B.415(5)(a) and has the same meaning as patient.

(56) "Remuneration" means compensation resulting from the employer-employee relationship, including wages, salaries, incentive pay, sick pay, compensatory pay, bonuses, commissions, stand-by pay, and tips.

(57) "Replacement card" means a new card issued in the event that:

(a) A patient's registry identification card, a designated primary caregiver's or a PRMG's identification card, or grow site registration card is lost or stolen; or

(b) A patient's designation of primary caregiver, PRMG or grow site has changed.

(58) "Resident" means an individual who has primary domicile within this state.

(59) "Safe" means:

(a) A metal receptacle with a locking mechanism capable of storing all usable marijuana at a registered premises that:

(A) Is rendered immobile by being securely anchored to a permanent structure of the building; or

(B) Weighs more than 750 pounds.

(b) A vault; or

(c) A refrigerator or freezer capable of being locked for storing edibles or other finished products that require cold storage that:

(A) Is rendered immobile by being securely anchored to a permanent structure of the building; or

(B) Weighs more than 750 pounds; and

(C) If it has a glass that makes up part or all of the door or exterior walls, the glass is rated unbreakable.

(60) "Secondary school" means a learning institution containing any combination of grades 9 through 12 and includes those institutions that provide junior high schools which include 9th grade.

(61) "Secure area" means a room:

(a) With doors that are kept locked and closed at all times except when the doors are in use;

(b) Where access is only permitted as authorized in these rules; and

(c) Not visible from outside the room or within public view.

(62) "Supplemental Security Income (SSI)" means the monthly benefit assistance program administered by the federal government for persons who are age 65 or older, or blind, or disabled and who have limited income and financial resources.

(63) "These rules" means OAR 333-008-0010 to 333-008-0750.

(64) "THC" means tetrahydrocannabinol.

(65)(a) "Usable marijuana" means the dried leaves and flowers of marijuana.

(b) "Usable marijuana" does not include:

(A) The seeds, stalks and roots of marijuana; or

(B) Waste material that is a by-product of producing marijuana.

(66) "Vault" means an enclosed area that is constructed of steel-reinforced or block concrete and has a door that contains a multiple-position combination lock or the equivalent, a relocking device or equivalent, and a steel plate with a thickness of at least one-half inch.

(67) "Written documentation" means a statement signed and dated by the attending physician of a person diagnosed with a debilitating medical condition or copies of the person's relevant medical records, maintained in accordance with standard medical record practices.

(68) "Zoned for residential use" means the only primary use allowed outright in the designated zone is residential.

Stat. Auth.: ORS 475B.525

Stats. Implemented: ORS 475B.400 – 475B.525

Hist.: OHD 15-1998(Temp), f. & cert. ef. 12-24-98 thru 6-22-99; OHD 3-1999, f. & cert. ef. 4-29-99; OHD 13-2000(Temp), f. & cert. ef. 12-21-00 thru 6-15-01; OHD 18-2001, f. & cert. ef. 8-9-01; OHD 19-2001(Temp), f. & cert. ef. 8-10-01 thru 1-31-02; Administrative correction 3-14-02; OHD 6-2002, f. & cert. ef. 3-25-02; PH 9-2003, f. 6-26-03, cert. ef. 7-1-03; PH 18-2005, f. 12-30-05, cert. ef. 1-1-06; PH 15-2007, f. 12-19-07, cert. ef. 1-1-08; PH 21-2010, f. & cert. ef. 9-13-10; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 8-2011, f. 9-30-11, cert. ef. 10-1-11; PH 1-2014, f. & cert. ef. 1-13-14; PH 2-2014(Temp), f. 1-14-14, cert. ef. 1-15-14 thru 7-13-14; PH 20-2014, f. & cert. ef. 7-11-14; PH 16-2015(Temp), f. & cert. ef. 9-22-15 thru 3-19-16; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

Patient, Designated Primary Caregiver, PRMG and Grow Site Registration

333-008-0020
New Registry Identification Card Application Process

(1) To apply for a registry identification card an individual must submit the following:

(a) An application form, prescribed by the Authority, signed and dated by the applicant.

(b) A legible copy of the individual's valid government issued photographic identification that includes the applicant's last name, first name, and date of birth.

(c) An APS or written documentation that may consist of relevant portions of the applicant's medical record, signed by the applicant's attending physician within 90 days of the date of receipt by the Authority, which describes the applicant's debilitating medical condition and states that the use of marijuana may mitigate the symptoms or effects of the applicant's debilitating medical condition.

(d) Proof of residency in accordance with OAR 333-008-0022.

(e) If applicable, a completed and notarized "Declaration of Person Responsible for Minor" form for a person under 18 years of age, signed and dated by the minor's parent or legal guardian.

(f) An application fee as specified in OAR 333-008-0021.

(g) If applicable, documentation required in OAR 333-008-0021 to qualify for a reduced fee.

(2) If the applicant is designating a primary caregiver, the applicant must complete the caregiver portion of the application and submit a legible copy of the designated primary caregiver's valid government issued photographic identification that includes the caregiver's last name, first name, and date of birth. The applicant may also designate an organization that provides hospice, palliative or home health care services, or a residential facility as defined in ORS 443.400, under ORS 475B.419, as an additional caregiver.

(3) If an applicant intends to produce marijuana for him or herself or designate another person to produce marijuana for him or

her, the applicant or the individual designated to be the PRMG must complete the grow site registration portion of the application and submit:

(a) A legible copy of the designated PRMG's valid government issued photographic identification that includes the last name, first name, and date of birth.

(b) The grow site address.

(c) If the grow site is within city limits, documentation that shows the zoning designation for the grow site address.

(d) Except for a patient producing marijuana for him or herself at his or her residence, the grow site registration fee as specified in OAR 333-008-0021(4), unless the Authority has established an online payment system for grow site registration in which case the fee must be paid online in accordance with instructions from the Authority.

(4) If the Authority establishes an online payment system for payment of a grow site registration fee the Authority must notify the person designated on the application as the PRMG with instructions for how to pay the fee online and the deadline by which the fee must be paid.

(5) Applications must be mailed to the address listed in section (6) of this rule or hand-delivered to the OMMP dropbox at 800 N.E. Oregon St., Portland, Oregon 97232, unless the Authority has established an electronic application process at which time applications and accompanying documentation must be submitted electronically.

(6) The application forms referenced in this rule may be downloaded at www.healthoregon.org/ommp or obtained by contacting OMMP at PO Box 14450, Portland, OR 97293-0450 or by calling 971-673-1234.

(7) Acceptable forms of current government issued photographic identification include but are not limited to:

(a) Driver's license;

(b) State identification card;

(c) Passport; or

(d) Military identification card.

Stat. Auth.: ORS 475B.415, 475B.419, 475B.525

Stats. Implemented: ORS 475B.415

Hist.: OHD 3-1999, f. & cert. ef. 4-29-99; OHD 13-2000(Temp), f. & cert. ef. 12-21-00 thru 6-15-01; OHD 18-2001, f. & cert. ef. 8-9-01; OHD 19-2001(Temp), f. & cert. ef. 8-10-01 thru 1-31-02; Administrative correction 3-14-02; OHD 6-2002, f. & cert. ef. 3-25-02; PH 9-2003, f. 6-26-03, cert. ef. 7-1-03; PH 38-2004, f. 12-22-04, cert. ef. 1-1-05; PH 17-2005, f. 11-25-05, cert. ef. 12-1-05; PH 18-2005, f. 12-30-05, cert. ef. 1-1-06; PH 15-2007, f. 12-19-07, cert. ef. 1-1-08; PH 14-2010(Temp), f. & cert. ef. 7-6-10 thru 12-31-10; PH 27-2010, f. & cert. ef. 12-28-10; PH 8-2011, f. 9-30-11, cert. ef. 10-1-11; PH 9-2013(Temp), f. & cert. ef. 10-2-13 thru 3-30-14; PH 1-2014, f. & cert. ef. 1-13-14; PH 2-2014(Temp), f. 1-14-14, cert. ef. 1-15-14 thru 7-13-14; PH 16-2014, f. & cert. ef. 6-5-14; PH 20-2014, f. & cert. ef. 7-11-14; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-0021
Patient and PRMG New and Renewal Fees

(1) All fees referenced in this rule are non-refundable.

(2) New and Renewal Application Fee. A patient must pay a $200 application fee unless the applicant qualifies for a reduced fee under section (3) of this rule.

(3) Reduced Fees.

(a) An applicant receiving SSI benefits: $20. In order to qualify for the reduced fee the applicant must submit at the time of application a copy of a current monthly SSI benefit statement showing dates of coverage.

(b) An applicant enrolled in OHP: $50. In order to qualify for the reduced fee the applicant must submit a copy of the applicant's current eligibility statement or card.

(c) An applicant receiving food stamp benefits through the Oregon SNAP: $60. In order to qualify for the reduced fee the applicant must submit at the time of application current proof of his or her food stamp benefits.

(d) An applicant who has served in the Armed Forces of the United States: $20. In order to qualify for the reduced fee the applicant must provide proof of having served in the Armed Forces, such as but not limited to, submitting a Veteran's Administration form DD-214.

(4) Grow Site Registration Fee: $200.

(5) Replacement Card Fees. If a patient, designated primary caregiver or PRMG needs to obtain a replacement card the fee is $100. If the patient qualifies for a reduced application fee of $20, the fee to receive any of the replacement cards is $20.

(6) All fees must be paid at the time a new or renewal application is submitted, or when an application to add or change a PRMG is submitted under OAR 333-008-0047 and may be paid in the form of bank check, money order, or personal check, unless the Authority has established an online payment system in which case payments must be made online. The Authority does not accept responsibility for payments that are lost in the mail or stolen in transit.

(7) The Authority shall notify an applicant who submits a reduced application fee if the applicant is not eligible for the reduced fee and will allow the applicant 14 calendar days from the date of notice to pay the correct application fee or submit current valid proof of eligibility for a reduced fee.

Stat. Auth.: ORS 475B.415, 475B.420, 475B.525

Stats. Implemented: ORS 475B.415

Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-0022

Proof of Residency

(1) If an applicant for a registry identification card does not have a valid Oregon driver license or Oregon identification card, the applicant must submit documentation that shows the applicant is a resident of Oregon, such as but not limited to a current lease agreement or current utility bill that has the applicant's name and address.

(2) Residency must be maintained by patients while registered with the Authority.

Stat. Auth.: ORS 475B.415, 475B.420, 475B.525

Stats. Implemented: ORS 475B.415

Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-0023
Patient Application Review Process

(1) The Authority must review a patient application to determine if it is complete.

(a) If an applicant does not provide all the information required in OAR 333-008-0020 or pay the applicable fee the Authority must notify the applicant of the information that is missing or the fee that was not paid, and allow the applicant 14 calendar days to submit the missing information.

(b) If an applicant does not provide the information requested in subsection (1)(a) of this rule the application must be denied in accordance with OAR 333-008-0035.

(2) The Authority may verify the information on each application, verify any accompanying documentation submitted with an application, or request additional information from the applicant or other individuals named on the application.

(3) If the Authority is unable to verify that the applicant's attending physician meets the definition under OAR 333-008-0010 the applicant will be allowed 30 days to submit a new APS or written documentation from a physician meeting the requirements of these rules. Failure to submit the required attending physician documentation is grounds for denial under ORS 475B.415(8) and OAR 333-008-0035.

(4) If an applicant fails to submit information necessary for the Authority to verify information on the application, fails to submit information necessary to verify any accompanying documentation submitted with an application, or fails to cooperate with the Authority in obtaining information, such as but not limited to refusing to sign an authorization for disclosure of medical records within timeframes established by the Authority, the Authority will reject the application as incomplete.

(5) An applicant whose application is rejected as incomplete may reapply at any time. If the individual reapplies within a year the application fee may be applied toward a new application.

(6) Upon receipt of a complete application, including payment of the required application fee, the Authority must issue a receipt to the applicant verifying that a complete application has been received. A receipt issued under this section has the same legal effect as a registry identification card for 30 days following the date on which the receipt was issued to the applicant.

(7) The Authority shall approve or deny an application within 30 days after receiving a complete application.

Stat. Auth.: ORS 475B.415, 475B.525
Stats. Implemented: ORS 475B.415
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-0025
Person Responsible for a Marijuana Grow Site Criteria; Grow Site Registration Application Review Process

(1) In order to be a PRMG an individual must:

(a) Be 21 years of age or older.

(b) Not have been convicted of a Class A or Class B felony under ORS 475.752 to 475.920 for the manufacture or delivery of a controlled substance in Schedule I or Schedule II:

(A) Within the previous two years; or

(B) More than once.

(2) In addition to the application review required in OAR 333-008-0023 the Authority must:

(a) Conduct a criminal background check on any PRMG.

(b) Verify the PRMG's age.

(c) Verify the zoning of the grow site address if the grow site is within city limits.

(d) Determine the number of plants that are permitted at the grow site address.

(3) Unless the Authority has received a request for a grandfathered grow site address under OAR 333-008-0500, the grow site plant limits, on and after March 1, 2016, are as follows:

(a) A maximum of 12 mature marijuana plants if the grow site location is within city limits and zoned residential; or

(b) A maximum of 48 mature marijuana plants if the grow site location is within city limits but not zoned residential or outside city limits.

(4) The Authority must notify a patient if a PRMG or a grow site address is ineligible for registration and the patient will be allowed 14 calendar days to identify another PRMG or grow site address in accordance with OAR 333-008-0047.

Stat. Auth.: ORS 475B.420, 475B.525
Stats. Implemented: ORS 475B.420
Hist.: PH 18-2005, f. 12-30-05, cert. ef. 1-1-06; PH 15-2007, f. 12-19-07, cert. ef. 1-1-08; PH 8-2011, f. 9-30-11, cert. ef. 10-1-11; PH 2-2014(Temp), f. 1-14-14, cert. ef. 1-15-14 thru 7-13-14; PH 20-2014, f. & cert. ef. 7-11-14; PH 16-2015(Temp), f. & cert. ef. 9-22-15 thru 3-19-16; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-0030
Approval of New and Renewal Patient Applications

(1) If the Authority approves a patient application, the Authority shall issue a serially numbered registry identification card to the patient within five business days.

(2) The registry identification card must include, but is not limited to:

(a) The patient's name, address, and date of birth;

(b) The effective date, date of issuance, and expiration date of the registry identification card; and

(c) The designated primary caregiver's name, address, and date of birth, if applicable.

(3) If a patient has specified a designated primary caregiver the Authority shall issue an OMMP identification card for the designated primary caregiver.

Stat. Auth.: ORS 475B.415, 475B.525
Stats. Implemented: ORS 475B.415
Hist.: OHD 3-1999, f. & cert. ef. 4-29-99; OHD 18-2001, f. & cert. ef. 8-9-01; OHD 19-2001(Temp), f. & cert. ef. 8-10-01 thru 1-31-02; OHD 21-2001(Temp), f. & cert. ef. 10-12-01 thru 1-31-02; Administrative correction 3-14-02; OHD 6-2002, f. & cert. ef. 3-25-02; PH 12-2004(Temp), f. & cert. ef. 4-1-04 thru 8-2-04; Administrative correction 8-19-04; PH 18-2005, f. 12-30-05, cert. ef. 1-1-06; PH 15-2007, f. 12-19-07, cert. ef. 1-1-08; PH 21-2010, f. & cert. ef. 9-13-10; PH 8-2011, f. 9-30-11, cert. ef. 10-1-11; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-0033
Approval of New or Renewal PRMG and Grow Site Application; Change of PRMG

(1) The Authority must register a PRMG and a grow site address listed on an application if:

(a) The PRMG:

(A) Meets the age requirements;

(B) Passes the criminal background check;

(C) Has not violated a provision of ORS 475B.400 to 475B.525, ORS 475B.580, ORS 475B.650, OAR chapter 333, division 7, these rules, or an ordinance adopted pursuant to ORS 475B.500; and

(D) Pays the applicable fee.

(b) The grow site address does not exceed the plant limits in ORS 475B.428(3) or (4).

(2) If the Authority registers a marijuana grow site it will issue an identification card and a grow site registration card that contains at least the following information:

(a) The PRMG's name, address, date of birth, and identification card number.

(b) The effective date, date of issuance, and expiration date of the identification card.

(c) The grow site address.

(d) The patient's registry identification card number.

(3) A PRMG, except for a patient growing only for him or herself at his or her residence who is not transferring usable marijuana, seeds or immature plants to a registered processing site or dispensary, must create an online account with the Authority through which the individual must at a minimum submit the information required in OAR 333-008-0630.

(4) The Authority must notify a PRMG at the time the grow site is registered the current number of mature marijuana plants permitted at the grow site address.

(5) The Authority shall also notify a patient if the PRMG and grow site address has been approved.

(6) The Authority may only register one grow site per patient, and may only register grow sites in Oregon.

Stat. Auth.: ORS 475B.420, 475B.525
Stats. Implemented: ORS 475B.420
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-0035
Denial of Patient Application

(1) The Authority may deny a new or renewal patient application if:

(a) The applicant or patient did not provide the information required to be submitted in OAR 333-008-0020;

(b) The Authority determines that the information provided was falsified;

(c) The Authority determines that the applicant or patient violated a provision of ORS 475B.400 to 475B.525, ORS 475B.580, ORS 475B.650, OAR chapter 333, division 7, these rules, or an ordinance adopted pursuant to ORS 475B.500.

(2) An individual whose application is denied may not reapply for at least six months from the date of the denial unless otherwise authorized by the Authority.

Stat. Auth.: ORS 475B.415, 475B.525
Stats. Implemented: ORS 475B.415
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-0037
Denial of Designation of Caregiver or Person Responsible for a Marijuana Grow Site; Denial of Grow Site Registration

(1) The Authority may deny a designation of a primary caregiver made under ORS 475B.418 if the Authority determines that the designee or the patient violated a provision of ORS 475B.400 to 475B.525, ORS 475B.580, 475B.650, OAR chapter 333, division 7, these rules, or an ordinance adopted pursuant to ORS 475B.500.

(2) A person whose designation has been denied may not be designated as a primary caregiver under ORS 475B.418 for six months from the date of the denial unless otherwise authorized by the Authority.

(3) The Authority may deny a designation of a PRMG if the Authority determines that the applicant or the PRMG violated a provision of ORS 475B.400 to 475B.525, 475B.580, 475B.650, OAR chapter 333, division 7, these rules, or an ordinance adopted pursuant to ORS 475B.500.

(4) The Authority may deny the registration of a PRMG and grow site address if the grow site registration fee has not been paid.

Stat. Auth.: ORS 475B.415, 475B.420 & 475B.525
Stats. Implemented: ORS 475B.415, 475B.420
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-0040
Annual Renewal

(1) A patient shall register on an annual basis to maintain active registration status by submitting:

(a) A renewal application prescribed by the Authority;

(b) An APS signed by the patient's attending physician within 90 days prior to the expiration date of the patient's current card, reconfirming the patient's debilitating medical condition and that the medical use of marijuana mitigates the symptoms of the patient's debilitating medical condition; and

(c) The additional information and fees required in OAR 333-008-0020.

(2) A renewal application may be submitted by mail at PO Box 14450, Portland, OR 97293-0450 or in person at the OMMP drop box located at 800 N.E. Oregon St., Portland, OR 97232.

(3) Between 60 to 90 calendar days prior to expiration, the Authority shall notify the patient of the upcoming expiration date.

(4) If a renewal application and accompanying information is not received by the expiration date on the patient's card, the patient's card and all other associated OMMP identification cards, if any, are expired. The expiration date may be extended, due to personal hardship, at the discretion of the Authority.

(5) Upon receipt of a complete renewal application, including payment of the required application fee, the Authority must issue a receipt to the applicant verifying that a complete renewal application has been received. A receipt issued under this section has the same legal effect as a registry identification card for 30 days following the date on which the receipt was issued to the applicant.

(6) The Authority shall review and verify the renewal application information in the same manner as specified in OAR 333-008-0023 and 333-008-0025 and shall approve or deny the application in accordance with OAR 333-008-0030 to 333-008-0037, as applicable.

Stat. Auth.: ORS 475B.415, 475B.418, 475B.420, 475B.525
Stats. Implemented: ORS 475B.415, 475B.418, 475B.420
Hist.: OHD 3-1999, f. & cert. ef. 4-29-99; PH 9-2003, f. 6-26-03, cert. ef. 7-1-03; PH 18-2005, f. 12-30-05, cert. ef. 1-1-06; PH 15-2007, f. 12-19-07, cert. ef. 1-1-08; PH 21-2010, f. & cert. ef. 9-13-10; PH 27-2010, f. & cert. ef. 12-28-10; PH 8-2011, f. 9-30-11, cert. ef. 10-1-11; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-0045
Notification of Changes

(1) Patient notification responsibilities.

(a) A patient must notify the Authority within 10 calendar days of any change in the patient's name, mailing address, electronic mail address, telephone number, attending physician, designated primary caregiver, PRMG, grow site address or residency, on a form prescribed by the Authority.

(b) If the patient is designating a caregiver for the first time or designating a different caregiver, the patient must include all the information and documentation specified in the form and required under OAR 333-008-0020.

(c) If a patient is adding or changing a PRMG or grow site address the patient must comply with OAR 333-008-0047.

(2) Caregiver notification responsibilities. A designated primary caregiver must notify the Authority within 10 calendar days of any change in the caregiver name, mailing address, electronic mail address, or telephone number.

(3) Person responsible for a marijuana grow site notification responsibilities. A PRMG must notify the Authority within 10 calendar days of:

(a) Any change in the person's name, mailing address, electronic mail address, or telephone number.

(b) A conviction of a Class A or Class B felony under ORS 475.752 to 475.920 for the manufacture or delivery of a controlled substance in Schedule I or Schedule II.

(4) If the Authority is notified by the patient that the patient has terminated the designation of a primary caregiver or a PRMG the Authority must notify the individuals confirming the termination, informing the individual that his or her card is no longer valid, and requesting that the card be returned to the Authority within seven calendar days. In addition the Authority must notify the PRMG whether the termination affects the person's ability to produce marijuana for other patients at the grow site address, in accordance with ORS 475B.428(6).

(5) Change in Medical Condition.

(a) If an attending physician notifies the Authority that a patient no longer has a debilitating medical condition or that that the medical use of marijuana is contraindicated for the patient's debilitating medical condition, the Authority must notify the patient that the patient's registry identification card will be invalid 30 days from the date of the notification unless the patient submits within 30 calendar days an APS or written documentation that may consist of relevant portions of the individual's medical record, signed by the individual's attending physician within the previous 90 days, which states the individual has been diagnosed with a debilitating medical condition and that the use of marijuana may mitigate the symptoms or effects of the individual's debilitating medical condition.

(b) If, due to circumstances beyond the patient's control he or she is unable to submit the documentation in subsection (a) of this section, the Authority may, upon receiving a written request from the patient, grant the patient additional time to obtain a second

opinion. The Authority must notify the patient how much additional time the patient has to submit the documentation.

(6) If a patient does not intend to submit the information or does not submit the information required in section (5) of this rule within the timeframes established by the Authority, the Authority must notify:

(a) The patient that the patient's card must be returned within seven calendar days; and

(b) If applicable, the patient's designated primary caregiver and PRMG that those identification cards must be returned within seven calendar days.

(7) The Authority will review and deny a caregiver designation or register a caregiver in accordance with OAR 333-008-0023 to 333-008-0037, as applicable.

(8) Change forms may only be submitted to the Authority via mail at PO Box 14450, Portland, OR 97293-0450 or in person at the OMMP drop box located at 800 N.E. Oregon St., Portland, OR 97232 and must be accompanied by any applicable fee as specified in OAR 333-008-0021.

Stat. Auth.: ORS 475B.415, 475B.418, 475B.420 & 475B.525
Stats. Implemented: ORS 475B.415, 475B.418 & 475B.420
Hist.: PH 27-2010, f. & cert. ef. 12-28-10; PH 8-2011, f. 9-30-11, cert. ef. 10-1-11; PH 1-2014, f. & cert. ef. 1-13-14; PH 2-2014(Temp), f. 1-14-14, cert. ef. 1-15-14 thru 7-13-14; PH 20-2014, f. & cert. ef. 7-11-14; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-0047
Interim Addition or Change of Person Responsible for a Marijuana Grow Site or Grow Site Address

(1) If a patient is adding a PRMG and grow site address at any time other than when applying for a new or renewal registry identification card, or if a patient is changing a PRMG or grow site address at any time other than when submitting a renewal application for a patient identification card, the patient must:

(a) Submit a PRMG and grow site registration change application, on a form prescribed by the Authority, that includes all the information and documentation specified in the form and required under OAR 333-008-0020(3); and

(b) Pay the fee required in OAR 333-008-0021 unless the PRMG is a patient growing only for him or herself.

(2) A PRMG and grow site registration change application shall be reviewed in accordance with OAR 333-008-0025 and approved or denied in accordance with OAR 333-008-0033 or 333-008-0037.

Stat. Auth.: ORS 475B.415, 475B.418, 475B.420 & 475B.525
Stats. Implemented: ORS 475B.415, 475B.418, & 475B.420
Hist.; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-0049
Timely Submission to the Oregon Health Authority

If an applicant, patient, designated primary caregiver, or PRMG is required to submit information or documentation to the Authority by a particular deadline it must be received by the Authority, regardless of the method used, by 5 p.m. Pacific Time.

Stat. Auth.: ORS 475B.525
Stats. Implemented: ORS 475B.525
Hist.; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-0080
Permissible Amounts of Medical Marijuana for Patients and Caregivers

(1) A patient or the patient's designated primary caregiver may jointly possess up to six mature marijuana plants and 24 ounces of usable marijuana.

(2) A patient or the patient's designated primary caregiver may only possess cannabinoid products, concentrates or extracts in the amounts described in ORS 475B.245.

(3) A patient and designated primary caregiver must have, in his or her possession, his or her registry identification card or OMMP identification card when transporting marijuana.

(4) A patient must have, in his or her possession, his or her registry identification card when using marijuana in a location other than the residence of the cardholder.

Stat. Auth.: ORS 475B.430
Stats. Implemented: ORS 475B.430
Hist.: OHD 3-1999, f. & cert. ef. 4-29-99; OHD 18-2001, f. & cert. ef. 8-9-01; PH 18-2005, f. 12-30-05, cert. ef. 1-1-06; PH 15-2007, f. 12-19-07, cert. ef. 1-1-08; PH 21-2010, f. & cert. ef. 9-13-10; PH 8-2011, f. 9-30-11, cert. ef. 10-1-11.; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-0090
Addition of Qualifying Diseases or Medical Conditions

(1) For the purposes of this rule, the following definitions apply:

(a) DSM means the latest published edition of Diagnostic and Statistical Manual of Mental Disorders.

(b) ICD means the most recent revision of the International Classification of Diseases published by the United Nations-sponsored World Health Organization that provides codes, up to six characters long, to classify diseases and a variety of signs, symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or disease.

(c) Peer-reviewed published scientific study means that a study has been cited by the Cochrane Review, the Institute of Medicine, or PubMed Central.

(d) Petitioner means an individual who has filed a petition in accordance with ORS 475B.517 and this rule.

(e) State Public Health Officer (SPHO) means the individual appointed by the Director of the Authority in accordance with ORS 431.045, or his or her designee.

(2) The Authority shall accept a written petition from any person requesting that a particular disease or condition be included among the diseases and conditions that qualify as a debilitating medical condition under ORS 475B.410.

(a) A petition may only request a single disease or condition be added as a debilitating medical condition. A separate petition must be submitted for each disease or condition proposed to be added as a debilitating medical condition.

(b) A petition must be submitted by mail using a form prescribed by the Authority and must include, along with the form, the following in an electronic format (e.g. compact disc (CD) or thumb drive):

(A) A specific description of the disease or condition proposed to be added and its characteristics, including the applicable ICD code or the specific diagnosis as described in the DSM;

(B) A general explanation of how or why the petitioner believes marijuana would mitigate the symptoms or effects of the disease or condition that is the subject of the petition; and

(C) At least one peer-reviewed published scientific study showing the efficacy in humans for use of medical marijuana for the disease or condition that is the subject of the petition.

(c) A petitioner may also include with the information required to be submitted in subsection (2)(b) of this rule letters of support from physicians or other licensed health care professionals knowledgeable about the disease or condition proposed to be added, and any other information the petitioner believes the SPHO should review in considering the petition.

(d) If a petitioner submits a petition to add the same or a substantially equivalent disease or condition that was the subject of a petition that was denied by the SPHO within the last five years from the date a new petition is submitted, a petitioner must submit at least one peer-reviewed published scientific study that was published since the date the SPHO denied the previous petition for the same or substantially equivalent disease or condition.

(e) A petition may not contain individually identifiable health information as that is defined in ORS 433.443 unless any individual identified in relation to health information submits an Authorization for Use and Disclosure of Information on a form prescribed by the Authority. A petition that contains individually identifiable health information that is submitted without the required authorization must be returned to the petitioner as incomplete.

(f) A petition that does not contain all the information required by section (2) of this rule shall be returned to the petitioner as incomplete. A petition returned as incomplete is not considered a denial for purposes of subsection (2)(d) of this rule.

(3) If the petitioner has submitted a petition with all the information required in section (2) of this rule, the SPHO must:

(a) Assign a petition number to the petition;

(b) Notify the petitioner by certified mail that the petition has been accepted;

(c) Post a notice, a copy of the petition and materials submitted by the petitioner on the Authority's website announcing that the petition has been accepted and is under consideration, and solicit information from individuals or organizations concerning experts in cannabis therapeutics and scientific studies, including but not limited to peer-reviewed published scientific studies;

(d) Notify the Advisory Committee on Medical Marijuana (ACMM) by electronic mail that the petition is under consideration, and request from the ACMM recommendations regarding relevant experts and information pertinent to the petition;

(e) Conduct an investigation that may, as the SPHO determines necessary, include:

(A) Consulting with one or more experts in cannabis therapeutics and one or more experts on the disease or condition that is the subject of the petition;

(B) Requesting a literature review and a summary of peer-reviewed published scientific studies related to the use of marijuana for the disease or condition that is the subject of the petition, from neutral persons knowledgeable about conducting such reviews; and

(C) Gathering any other information the SPHO believes relevant to making a decision on the petition.

(f) Hold a public hearing at a time and place determined by the SPHO. At the public hearing the petitioner shall have the opportunity to address the SPHO in person or by telephone. Written comments shall be accepted by the SPHO for one week following the close of the public hearing.

(4) Following the investigation identified in subsection (3)(e) of this rule and the close of the public comment period specified in subsection (3)(f) of this rule, the SPHO must issue a Notice of Intent to either approve or deny the petition.

(a) The SPHO must issue a Notice of Intent to Approve the petition if, based on the evidence presented to and considered by the SPHO, the SPHO finds that:

(A) Marijuana is efficacious for the disease or condition that is the subject of the petition or marijuana may mitigate the symptoms or effects of the disease or condition that is the subject of the petition; and

(B) Any risk of physical or mental harm from using marijuana for the disease or condition that is the subject of the petition is outweighed by the physical or mental benefit of using marijuana for that disease or condition.

(b) The SPHO must issue a Notice of Intent to Deny the petition if the SPHO determines that the evidence presented to and considered by the SPHO does not meet the standards established in subsection (4)(a) of this rule.

(c) The Notice of Intent must be in writing and must describe all evidence and information upon which the decision of the SPHO is based, including the identity and credentials of all experts relied upon.

(d) If the Authority issues a Notice of Intent to Deny the petitioner is entitled to a contested case hearing as provided under ORS Chapter 183. The petitioner has 30 days to request a hearing.

(5) At a contested case hearing, the petitioner has the burden of proving the decision of the SPHO was without a reasonable basis in fact.

(6) The SPHO must issue a final order within 180 days of receipt of a complete petition.

(7) A petitioner may withdraw his or her petition without prejudice at any time prior to the public hearing specified in subsection (3)(f) of this rule. A petition withdrawn after the public hearing specified in subsection (3)(f) of this rule shall be deemed denied for purposes of this rule.

Stat. Auth.: ORS 475B.517 & 475B.525
Stats. Implemented: ORS 475B.517
Hist.: OHD 3-1999, f. & cert. ef. 4-29-99; OHD 18-2001, f. & cert. ef. 8-9-01; OHD 6-2002, f. & cert. ef. 3-25-02; PH 18-2005, f. 12-30-05, cert. ef. 1-1-06; PH 15-2007, f. 12-19-07, cert. ef. 1-1-08; PH 18-2012, f. 12-26-12, cert. ef. 1-1-13

333-008-0110
Advisory Committee on Medical Marijuana

(1) The Advisory Committee on Medical Marijuana (ACMM) shall advise the Director of the Authority on the administrative aspects of ORS 475B.400 to 475B.525, including rules and fees adopted and proposed for adoption under ORS 475B.400 to 475B.525.

(2) The Authority will provide staff support to the ACMM by assisting with the scheduling of meetings, recording of minutes, and dissemination of meeting-related materials.

(3) The ACMM will adopt a Charter and By-Laws that detail:

(a) How meetings will be conducted;

(b) The election of presiding officers; and

(c) The scheduling of at least four public meetings per year.

Stat. Auth.: ORS 475.338
Stats. Implemented: ORS 475.300 - 475.346
Hist.: PH 18-2005, f. 12-30-05, cert. ef. 1-1-06; PH 15-2007, f. 12-19-07, cert. ef. 1-1-08; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

Persons Responsible for a Marijuana Grow Site

333-008-0500
Request for Grandfathered Grow Site

(1) An individual or group of individuals may submit a petition, on a form prescribed by the Authority, requesting that a grow site address be approved as a grandfathered grow site.

(2) A petition submitted under section (1) of this rule must include:

(a) For all individuals currently growing at the grow site address:

(A) Names and contact information.

(B) Copies of legible and valid government issued photographic identification that includes last name, first name, and date of birth.

(C) Copies of all current grow site registration cards issued to the PRMG for the grow site address.

(D) An attestation that the PRMG was registered at the grow site address on December 31, 2014, and has continuously been registered at the grow site address since that date.

(b) The physical address of the grow site where marijuana is being produced or intending to be produced.

(c) Documentation from a local government that indicates whether the address is within city limits and if so, the zoning designation for the address.

(d) The names and registry identification card numbers for all patients for whom each PRMG is producing at the grow site address.

(e) How many patients each PRMG was growing for on December 31, 2014.

(3) A petition that does not contain all the required information or is not accompanied by all of the documentation required to be submitted in section (2) of this rule is incomplete and will be returned to the applicant.

(4) A petition that does not include all the PRMGs currently growing at the grow site address may be considered by the Authority to be incomplete and may be returned to the applicant.

(5) Acceptable forms of current government issued photographic identification include but are not limited to:

(a) Driver's license;

(b) State identification card;

(c) Passport; or

(d) Military identification card.

Stat. Auth.: ORS 475B.525
Stats. Implemented: ORS 475B.428
Hist.: PH 33-2015(Temp), f. 12-29-15, cert. ef. 1-1-16 thru 2-29-16; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-0510
Review of Petition For Grandfathered Grow Site

(1) Once the Authority has determined that a petition is complete it must:

(a) Conduct a criminal background check on all PRMGs listed on the application;

(b) Verify that:

(A) Each person listed on the application is 21 years of age or older;

(B) Each person has a current valid registration card and is currently registered at the grow site address;

(C) All the patients listed on the application have valid cards; and

(D) All persons were registered with the Authority on December 31, 2014, at the grow site address listed on the application and have been continuously registered at the grow site since the petition was submitted; and

(c) Verify the number of patients each PRMG was producing marijuana for, at that address on December 31, 2014.

(2) If a PRMG listed on a petition does not meet the age requirements or is disqualified to be a PRMG based on criminal convictions, the Authority must notify:

(a) The PRMG that his or her designation is revoked; and

(b) The patient that the patient's PRMG is ineligible and that the patient may submit a change form, in accordance with OAR 333-008-0047 designating a new PRMG and grow site address.

Stat. Auth.: ORS 475B.525
Stats. Implemented: ORS 475B.428
Hist.; PH 33-2015(Temp), f. 12-29-15, cert. ef. 1-1-16 thru 2-29-16; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-0520
Approval of Petition for Grandfathered Grow Site

(1) The Authority will grant a petition for a grandfathered grow site if, based on the information in the petition and the Authority's review of the petition:

(a) The grow site address is currently registered with the Authority;

(b) The petition includes all PRMGs currently growing at the grow site address;

(c) With the exception of any PRMG whose designation was revoked under OAR 333-008-0510(2), the PRMGs listed in the petition are qualified to be a PRMG;

(d) All qualified PRMGs listed in the petition were registered at the grow site address on December 31, 2014, and were all continuously registered there at the time the petition was submitted; and

(e) The number of patients registered at the grow site address would not result in the grow site address exceeding:

(A) 24 mature marijuana plants if the location is within city limits and zoned residential; or

(B) 96 mature marijuana plants if the location is within city limits but not zoned residential or not within city limits.

(2) The actual grow site address plant limit is based on the number of patients registered at the grow site address on December 31, 2014, assuming six mature plants per patient.

(3) If a grow site address is approved under this rule the Authority may not register any additional PRMG at that address unless the grandfathered grow site approval has been terminated.

Stat. Auth.: ORS 475B.525
Stats. Implemented: ORS 475B.428
Hist.: PH 33-2015(Temp), f. 12-29-15, cert. ef. 1-1-16 thru 2-29-16; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-0530
Denial of Petition for Grandfathered Grow Site

(1) The Authority must deny a petition for a grandfathered grow site if based on the information in the petition and the Authority's review of the petition:

(a) The grow site address is not currently registered with the Authority;

(b) The petition does not include all PRMGs currently producing marijuana at the grow site address;

(c) None of the PRMGs listed in the petition are qualified or the number of PRMGs eligible to produce marijuana at the grow site address would result in the grow site address exceeding the maximum plant limits, depending on the location of the grow site address;

(d) Not all of the qualified PRMGs listed in the petition were registered at the grow site address on December 31, 2014, or were not all continuously registered there at the time the petition was submitted; or

(e) The number of patients registered at the grow site address exceed the plant limits in ORS 475B.428(3)(b) or 475B.428(4)(b).

(2) An individual or group of individuals whose petition is denied may resubmit a petition at any time.

(3) If a petition is denied the maximum plant limits at the grow site address for which the petition was filed are:

(a) 12 mature marijuana plants if the location is within city limits and zoned residential; or

(b) 48 mature marijuana plants if the location is within city limits but not zoned residential or not within city limits.

Stat. Auth.: ORS 475B.525
Stats. Implemented: ORS 475B.428
Hist.: PH 33-2015(Temp), f. 12-29-15, cert. ef. 1-1-16 thru 2-29-16; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-0540
Requirements for Grandfathered Grow Sites; Termination of PRMG Designation; Suspension or Revocation of PRMG Registration

(1) A grandfathered grow site may only have the number of plants authorized by the Authority, based on the number of patients designating the address as a grow site on December 31, 2014. A PRMG producing marijuana at a grandfathered grow site may replace an existing patient with a new patient unless the person's designation has been terminated under ORS 475B.428(6).

(2) If the Authority suspends or revokes the registration of a PRMG that is producing marijuana at a grandfathered grow site the PRMG may not continue to grow at that address or any other grow site address that has more than:

(a) 12 mature marijuana plants if the location is within city limits and zoned residential; or

(b) 48 mature marijuana plants if the location is within city limits but not zoned residential or not within city limits.

(3) If a patient terminates the designation of a PRMG that person may not be designated to produce marijuana by another patient at the grandfathered grow site address and may not produce marijuana at any other grow site address that is authorized to have more than 48 mature marijuana plants.

(4) Approval of a grandfathered grow site is terminated once the number of mature marijuana plants, based on number of PRMGs who have been authorized to produce medical marijuana at the grow site address and the number of patients each person is producing for is less than:

(a) 12 mature marijuana plants if the location is within city limits and zoned residential; or

(b) 48 mature marijuana plants if the location is within city limits but not zoned residential or not within city limits.

Stat. Auth.: ORS 475B.525
Stats. Implemented: ORS 475B.428
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-0550
General Person Responsible for a Marijuana Grow Site Requirements

(1) A PRMG may not grow marijuana for more than four patients at any one time.

(2) A PRMG must display a marijuana grow site registration card at the marijuana grow site at all times for each patient for whom marijuana is being produced.

(3) All seeds, immature marijuana plants, mature marijuana plants and usable marijuana associated with the production of marijuana for a patient by a PRMG are the property of the patient and must be provided to the patient upon request, unless the patient has assigned a portion of the right to possess the seeds, immature plants and usable marijuana to the PRMG in accordance with ORS 475B.425.

(4) All marijuana produced for a patient must be provided to the patient or designated primary caregiver when the PRMG ceases producing marijuana for the patient, unless the patient has assigned a portion of the right to possess the seeds, immature plants and usable marijuana to the PRMG in accordance with ORS 475B.425.

(5) All usable marijuana associated with the production of marijuana for a patient must be transferred to a marijuana processing site upon the patient's request.

(6) All seeds, immature marijuana plants and usable marijuana associated with the production of marijuana for a patient must be transferred to a medical marijuana dispensary upon the patient's request.

(7) If a patient terminates the designation of a PRMG that PRMG may not be designated to produce marijuana by another patient unless the grow site address is authorized to have no more than 48 mature marijuana plants.

(8) A PRMG must return the grow site registration card to the Authority when the person's designation has been terminated by a patient or the person ceases producing marijuana for him or herself or another patient.

(9) A PRMG registered with the Authority, except for a patient growing only for him or herself at his or her own residence and not transferring usable marijuana, seeds or immature plants to a registered processing site or dispensary, must create an online account with the Authority through which the individual must at a minimum submit the information required in OAR 333-008-0630.

(10) A PRMG must comply with the advertising restrictions in OAR 333-008-2070 and must remove any sign, display or advertisement if the Authority determines the PRMG has violated OAR 333-008-2070.

Stat. Auth.: ORS 475B.420 - 475B.428 & 475B.525
Stats. Implemented: ORS 475B.420 - 475B.428
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-0560
Grow Site Plant Limits

(1) A PRMG may not produce more than six mature marijuana plants per patient.

(2) Unless a petition has been granted under OAR 333-008-0520 or except as authorized under Oregon Laws 2016, chapter 83, section 2, a grow site address may not have more than:

(a) 12 mature marijuana plants if the location is within city limits and zoned residential; or

(b) 48 mature marijuana plants if the location is within city limits but not zoned residential or not within city limits.

(3) For purposes of determining plant limits the Authority presumes that a PRMG grows six mature plants for each patient.

Stat. Auth.: ORS 475B.428, 475B.525
Stats. Implemented: ORS 475B.428
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-0570
Designation of Plants at Grow Site Address

(1) A PRMG producing marijuana at a grow site where multiple PRMGs are registered must physically identify the marijuana plants at a grow site address that are being grown by that PRMG by either:

(a) Tagging each marijuana plant with the PRMG's name, identification card number and patient identification number; or

(b) Fencing or cordoning off the PRMG's marijuana plants and posting all grow site registration cards at the location where the plants are located.

(2) If during an investigation the Authority determines that marijuana plants have not been designated by a PRMG in accordance with section (1) of this rule or there are marijuana plants at the grow site designated by an individual who is not authorized to produce marijuana at that grow site the Authority may suspend or revoke the registration of the grow site address for all PRMGs at that grow site and all the PRMG's identification cards.

(3) If during an investigation the Authority determines that a PRMG is producing marijuana plants in excess of the number of plants allowed in ORS 475B.428 the Authority may suspend or revoke the registration of the PRMG for each patient who has designated the PRMG.

Stat. Auth.: ORS 475B.428, 475B.525
Stats. Implemented: ORS 475B.428
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-0580
Usable Marijuana Possession Limits for a Person Designated to Produce Marijuana by a Patient

(1) Subject to section (2) of this rule, a person designated to produce marijuana by a patient may possess the amount of usable marijuana that the person harvests from his or her mature marijuana plants, provided that the person may not possess usable marijuana in excess of the amount of usable marijuana in the person's possession as reported to the Authority under OAR 333-008-0630.

(2) A person designated to produce marijuana by a patient may not possess usable marijuana in excess of:

(a) For a marijuana grow site located outdoors, 12 pounds of usable marijuana per mature marijuana plant; or

(b) For a marijuana grow site located indoors, six pounds of usable marijuana per mature marijuana plant.

(3) Unless a PRMG falls within the definition of a person designated to produce marijuana by a patient the PRMG may only possess the amount of usable marijuana that is permitted under ORS 475B.245.

(4) A PRMG producing marijuana at a grow site where there are multiple PRMGs registered must physically segregate the usable marijuana at the grow site address that is the property of the PRMG or the PRMG's patients by placing the usable marijuana in a receptacle or multiple receptacles and attaching a label to the receptacle that includes the PRMG's name, identification card number and patient identification number.

(5) If during an investigation the Authority determines that usable marijuana has not been segregated in accordance with section (4) of this rule or that usable marijuana at the grow site is identified as belonging to an individual who is not registered at the grow site, the Authority may suspend or revoke the registration of the grow site address for all PRMGs producing at that grow site and the PRMG's cards.

Stat. Auth.: ORS 475B.525
Stats. Implemented: ORS 475B.430
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-0600
PRMG Testing Requirements

On and after October 1, 2016, a PRMG who transfers usable marijuana to a registered processing site or dispensary must comply with the testing requirements in OAR 333-007-0300 to 333-007-0490.

Stat. Auth.: ORS 475B.555
Stats. Implemented: ORS 475B.555
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-0630
PRMG Documentation Requirements

(1) The reporting requirements in this rule do not apply to a patient growing only for him or herself at his or her residence, unless the patient is transferring usable marijuana to a registered processing site or dispensary.

(2) Beginning in June 2016, and on a monthly basis thereafter, no later than the 10th day of each month, a PRMG, who is not a person designated to produce marijuana by a patient, as that is defined in OAR 333-008-0010, must submit the following information to the Authority:

(a) The number of immature and mature marijuana plants and amount of usable marijuana transferred to each patient for whom the PRMG is producing marijuana;

(b) The amount of usable marijuana transferred to each registered marijuana processing site through an agreement with the patient; and

(c) The number of seeds or immature plants and the amount of usable marijuana transferred to each registered dispensary through an agreement with the patient.

(3) Beginning in June 2016, and on a monthly basis thereafter, no later than the 10th day of each month, a person designated to produce marijuana by a patient as that term is defined in OAR 333-008-0010, must submit the following information to the Authority:

(a) The number of mature marijuana plants and immature marijuana plants, the amount of marijuana leaves and flowers being dried, and the amount of usable marijuana, in the person's possession;

(b) The number of mature marijuana plants and immature marijuana plants, and the amount of usable marijuana transferred to each patient for whom the person produces marijuana, or that patient's designated primary caregiver during the previous month;

(c) The amount of usable marijuana transferred to each marijuana processing site during the previous month; and

(d) The number of immature marijuana plants, and the amount of usable marijuana transferred to each medical marijuana dispensary during the previous month.

(4) The information required to be submitted under this rule must be submitted electronically in a manner prescribed by the Authority.

(5) In addition to submitting the information as required in section (3) of this rule a person designated to produce marijuana by a patient must keep a record of the information described in section (3) of this rule for two years after the date on which the person submits the information to the Authority.

(6) A person designated to produce marijuana by a patient, as that term is defined in OAR 333-008-0010, may delegate his or her duty to report information under section (3) of this rule to another person designated to produce marijuana by a patient if the marijuana grow site addresses are the same.

(a) The person to whom the duty is delegated must submit a notice, on a form prescribed by the Authority, of the delegation.

(b) A delegation under this section does not relieve a person designated to produce marijuana by a patient, who delegates the duty to report, from complying with any of these rules, except for the duty to report.

(c) If a person to whom the reporting duty has been delegated fails to report in accordance with section (3) of this rule the Authority may suspend or revoke the registration of the person to whom the reporting duty was delegated.

(d) If the person to whom the reporting duty has been delegated fails to report in accordance with section (3) of this rule for any person designated to produce marijuana by a patient the delegation is void and the person who delegated the reporting duty must report the information to the Authority within 10 business days of being informed by the Authority of the failure to report.

Stat. Auth.: ORS 475B.420, 475B.423, 475B.525
Stats. Implemented: ORS 475B.420, 475B.423
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-0640
PRMG Security Requirements

A PRMG must effectively prevent public access and obscure from public view all areas where marijuana is being produced.

Stat. Auth.: ORS 475B.525
Stats. Implemented: 475B.525
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-0650
Pesticides

(1) A PRMG may only use pesticides in accordance with ORS Chapter 634 and OAR chapter 603, division 57.

(2) The Authority may investigate any violation of this rule based on:

(a) A failed pesticide test received on or after October 1, 2016;

(b) Information provided by any other state agency;

(c) A grow site inspection; or

(d) The receipt of a complaint alleging unlawful pesticide use.

(3) If the Authority determines that a violation of this rule has occurred, it may provide information obtained by the Authority to the Oregon Department of Agriculture.

Stat. Auth.: ORS 475B.420, 475B.525, 475B.555
Stats. Implemented: ORS 475B.420, 475B.555
Hist.: PH 30-2016(Temp), f. 10-27-16, cert. ef. 10-28-16 thru 4-25-17

OMMP Monitoring, Investigation, and Enforcement

333-008-0700
Monitoring and Investigations

(1) The Authority may, at any time, contact a patient, designated primary caregiver, PRMG, or a patient's attending physician by telephone, mail or in person to verify the current accuracy of information included in the registration system.

(2) The Authority may, when it has reasonable basis for believing a violation of ORS 475B.400 through 475B.525, 475B.555, 475B.605, 475B.615, OAR chapter 333, division 7 or these rules has occurred, either conduct an investigation or arrange for this responsibility to be assumed by the proper state or local authorities.

(3) A patient, designated primary caregiver or PRMG must cooperate with the Authority during an investigation.

(4) If the Authority records show that any one physician is the attending physician of record for more than 450 patients at any point in time, the Authority shall request, in writing, that the physician do one of the following:

(a) Provide information for each new patient over the 450 threshold, including:

(A) Documentation that the patient's medical records have been reviewed;

(B) Patient chart notes documenting the patient was examined by the physician and the date of the examination; and

(C) Documentation showing provided or planned follow-up care;

(b) Provide a letter from a clinic at which the physician provides care requesting that the physician be exempted from this section and provide documentation from the clinic that it:

(A) Has clear systems for ensuring medical records are reviewed and that each patient is examined by a physician;

(B) Provides follow-up care for patients;

(C) Maintains a record system documenting the review of medical records, physician examination, and follow-up care; and

(D) Will allow on-site inspections by the Authority to confirm compliance; or

(c) Provide a written statement explaining why the physician should be released from the requirements in this section, for example, an explanation that the physician:

(A) Has a practice that includes a disproportionately high percentage of patients with qualifying conditions;

(B) Serves as a consultant for other health care providers who refer patients requesting medical marijuana; or

(C) Has multiple practice sites and at one of the practice sites the physician clearly meets the attending physician definition.

(5) If the Authority receives a request from a physician to be exempted from the requirement in section (4) of this rule, the Authority shall provide the physician a decision, in writing, explaining whether the physician is or is not exempted from the requirement in section (4) of this rule. The Authority's written decision shall explain the basis for the Authority's decision.

(6) The Authority shall refer criminal complaints against a patient, designated primary caregiver, or PRMG; or medical practice complaints against an attending physician to the appropriate state or local authorities.

Stat. Auth.: ORS 475B.525
Stats. Implemented: ORS 475B.415 - 475B.420
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-0710
Grow Site Inspections

The Authority may inspect the following to ensure compliance with ORS 475B.420, 475B.423 and 475B.428, and any rule adopted under ORS 475B.420, 475B.423 and 475B.428:

(1) The marijuana grow site of a person designated to produce marijuana by a patient; and

(2) The records of a person designated to produce marijuana by a patient.

Stat. Auth.: ORS 475B.420 & 475B.490
Stats. Implemented: ORS 475B.420 & 475B.490
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-0720
Violations

In addition to failure to comply with any applicable provision of ORS 475B.400 to 475B.525, 475B.555, 475B.605, 475B.615, OAR chapter 333, division 7 or these rules, it is a violation:

(1) For a PRMG to transfer seeds, immature plants or usable marijuana to a registered processing site or dispensary without a valid patient authorization or personal agreement.

(2) To fail to cooperate with the Authority during an inspection or investigation.

(3) To fail to pay a civil penalty.

Stat. Auth.: ORS 475B.525
Stats. Implemented: ORS 475B.525
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-0730
Suspension and Revocation

(1) Patient Suspension or Revocation.

(a) The Authority may suspend or revoke a patient's card if the Authority determines that the patient:

(A) Provided false information; or

(B) Violated a provision of ORS 475B.400 to 475B.525, 475B.555, 475B.605, 475B.615, OAR chapter 333, division 7 or these rules.

(b) If a patient's card is revoked, any designated primary caregiver issued under ORS 475B.415(5)(b) or PRMG identification card or grow site registration card issued under ORS 475B.420 shall also be revoked.

(c) An individual whose registry identification card is revoked under this rule may not reapply for a registry identification card for six months from the date of the revocation unless otherwise authorized by the Authority.

(2) Designated Primary Caregiver Suspension or Revocation.

(a) The Authority may suspend or revoke a caregiver's identification card issued under ORS 475B.415(5)(b) if the Authority determines that the designated primary caregiver violated a provision of ORS 475B.400 to 475B.525, 475B.555, 475B.605, 475B.615, OAR chapter 333, division 7 or these rules.

(b) An individual whose designated primary caregiver identification card has been revoked under this rule may not be designated as a primary caregiver under ORS 475B.418 for six months from the date of the revocation unless otherwise authorized by the Authority.

(3) Person Responsible for a Marijuana Grow Site Suspension or Revocation.

(a) The Authority may suspend or revoke the registration of a PRMG if the Authority determines that a PRMG violated a provision of ORS 475B.400 to 475B.525, 475B.555, 475B.605, 475B.615, OAR chapter 333, division 7, these rules or an ordinance adopted pursuant to ORS 475B.500.

(b) If the Authority suspends or revokes the registration of a PRMG the person's registration is suspended or revoked for all patients the person is producing marijuana for and the person must:

(A) Return all marijuana that is the property of the person's patients, to the patients; or

(B) If the patient agrees, transfer usable marijuana to a marijuana registered processing site or transfer seeds, immature plants or usable marijuana to a registered dispensary.

(c) A PRMG must document the information, including how much was transferred, the date of transfer, and to whom the transfer was made, and provide that documentation to the Authority upon request.

(d) Failure to comply with the return, transfer, or documentation requirements is a violation and may result in further enforcement action.

Stat. Auth.: ORS 475B.415, 475B.420, 475B.525, 475B.580
Stats. Implemented: ORS 475B.415, 475B.420, 475B.580
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-0740
Civil Penalties

In addition to any other liability or penalty provided by law, the Authority may impose for each violation of a provision of ORS 475B.400 to 475B.525, 475B.555, 475B.605, 475B.615, or for each violation of these rules, a civil penalty that does not exceed $500 for each day that the violation occurs.

Stat. Auth.: ORS 475B.495, 475B.525, 475B.585, 475B.655
Stats. Implemented: ORS 431A.010, 475B.495, 475B.585, 475B.655
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-0750
General Powers

The Authority may possess, seize or dispose of marijuana or usable marijuana as is necessary for the Authority to ensure compliance with and enforce the provisions of ORS 475B.400 to 475B.525, 475B.555, 475B.605, 475B.615, OAR chapter 333, division 7, and these rules.

Stat. Auth.: ORS 431A.010, 475B.360, 475B.510
Stats. Implemented: ORS 431A.010, 475B.360, 475B.510
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

Medical Marijuana Dispensaries

333-008-1000
Applicability

(1) A person may not establish, conduct, maintain, manage or operate an establishment for the purpose of providing the services in ORS 475B.450(1)(a) unless the person is registered by the Authority under these rules.

(2) Nothing in these rules exempts a dispensary registrant or dispensary representative from complying with any other applicable state or local laws.

(3) Registration of a dispensary does not protect a dispensary registrant or dispensary representative from possible criminal prosecution under federal law.

(4) Registration by the Authority is not a guarantee that a dispensary is permitted to operate under applicable land use or other local government laws where the dispensary is located.

(5) These rules apply to any initial or renewal application filed on or after June 24, 2016, and to any application filed prior to June 24, 2016 that the Authority has not approved or denied.

Stat. Auth.: ORS 475B.450 & 475B.525
Stats. Implemented: ORS 475B.450
Hist.: PH 2-2014(Temp), f. 1-14-14, cert. ef. 1-15-14 thru 7-13-14; PH 20-2014, f. & cert. ef. 7-11-14; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1010
Definitions

For the purposes of OAR 333-008-1000 through 333-008-2200 the following definitions apply:

(1) "Dispensary representative" means an owner, director, officer, PRD, manager, employee, agent or other representative of a registered medical marijuana dispensary, to the extent that the person acts in a representative capacity.

(2) "Dispensary registrant" means:

(a) An individual who owns a registered medical marijuana dispensary or, if a business entity owns the registered medical marijuana dispensary, each individual who has a financial interest in the registered medical marijuana dispensary; and

(b) Any PRD.

(3) "Person responsible for a medical marijuana dispensary" or "PRD" means an individual who is directly involved in the day-

to-day operations of a dispensary and is identified as a PRD on an application.

(4) "Primary PRD" means a PRD designated by the owner of the dispensary as the primary point of contact for the Authority and who is authorized to receive any and all communications and legal notices from the Authority.

(5) "These rules" means OAR 333-008-1000 to 333-008-1248 and 333-008-2000 to 333-008-2200.

Stat. Auth.: ORS 475B.450 & 475B.525
Stats. Implemented: ORS 475B.450
Hist.: PH 2-2014(Temp), f. 1-14-14, cert. ef. 1-15-14 thru 7-13-14; PH 20-2014, f. & cert. ef. 7-11-14; PH 4-2015, f. & cert. ef. 1-28-15; PH 16-2015(Temp), f. & cert. ef. 9-22-15 thru 3-19-16; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-1020
Application for Medical Marijuana Dispensary Registration

(1) To register a medical marijuana dispensary a person must:

(a) Submit an initial application on a form prescribed by the Authority that includes but is not limited to:

(A) The name of the individual who owns the dispensary or, if a business entity owns the dispensary, the name of each individual who has a financial interest in the dispensary;

(B) The name of the individual or individuals responsible for the dispensary, if different from the name of the individual who owns the dispensary, with one of the individuals responsible for the dispensary identified as the primary PRD;

(C) The physical and mailing address of the medical marijuana dispensary; and

(b) Application and registration fee.

(2) An initial application for the registration of a dispensary must be submitted electronically via the Authority's website, www.healthoregon.org/ommp.

(3) If an initial application is submitted along with the required fees the Authority will notify the applicant in writing that the application has been received and that within 30 calendar days of the date the written notice is mailed the following information must be received by the Authority:

(a) For each individual named in the application:

(A) A legible copy of the individual's valid government issued photographic identification that includes last name, first name and date of birth;

(B) Information, fingerprints and fees required for a criminal background check in accordance with OAR 333-008-2020; and

(C) An Individual History Form and any information identified in the form that is required to be submitted;

(b) A written statement from an authorized official of the local government that the proposed location of the dispensary is not located in an area that is zoned for residential use as that term is defined in OAR 333-008-0010;

(c) Proof that the business is registered or has filed an application to register as a business with the Oregon Office of the Secretary of State, including proof of registration for any DBA (doing business as) registration;

(d) Documentation, in a format prescribed by the Authority that the proposed location of the dispensary is not within 1,000 feet of:

(A) The real property comprising a public or private elementary or secondary school, except as provided in Oregon Laws 2016, chapter 83, section 29; or

(B) A registered dispensary.

(e) A scaled site plan of the parcel on which the premises proposed for registration is located, including:

(A) Cardinal directional references;

(B) Bordering streets and the names of the streets;

(C) Identification of the building or buildings in which the proposed dispensary is to be located;

(D) The dimensions of the proposed premises of the dispensary;

(E) Identification of other buildings or property owned by or under the control of the applicant on the same parcel or tax lot as the premises proposed for registration that will be used in the business; and

(F) Identification of any residences on the parcel or tax lot.

(f) A scaled floor plan of all enclosed areas of the premises at the proposed location that will be used in the business with clear identification of walls, partitions, counters, windows, all areas of ingress and egress, intended uses of all spaces and all limited access areas; and

(g) Documentation that shows the applicant has lawful possession of the proposed location of the dispensary.

(4) The documentation required in section (3) of this rule may be submitted electronically to the Authority or may be mailed to the Oregon Medical Marijuana Program, Oregon Health Authority, PO Box 14116, Portland, OR 97293.

(a) If documentation is mailed it must be received by the Authority within 30 calendar days of the date the Authority mailed the notice to the applicant that the initial application was received or the application will be considered incomplete.

(b) If documentation is submitted electronically it must be received by the Authority by 5 p.m. Pacific Time within 30 calendar days of the date the Authority mailed the notice to the applicant that the initial application was received or the application will be considered incomplete.

(5) Application and registration fees must be paid online at the time of application.

(6) Criminal background check fees must be paid by check or money order and must be mailed to the Oregon Medical Marijuana Program, PO Box 14116, Portland, OR 97293, and must be received by the Authority in accordance with provisions in section (4) of this rule.

(7) If the Authority does not receive a complete application, including all documentation required in sections (1) and (3) of this rule, and all required fees within the time frames established in this rule, the application will be considered incomplete.

(8) If an applicant provides the documentation required in section (3) of this rule the Authority will review the information to determine if it is complete.

(a) If the documentation is not complete or is insufficient the Authority must notify the applicant in writing and the applicant will have 10 calendar days from the date such written notice is mailed by the Authority to provide the additional documentation.

(b) If the applicant does not provide the additional documentation within 10 calendar days or if any responsive documents are incomplete, insufficient or otherwise do not demonstrate compliance with ORS 475B.450 and these rules the application will be declared incomplete.

(9) A person who wishes to register more than one location must submit a separate application, registration fees, and all documentation described in sections (1) and (3) of this rule for each location.

(10) An application that is incomplete is treated by the Authority as if it was never received.

Stat. Auth.: ORS 475B.450 & 475B.525
Stats. Implemented: ORS 475B.450
Hist.: PH 2-2014(Temp), f. 1-14-14, cert. ef. 1-15-14 thru 7-13-14; PH 20-2014, f. & cert. ef. 7-11-14; PH 4-2015, f. & cert. ef. 1-28-15; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1030
Dispensary Fees

(1) The initial fees for the registration of a dispensary are:

(a) A non-refundable application fee of $500; and

(b) A $3,500 registration fee.

(2) The annual renewal fees for the registration of a dispensary are:

(a) A $500 non-refundable renewal fee; and

(b) A $3,500 registration fee.

(3) The criminal background check fee is $35 per individual.

(4) The Authority must return the registration fee if:

(a) An application is incomplete; or

(b) An applicant withdraws an application.

(5) The Authority may return the registration fee if an application is denied.

Stat. Auth.: ORS 475B.450 & 475B.525
Stats. Implemented: ORS 475B.450

Hist.: PH 2-2014(Temp), f. 1-14-14, cert. ef. 1-15-14 thru 7-13-14; PH 20-2014, f. & cert. ef. 7-11-14; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-1040
Dispensary Application Review

(1) Applications will be reviewed in the order they are received by the Authority. An application is considered received as of the date and time that payment of application and registration fees is authorized by the entity that issued the credit or debit card used to pay the fees.

(2) Once the Authority has determined that an application is complete it will review an application to the extent necessary to determine compliance with ORS 475B.450 and these rules.

(3) The Authority may, in its discretion, prior to acting on an application:

(a) Contact any individual listed on the application and request additional documentation or information;

(b) Inspect the premises of the proposed dispensary; or

(c) Verify any information submitted by the applicant.

(4) Prior to making a decision whether to approve or deny an application the Authority must:

(a) Review the criminal background check results for each individual named on the application;

(b) Determine whether the proposed location of the dispensary is the same location as a registered grow site under OAR 333-008-0025;

(c) Review documentation submitted by the applicant to determine, based on the information provided by the applicant, whether the proposed location of the dispensary is located within 1,000 feet of:

(A) The real property comprising a public or private elementary or secondary school, except as provided in Oregon Laws 2016, chapter 83, section 29; or

(B) Another registered dispensary;

(d) Verify that the applicant is registered as a business with the Office of the Secretary of State; and

(e) Verify that the proposed location of the dispensary is not:

(A) Located in an area that is zoned for residential use; or

(B) In a city or county that has adopted an ordinance under ORS 475B.800 or section 133 chapter 614, Oregon Laws 2015, prohibiting dispensaries.

(5) If during the review process the Authority determines that the application or supporting documentation contains intentionally false or misleading information the Authority may declare the application incomplete or issue a notice of denial under OAR 333-008-1060.

(6) The Authority will notify the applicant in writing that the applicant has 60 calendar days from the date of the written notice to submit a Readiness Form, prescribed by the Authority, indicating that the applicant is prepared for an inspection and is in compliance with these rules if:

(a) There is no basis for denial under OAR 333-008-1060;

(b) The proposed dispensary is in compliance with ORS 475B.450(3)(a) through (e);

(c) Each individual named in the application passes the criminal background check; and

(d) Each individual named as a PRD in the application meets age requirements.

(7) If the Authority does not receive the Readiness Form in accordance with section (6) of this rule the applicant's application will be declared incomplete, unless an extension has been granted under section (8) of this rule.

(8) An applicant may request one extension of the 60-day deadline in section (6) of this rule if the applicant can demonstrate to the Authority that the deadline cannot be met for reasons outside of the applicant's control, such as but not limited to the applicant's inability to obtain local government building permits.

(a) A request for an extension must be in writing, must be received within 60 calendar days of the notice described in section (6) of this rule and must explain and provide documentation that shows the applicant cannot, for reasons outside of the applicant's control, meet the 60-day deadline, and must specify when the applicant believes it can submit the Readiness Form.

(b) A request for an extension tolls the 60-day deadline.

(c) The Authority will review the request and provide, in writing to the applicant, its decision and the reason for the decision.

(d) If an extension is granted the Authority must inform the applicant of the new deadline for submission of the Readiness Form, but in any case an extension may not exceed 60 calendar days.

Stat. Auth.: ORS 475B.450 & 475B.525
Stats. Implemented: ORS 475B.450
Hist.: PH 2-2014(Temp), f. 1-14-14, cert. ef. 1-15-14 thru 7-13-14; PH 20-2014, f. & cert. ef. 7-11-14; PH 4-2015, f. & cert. ef. 1-28-15; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1050
Dispensary Pre-Approval Inspection; Approval of Application

(1) The Authority must perform a site visit within 30 days of receiving a timely Readiness Form, as that is described in OAR 333-008-1040 to determine whether the applicant and dispensary are in compliance with these rules.

(2) If, after the site visit the Authority determines that the applicant and dispensary are in compliance with these rules the Authority must provide the primary PRD with proof of registration that includes a unique registration number, and notify the primary PRD in writing that the dispensary may operate.

(3) If, after the site visit the Authority determines that the dispensary is not in compliance with these rules the Authority may:

(a) Give the applicant 10 business days to come into compliance;

(b) Propose to deny the application in accordance with OAR 333-008-1060; or

(c) Consider the application to be incomplete.

(4) A registered dispensary must at all times display proof of registration in a prominent place inside the dispensary so that proof of registration is easily visible to individuals authorized to transfer marijuana items to the dispensary and individuals who are authorized to receive a transfer of marijuana items from the dispensary.

(5) A registered dispensary may not use the Authority or the OMMP name or logo except to the extent that information is contained on the proof of registration on any signs at the dispensary, on its website, or in any advertising or social media.

(6) A dispensary's registration:

(a) Is only valid for the location indicated on the proof of registration.

(b) May not be transferred to another location.

Stat. Auth.: ORS 475B.450 & 475B.525
Stats. Implemented: ORS 475B.450
Hist.: PH 2-2014(Temp), f. 1-14-14, cert. ef. 1-15-14 thru 7-13-14; PH 20-2014, f. & cert. ef. 7-11-14; PH 4-2015, f. & cert. ef. 1-28-15; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-1060
Denial of Dispensary Application

(1) The Authority must deny an application if:

(a) An application, supporting documentation provided by the applicant, or other information obtained by the Authority shows that the qualifications for a dispensary in ORS 475B.450 or these rules have not been met; or

(b) An individual named in an application has been:

(A) Convicted for the manufacture or delivery of a controlled substance in Schedule I or Schedule II within two years from the date the application was received by the Authority; or

(B) Convicted more than once for the manufacture or delivery of a controlled substance in Schedule I or Schedule II; or

(c) The city or county in which the facility is located has prohibited dispensaries in accordance with sections 133 chapter 614, Oregon Laws 2015, or ORS 475B.800, unless the dispensary meets the criteria in sections 133(6), chapter 614, Oregon Laws 2015 or ORS 475B.800(6).

(2) The Authority may deny an applicant if it determines that the applicant, the owner of the dispensary, a PRD, or an employee of the medical marijuana dispensary:

(a) Submitted intentionally false or misleading information to the Authority; or

(b) Violated at any time a provision of ORS 475B.400 to 475B.525, 475B.555, 475B.605, 475B.615, OAR chapter 333, division 7, these rules or an ordinance adopted pursuant to ORS 475B.500.

(3) If an individual named in an application is not qualified based on age or the criminal background check, the Authority will permit a change form to be submitted in accordance with OAR 333-008-1078 or 333-008-2030, along with the applicable criminal background check fee. If the individual named in the change form is not qualified the Authority must deny the application in accordance with section (1) of this rule.

(4) If the Authority intends to deny an application for registration it must issue a Notice of Proposed Denial in accordance with ORS 183.411 through 183.470.

Stat. Auth.: ORS 475B.450 & 475B.525
Stats. Implemented: ORS 475B.450
Hist.: PH 2-2014(Temp), f. 1-14-14, cert. ef. 1-15-14 thru 7-13-14; PH 20-2014, f. & cert. ef. 7-11-14; PH 4-2015, f. & cert. ef. 1-28-15; PH 16-2015(Temp), f. & cert. ef. 9-22-15 thru 3-19-16; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1063
Withdrawal of Dispensary Application

An applicant may withdraw an initial or renewal application at any time prior to the Authority acting on the application unless the Authority has determined that the applicant submitted false or misleading information or there is a pending investigation or enforcement action in which case the Authority may refuse to accept the withdrawal and may issue a notice of proposed denial in accordance with OAR 333-008-1060.

Stat. Auth.: ORS 475B.450 & 475B.525
Stats. Implemented: ORS 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-1070
Expiration and Renewal of Dispensary Registration

(1) A dispensary's registration expires one year following the date of application approval.

(2) A dispensary registrant must submit not more than 90 but at least 30 calendar days before the registration expires:

(a) A renewal application on a form prescribed by the Authority;

(b) Renewal fees;

(c) For each individual named in the renewal application:

(A) A legible copy of the individual's valid government issued photographic identification that includes last name, first name and date of birth;

(B) Information, fingerprints and fees required for a criminal background check in accordance with OAR 333-008-2020;

(C) An Individual History Form and any information identified in the form that is required to be submitted;

(d) Current proof of business registration with the Secretary of State, including all DBA (doing business as) registrations;

(e) Documentation that shows the applicant has lawful possession of the location of the registered dispensary;

(f) Any information required during an initial application; and

(g) A current scaled floor plan of all enclosed areas at the registered dispensary that are used in the business with clear identification of walls, partitions, counters, windows, all areas of ingress and egress, and all limited access areas.

(3) A registrant who files a completed renewal application with the Authority prior to the expiration date of the registration may continue to operate, even after the registration expiration date, pending a decision on the renewal application by the Authority.

(4) A dispensary registrant that does not submit timely renewal documentation in accordance with sections (1) and (2) of this rule may be subject to the imposition of civil penalties.

(5) If a dispensary registrant does not submit all the forms, fees and information required in section (2) of this rule prior to the registration's expiration, the registration is expired and is no longer valid.

(6) Renewals will be processed in accordance with OAR 333-008-1040 to 333-008-1060, as applicable.

(7) A renewal applicant may be required to submit a Readiness Form, as described in OAR 333-008-1040 and may be subject to inspection prior to the Authority acting on a renewal application.

(8) For purposes of this rule a completed application shall be deemed submitted upon receipt by the Authority of all application forms, supporting documents and renewal fees described in section (2) of this rule.

Stat. Auth.: ORS 475B.450 & 475B.525
Stats. Implemented: ORS 475B.450
Hist.: PH 2-2014(Temp), f. 1-14-14, cert. ef. 1-15-14 thru 7-13-14; PH 20-2014, f. & cert. ef. 7-11-14; PH 4-2015, f. & cert. ef. 1-28-15; PH 16-2015(Temp), f. & cert. ef. 9-22-15 thru 3-19-16; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1075
PRD Criteria and Responsibilities

(1) A PRD must:

(a) Be 21 years or age or older;

(b) Have legal authority to act on behalf of the dispensary; and

(c) Be responsible for ensuring the registered dispensary complies with applicable laws.

(2) A PRD may not:

(a) Have been convicted in any state for the manufacture or delivery of a controlled substance in Schedule I or Schedule II within two years from the date of application; or

(b) Have been convicted more than once in any state for the manufacture or delivery of a controlled substance in Schedule I or Schedule II.

(3) At least one PRD must be on site at a dispensary during Authority inspections or investigations at the time of the inspection or investigation or within one hour of being notified that an inspection or investigation is taking place.

(4) A PRD is accountable for any intentional or unintentional action of registrant representatives, with or without the knowledge of the PRD, who violate ORS 475B.450, 475B.453 or these rules, and is responsible for any unlawful conduct that occurs on the premises of the dispensary or any property outside the registered dispensary that is owned by or under the control of the dispensary registrant.

Stat. Auth.: ORS 475B.450 & 475B.525
Stats. Implemented: ORS 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1078
Removal, Addition, Change, Designation or Assignment of PRD

(1) If an owner of a registered dispensary is adding or changing a PRD or primary PRD, an individual with legal authority to act on behalf of the registered dispensary must submit:

(a) A form, prescribed by the Authority;

(b) A legible copy of the individual's valid government issued photographic identification that includes last name, first name and date of birth;

(c) Information and fingerprints required for a criminal background check in accordance with OAR 333-008-2020; and

(d) A criminal background check fee of $35.

(2) A PRD who is designating or assigning the responsibilities of a PRD to another individual must submit the information and fees required in section (1) of this rule. The responsibilities of a primary PRD may not be designated or assigned.

(3) The Authority will review and approve the addition or change of a PRD or primary PRD if the individual meets the requirements in OAR 333-008-1075.

(4) The Authority will review and approve the designation or assignment of the responsibilities of a PRD to another individual if that individual meets the requirements in OAR 333-008-1075. An

individual to whom a designation or assignment is made, and who is approved by the Authority, has the same legal obligations as a PRD.

(5) An individual may not act in the capacity of a PRD without approval from the Authority.

(6) If the Authority denies the request to add or change a PRD or primary PRD, or denies the request to designate or assign the responsibilities of a PRD to another individual, the Authority must notify the individual that submitted the request of the denial and the current primary PRD, and describe the reason for the denial.

(7) A registered dispensary may not be open for business or receive or transfer any marijuana items without at least one Authority approved PRD and a primary PRD.

Stat. Auth.: ORS 475B.450 & 475B.525
Stats. Implemented: ORS 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1110
Locations of Medical Marijuana Dispensaries; Dispensary Premises Restrictions and Requirements

(1) A dispensary may not be located:

(a) In an area that is zoned for residential use.

(b) At the same address as a registered marijuana grow site;

(c) Within 1,000 feet of the real property comprising a public or private elementary or secondary school, except as provided in Oregon Laws 2016, chapter 83, section 29; or

(d) Within 1,000 feet of another medical marijuana dispensary.

(2) For purposes of implementing ORS 475B.450(3)(d), the Authority will consider a location to be a school if it has at least the following characteristics:

(a) Is a public or private elementary or secondary school as those terms are defined OAR 333-008-0010;

(b) There is a building or physical space where students gather together for education purposes on a regular basis;

(c) A curriculum is provided;

(d) Attendance is compulsory under ORS 339.020 or children are being taught as described in ORS 339.030(1)(a); and

(e) Individuals are present to teach or guide student education.

(3) For purposes of determining the distance between a dispensary and a school "within 1,000 feet" means a straight line measurement in a radius extending for 1,000 feet or less in any direction from the closest point anywhere on the boundary line of the real property comprising an existing public or private elementary or secondary school to the closest point of the premises of a dispensary. If any portion of the premises of a proposed or registered dispensary is within 1,000 feet of a public or private elementary or secondary school it may not be registered.

(4) For purposes of determining the distance between a dispensary and another registered dispensary "within 1,000 feet" means a straight line measurement in a radius extending for 1,000 feet or less in every direction from the closest point anywhere on the premises of a registered dispensary to the closest point anywhere on the premises of a proposed dispensary. If any portion of the premises of a proposed dispensary is within 1,000 feet of a registered dispensary it may not be registered.

(5) In order to be registered a dispensary must operate at a particular location as specified in the application and may not be mobile.

(6) Minors on Premises. A dispensary registrant may not permit a minor to be present in any limited access or point of sale area of a registered dispensary.

(7) On Premises Consumption.

(a) A dispensary registrant may not permit the ingestion, inhalation or topical application of a marijuana item anywhere on the premises of the registered dispensary, except as described in subsection (b) of this section.

(b) An employee of a registered dispensary who is a patient may consume a marijuana item during his or her work shift on the premises of the registered dispensary as necessary for his or her medical condition, if the employee is:

(A) Alone and in a closed room where no dispensary marijuana items are present;

(B) Not visible to patients or caregivers on the premises of the registered dispensary to receive a transfer of a marijuana item; and

(C) Not visible to the public outside the dispensary.

(c) For purposes of this section consume does not include smoking, combusting, inhaling, vaporizing, or aerosolizing a marijuana item.

(8) General Public and Visitor Access. The general public is not permitted on the premises of a registered dispensary, except as permitted by OAR 333-008-1500 and in accordance with this rule.

(a) In addition to registrant representatives, the following visitors are permitted on the premises of a dispensary, including limited access areas, subject to the requirements in section (9) of this rule:

(A) Laboratory personnel, if the laboratory is accredited by the Authority;

(B) A contractor authorized by a registrant representative to be on the premises; or

(C) Individuals authorized to transfer marijuana items to a registered dispensary.

(b) A registered dispensary may permit up to seven invited guests 21 years of age and older, per week, on the premises of a registered dispensary, including limited access areas, subject to the requirements in section (9) of this rule.

(9) Visitor Escort, Log and Badges.

(a) Prior to entering the premises of a registered dispensary all visitors permitted by section (8) of this rule must be documented and issued a visitor identification badge from a registrant representative that must remain visible while on the premises. All visitors described in section (8) of this rule must be accompanied by a registrant representative at all times.

(b) A dispensary registrant must maintain a log of all visitor activity and the log must contain the first and last name and date of birth of every visitor, and the date they visited.

(10) Government Access. Nothing in this rule is intended to prevent or prohibit Authority employees or contractors, or other state or local government officials that have jurisdiction over some aspect of the premises or a dispensary registrant to be on the premises.

(a) A visitor badge is not required for government officials.

(b) A dispensary must log every government official that enters the premises but the dispensary may not request that the government official provide a date of birth for the log.

(11) Limited Access Areas.

(a) All limited access areas must be physically separated from any area where the general public is permitted, by a floor to ceiling wall that prevents physical access between a point of sale area and an area that is open to the general public except through a door that is kept locked by a dispensary when the door is not immediately in use.

(b) An applicant or registered dispensary may request, in writing, an exception from the Authority from the requirement to have a floor to ceiling wall. The request must include the reason the exception is being sought, pictures of the area in question, and a description of an alternative barrier that accomplishes the goal of providing a significant physical barrier between the general public and any marijuana items on the premises of the dispensary.

(12) A dispensary must have:

(a) A designated limited access area or areas where transfers of marijuana items are received and such an area may not be accessible to patients or designated primary caregivers on the premises to receive the transfer of a marijuana item or the general public; and

(b) A designated area within the premises where patients and designated primary caregivers and other visitors enter the dispensary and are checked in.

(13) The areas described in section (12) of this rule must be clearly marked on the floor or plot plan sketch required in OAR 333-008-1040.

(14) Point of Sale Areas.

(a) All point of sale areas must be physically separated from any area where the general public is permitted by a floor to ceiling wall that prevents physical access between a point of sale area and an area that is open to the general public except through a door that is kept locked by a dispensary when the door is not immediately in use.

(b) All areas where marijuana items are available for transfer to a patient or designated primary caregiver must be supervised by a dispensary representative at all times when a patient or designated primary caregiver is present.

(c) A dispensary may not transfer a marijuana item to a patient or designated primary caregiver through a drive-through window.

(15) A dispensary may not sublet or share with any other business any portion of the dispensary premises.

Stat. Auth.: ORS 475B.450 & 475B.525
Stats. Implemented: ORS 475B.450
Hist.: PH 2-2014(Temp), f. 1-14-14, cert. ef. 1-15-14 thru 7-13-14; PH 20-2014, f. & cert. ef. 7-11-14; PH 4-2015, f. & cert. ef. 1-28-15; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1190
Testing

(1) This rule is in effect until October 1, 2016.

(a) Nothing in this rule prohibits a dispensary or an accredited laboratory from complying with the testing rules in OAR 333-007-0300 to 333-007-0490 and providing or accepting a test result that is in compliance with OAR 333-064-0100 and 333-064-0110 in lieu of a test result required in this rule.

(b) Nothing in this rule prohibits an accredited laboratory from performing sampling and testing for a registrant in accordance with this rule, prior to October 1, 2016.

(2) For purposes of this rule:

(a) "Batch" has the same meaning given that term in OAR 333-007-0310.

(b) "TNI" has the same meaning given that term in OAR 333-007-0310.

(c) "TNI standards" has the same meaning given that term in OAR 333-007-0310.

(3) Prior to being registered a PRD must have documentation that identifies at least one laboratory that will do the testing in accordance with this rule.

(4) A registered dispensary may only accept laboratory test results from a laboratory on the Authority's list posted on the Authority's website, www.healthoregon.org/ommp.

(5) A PRD must have a test report that complies with section (11) of this rule that can be linked to the batch from which each sample was taken and to each marijuana item available for transfer, before the marijuana item is available for transfer to a patient or a designated primary caregiver.

(6) A registered dispensary may submit samples for testing in accordance with section (7) of this rule or a PRD may accept test results if:

(a) A copy of the test results is obtained at the time of transfer that clearly links the test results to the marijuana item being transferred;

(b) The PRD can demonstrate to the Authority that random samples from the batch were taken and submitted for testing; and

(c) The PRD can demonstrate to the Authority that the batch from where samples were taken was sealed and not tampered with from the time samples for testing were taken and when they were delivered to the dispensary.

(7) Prior to October 1, 2016, if a dispensary accepts the transfer of a marijuana item that has not been tested in accordance with this rule a dispensary representative must:

(a) Segregate each untested batch and place the batch in an individual container or bag with a label attached to the container or bag that includes at least the following information:

(A) A unique identifier;

(B) The name of the product;

(C) The name of the person who transferred the marijuana item;

(D) The date the marijuana item was received; and

(E) "PRODUCT NOT TESTED" in bold, capital letters, no smaller than 12 point font.

(b) Take random samples from each batch in an amount necessary to conduct the applicable test, label each sample with the batch's unique identifier, and submit the samples for testing.

(c) Once samples have been taken for the purpose of testing, store and secure the untested item in a manner that prevents the item from being tampered with or transferred prior to test results being reported.

(8) Pesticide Testing. A marijuana item, except for seeds and immature plants, must be tested for pesticides by testing for individual pesticides (analytes) in the following categories, using valid testing methodologies:

(a) Chlorinated Hydrocarbons;

(b) Organophosphates;

(c) Carbamates; and

(d) Pyrethroid.

(9) THC and CBD Testing. A marijuana item, except for seeds and immature plants, must be tested to determine the levels of THC and CBD using valid testing methodologies.

(10) Laboratory Requirements. A PRD must be able to show that the laboratory that conducted the testing required in this rule:

(a) Uses valid testing methodologies; and

(b) Has a Quality System for testing of pesticides that is compliant with the:

(A) 2005 International Organization for Standardization 17025 Standard; or

(B) 2009 National Environmental Laboratory Accreditation Conference Institute TNI Standards.

(11) Testing Results. A laboratory test result must:

(a) Comply with the standards in TNI 2009, Volume 1, Module 2, Section 5.10, incorporated by reference.

(b) Include the following information:

(A) The name of each specific analyte tested;

(B) The limit of quantitation (LOQ) as that is defined in TNI 2009, Volume 1, Module 2, Section 3.1 and TNI 2009, Volume 1, Module 4, Section 1.5, incorporated by reference;

(C) The pesticide results as a numerical value in units of either parts per million or parts per billion if the analyte was detected or a statement that the level detected was less than the LOQ;

(D) The levels of THC and CBD calculated in accordance with OAR 333-064-0100; and

(E) The quality control results from the blank and quality control samples associated with the sample testing.

(c) Be signed by an official of the laboratory with an attestation that the results are accurate and that testing was done using valid testing methodologies and a quality system as required in this rule.

(12) A sample of a marijuana item shall be deemed to test positive for pesticides with a detection of more than 0.1 parts per million of any pesticide.

(13) If a marijuana item tests positive for pesticides based on the standards in this rule the PRD must:

(a) Return the entire batch from which the sample was taken to the individual who transferred the marijuana item to the dispensary and document how many or how much was returned, to whom, and the date it was returned; or

(b) Dispose of the entire batch in a manner specified by the Authority.

(14) The PRD may permit laboratory personnel or other persons authorized to do testing access to secure or restricted access areas of the dispensary where marijuana items are stored. A dispensary representative must log the date and time in and out of all such persons.

(15) If the Authority determines that a laboratory is not using valid testing methodologies, does not have a quality system, or is not producing test result reports in accordance with this rule the Authority may remove the name of the laboratory from the list on the Authority's website.

(16) The Authority may do audit testing of a marijuana item in order to determine whether a dispensary is in compliance with this rule.

[ED. NOTE: Appendix referenced are available from the agency.]

Stat. Auth.: ORS 475B.450 & 475B.525

Stats. Implemented: ORS 475B.450

Hist.: PH 2-2014(Temp), f. 1-14-14, cert. ef. 1-15-14 thru 7-13-14; PH 8-2014(Temp), f. 2-19-14, cert. ef. 2-21-13 thru 7-13-14; PH 20-2014, f. & cert. ef. 7-11-14; PH 4-2015, f. & cert. ef. 1-28-15; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1200
Operation of Registered Dispensaries

(1) Policies and Procedures. In order to obtain a registration and to retain registration a dispensary registrant must have written detailed policies and procedures and training for employees on the policies and procedures that, at a minimum, cover the following:

(a) Security;

(b) Transfers of marijuana items to and from the dispensary;

(c) Operation of a registered dispensary;

(d) Required record keeping;

(e) Testing requirements;

(f) Packaging and labeling requirements;

(g) Employee training;

(h) Compliance with these rules, including but not limited to violations and enforcement; and

(i) Roles and responsibilities for employees and PRDs in assisting the Authority during inspections or investigations.

(2) Employees. A registered dispensary may employ an individual between the ages of 18 and 20 if the individual is a patient. Otherwise, dispensary employees must be 21 years of age or older.

(3) Standardized Scales. In order to obtain a registration and to retain registration a dispensary registrant must own, maintain on the premises and use a weighing device that is licensed by the Oregon Department of Agriculture. Licensed weighing devices must be used by a registered dispensary whenever marijuana items are:

(a) Transferred to or from the dispensary and the transfer is by weight;

(b) Packaged for transfer by weight; or

(c) Weighed for purposes of documenting information required in OAR 333-008-1230, 333-008- 1245, 333-008-1247 and 333-008-1248.

(4) Inventory Tracking and Point of Sale System: In order to obtain a registration and to retain registration a registered dispensary must have an installed and fully operational integrated inventory tracking and point of sale system that can and does, at a minimum:

(a) Produce bar codes or similar unique identification numbers for each marijuana item lot transferred to a registered dispensary;

(b) Trace back or link each transfer of a marijuana item to a patient or caregiver to the marijuana item lot;

(c) Capture all information electronically that is required to be documented in OAR 333-008- 1230 and 333-008-1245;

(d) Generate inventory, transaction, and transfer reports viewable in excel format; and

(e) Produce all the information required to be submitted to the Authority pursuant to OAR 333- 0080-1248.

(5) Online Verification of Registration Status. A dispensary must verify an individual's registration status with the Authority when receiving or making the transfer of a marijuana item if the Authority has available an online system for such verification.

(6) Inventory On-Site. Marijuana items must be kept on-site at the dispensary. The Authority may take enforcement action against a dispensary registrant if during an inspection a dispensary registrant cannot account for its inventory or if the amount of usable marijuana at the registered dispensary is not within five percent of the documented inventory.

(7) Testing. A dispensary registrant may not:

(a) Accept a transfer of a marijuana item that has not been tested in accordance with OAR 333- 007-0300 to 333-007-0490.

(b) Transfer a marijuana item that has not been tested in accordance with OAR 333-007-0300 to 333-007-0490 unless it was transferred to the dispensary prior to October 1, 2016 and is labeled in accordance with OAR 333-007-0300(5).

(c) Transfer a marijuana item that was received prior to October 1, 2016, that has not been tested in accordance with OAR 333-007-0300 to 333-007-0490, after December 31, 2016.

(8) Packaging and Labeling.

(a) A dispensary may not accept a transfer of a marijuana item or transfer a marijuana item that does not comply with the labeling requirements in OAR 333-007-0010 to 333-007-0100, or that does not comply with the packaging requirements in OAR 845-025-7000 to 845-025-7020 and 845-025-7060.

(b) A marijuana item that was transferred to a dispensary prior to October 1, 2016 is not required to have gone through the Commission's pre-approval process for packaging and labeling but still must meet the labeling requirements in OAR 333-007-0010 to 333-007-0100 and the packaging requirements in OAR 845-025-7000 to 845-025-7020 and 845-025-7060.

(c) On and after October 1, 2016, a dispensary may not accept a transfer of a marijuana item unless the item has a label and package that has been pre-approved by the Commission, unless pre-approval is not required under OAR 845-025-7060(9) to (12).

(9) Oregon Department of Agriculture Licensure. On and after January 1, 2017, a registered dispensary that sells or handles food, as that term is defined in ORS 616.695, or cannabinoid edibles, must be licensed by the Oregon Department of Agriculture under ORS 616.706.

(10) Industrial Hemp Products.

(a) A dispensary may only accept the transfer of and may only transfer a product that contains THC or CBD that is derived from marijuana.

(b) Nothing in this section prohibits a dispensary from buying or selling hemp products not intended for human application, consumption, inhalation, ingestion, or absorption, such as hemp clothing.

(11) Tobacco. A dispensary may not offer or sell tobacco products in any form including, but not limited to, loose tobacco, pipe tobacco, cigarettes as defined in ORS 323.010 and cigarillos as that is defined in OAR 333-015-0030.

(12) For purposes of this rule "marijuana item lot" means a quantity of seeds, immature plants, usable marijuana, medical cannabinoid products, concentrates or extracts transferred to a registered dispensary at one time and that is from the same harvest lot or process lot as those terms are defined in OAR 333-007-0020.

Stat. Auth.: ORS 475B.450 & 475B.525

Stats. Implemented: ORS 475B.450

Hist.: PH 2-2014(Temp), f. 1-14-14, cert. ef. 1-15-14 thru 7-13-14; PH 20-2014, f. & cert. ef. 7-11-14; PH 4-2015, f. & cert. ef. 1-28-15; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16; PH 26-2016(Temp), f. & cert. ef. 9-9-16 thru 3-7-17; PH 27-2016(Temp), f. & cert. ef. 9-30-16 thru 3-1-17

333-008-1205
Registered Dispensary Signage

(1) In order to obtain a registration and to retain registration a dispensary registrant must post:

(a) At every entrance to the dispensary:

(A) If a dispensary does not participate in limited marijuana retail sales a sign that reads "Medical Marijuana Patients Only";

(B) If a dispensary is permitted to sell limited marijuana retail products in accordance with OAR 333-008-1500, signs that comply with OAR 333-008-1500 and 333-008-1501(1)(b); and

(C) "No On-Site Consumption of Marijuana".

(b) At all areas of ingress to a limited access area signs that reads:

(A) "Restricted Access Area — Authorized Personnel Only".

(B) "No Minors Allowed".

(c) At all areas of ingress to a point of sale area a sign that reads: "Restricted Access Area — No Minors Allowed".

(d) At the point of sale, the following posters prescribed by the Authority, measuring 22 inches high by 17 inches wide that can be downloaded at www.healthoregon.org/ommp:

(A) A Pregnancy Warning Poster; and

(B) A Poisoning Prevention Poster.

(2) All signs required by this rule must be:

(a) Legible, not less than 8 1/2 inches by and 11 inches, composed of letters not less than one-half inch in height;

(b) In English and Spanish, if a Spanish version is available through the Authority; and

(c) Posted in a conspicuous location where the signs can be easily read by individuals entering or on the dispensary premises.

(3) All signs may be downloaded at www.healthoregon.org/ommp.

Stat. Auth.: ORS 475B.450 & 475B.525
Stats. Implemented: ORS 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1220
Labeling

(1) This rule is in effect from March 1, 2016, until October 1, 2016. Nothing in this rule prohibits a dispensary from complying with the labeling rules in OAR 333-007-0010 to 333-007-0100 prior to October 1, 2016.

(2) Prior to transferring a marijuana item a PRD must ensure that a label is affixed to the marijuana item that includes but is not limited to:

(a) Usable marijuana:

(A) Percentage of THC and CBD;

(B) Weight in grams;

(C) Testing batch number and date tested;

(D) Who performed the testing; and

(E) Description of the product (strain).

(b) Seeds:

(A) Weight in grams; and

(B) Description of the product (strain).

(c) Immature plants: Description of the product (strain).

(d) Marijuana items other than usable marijuana, seeds or immature plants:

(A) THC and CBD potency expressed as a percentage of weight or volume;

(B) The weight or volume of usable marijuana in the product in grams, milligrams, or milliliters, as applicable;

(C) Testing batch number and date tested;

(D) Who performed the testing; and

(E) Warning label in accordance with section (3) of this rule.

(3) If the registered facility transfers a cannabinoid product, concentrate or extract the PRD must ensure it has a warning label on the outside of the packaging that includes the following: "WARNING: MEDICINAL PRODUCT — KEEP OUT OF REACH OF CHILDREN" in bold capital letters, in a font size that is larger than the type-size of the other printing on the label such that it is easy to read and prominently displayed on the product.

Stat. Auth.: ORS 475B.450 & 475B.525
Stats. Implemented: ORS 475B.450
Hist.: PH 2-2014(Temp), f. 1-14-14, cert. ef. 1-15-14 thru 7-13-14; PH 20-2014, f. & cert. ef. 7-11-14; PH 4-2015, f. & cert. ef. 1-28-15; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-1225
Packaging

(1) This rule is in effect from March 1, 2016 until October 1, 2016. Nothing in this rule prohibits a dispensary from complying with the packaging rules in OAR 845-025-7000 to 845-025-7060 prior to October 1, 2016.

(2) For purposes of this rule:

(a) "Child-resistant safety packaging" means:

(A) Containers designed and constructed to be significantly difficult for children under five years of age to open and not difficult for adults to use properly;

(B) Closable for any product intended for more than a single use or containing multiple servings; and

(C) Labeled in accordance with OAR 333-008-1220.

(b) "Container" means a sealed, hard or soft-bodied receptacle in which a tetrahydrocannabinol-infused product is placed prior to being transferred to a patient or caregiver.

(c) "Packaged in a manner not attractive to minors" means the tetrahydrocannabinol-infused product is not in a container that is brightly colored, depicts cartoons or images other than the logo of the facility, unless the logo of the facility depicts cartoons, in which case only the name of the facility is permitted.

(3) A dispensary may not transfer a medical cannabinoid product, extract or concentrate to a patient or caregiver unless the product, extract or concentrate is in child-resistant safety packaging.

Stat. Auth.: ORS 475B.450 & 475B.525
Stats. Implemented: ORS 475B.450
Hist.: PH 9-2014(Temp), f. & cert. ef. 4-1-14 thru 9-27-14; PH 25-2014, f. & cert. ef. 9-24-14; PH 4-2015, f. & cert. ef. 1-28-15; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 13-2016(Temp), f. 4-13-16, cert. ef. 4-15-16 thru 9-30-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1230
Transfers to a Registered Dispensary

(1) Transfer of Usable Marijuana, Seeds and Immature Plants. A patient, caregiver, or PRMG may transfer usable marijuana, seeds and immature plants produced by a PRMG to a registered dispensary, subject to the requirements in this rule.

(a) A registered dispensary may only accept a transfer of usable marijuana, seeds or immature marijuana plants from a caregiver or PRMG if the individual transferring the usable marijuana, seeds or immature plants provides the original or a copy of a valid:

(A) Authorization to Transfer form prescribed by the Authority; or

(B) Personal agreement as that is defined in OAR 333-008-0010.

(b) Authorization to Transfer Forms. In order to be valid an Authorization to Transfer form must include at least:

(A) The patient's name, OMMP card number or receipt number and expiration date and contact information;

(B) The name and contact information of the individual who is authorized to transfer the usable marijuana, seeds or immature marijuana plants to the registered dispensary and that individual's OMMP card number and expiration date;

(C) The name and address of the registered dispensary that is authorized to receive the usable marijuana, seeds or immature marijuana plants; and

(D) The date the authorization expires, if earlier than the expiration date of the patient's OMMP card.

(c) Personal Agreements. In order to be valid a personal agreement must include at least:

(A) The patient's name, OMMP card number and expiration date and contact information;

(B) The name and contact information of the PRMG to whom the patient's property rights have been assigned and the producer's OMMP card number and expiration date, and the grow site address;

(C) The portion of the patient's rights to possess seeds, immature plants and usable marijuana that is being assigned to the producer.

(2) Transfer of medical cannabinoid products, concentrates, and extracts.

(a) Beginning October 1, 2016, until January 1, 2017, a registered dispensary may accept the transfer of a cannabinoid product or concentrate from an applicant that has submitted a complete application for registration of a marijuana processing site.

(b) On and after January 1, 2017, a registered dispensary may only accept a transfer of a medical cannabinoid product, concentrate or extract from a registered medical marijuana processing site.

(c) Beginning October 1, 2016, until January 1, 2017, a registered dispensary may accept the transfer of a medical cannabinoid extract from an applicant that has submitted a complete application for registration of a marijuana processing site.

(3) A registered dispensary may only accept a transfer of cannabinoid products, concentrates or extracts from registered processing site if the individual transferring the products, concentrates or extracts provides the dispensary with a Processing Site Authorization to Transfer form prescribed by the Authority. In addition to retaining a copy of the Processing Site Authorization to Transfer form the dispensary must obtain a copy of the photo identification

of the individual transferring the cannabinoid product, concentrate or extract as required in section (4)(b)(B) of this rule.

(4) Transfer Records. At the time a marijuana item is transferred to a dispensary the dispensary registrant must:

(a) Document, as applicable:

(A) The weight in metric units of all usable marijuana received by the registered dispensary;

(B) The number of seeds and immature plants received by the registered dispensary;

(C) The amount of a medical cannabinoid product, concentrate, or extract received by the registered dispensary, including, as applicable, the weight in metric units, or the number of units;

(D) The name of the marijuana item;

(E) The date the marijuana item was received; and

(F) The amount of reimbursement paid by the registered dispensary.

(b) Obtain and maintain a copy of, as applicable:

(A) Documents required in section (1) of this rule including the date it was received;

(B) The photo identification of the individual transferring the marijuana item to the dispensary, if such a copy is not already on file;

(C) The OMMP card of the individual transferring usable marijuana, seeds or immature plants;

(D) The medical marijuana processing site registration; and

(E) Test results for marijuana items transferred to the dispensary unless the dispensary plans to arrange for the testing of the marijuana item.

(5) Prior to October 1, 2016, if a dispensary accepts the transfer of a marijuana item that has not been tested in accordance with OAR 333-007-0300 to 333-007-0490 the dispensary must comply with OAR 333-008-1190(7).

(6) Once a marijuana item has been sampled in accordance with OAR 333-007-0360 the marijuana item must be labeled and stored in accordance with OAR 333-007-0380.

(7) Nothing in these rules requires a dispensary registrant to accept a transfer of a marijuana item.

(8) All documentation required in this rule must be maintained electronically in an integrated inventory tracking and point of sale system or the electronic data management system described in OAR 333-008-1247.

Stat. Auth.: ORS 475B.450 & 475B.525
Stats. Implemented: ORS 475B.450
Hist.: PH 2-2014(Temp), f. 1-14-14, cert. ef. 1-15-14 thru 7-13-14; PH 20-2014, f. & cert. ef. 7-11-14; PH 4-2015, f. & cert. ef. 1-28-15; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16; PH 26-2016(Temp), f. & cert. ef. 9-9-16 thru 3-7-17

333-008-1245
Transfers From a Registered Dispensary to a Patient or Designated Primary Caregiver

(1) A dispensary registrant must, prior to permitting an individual to enter a point of sale area on the dispensary premises, except as permitted under OAR 333-008-1500, verify that the individual is a current patient or designated primary caregiver.

(2) A registered dispensary must, prior to transferring a marijuana item to a patient or a designated primary caregiver:

(a) Verify the individual is currently registered with the Authority by viewing the individual's government issued photo identification and Authority issued patient or caregiver card, or the patient's receipt, as described in OAR 333-008-0023(6) or OAR 333-008-0040(5) and making sure the identities match.

(b) Obtain and retain, if not already on file, a copy of the patient's or caregiver's:

(A) OMMP identification card or receipt; and

(B) Government issued photo identification.

(c) Document:

(A) The name, OMMP card number and expiration date of the card of each person to whom the registered facility transfers a marijuana item;

(B) If the marijuana item was transferred to a designated primary caregiver, the patient's name and registration number for whom the caregiver was receiving the transfer;

(C) The amount of usable marijuana transferred in metric units, if applicable;

(D) The number of seeds or immature plants transferred, if applicable;

(E) The amount of a medical cannabinoid product concentrate, or extract, if applicable;

(F) The brand name of the marijuana item and a description of what was transferred;

(G) The date of the transfer; and

(H) The amount of money paid by the patient or designated primary caregiver for the transfer.

(3) A dispensary registrant may not transfer at any one time to a patient or designated primary caregiver, within one day, more than:

(a) 24 ounces of usable marijuana;

(b) 16 ounces of a medical cannabinoid product in solid form;

(c) 72 ounces of a medical cannabinoid product in liquid form;

(d) 16 ounces of a cannabinoid concentrate whether sold alone or contained in an inhalant delivery system;

(e) Five grams of a cannabinoid extract whether sold alone or contained in an inhalant delivery system;

(f) Four immature marijuana plants; and

(g) 50 seeds.

(4) All documentation required in this rule must be maintained electronically in an integrated inventory tracking and point of sale system or the electronic data management system described in OAR 333-008-1247.

Stat. Auth.: ORS 475B.450 & 475B.525
Stats. Implemented: ORS 475B.450
Hist.: PH 9-2014(Temp), f. & cert. ef. 4-1-14 thru 9-27-14; PH 25-2014, f. & cert. ef. 9-24-14; PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1247
Registered Dispensary Record Keeping

(1) In order to obtain a registration and to retain registration a PRD must have an installed and fully operational electronic data management system that is either the same as or different than the integrated inventory tracking and point of sale system required in OAR 333-008-1200 capable of maintaining:

(a) All copies of documents required to be obtained and retained in OAR 333-008-1230 and 333-008-1245;

(b) Any revocation of an Authorization to Transfer form or personal agreement; and

(c) All other information required to be documented and retained by these rules if such information is not contained in the inventory tracking and point of sale system required in OAR 333-008-1200.

(2) A dispensary registrant must maintain all information required to be documented in these rules in a safe and secure manner that protects the information from unauthorized access, theft, fire, or other destructive forces, and is easily accessed and retrievable by the Authority upon request, either at the registered dispensary or online.

(3) The electronic data management system described in section (1) of this rule must:

(a) Provide for an off-site or secondary backup system; and

(b) Provide security measures to ensure patient records are kept confidential.

(4) Documents and information required to be maintained in these rules must be retained by a PRD for at least two years.

(5) A dispensary registrant must provide the Authority with any documentation required to be maintained in these rules upon request, in the format requested by the Authority, or permit the Authority access to such documentation on-site.

Stat. Auth.: ORS 475B.450 & 475B.525
Stats. Implemented: ORS 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-1248
Registered Dispensary Reporting to the Authority

(1) On and after June 1, 2016, a PRD must submit to the Authority electronically in a manner specified by the Authority, by the 10th of each month, the following information:

(a) The amount of usable marijuana transferred to and by the medical marijuana dispensary during the previous month.

(b) The amount and type of medical cannabinoid products transferred to and by the medical marijuana dispensary during the previous month. For purposes of this section "type" means:

(A) Cannabinoid edibles;

(B) Cannabinoid topicals;

(C) Cannabinoid tinctures;

(D) Cannabinoid capsules;

(E) Cannabinoid suppositories;

(F) Cannabinoid transdermal patches and

(G) Cannabinoid product other than products listed in paragraphs (A) to (F) of this subsection.

(c) The amount and type of cannabinoid concentrates transferred to and by the medical marijuana dispensary during the previous month. For purposes of this section "type" means:

(A) Cannabinoid concentrate in solid form; and

(B) Cannabinoid concentrate in liquid form.

(d) The amount and type of cannabinoid extracts transferred to and by the medical marijuana dispensary during the previous month. For purposes of this section "type" means:

(A) Cannabinoid extract in solid form; and

(B) Cannabinoid extract in liquid form.

(e) The quantity of immature marijuana plants transferred to and by the medical marijuana dispensary during the previous month.

(f) The quantity of seeds transferred to and by the medical marijuana dispensary during the previous month.

(2) Information submitted to the Authority under this rule must:

(a) List each type of marijuana item separately;

(b) Provide the total aggregate amount of a type of marijuana item transferred to a dispensary by each patient, designated primary caregiver, PRMG or processing site during the previous month; and

(c) Provide the total aggregate amount of a type of marijuana item transferred by a dispensary to each patient or designated primary caregiver during the previous month.

(3) In addition to submitting the information as required by section (1) of this rule, a person responsible for a dispensary must keep a record of the information described in section (1) of this rule for two years after the date on which the person submits the information to the Authority.

Stat. Auth.: ORS 475B.450 & 475B.525
Stats. Implemented: ORS 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-1500
Limited Marijuana Retail Sales

(1) For purposes of OAR 333-008-1500 through 333-008-1505 the following definitions apply:

(a) "Cannabinoid concentrate" means a substance obtained by separating cannabinoids from marijuana by:

(A) A mechanical extraction process;

(B) A chemical extraction process using a nonhydrocarbon-based solvent, such as vegetable glycerin, vegetable oils, animal fats, isopropyl alcohol or ethanol; or

(C) A chemical extraction process using the hydrocarbon-based solvent carbon dioxide, provided that the process does not involve the use of high heat or pressure.

(b) "Cannabinoid edible" means:

(A) A food or potable liquid into which a cannabinoid concentrate, cannabinoid extract or dried marijuana leaves or flowers have been incorporated.

(B) "Cannabinoid edible" does not include a tincture or a cannabinoid product intended to be placed under the tongue or in the mouth using a dropper or spray delivery method, such as but not limited, to a sublingual spray.

(c) "Cannabinoid extract" means a substance obtained by separating cannabinoids from marijuana by:

(A) A chemical extraction process using a hydrocarbon-based solvent, such as butane, hexane or propane; or

(B) A chemical extraction process using the hydrocarbon-based solvent carbon dioxide, if the process uses high heat or pressure.

(d)(A) "Cannabinoid product" means a cannabinoid edible and any other product intended for human consumption or use, including a product intended to be applied to the skin or hair, which contains cannabinoids or dried marijuana leaves or flowers.

(B) "Cannabinoid product" does not include:

(i) Usable marijuana by itself;

(ii) A cannabinoid concentrate by itself;

(iii) A cannabinoid extract by itself; or

(iv) Industrial hemp, as defined in ORS 571.300.

(e) "Cannabinoid tincture" means a solution of alcohol, cannabinoid concentrate or extract, and perhaps other ingredients intended for human consumption or ingestion, and that is exempt from the Liquor Control Act under ORS 471.035.

(f) "Cannabinoid topical" means a cannabinoid product intended to be applied to skin or hair.

(g) "Dried leaves and flowers of marijuana" means the cured and dried leaves and flowers from a mature marijuana plant that have not been chemically altered or had anything added to them.

(h) "Immature marijuana plant" means a marijuana plant that is not flowering.

(i) "Individual" means a person 21 years of age or older who is not a patient or designated primary caregiver.

(j) "Limited marijuana retail product" means:

(A) The seeds of marijuana;

(B) The dried leaves and flowers of marijuana;

(C) An immature marijuana plant;

(D) Cannabinoid edibles;

(E) Nonpsychoactive medical cannabinoid products intended to be applied to a person's skin or hair; and

(F) Prefilled receptacles of cannabinoid extracts.

(k) "Low-dose cannabinoid edible" means a cannabinoid edible that has no more than 15 milligrams of THC in a unit.

(l) "Marijuana" means the plant Cannabis family Cannabaceae, any part of the plant Cannabis family Cannabaceae and the seeds of the plant Cannabis family Cannabaceae.

(m) "Medical cannabinoid product" has the meaning given that term in ORS 475B.410.

(n) "Medical marijuana dispensary" or "dispensary" means an entity registered with the Oregon Health Authority under ORS 475B.450.

(o) "Nonpsychoactive medical cannabinoid product intended to be applied to a person's skin or hair":

(A) Means a cannabinoid topical with a THC content of not more than six percent that does not affect the mind or mental processes.

(B) Does not mean a transdermal patch.

(p) "Photographic identification" means valid government issued identification with a photograph of the individual that includes the individual's last name, first name, and date of birth.

(q) "Prefilled receptacle of cannabinoid extract" means a single use cartridge prefilled with a cannabinoid extract by itself.

(r) "Unit" means a package for sale.

(2) Until January 1, 2017, a medical marijuana dispensary may sell limited marijuana retail product to an individual in accordance with this rule if:

(a) The dispensary, five days prior to selling any limited marijuana retail product notifies the Authority, on a form prescribed by the Authority, that the dispensary intends to sell limited marijuana retail product;

(b) The city or county in which the dispensary operates has not adopted an ordinance prohibiting the sale of limited marijuana retail product; and

(c) The Authority has not prohibited the dispensary from selling limited marijuana retail product under section (14) of this rule.

(3) A dispensary that is permitted to sell limited marijuana retail product:

(a) Must examine the photo identification of all individuals before entering the dispensary to ensure the individual is 21 years of age or older.

(b) Must verify at the time of sale that the individual is 21 years of age or older by examining the individual's photographic identification.

(c) May only sell limited marijuana retail product as specified in sections (4) to (6) of this rule.

(4) A dispensary may sell one-quarter ounce of dried leaves and flowers to an individual per day.

(5) Between June 2 and December 31, 2016 a dispensary may sell:

(a) One unit of a single-serving, low-dose cannabinoid edible to an individual per day. A unit of a low-dose cannabinoid edible can contain more than one edible as long as the total THC in the unit does not exceed 15 milligrams.

(b) One prefilled receptacle of a cannabinoid extract that does not contain more than 1,000 milligrams of THC to an individual per day.

(c) Nonpsychoactive medical cannabinoid products intended to be applied to a person's skin or hair.

(6) A dispensary may sell up to four immature marijuana plants to the same individual at any time between October 1, 2015 and December 31, 2016.

(7) A dispensary may not:

(a) Offer, sell or provide a cannabinoid product, extract or concentrate to an individual except as provided in sections (4) through (6) of this rule; or

(b) Give away a limited marijuana retail product to an individual.

(8) For each limited marijuana retail product sale, a dispensary must document:

(a) The limited marijuana retail product that was sold and the amount in metric units or number sold as applicable;

(b) The birth date of the individual who bought the product;

(c) The sale price; and

(d) The date of sale.

(9) A dispensary may sell non-marijuana items to an individual, such as but not limited to branded clothing.

(10) A dispensary is not required to maintain a record of the name of the individual to whom a limited marijuana retail product was sold but the dispensary must have a system in place that is outlined in its policies and procedures for ensuring that an individual is not sold more than the amount or number of a limited retail marijuana product permitted under this rule.

(11) Records of sale transactions and the documentation required in section (8) of this rule shall be maintained in accordance with the Authority's record keeping requirements for dispensaries.

(12) A dispensary that chooses to sell limited marijuana retail product to individuals must:

(a) Post at the point the sale, the following posters prescribed by the Authority, measuring 22 inches high by 17 inches wide that can be downloaded at www.healthoregon.org/marijuana:

(A) A Pregnancy Warning Poster; and

(B) A Poisoning Prevention Poster.

(b) Post at the point of sale a color copy of the "Educate Before You Recreate" flyer measuring 22 inches high by 17 inches wide that can be downloaded at WHATSLEGALOREGON.COM.

(c) Distribute to each individual at the time of sale, a Marijuana Information Card, prescribed by the Authority, measuring 3.5 inches high by 5 inches long that can be downloaded at www.healthoregon.org/marijuana.

(d) Comply with all rules in OAR chapter 333, division 7 and 8 that apply to dispensaries including but not limited to all security, testing, labeling, except as provided in section (13) of this rule, packaging and documentation rules except rules that:

(A) Prohibit individuals from entering or being present in a dispensary; and

(B) Prohibit a dispensary from transferring marijuana to an individual.

(e) On and after January 4, 2016:

(A) Collect a tax of 25 percent of the retail sales price of a limited marijuana retail product in the same manner that a marijuana retailer that holds a license under section 22, chapter 1, Oregon Laws 2015, collects the tax imposed under section 2, chapter 699, Oregon Laws 2015;

(B) Comply with all requirements in sections 1 through 13, chapter 699, Oregon Laws 2015, and any applicable administrative rules adopted by the Department of Revenue; and

(C) If requested by the Authority, sign an authorization to permit the sharing of information between the Authority and the Department of Revenue concerning tax collection required by section 21a, chapter 699, Oregon Laws 2015.

(13) A dispensary:

(a) May substitute a warning that reads "For use by adults 21 and older. Keep out of reach of children" for the warning "For use by OMMP patients only. Keep out of reach of children" on labels for limited marijuana retail products.

(b) Between June 2 and October 1, 2016, may not sell a low-dose cannabinoid edible or a prefilled receptacle of a cannabinoid extract unless it is in child-resistant safety packaging, as that is defined in OAR 333-008-1225.

(c) On and after October 1, 2016, must:

(A) Comply with the packaging requirements in OAR 845-025-7000 to 845-025-7060 for all limited marijuana retail products.

(B) Comply with any labeling requirements in OAR 333-007-0010 to 333-007-0100 for limited marijuana retail products that would be applicable to a similar item sold by an Oregon Liquor Control Commission licensee.

(14) The Authority may, if it determines that a dispensary has violated OAR 333-008-1500 through 333-008-1505:

(a) Prohibit a dispensary from selling limited marijuana retail product; and

(b) Take any action authorized under OAR 333-008-2190.

(15) A dispensary may not sell limited marijuana retail product to individuals if the dispensary is located in a city or county that has adopted an ordinance prohibiting such sales in accordance with section 3, chapter 784, Oregon Laws 2015.

(16) A dispensary that has had its registration suspended may not sell limited marijuana retail product while the registration is suspended.

(17) This rule is only in effect until January 1, 2017.

Stat. Auth.: ORS 475.314 & 475.338, OL 2015, ch. 784 & sec. 21a, ch. 699, OL 2015

Stats. Implemented: ORS 475.314, OL 2015, ch. 784 & sec. 21a, ch. 699, OL 2015

Hist.: PH 16-2015(Temp), f. & cert. ef. 9-22-15 thru 3-19-16; PH 8-2016, f. 2-26-16, cert. ef. 3-1-16; PH 16-2016(Temp), f. 5-20-16, cert. ef. 6-2-16 thru 11-28-16

333-008-1501
Dispensary Signs

(1) Between October 1, 2015 and December 31, 2016, a registered dispensary must post signs at any point of public entry that read:

(a) "Medical Marijuana Patients Only"; or

(b) If a dispensary has properly notified the Authority that it intends to sell limited marijuana retail products:

(A) "Medical Marijuana Patients and Persons 21 and Older Permitted"; and

(B) "NO PERSON UNDER 21 PERMITTED ON THE PREMISES WITHOUT AN OMMP CARD".

(2) The signs described in section (1) of this rule must be:

(a) In bold, 80 point Times New Roman, Helvetica or Arial font; and

(b) Affixed to the exterior of the dispensary in a conspicuous location that can be easily seen by the public from outside the dispensary.

Stat. Auth.: ORS 475.314 & 475.338, OL 2015, ch. 784
Stats. Implemented: ORS 475.314, OL 2015, ch. 784
Hist.: PH 16-2015(Temp), f. & cert. ef. 9-22-15 thru 3-19-16; PH 8-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-1505
Reporting Requirements

(1) A dispensary that is selling limited marijuana retail products to individuals must by April 10, 2016, July 10, 2016, October 10, 2016, and January 10, 2017, report to the Authority, in a manner prescribed by the Authority, the information required to be documented in OAR 333-008-1500(8) for the previous quarter.

(2) A dispensary must submit, by April 10, 2016, the information required to be documented in OAR 333-008-1500(8) for October 1, 2015 through December 31, 2015.

(3) A dispensary selling limited marijuana retail products to individuals must provide proof to the Authority by May 10, 2016, August 10, 2016, November 10, 2016, and February 10, 2017. in a manner prescribed by the Authority, that it has paid the tax required by the Department of Revenue for the previous quarter. Documentation may include but is not limited a copy of the marijuana tax returns, reports, payment vouchers, payment receipts or any related documents filed with the Department.

Stat. Auth.: ORS 475B.450 & 475B.525, OL 2015, ch. 784
Stats. Implemented: ORS 475B.450, OL 2015, ch. 784
Hist.: PH 8-2016, f. 2-26-16, cert. ef. 3-1-16; PH 16-2016(Temp), f. 5-20-16, cert. ef. 6-2-16 thru 11-28-16

Medical Marijuana Processors

333-008-1600
Applicability

(1) OAR 333-008-1600 to 333-008-2200 applies to any person processing marijuana for transfer to a registered dispensary.

(2) A person may not process marijuana unless the person is registered in accordance with these rules, except for a person:

(a) Processing marijuana under a license issued by the Commission under ORS 475B.090; or

(b) Who has been designated as a primary caregiver under ORS 475B.418 who processes a medical cannabinoid product or a cannabinoid concentrate for the caregiver's patient and who does not transfer medical cannabinoid product or cannabinoid concentrate to a dispensary.

Stat. Auth.: ORS 475B.435, 475B.445
Stats. Implemented: ORS 475B.435, 475B.445
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-1610
Definitions

For purposes of OAR 333-008-1600 to 333-008-2200:

(1) "Cannabinoid capsule" means a small soluble container, usually made of gelatin, that encloses a dose of a cannabinoid product, concentrate or extract intended for human ingestion.

(2) "Cannabinoid edible" means a food or potable liquid into which a cannabinoid concentrate or extract or the dried leaves or flowers of marijuana have been incorporated.

(3) "Cannabinoid suppository" means a small soluble container designed to melt at body temperature within a body cavity other than the mouth, especially the rectum or vagina, containing a cannabinoid product, concentrate or extract.

(4) "Cannabinoid tincture" means a solution of alcohol, cannabinoid concentrate or extract, and perhaps other ingredients intended for human consumption or ingestion, and that is exempt from the Liquor Control Act under ORS 471.035.

(5) "Cannabinoid topical" means a cannabinoid product intended to be applied to skin or hair.

(6) "Cannabinoid transdermal patch" means an adhesive substance applied to human skin that contains a cannabinoid product, concentrate or extract for absorption into the bloodstream.

(7) "Food" means a raw, cooked, or processed edible substance, beverage or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum.

(8) "Person responsible for the marijuana processing site" or "PRP" means an individual who is directly involved in the day-to-day operation of a processing site and is identified as a PRP on an application.

(9) "Primary PRP" means a PRP designated by the owner of the processing site as the primary point of contact for the Authority and who is authorized to receive any and all communications and legal notices from the Authority.

(10) "Processing site representative" means an owner, director, officer, PRP, manager, employee, agent or other representative of a registered processing site, to the extent that the person acts in a representative capacity.

(11) "Processing site registrant" means:

(a) An individual who owns a registered processing site or if a business entity owns the registered processing site, each individual who has a financial interest in the registered processing site; and

(b) Any PRP.

(12) "These rules" means OAR 333-008-1600 to 333-008-2200.

Stat. Auth.: ORS 475B.435
Stats. Implemented: ORS 475B.435
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1620
Application for Medical Marijuana Processing Site Registration

(1) This rule applies to any initial application filed on or after June 24, 2016 and to any initial application filed prior to June 24, 2016 that the Authority has not yet approved or denied.

(2) To register a medical marijuana processing site a person must:

(a) Submit an initial application on a form prescribed by the Authority that includes but is not limited to:

(A) The name of the individual who owns the processing site or, if a business entity owns the processing site, the name of each individual who has a financial interest in the processing site;

(B) The name of the individual or individuals responsible for the processing site, if different from the name of the individual who owns the processing site, with one of the individuals responsible for the processing site identified as the primary PRP;

(C) The address of the marijuana processing site; and

(b) Application and registration fees.

(c) An initial application for the registration of a processing site must be submitted electronically via the Authority's website, www.healthoregon.org/ommp.

(3) If an initial application is submitted along with the required fees the Authority will notify the applicant that the initial application has been received and that within 30 calendar days the following information must be received by the Authority:

(a) For each individual named in the application:

(A) A legible copy of the individual's valid government issued photographic identification that includes last name, first name and date of birth;

(B) Information, fingerprints and fees required for a criminal background check in accordance with OAR 333-008-2020; and

(C) An Individual History Form and any information identified in the form that is required to be submitted.

(b) If the applicant intends to process extracts, proof from the local government that the proposed location of the processing site is not located in an area that is zoned for residential use;

(c) Proof that the business is registered or has filed an application to register as a business with the Oregon Office of the Secretary of State, including proof of registration of any DBA (doing business as) registration;

(d) A scaled site plan of the parcel or premises on which the premises proposed for registration, is located, including:

(A) Cardinal directional references;

(B) Bordering streets and the names of the streets;

(C) Identification of the building or buildings in which the proposed processing site is to be located;

(D) The dimensions of the proposed premises of the processing site;

(E) Identification of other buildings or property owned by or under the control of the applicant on the same parcel or tax lot as

the premises proposed for registration that will be used in the business; and

(F) Identification of any residences on the parcel or tax lot;.

(e) A scaled floor plan of all enclosed areas of the premises at the proposed location that will be used in the business with clear identification of walls, partitions, counters, windows, all areas of ingress and egress, intended uses of all spaces;

(f) Documentation that shows the applicant has lawful possession of the proposed location of the processing site;

(g) A description of the type of products to be processed, a description of equipment to be used, including any solvents, gases, chemicals or other compounds used to create extracts or concentrates on a form prescribed by the Authority; and

(h) The proposed endorsements as described in OAR 333-008-1700.

(4) The information and documentation required in section (3) of this rule may be submitted electronically to the Authority or may be mailed to the Oregon Medical Marijuana Program, Oregon Health Authority, PO Box 14116, Portland, OR 97293.

(a) If documentation is mailed, it must be received by the Authority within 30 calendar days of the date the Authority mailed the notice to the applicant that the application was received or the application will be considered incomplete.

(b) If documentation is submitted electronically it must be received by the Authority within 30 calendar days of the date the Authority mailed the notice to the applicant that the application was received or the application will be considered incomplete.

(5) Application and registration fees must be paid online at the time of application.

(6) Criminal background check fees must be paid by check or money order and must be mailed to the Oregon Medical Marijuana Program, Oregon Health Authority, PO Box 14116, Portland, OR 97293 and must be received by the Authority in accordance with provisions in section (4) of this rule.

(7) If the Authority does not receive a complete application, all documentation required in sections (2) and (3) of this rule, and all required fees within the time frames established in this rule, the application will be considered incomplete.

(8) If the applicant provides the documentation required in section (3) of this rule, the Authority will review the information to determine if it is complete.

(a) If the documentation is not complete or is insufficient the Authority must notify the applicant in writing and the applicant will have 10 calendar days from the date such written notice is mailed by the Authority to provide the additional documentation.

(b) If the applicant does not provide the additional documentation within 10 calendar days or if any responsive documents are incomplete, insufficient or otherwise do not demonstrate compliance with ORS 475B.450 and these rules the application will be declared incomplete.

(9) A person who wishes to register more than one location must submit a separate application, registration fees, and all documentation described in sections (2) and (3) of this rule for each location.

(10) An application that is incomplete is treated by the Authority as if it was never received.

Stat. Auth.: ORS 475B.435
Stats. Implemented: ORS 475B.435
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1630
Processing Site Fees

(1) The initial fees for the registration of a processing site are:

(a) A non-refundable application fee of $500; and

(b) A $3,500 registration fee.

(2) The annual renewal fees for the registration of a processing site are:

(a) A $500 non-refundable renewal fee; and

(b) A $3,500 registration fee.

(3) The criminal background check fee is $35 per individual.

(4) The Authority must return the registration fee if:

(a) An application is incomplete; or

(b) An applicant withdraws an application.

(5) The Authority may return the registration fee if an application is denied.

Stat. Auth.: ORS 475B.435
Stats. Implemented: ORS 475B.435
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-1650
Processing Site Application Review

(1) Applications will be reviewed in the order they are received by the Authority. An application is considered received as of the date and time that payment of fees is authorized by the entity that issued the credit or debit card used to pay the fees.

(2) Once the Authority has determined that an application is complete it will review an application to the extent necessary to determine compliance with ORS 475B.435 and these rules.

(3) The Authority may, in its discretion, prior to acting on an application:

(a) Contact any individual listed on the application and request additional documentation or information;

(b) Inspect the premises of the proposed processing site; or

(c) Verify any information submitted by the applicant.

(4) Prior to making a decision whether to approve or deny an application the Authority must:

(a) Review the criminal background check results for each individual named on the application;

(b) Verify that the applicant is registered as a business with the Office of the Secretary of State; and

(c) Verify that the proposed location of the processing site is not located:

(A) In an area that is zoned for residential use if the processor intends to make extracts; and

(B) Is not in a city or county that has adopted an ordinance under ORS 475B.800 or section 133, chapter 614, Oregon Laws 2015, prohibiting processing sites.

(5) If during the review process the Authority determines that the application or supporting documentation contains intentionally false or misleading information the Authority may declare the application incomplete or deny the application in accordance with OAR 333-008-1670.

(6) The Authority will notify the applicant in writing that the applicant has 60 calendar days from the date of the written notice to submit a Readiness Form, prescribed by the Authority, indicating that the applicant is prepared for an inspection and is in compliance with these rules if:

(a) There is no basis for denial under OAR 333-008-1670;

(b) The proposed processing site is in compliance with ORS 475B.435 and these rules;

(c) Each individual named in the application passes the criminal background check; and

(d) Each individual named as a PRP in the application meets the age requirement.

(7) If the Authority does not receive the Readiness Form in accordance with section (6) of this rule the applicant's application will be declared incomplete, unless an extension has been granted under section (8) of this rule.

(8) An applicant may request one extension of the 60-day deadline in section (6) of this rule if the applicant can demonstrate to the Authority that the deadline cannot be met for reasons outside of the applicant's control, such as but not limited to the applicant's inability to obtain local government building permits.

(a) A request for an extension must be in writing, must be received within 60 calendar days of the notice described in section (6) of this rule, and must explain and provide documentation that shows the applicant cannot, for reasons outside of the applicant's control, meet the 60-day deadline.

(b) A request for an extension tolls the 60-day deadline.

(c) The Authority will review the request and provide, in writing to the applicant, its decision and the reason for the decision.

(d) If an extension is granted the Authority must inform the applicant of the new deadline for submission of the Readiness

Form, but in any case an extension may not exceed 60 calendar days.

Stat. Auth.: ORS 475B.435

Stats. Implemented: ORS 475B.435

Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1660

Processing Site Pre-Approval Inspection; Approval of Application

(1) The Authority must perform a site visit within 30 days of receiving a timely Readiness Form, as that is described in OAR 333-008-1650 to determine whether the applicant and processing site are in compliance with these rules.

(2) If, after the site visit the Authority determines that the applicant and processing site are in compliance with these rules the Authority must provide the primary PRP with proof of registration that includes a unique registration number, and notify the primary PRP in writing that the processing site may operate, and issue any applicable endorsements.

(3) If, after the site visit the Authority determines that the processing site is not in compliance with these rules the Authority may:

(a) Give the applicant 10 business days to come into compliance;

(b) Propose to deny the application in accordance with OAR 333-008-1670; or

(c) Consider the application to be incomplete.

(4) A processing site must at all times display proof of registration in a prominent place inside the processing site so that proof of registration is easily visible to individuals authorized to be on the premises of the processing site.

(5) A registered processing site may not use the Authority or the OMMP name or logo except to the extent that information is contained on the proof of registration on any signs at the processing site, on its website, or in any advertising or social media.

(6) A processing site's registration:

(a) Is only valid for the location indicated on the proof of registration.

(b) May not be transferred to another location.

Stat. Auth.: ORS 475B.435

Stats. Implemented: ORS 475B.435

Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-1670

Denial of Processing Site Application

(1) The Authority must deny an application for the registration of a processing site if:

(a) An application, supporting documentation provided by the applicant, or other information obtained by the Authority shows that the qualifications for a processing site in ORS 475B.435 or these rules have not been met; or

(b) An individual named in an application has been:

(A) Convicted for the manufacture or delivery of a controlled substance in Schedule I or Schedule II within two years from the date the application was received by the Authority; or

(B) Convicted more than once for the manufacture or delivery of a controlled substance in Schedule I or Schedule II; or

(c) The city or county in which the facility is located has prohibited processing sites in accordance with ORS 475B.800 or section 133, chapter 614, Oregon Laws 2015.

(2) The Authority may deny an applicant if it determines that the applicant, the owner of the processing site, a PRP, or an employee of the processing site:

(a) Submitted false or misleading information to the Authority; or

(b) Violated a provision of ORS 475B.400 to 475.525, 475B.555, 475B.605, 475B.615, OAR chapter 333, division 7, these rules or an ordinance adopted pursuant to ORS 475B.500.

(3) If an individual named in an application is not qualified based on age, or the criminal background check, the Authority will permit a change form to be submitted in accordance with OAR 333-008-1720 or 333-008-2030, along with the applicable criminal background check fee. If the individual named in the change form is not qualified the Authority must deny the application in accordance with section (1) of this rule.

(4) If the Authority intends to deny an application for registration it must issue a Notice of Proposed Denial in accordance with ORS 183.411 through 183.470.

Stat. Auth.: ORS 475B.435

Stats. Implemented: ORS 475B.435

Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1680

Withdrawal of Processing Site Application

An applicant for a processing site registration may withdraw an initial or renewal application at any time prior to the Authority acting on the application unless the Authority has determined that the applicant submitted false or misleading information or there is a pending investigation or enforcement action in which case the Authority may refuse to accept the withdrawal and may issue a notice of proposed denial in accordance with OAR 333-008-1670.

Stat. Auth.: ORS 475B.435

Stats. Implemented: ORS 475B.435

Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-1690

Expiration and Renewal of Registration for Processing Site

(1) A processing site's registration expires one year following the date of application approval.

(2) A processing site registrant must submit not more than 90 but at least 30 calendar days before the registration expires:

(a) A renewal application on a form prescribed by the Authority;

(b) Renewal fees;

(c) For each individual named in the renewal application:

(A) A legible copy of the individual's valid government issued photographic identification that includes last name, first name and date of birth;

(B) Information, fingerprints and fees required for a criminal background check in accordance with OAR 333-008-2020; and

(C) An Individual History Form and any information identified in the form that is required to be submitted.

(d) Current proof of business registration with the Secretary of State, including all DBA (doing business as) registrations;

(e) Documentation that shows the applicant has lawful possession of the location of the registered processing site; and

(f) A current scaled floor plan of all enclosed areas at the proposed location that will be used in the business with clear identification of walls, partitions, counters, windows, all areas of ingress and egress, uses of all spaces and all limited access areas.

(3) A registrant who files a completed renewal application, fees, and all the information required in section (2) of this rule with the Authority prior to the expiration date of the registration may continue to operate, even after the registration expiration date, pending a decision on the renewal application by the Authority.

(4) A processing site registrant that does not submit a timely application, fees and all the information required in section (2) of this rule may be subject to the imposition of civil penalties.

(5) If a processing site registrant does not submit the renewal application, fees and all the information required in section (2) of this rule prior to the registration's expiration, the registration is expired and is no longer valid.

(6) Renewals will be processed in accordance with OAR 333-008-1650 to 333-008-1670, as applicable.

(7) A renewal applicant may be required to submit a Readiness Form, as described in OAR 333-008-1650(9) and may be subject to inspection prior to the Authority acting on a renewal application.

Stat. Auth.: ORS 475B.435
Stats. Implemented: ORS 475B.435
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1700
Processing Site Endorsements

(1) A marijuana processor may only process and transfer medical cannabinoid products, concentrates or extracts if the processor has received an endorsement from the Authority for that type of processing activity. Endorsements types are:

(a) Cannabinoid edible processor;

(b) Cannabinoid topical processor;

(c) Cannabinoid concentrate processor;

(d) Cannabinoid extract processor; and

(e) Cannabinoid tincture, capsule, suppository, or transdermal patch processor.

(2) An applicant must request an endorsement upon submission of an initial application but may also request an endorsement at any time following registration.

(3) In order to apply for an endorsement an applicant or processing site registrant must submit a form prescribed by the Authority that includes a description of the type of products to be processed, a description of equipment to be used, and any solvents, gases, chemicals or other compounds proposed to be used to create extracts or concentrates.

(4) Only one application and registration fee is required regardless of how many endorsements an applicant or registrant requests or at what time the request is made.

(5) A processing site registrant may hold multiple endorsements.

(6) For the purposes of endorsements any cannabinoid product that is intended to be consumed orally is considered a cannabinoid edible.

(7) If a processor is no longer going to process the product for which the processor is endorsed the processor must notify the Authority in writing and provide the date on which the processing of that product will cease.

Stat. Auth.: ORS 475B.435, 475B.440
Stats. Implemented: ORS 475B.435, 475B.440
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-1710
PRP Criteria and Responsibilities

(1) A PRP must:

(a) Be 21 years or age or older;

(b) Have legal authority to act on behalf of the registered processing site; and

(c) Be responsible for ensuring the registered processing site complies with applicable laws.

(2) A PRP may not:

(a) Have been convicted in any state for the manufacture or delivery of a controlled substance in Schedule I or Schedule II within two years from the date of application; or

(b) Have been convicted more than once in any state for the manufacture or delivery of a controlled substance in Schedule I or Schedule II.

(3) At least one PRP must be on site at a processing site during Authority inspections or investigations at the time of the inspection or investigation or within one hour of being notified that an inspection or investigation is taking place.

(4) A PRP is accountable for any intentional or unintentional action of a processing site representative, with or without the knowledge of the PRP, who violates ORS 475B.435 to 475B.440 or these rules, and is responsible for any unlawful conduct that occurs on the premises of the processing site or any property outside the registered processing site that is owned by or under the control of the processing site registrant.

Stat. Auth.: ORS 475B.435
Stats. Implemented: ORS 475B.435
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1720
Removal, Addition, Change, Designation or Assignment of PRP

(1) If an owner of a registered processing site is adding or changing a PRP or primary PRP, an individual with legal authority to act on behalf of the registered processing site must submit:

(a) A form, prescribed by the Authority;

(b) A legible copy of the individual's valid government issued photographic identification that includes last name, first name and date of birth;

(c) Information and fingerprints required for a criminal background check in accordance with OAR 333-008-2020; and

(d) A criminal background check fee of $35.

(2) A PRP who is designating or assigning the responsibilities of a PRP to another individual must submit the information and fees required in section (1) of this rule. The duties of a primary PRP may not be designated or assigned.

(3) The Authority will review and approve the addition or change of a PRP or primary PRP if the individual meets the requirements in OAR 333-008-1710.

(4) The Authority will review and approve the designation or assignment of the responsibilities of a PRP to another individual if that individual meets the requirements in OAR 333-008-1710. An individual to whom a designation or assignment is made, and who is approved by the Authority, has the same legal obligations as a PRP.

(5) An individual may not act in the capacity of a PRP without approval from the Authority.

(6) If the Authority denies the request to add or change a PRP or primary PRP, or denies the request to designate or assign the responsibilities of a PRP to another individual, the Authority must notify the individual that submitted the request of the denial and the current primary PRP and describe the reason for the denial.

(7) A registered processing site may not process marijuana or receive or transfer any marijuana items without at least one Authority approved PRP and a primary PRP.

Stat. Auth.: ORS 475B.435
Stats. Implemented: ORS 475B.435
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1730
Registered Processing Site Premises Restrictions and Requirements

(1) A registered processing site may not be located in an area that is zoned for residential use if the processing site is endorsed to make cannabinoid extracts.

(2) In order to be registered a processing site must operate at a particular location as specified in the application and may not be mobile.

(3) Minors on Premises. A registered processing site may not permit a minor to be present in any limited access area of a registered processing site.

(4) On Premises Consumption.

(a) A registered processing site may not permit the ingestion, inhalation or topical application of a marijuana item anywhere on the premises of the processing site, except as described in subsection (b) of this section.

(b) An employee of a registered processing site who is a patient may consume a marijuana item during his or her work shift on the premises of the registered processing site as necessary for his or her medical condition, if the employee is:

(A) Alone and in a closed room where no processing site marijuana items are present; and

(B) Not visible to the public outside the registered processing site.

(c) For purposes of this section consume does not include smoking, combusting, inhaling, vaporizing, or aerosolizing a marijuana item.

(5) General Public and Visitor Access. The general public is not permitted on the premises of registered processing site, except as permitted by this rule.

(a) In addition to registrant representatives, the following visitors are permitted on the premises of a processing site, including limited access areas, subject to the requirements in section (6) of this rule:

(A) Laboratory personnel, if the laboratory is accredited by the Authority;

(B) A contractor authorized by a registrant representative to be on the premises; or

(C) Individuals authorized to transfer marijuana items to a registered processing site.

(b) A registered processing site may permit up to seven invited guests 21 years of age and older, per week, on the premises of a registered processing site, including limited access areas, subject to the requirements in section (6) of this rule.

(6) Visitor Escort, Log and Badges.

(a) Prior to entering the premises of a registered processing site all visitors permitted by section (5) of this rule must be documented and issued a visitor identification badge from a registrant representative that must remain visible while on the premises. A visitor badge is not required for government officials. All visitors described in section (5) of this rule must be accompanied by a registrant representative at all times.

(b) A processing site registrant must maintain a log of all visitor activity and the log must contain the first and last name and date of birth of every visitor, and the date they visited.

(7) Government Access. Nothing in this rule is intended to prevent or prohibit Authority employees or contractors, or other state or local government officials that have jurisdiction over some aspect of the premises or a registered processing site to be on the premises.

(a) A visitor badge is not required for government officials.

(b) A processing site must log every government official that enters the premises but the processing site may not request that the government official provide a date of birth for the log.

(8) A registered processing site must have:

(a) A designated limited access area or areas where transfers of marijuana items are received; and

(b) A designated area where visitors enter the processing site premises and are checked in.

(9) The areas described in section (8) of this rule must be clearly marked on the floor or plot plan sketch required in OAR 333-008-1650.

(10) Signage. A registered processing site must post:

(a) At every entrance to the processing site a sign that reads: "No On-Site Consumption of Marijuana".

(b) At all areas of ingress to a limited access area signs that reads:

(A) "Restricted Access Area — Authorized Personnel Only".

(B) "No Minors Allowed".

(11) A processing site may not sublet or share with any other business any portion of the processing site premises, except as permitted in OAR 333-008-1790.

Stat. Auth.: ORS 475B.435

Stats. Implemented: ORS 475B.435

Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1740

Operation of Registered Processing Site

(1) Policies and Procedures. In order to be registered and remain registered a processing site must create and maintain written, detailed standard policies and procedures that include but are not limited to:

(a) Instructions for making each medical cannabinoid product, concentrate or extract.

(b) The ingredients and the amount of each ingredient for each process lot.

(c) The process for making each product.

(d) The number of servings in a process lot.

(e) The intended amount of THC per serving and in a unit of sale of the product.

(f) The process for ensuring that the amount of THC is consistently distributed throughout each process lot.

(g) If processing a cannabinoid concentrate or extract:

(A) Conducting necessary safety checks prior to commencing processing; and

(B) Purging any solvent or other unwanted components from a cannabinoid concentrate or extract.

(h) Procedures for cleaning all equipment, counters and surfaces thoroughly.

(i) Proper handling and storage of any solvent, gas or other chemical used in processing or on the processing site premises in accordance with material safety data sheets and any other applicable laws.

(j) Proper disposal of any waste produced during processing in accordance with all applicable local, state and federal laws, rules and regulations.

(k) Quality control procedures designed to, at a minimum, ensure that the amount of THC is consistently distributed throughout each process lot and that potential product contamination is minimized.

(l) Appropriate use of any necessary safety or sanitary equipment.

(m) Emergency procedures to be followed in case of a fire, chemical spill or other emergency. (n) Security.

(o) Transfers of marijuana items to and from the processing site.

(p) Testing.

(q) Packaging and labeling if the processor intends to or is packaging and labeling marijuana items after transfer to the processing site.

(r) Employee training.

(s) Compliance with these rules, including but not limited to violations and enforcement.

(t) Roles and responsibilities for employees and PRPs in assisting the Authority during inspections or investigations.

(2) Prohibitions. A registered processing site may not process or transfer a marijuana item:

(a) That by its shape, design or flavor is likely to appeal to minors, including but not limited to: (A) Products that are modeled after non-cannabis products primarily consumed by and marketed to children; or

(B) Products in the shape of an animal, vehicle, person or character.

(b) That is made by applying cannabinoid concentrates or extracts to commercially available candy or snack food items.

(c) That contains dimethyl sulfoxide (DMSO).

(3) Employees. A registered processing site may employ an individual between the ages of 18 and 20 if the individual is a patient. Otherwise, processing site employees must be 21 years of age or older.

(4) Standardized Scales. In order to obtain a registration and to retain registration a processing site registrant must own, maintain on the premises and use a weighing device that is licensed by the Oregon Department of Agriculture. Licensed weighing devices must be used by a processing site whenever marijuana items are:

(a) Transferred to or from the processing site and the transfer is by weight;

(b) Packaged for transfer by weight; or

(c) Weighed for purposes of documenting information required in OAR 333-008-1760, 333-008- 1770, 333-008-1820, and 333-008-1830.

(5) Inventory Tracking and Point of Sale System: A registered processing site must have an integrated inventory tracking and point of sale system that can and does, at a minimum:

(a) Produce bar codes or similar unique identification numbers for each lot of usable marijuana transferred to a registered processing site and for each lot of a medical cannabinoid product, concentrate or extract transferred to a registered dispensary;

(b) Capture all information required to be documented in OAR 333-008-1760 and 333-008-1770; (c) Generate inventory, transaction, transport and transfer reports requested by the Authority viewable in PDF format; and

(d) Produce all the information required to be submitted to the Authority pursuant to OAR 333- 0080-1830.

(6) Online Verification of Registration Status. A registered processing site must verify an individual's or processing site's registration status with the Authority when receiving a transfer of a marijuana item if the Authority has available an online system for such verification.

(7) Transfers from and to patients or designated primary caregivers.

(a) A registered marijuana processing site may transfer a medical cannabinoid product, concentrate or extract to a patient, or a patient's designated primary caregiver if the patient or the patient's designated primary caregiver provides the marijuana processing site with the marijuana to be processed into the medical cannabinoid product, concentrate or extract and the marijuana processing site receives no compensation for the transfer of the marijuana.

(b) A registered processing site must document each transfer of marijuana by a patient or the patient's designated primary caregiver to the processing site in accordance with OAR 333-008- 1760 and 333-008-1770.

(c) A registered processing site must document each transfer of a cannabinoid product, concentrate or extract to a patient or the patient's designated primary caregiver in accordance with OAR 333-008-1760 and 333-008-1770.

(d) A registered processing site may be compensated by the patient or the patient's designated primary caregiver for all costs associated with the processing of marijuana for the patient.

(8) Inventory On-Site. Marijuana items must be kept on-site at the registered processing site. The Authority may take enforcement action against a registered processing site if during an inspection a processing site cannot account for its inventory or if the amount of usable marijuana at the processing site is not within five percent of the documented inventory.

(9) Testing. On and after October 1, 2016, a processing site must comply with the applicable sampling and testing requirements in OAR 333-007-0300 to 333-007-0490 and may not:

(a) Accept a transfer of a marijuana item that has not been tested in accordance with OAR 333- 007-0300 to 333-007-0490.

(b) Transfer a medical cannabinoid product, concentrate or extract that has not been tested in accordance with OAR 333-007-0300 to 333-007-0490.

(10) Packaging and Labeling.

(a) On and after October 1, 2016, a processing site must comply with the labeling requirements in OAR 333-007-0010 to 333-007-0100, and the packaging requirements in OAR 845-025-7000 to 845-025-7020 and 845-025-7060.

(b) On and after October 1, 2016, a processing site must have its packages and labels pre-approved by the Commission, unless pre-approval is not required under OAR 845-025-7060(9) to (12).

(11) Industrial Hemp Products. A processing site may only accept the transfer of and may only transfer a product that contains THC or CBD that is derived from marijuana.

(12) Sampling. A registered processing site may provide a sample of a medical cannabinoid product, concentrate or extract to a dispensary for the purpose of the dispensary determining whether to purchase the product, concentrate or extract but the product, concentrate or extract may not be consumed on the processing site. Any sample provided to a dispensary must be recorded in the database.

(13) For purposes of this rule:

(a) "Lot of usable marijuana" means a quantity of usable marijuana transferred to a registered processing site from the same harvest lot as that term is defined in OAR 333-007-0020; and

(b) "Lot of medical cannabinoid products, concentrates or extracts" means a quantity of a medical cannabinoid product, concentrate or extract transferred to a registered dispensary at one time and that is from the same process lot as that term is defined in OAR 333-007-0020.

Stat. Auth.: ORS 475B.435, 475B.440
Stats. Implemented: ORS 475B.435, 475B.440
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16; PH 27-2016(Temp), f. & cert. ef. 9-30-16 thru 3-1-17

333-008-1750
Processor Training Requirements

(1) In order to be registered and remain registered a processing site must have a comprehensive training program that includes, at a minimum, the following topics:

(a) The standard operating policies and procedures.

(b) The hazards presented by all solvents or other chemicals used in processing and on the registered premises as described in the material safety data sheet for each solvent or chemical.

(c) Applicable Authority statutes and rules.

(2) At the time of hire and prior to engaging in any processing, and once yearly thereafter, each employee involved in the processing of a medical cannabinoid product, concentrate or extract must be trained in accordance with the processing site's training program.

Stat. Auth.: ORS 475B.435, 475B.440
Stats. Implemented: ORS 475B.435, 475B.440
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-1760
Transfers to a Registered Processing Site

(1) Transfers of Marijuana by a Patient or Designated Primary Caregiver to Process for a Patient. A patient or designated primary caregiver may transfer marijuana to a registered processing site for no compensation for the purpose of the registered processing site processing the marijuana into a cannabinoid product, concentrate or extract.

(a) If a designated primary caregiver is transferring the marijuana, a registered processing site may only accept a transfer of marijuana under this section if the caregiver provides the original or a copy of a valid Authorization to Transfer form prescribed by the Authority.

(b) In order to be valid an Authorization to Transfer form must include at least:

(A) The patient's name, OMMP card number, OMMP receipt number if applicable and expiration date and contact information;

(B) The name and contact information of the individual who is authorized to transfer the usable marijuana to the registered processing site and that individual's OMMP card number and expiration date;

(C) The name and address of the registered processing site that is authorized to receive the usable marijuana; and

(D) The date the authorization expires, if earlier than the expiration date of the patient's OMMP card or receipt.

(2) Transfer of Usable Marijuana. A patient, caregiver, or PRMG may transfer usable marijuana to a registered processing site, subject to the requirements in this rule.

(a) A registered processing site may only accept a transfer of usable marijuana if the individual transferring the usable marijuana provides the original or a copy of a valid:

(A) Authorization to Transfer form prescribed by the Authority; or

(B) Personal agreement as that is defined in OAR 333-008-0010.

(b) Authorization to Transfer Forms. In order to be valid an Authorization to Transfer form must include at least:

(A) The patient's name, OMMP card number and expiration date and contact information;

(B) The name and contact information of the individual who is authorized to transfer the usable marijuana to the registered processing site and that individual's OMMP card number and expiration date;

(C) The name and address of the registered processing site that is authorized to receive the usable marijuana; and

(D) The date the authorization expires, if earlier than the expiration date of the patient's OMMP card.

(c) Personal Agreements. In order to be valid a personal agreement must include at least:

(A) The patient's name, OMMP card number and expiration date and contact information;

(B) The name and contact information of the PRMG to whom the patient's property rights have been assigned and the producer's OMMP card number and expiration date;

(C) The portion of the patient's rights to possess usable marijuana that is being assigned to the producer.

(3) Transfer of medical cannabinoid products, concentrates or extracts. A registered processing site may only accept a transfer of a medical cannabinoid product, concentrate or extract from another registered medical marijuana processing site.

(4) A registered processing site may only accept a transfer of a medical cannabinoid product, concentrate or extract from a registered processing site that provides a Processing Site Authorization to Transfer form, prescribed by the Authority. In addition the registered processing site must obtain a copy of the photo identification of the individual transferring the product, concentrate or extract as required in section (5)(b)(B) of this rule.

(5) Transfer Records. At the time marijuana, usable marijuana or a medical cannabinoid product, concentrate or extract is transferred to a registered processing site a processing site representative must:

(a) Document, as applicable:

(A) The weight in metric units of all usable marijuana received by the processing site;

(B) The amount of a medical cannabinoid product, concentrate or extract received by the processing site, including, as applicable, the weight in metric units, or the number of units;

(C) The name of the usable marijuana or medical cannabinoid product, concentrate or extract;

(D) The date the usable marijuana or medical cannabinoid product, concentrate or extract was received; and

(E) The amount of reimbursement paid by the registered processing site.

(b) Obtain and maintain a copy of, as applicable:

(A) Documents required in section (1) of this rule including the date it was received;

(B) The photo identification of the individual transferring the usable marijuana or medical cannabinoid product, concentrate or extract to the registered processing site, if such a copy is not already on file;

(C) The OMMP card of the individual transferring usable marijuana;

(D) The medical marijuana processing site registration; and

(E) Test results for marijuana items transferred to the processing site unless the processing site plans to arrange for the testing of the marijuana item.

(6) Prior to October 1, 2016, if a registered processing site accepts the transfer of usable marijuana or a medical cannabinoid product, concentrate or extract that has not been tested in accordance with OAR 333-008-1190 or OAR 333-007-0300 to 333-007-0490 the processing site must segregate that item in accordance with OAR 333-008-1190(7).

(7) Once samples of the usable marijuana or a medical cannabinoid product, concentrate or extract have been taken for the purpose of testing the item must be stored and secured in a manner that prevents the product from being tampered with or transferred prior to test results being reported.

(8) Nothing in these rules requires a registered processing site to accept a transfer of a marijuana item.

(9) All documentation required in this rule must be maintained electronically in an integrated inventory tracking and point of sale system.

Stat. Auth.: ORS 475B.435, 475B.440
Stats. Implemented: ORS 475B.435, 475B.440
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1770
Transfers From a Registered Processing Site

(1) A registered processing site must, in addition to the completing a Processing Site Authorization to Transfer form, prescribed by the Authority, document the following for transfers to a registered dispensary or registered processing site:

(a) The name, address, and registration number of the dispensary or processing site to which a medical cannabinoid product, concentrate or extract was transferred;

(b) The amount of medical cannabinoid product, concentrate, or extract transferred;

(c) The name of the medical cannabinoid product, concentrate, or extract transferred;

(d) The date of the transfer; and

(e) The amount of money paid by the registered dispensary or processing site for the transfer.

(2) A registered processing site must document the following for the transfer of a medical cannabinoid product, concentrate or extract to a patient or designated primary caregiver pursuant to ORS 475B.443(1)(b) and (c):

(a) The name and registration number or OMMP receipt number of the patient or designated primary caregiver to which a medical cannabinoid product, concentrate or extract was transferred;

(b) If the medical cannabinoid product, concentrate or extract was transferred to a designated primary caregiver, the patient's name and registration number for whom the caregiver was receiving the transfer;

(c) The amount of medical cannabinoid product, concentrate, or extract transferred;

(d) The name of the medical cannabinoid product, concentrate, or extract transferred;

(e) The date of the transfer; and

(f) The amount of money paid by the patient or designated primary caregiver for the transfer.

(3) All documentation required in this rule must be maintained electronically in an integrated inventory tracking and point of sale system.

Stat. Auth.: ORS 475B.435
Stats. Implemented: ORS 475B.435 & 475B.443
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1780
General Processing Site Health and Safety Requirements

(1) A processing site must:

(a) Use equipment, counters and surfaces for processing that are food-grade and do not react adversely with any solvent being used.

(b) Have counters and surface areas that are constructed in a manner that reduce the potential for development of microbials, molds and fungi and that can be easily cleaned.

(c) Maintain the processing site in a manner that is free from conditions which may result in contamination and that is suitable to facilitate safe and sanitary operations for product preparation purposes.

(2) A processing site may not treat or otherwise adulterate a medical cannabinoid product, concentrate or extract with any addi-

tives that would increase potency, toxicity, or addictive potential, or that would create an unsafe combination with other psychoactive substances. Prohibited additives include but are not limited to nicotine, alcohol, caffeine, or chemicals that increase carcinogenicity.

Stat. Auth.: ORS 475B.435, 475B.440
Stats. Implemented: ORS 475B.435, 475B.440
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1790
Cannabinoid Edible Processor Requirements

(1) A processing site endorsed to make cannabinoid edibles may only process in a food establishment licensed by the Oregon Department of Agriculture (ODA) and must comply with the applicable provisions of OAR chapter 603, division 21, division 24, division 25, with the exception of OAR 603-025-0020(17), and division 28.

(2) A processing site endorsed to make cannabinoid edibles may not:

(a) Engage in processing in a location that is operating as a restaurant, seasonal temporary restaurant, intermittent temporary restaurant, limited service restaurant or single-event temporary restaurant licensed under ORS chapter 624;

(b) Share a food establishment with a person not registered with the Authority as a cannabinoid edible processor;

(c) Process cannabinoid edibles and food in the same food establishment; or

(d) Use a cannabinoid concentrate or extract in a cannabinoid edible unless that concentrate or extract was processed in a food establishment licensed by ODA under OAR chapter 603, division 21, division 24, division 25, with the exception of OAR 603-025-0020(17), and division 28.

(3) A processing site endorsed to make cannabinoid edibles may share a food establishment with another Authority registered cannabinoid edible processor if:

(a) The schedule, with specific hours and days that each processor will use the food establishment, is prominently posted at the entrance to the food service establishment.

(b) Each registrant designates a separate area to secure, in accordance with OAR 333-008-2080 any marijuana, medical cannabinoid products, concentrates or extracts that a registrant stores at the food establishment. If a cannabinoid edible processor does not store marijuana, medical cannabinoid products, concentrates or extracts at the food establishment those items must be stored on a registered processing site under the processor's control.

(4) A food establishment used by a processing site endorsed to make cannabinoid edibles is considered a registered processing site and must meet the security and other premises requirements in these rules.

(5) A processing site endorsed to make cannabinoid edibles is strictly liable for any violation found at a shared food establishment during that processor's scheduled time, as reflected on the posted schedule or within that processor's designated area in the food establishment.

(6) If the Authority cannot determine by viewing the schedule or video surveillance footage who was responsible for the violation, each processor at the shared food establishment is individually and jointly liable for any documented violations.

(7) A processing site must make cannabinoid edibles in a manner that results in the THC being distributed consistently throughout the edible.

Stat. Auth.: ORS 475B.435 & 475B.440
Stats. Implemented: ORS 475B.435 & 475B.440
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1800
Cannabinoid Concentrate and Extract Processor Requirements

(1) Cannabinoid Concentrates or Extracts. A processing site endorsed to make cannabinoid concentrates or extracts:

(a) May not use Class I solvents as those are classified in the Federal Drug Administration Guidance, Table I, published in the Federal Register on December 24, 1997 (62 FR 67377).

(b) Must:

(A) Only use a hydrocarbon-based solvent that is at least 99 percent purity.

(B) Only use a non-hydrocarbon-based solvent that is food-grade.

(C) Work in an environment with proper ventilation, controlling all sources of ignition where a flammable atmosphere is or may be present.

(D) Use only potable water and ice made from potable water in processing.

(E) If making a concentrate or extract that will be used in a cannabinoid edible, be endorsed as a cannabinoid edible processor.

(2) Cannabinoid Extracts. A processing site endorsed to make cannabinoid extracts:

(a) May not use pressurized canned flammable fuel, including but not limited to butane and other fuels intended for use in camp stoves, handheld torch devices, refillable cigarette lighters and similar consumer products

(b) Must:

(A) Process in a:

(i) Fully enclosed room clearly designated on the current diagram of the registered premises.

(ii) Room and with equipment, including all electrical installations, that meet the requirements of the Oregon Structural Specialty Code, related Oregon Specialty Codes and the Oregon Fire Code..

(B) Use a commercially manufactured professional grade closed loop extraction system designed to recover the solvents and built to recognized and generally accepted good engineering standards, such as those of:

(i) American National Standards Institute (ANSI);

(ii) Underwriters Laboratories (UL); or

(iii) The American Society for Testing and Materials (ASTM).

(C) If using carbon dioxide in processing, use a professional grade closed loop carbon dioxide gas extraction system where every vessel is rated to a minimum of 600 pounds per square inch.

(D) For extraction system engineering services, including but not limited to consultation on and design of extraction systems or components of extraction systems, use the services of a professional engineer registered with the Oregon State Board of Examiners for Engineering and Land Surveying, unless an exemption under ORS 672.060 applies;

(E) Have an emergency eye-wash station in any room in which cannabinoid extract is being processed.

(F) Have all applicable material safety data sheets readily available to personnel working for the processor.

(3) Cannabinoid Concentrates. A processing site endorsed to make cannabinoid concentrates:

(a) May not:

(A) Use denatured alcohol.

(B) If using carbon dioxide, apply high heat or pressure.

(b) Must only use or store dry ice in a well ventilated room to prevent against the accumulation of dangerous levels of carbon dioxide.

(c) May use:

(A) A mechanical extraction process;

(B) A chemical extraction process using a nonhydrocarbon-based or other solvent, such as water, vegetable glycerin, vegetable oils, animal fats, isopropyl alcohol or ethanol; or

(C) A chemical extraction process using the hydrocarbon-based solvent carbon dioxide, provided that the process does not involve the use heat over 180 degrees or pressure.

Stat. Auth.: ORS 475B.435, 475B.440
Stats. Implemented: ORS 475B.435, 475B.440
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1810
Cannabinoid Topical, Tincture, Capsule, Suppository or Transdermal Patch Processor

(1) A processing site endorsed to make cannabinoid topicals, tinctures, capsules, suppositories or transdermal patches may not

engage in processing in a location that is operating as a restaurant, seasonal temporary restaurant, intermittent temporary restaurant, limited service restaurant or single-event temporary restaurant licensed under ORS chapter 624.

(2) A registered processing site making cannabinoid tinctures may only process in a food establishment licensed by the Oregon Department of Agriculture (ODA) and must comply with the applicable provisions of OAR chapter 603, division 21, division 24, division 25, with the exception of OAR 603-025-0020(17), and division 28.

Stat. Auth.: ORS 475B.435 & 475B.440
Stats. Implemented: ORS 475B.435 & 475B.440
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-1820
Registered Processing Site Recordkeeping

(1) In addition to other record keeping required in these rules a registered processing site must keep records documenting the following:

(a) How much marijuana is in each process lot, as that term is defined in OAR 333-007-0020.

(b) If a product is returned by a registered dispensary, how much product is returned and why.

(c) If a defective product was reprocessed, how the defective product was reprocessed.

(d) Each training provided in accordance with OAR 333-008-1750, the names of employees who participated in the training, and a summary of the information provided in the training.

(e) All testing results.

(2) A processor must obtain a material safety data sheet for each solvent used or stored on the licensed premises and maintain a current copy of the material safety data sheet and a receipt of purchase for all solvents used or to be used in an extraction process on the licensed premises.

(3) If the Authority requires a processor to submit or produce documents to the Authority that the processor believes falls within the definition of a trade secret as defined in ORS 192.501, the processor must mark each document "confidential" or "trade secret".

Stat. Auth.: ORS 475B.435, 475B.440
Stats. Implemented: ORS 475B.435, 475B.440
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-1830
Registered Marijuana Processing Site Required Reporting to the Authority

(1) The individual or individuals responsible for a marijuana processing site shall maintain documentation of each transfer of usable marijuana, medical cannabinoid products, cannabinoid concentrates and cannabinoid extracts and on and after June 1, 2016, must submit to the Authority electronically, by the 10th of each month, the following information:

(a) The amount of usable marijuana transferred to the marijuana processing site during the previous month.

(b) The amount and type of a medical cannabinoid concentrate or extract transferred by another registered processing site during the previous month. For purposes of this section "type" means:

(A) Cannabinoid concentrate in solid form; and

(B) Cannabinoid concentrate in liquid form.

(c) The amount and type of medical cannabinoid products transferred by the marijuana processing site to a dispensary. For purposes of this section "type" means:

(A) Cannabinoid edibles;

(B) Cannabinoid topicals;

(C) Cannabinoid tinctures;

(D) Cannabinoid capsules;

(E) Cannabinoid suppositories;

(F) Cannabinoid transdermal patches; and

(G) Cannabinoid product other than products listed in paragraphs (A) to (F) of this subsection.

(d) The amount and type of cannabinoid concentrates transferred by the marijuana processing site during the previous month. For purposes of this section "type" means:

(A) Cannabinoid concentrate in solid form; and

(B) Cannabinoid concentrate in liquid form.

(e) The amount and type of cannabinoid extracts transferred by the marijuana processing site during the previous month. For purposes of this section "type" means:

(A) Cannabinoid extract in solid form; and

(B) Cannabinoid extract in liquid form.

(f) The amount and type of medical cannabinoid products transferred by the marijuana processing site to a patient or the patient's designated primary caregiver during the previous month. For purposes of this section "type" means:

(A) Cannabinoid edibles;

(B) Cannabinoid topicals;

(C) Cannabinoid tinctures;

(D) Cannabinoid capsules;

(E) Cannabinoid suppositories;

(F) Cannabinoid transdermal patches; and

(G) Cannabinoid product other than products listed in paragraphs (A) to (F) of this subsection.

(g) The amount and type of cannabinoid concentrates or extracts transferred by the marijuana processing site to a patient or the patient's designated primary caregiver during the previous month. For purposes of this section "type" means;

(A) Cannabinoid concentrate or extract in liquid form; and

(B) Cannabinoid concentrate or extract in solid form.

(2) Information submitted to the Authority under this rule must:

(a) List each type of marijuana item separately;

(b) Provide the total aggregate amount of a type of marijuana item transferred to a processing site by a patient, designated primary caregiver, PRMG or other registered processing site during the previous month; and

(c) Provide the total aggregate amount of a type of marijuana item transferred from a processing site to a registered dispensary, patient, designated primary caregiver, or other registered processing site during the previous month.

(3) In addition to submitting the information as required by section (1) of this rule, a person responsible for a processing site must keep a record of the information described in section (1) of this rule for two years after the date on which the person submits the information to the Authority.

Stat. Auth.: ORS 475B.438
Stats. Implemented: ORS 475B.438
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

General Requirements for Medical Marijuana Processing Sites and Dispensaries

333-008-2000
Definitions

For purposes of OAR 333-008-2000 to 333-008-2200:

(1) "Applicant" means a person applying for a new or renewal registration for a dispensary or processing site.

(2) "Registrant" means a registered dispensary or registered processing site.

(3) "Registrant representative" means an owner, director, officer, PRD, PRP manager, employee, agent or other representative of a registrant to the extent that the person acts in a representative capacity.

(4) "These rules" means OAR 333-008-2000 to 333-008-2200.

Stat. Auth.: ORS 475B.435, 475B.450, 475B.525
Stats. Implemented: ORS 475B.435, 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-2010
Communication with the Oregon Health Authority

If an applicant or registrant is required to or elects to submit information or documentation to the Authority by a particular deadline it must be received, regardless of the method used to submit the writing, by 5 p.m. Pacific Time.

Stat. Auth.: ORS 475B.435, 475B.450, 475B.525

Stats. Implemented: ORS 475B.435, 475B.450

333-008-2020
Criminal Background Checks

(1) An individual named in a new or renewal application as required by OAR 333-008-1020 or 333-008-1620, or if otherwise required by these rules, must provide to the Authority:

(a) A criminal background check request form, prescribed by the Authority that includes but is not limited to:

(A) First, middle and last name;

(B) Any aliases;

(C) Date of birth; and

(D) Address and recent residency information.

(b) Fingerprints in accordance with the instructions on the Authority's webpage: www.healthoregon.org/ommp.

(c) A copy of the individual's driver license.

(2) The Authority may request that an individual disclose his or her Social Security Number if notice is provided that:

(a) Indicates the disclosure of the Social Security Number is voluntary; and

(b) That the Authority requests the Social Security Number solely for the purpose of positively identifying the individual during the criminal records check process.

(3) The Authority shall conduct a criminal records check in order to determine whether the individual has been convicted of the manufacture or delivery of a controlled substance in Schedule I or Schedule II in any state.

(4) If an individual wishes to challenge the accuracy or completeness of information provided by the Department of State Police, the Federal Bureau of Investigation and agencies reporting information to the Department of State Police or Federal Bureau of Investigation, those challenges must be made through the Department of State Police, Federal Bureau of Investigation or reporting agency and not through a contested case process.

(5) Any criminal background information received by the Authority during the criminal background check process is confidential and is not subject to disclosure without a court order.

Stat. Auth.: ORS 475B.435, 475B.450, 475B.525
Stats. Implemented: ORS 475B.435, 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-2030
Notification of Changes

(1) A registrant must notify the Authority within 10 calendar days of any of the following:

(a) The conviction for the manufacture or delivery of a controlled substance in Schedule I or Schedule II of any individual named in the application;

(b) A change in any contact information for anyone listed in an application or subsequently identified as an owner, an individual with a financial interest, a PRD or a PRP;

(c) A decision to remove a PRD, PRP, primary PRD or primary PRP;

(d) A decision to permanently close the dispensary or processing site at that location;

(e) For a dispensary, the location of a public or private elementary or secondary school within 1,000 feet of the dispensary; and

(f) The suspected theft of marijuana items.

(2) The notification required in section (1) of this rule must include a description of what has changed or the event and any documentation necessary for the Authority to determine whether the dispensary or processing site or dispensary or processing site registrant is still in compliance with ORS 475B.435, 475B.450 and these rules including but not limited to, as applicable:

(a) A copy of the criminal judgment or order;

(b) The location of the school that has been identified as being within 1,000 feet of the dispensary; or

(c) A copy of the police report documenting that the suspected theft of marijuana items was reported to law enforcement, if it was reported.

(3) Changes in Ownership, Financial Interest or Business Structure. A registrant that proposes to change its corporate structure, ownership structure or change who has a financial

Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

interest in the business must submit a form prescribed by the Authority, any information identified in the form to be submitted, and criminal background check fees, if applicable, to the Authority, prior to making such a change.

(a) The Authority must review the form and other information submitted and will approve the change if the change would not result in an initial or renewal application denial under OAR 333-008-1060 or 333-008-1670, or serve as the basis of a registration suspension or revocation.

(b) If the Authority denies the change but the registrant proceeds with the change the registrant must surrender the registration or the Authority will propose to suspend or revoke the registration.

(4) Failure of a registrant to notify the Authority in accordance with this rule may result in the imposition of civil penalties or the suspension or revocation of a dispensary or processing site's registration.

Stat. Auth.: ORS 475B.435, 475B.450, 475B.525
Stats. Implemented: ORS 475B.435, 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-2040
Changing, Altering, or Modifying Licensed Premises

(1) A registrant may not make any physical changes to the premises that materially or substantially alters the premises or the usage of the premises from the plans originally reviewed by the Authority, without the Authority's prior written approval.

(2) A registrant intending to make any material or substantial changes to the premises must submit a form prescribed by the Authority, and submit any information identified in the form to be submitted, to the Authority, prior to making any such changes.

(3) The Authority must review the form and other information submitted under section (2) of this rule, and will approve the changes if the changes would not result in an initial or renewal application denial under OAR 333-008-1060 or OAR 333-008-1670.

(4) If the Authority denies the change but the registrant proceeds with the change the registrant must surrender the registration or the Authority will propose to suspend or revoke the registration.

(5) For purposes of this rule a material or substantial change requiring approval includes, but is not limited to:

(a) Any increase or decrease in the total physical size or capacity of the premises;

(b) The sealing off, creation of or relocation of a common entryway, doorway, passage or other such means of public ingress or egress, when such common entryway, doorway or passage alters or changes limited access areas, such as the areas in which the transfer of marijuana items occurs within the premises; or

(c) Any physical change that would require the installation of additional video surveillance cameras or a change in the security system.

Stat. Auth.: ORS 475B.435, 475B.450, 475B.525
Stats. Implemented: ORS 475B.435, 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-2050
Change in Location

(1) A registrant that wishes to change its location must submit a new application that complies with OAR 333-008-1020 or 333-008-1620.

(2) A registrant may not operate at a new location unless it is registered by the Authority.

(3) If a registrant is applying for a registration at a new location because the registrant wishes to change the location of the currently registered dispensary, and the new location is within 1,000 feet of the currently registered dispensary, the Authority will not deny the application based on the new location being within 1,000 feet of a registered dispensary. The Authority shall condition approval of the registration at the new location on the surrender of the registration at the current location.

(4) A dispensary or processing site that is approved to operate at a new location must comply with any instructions provided by the Authority for transferring marijuana items from the previous location to the new location.

Stat. Auth.: ORS 475B.435, 475B.450, 475B.525
Stats. Implemented: ORS 475B.435 , 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-2060
Secretary of State Registration Required

A registrant must maintain a current registration as a business with the Office of the Secretary of State in order to receive or maintain registration.

Stat. Auth.: ORS 475B.435, 475B.450, 475B.525
Stats. Implemented: ORS 475B.435, 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-2070
Advertising Restrictions

(1) A registrant may not have advertising that:

(a) Contains statements that are deceptive, false, or misleading;

(b) Contains any content that can reasonably be considered to target minors including but not limited to cartoon characters, toys, or similar images and items typically marketed towards minors;

(c) Specifically encourages the transportation of marijuana items across state lines;

(d) Asserts that marijuana items are safe or safer for reasons including but not limited to because they are regulated by the Authority or have been tested by a certified laboratory;

(e) Make claims that a marijuana item has curative or therapeutic effects unless the claim is supported by the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner consistent with generally recognized scientific procedures and principles) and for which there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims; or

(f) Display consumption of marijuana items.

(2) A registrant may not make any deceptive, false, or misleading assertions or statements on any product, any sign, or any document provided to a patient, caregiver, or to an individual as that term is defined in OAR 333-008-1500.

(3) A registrant must include the following statement on all advertising:

(a) "Do not operate a vehicle or machinery under the influence of marijuana".

(b) "Keep marijuana out of the reach of children".

(4) A registrant must remove any sign, display, or advertisement if the Authority finds it violates this rule.

(5) The Authority will notify the registrant and specify a reasonable time period for the registrant to remove any sign, display or advertisement that the Authority finds objectionable.

Stat. Auth.: ORS 475B.435, 475B.450 & 475B.525
Stats. Implemented: ORS 475B.435 & 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-2080
Security Requirements

In order to be registered and remain registered a registrant must:

(1) Have an installed and fully operational security alarm system, installed by an alarm installation company, activated at all times when the premises is closed for business on all:

(a) Entry or exit points to and from the premises; and

(b) Perimeter windows, if applicable.

(2) Have a security alarm system that:

(a) Detects movement inside the premises;

(b) Is programmed to notify a security company that will notify a registrant representative or his or her designee in the event of a breach; and

(c) Has at least two operational "panic buttons" located inside the premises that are linked with the alarm system that notifies a security company.

(3) Have commercial grade, non-residential door locks installed on every external door of a registered premises where marijuana items are present.

(4) During all hours when the registrant is not operating:

(a) Securely lock all entrances to and exits from the registered premises and ensure any keys or key codes to the enclosed area remain in the possession of the registrant or registrant representative;

(b) Have a safe or vault as those terms are defined in OAR 333-008-0010 for the purpose of securing all marijuana items as required by these rules.

(5) Have a password protected network infrastructure.

(6) Have an electronic back-up system for all electronic records.

(7) Keep all video recordings and archived required records not stored electronically in a locked storage area. Current records may be kept in a locked cupboard or desk outside the locked storage area during hours when the registered business is open.

Stat. Auth.: ORS 475B.435, 475B.450, 475B.525
Stats. Implemented: ORS 475B.435, 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-2090
Video Surveillance Equipment

In order to be registered and remain registered a registrant must:

(1) Have an installed and fully operational video surveillance recording system with video surveillance equipment that at a minimum:

(a) Consists of:

(A) Digital or network video recorders;

(B) Cameras capable of meeting the requirements of OAR 333-008-2110 and this rule;

(C) Video monitors;

(D) Digital archiving devices;

(E) A minimum of one monitor on premises capable of viewing video; and

(F) A color printer capable of producing still photos.

(b) Is equipped with a failure notification system that immediately notifies a registrant representative of any surveillance interruption or failure that is longer than five minutes; and

(c) Has sufficient battery backup to support a minimum of one hour of recording time in the event of a power outage.

(2) Have a video surveillance system capable of recording all pre-determined surveillance areas in any lighting conditions.

(3) Have, in limited access and point of sale areas, cameras that have minimum resolution of 1280 x 720 pixels (px) and record at 10 fps (frames per second).

(4) Have, in exterior perimeter and non-limited access areas (except for restrooms) cameras that have a minimum resolution of 1280 x 720 px and record at least 5 fps, except where coverage overlaps any limited access areas such as entrances or exits and in those overlap areas cameras must record at 10 fps.

Stat. Auth.: ORS 475B.435, 475B.450, 475B.525
Stats. Implemented: ORS 475B.435, 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-2100
Required Camera Coverage and Camera Placement

In order to be registered and remain registered a registrant must:

(1) Have security camera coverage for:

(a) All secure and limited access areas;

(b) All areas where marijuana items will be and are transferred to or from a registered premises;

(c) All areas where the general public is permitted (except for restrooms);

(d) All points of entry to and exit from limited access areas and areas where marijuana items will be and are transferred to or from a registered premises; and

(e) All points of entry to and exit from the premises.

(2) Have cameras that are positioned so that they capture clear and certain images of any individual and activity occurring:

(a) Within 15 feet both inside and outside of all points of entry to and exit from the premises;

(b) Anywhere within a secure or limited access area on the premises; and

(c) Anywhere within an area where marijuana items will be and are transferred to or from a registered premises.

Stat. Auth.: ORS 475B.435, 475B.450, 475B.525
Stats. Implemented: ORS 475B.435, 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-2110
Video Recording Requirements

(1) In order to be registered and remain registered a registrant must:

(a) Have cameras that are installed, operational, and continuously record 24 hours a day in all areas where marijuana items will be or are on the premises, including areas where the general public is permitted (except restrooms).

(b) Use cameras that record at a minimum resolution of 1280 x 720 px;

(c) Have an installed and operational surveillance system that:

(A) Can produce a color still photograph from any camera image; and

(B) Embeds the date and time on all surveillance recordings without significantly obscuring the picture;

(2) A registrant must:

(a) Keep all surveillance recordings a minimum of 45 calendar days and in a format that can be easily accessed for viewing;

(b) Archive video recordings in a format that ensures authentication of the recording as a legitimately-captured video and guarantees that no alterations of the recorded image has taken place;

(c) Provide video surveillance records and recordings immediately upon request to the Authority for the purpose of ensuring compliance with ORS 475B.450 and these rules;

(d) Keep surveillance recordings for periods exceeding 45 calendar days upon request of the Authority; and

(e) Immediately notify the Authority of any equipment failure or system outage lasting 30 minutes or more.

Stat. Auth.: ORS 475B.435, 475B.450, 475B.525
Stats. Implemented: ORS 475B.435, 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-2120
Location and Maintenance of Surveillance Equipment

(1) A registrant must:

(a) Have the surveillance room or surveillance area in a limited access area.

(b) Have the surveillance recording equipment housed in a designated, locked, and secured room or other enclosure with access limited to:

(A) The registrant and authorized personnel of the registrant;

(B) Employees of the Authority;

(C) State or local law enforcement agencies for any other state or local law enforcement purpose; and

(D) Service personnel or contractors.

(c) Keep a current list of all authorized personnel and service personnel who have access to the surveillance system and room on the registered premises.

(d) Keep a surveillance equipment maintenance activity log on the registered premises to record all service activity including the identity of any individual performing the service, the service date and time and the reason for service to the surveillance system.

(2) A registrant may store video recordings offsite as long as a PRD or PRP can demonstrate that the recordings are secure and protected, that the recordings are kept for a minimum of 45 calendar days as required in OAR 333-008-2110 and that the Authority can access the video recordings upon request.

Stat. Auth.: ORS 475B.435, 475B.450, 475B.525
Stats. Implemented: ORS 475B.435, 475B.450

Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-2130
Waiver of Security Requirements

(1) A registrant may request that the Authority waive one or more of the security requirements described in OAR 333-008-2080 to 333-008-2120 by submitting a request, in writing to the Authority. The request must include:

(a) The specific rules and subsections of a rule that is requested to be waived;

(b) The reason for the waiver;

(c) A description of an alternative safeguard the registrant can put in place in lieu of the requirement that is the subject of the waiver; and

(d) An explanation of how and why the alternative safeguard accomplishes the goals of the security rules, specifically public safety, prevention of diversion, accountability, and prohibiting access to unauthorized individuals.

(2) The Authority may, in its discretion and on a case by case basis, approve the waiver if it finds:

(a) The reason the registrant is requesting the waiver is because another state or local law prohibits the particular security measure that is required; or

(b) The registrant cannot, for reasons beyond the registrant's control or because the security measure is cost prohibitive, comply with the particular security measure that is required; and

(c) The alternative safeguard that is proposed meets the goals of the security rules.

(3) The Authority must notify the registrant in writing, whether the waiver has been approved. If the waiver is approved the notice must specifically describe the alternate safeguards that are required and, if the waiver is time limited, must state the time period the wavier is in effect.

(4) The Authority may withdraw approval of the waiver at any time upon a finding that the previously-approved alternative measures are not sufficient to accomplish the goals of the security rules. If the Authority withdraws its approval of the waiver, the registrant will be given a reasonable period of time to come into compliance with the security requirement that was waived.

Stat. Auth.: ORS 475B.435, 475B.450, 475B.525
Stats. Implemented: ORS 475B.435, 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-2140
State and Local Safety Inspections

(1) A registered premises may be subject to inspection by state or local government officials to determine compliance with state or local health and safety laws.

(2) A person responsible for a registered marijuana processing site must contact any utility provider to ensure that the registrant complies with any local ordinance or utility requirements such as water use, discharge into the sewer system, or electrical use.

(3) The Authority may require a registered processing site or dispensary to obtain a certificate of occupancy issued by a local building official or the Department of Consumer and Business Services Building Codes Division, if the Authority has concerns about the public health and safety of the registered premises.

Stat. Auth.: ORS 475B.435, 475B.450, 475B.525
Stats. Implemented: ORS 475B.435, 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-2150
General Sanitary Requirements

(1) A registrant must:

(a) Prohibit any individual working on the registered premises who has or appears to have a communicable disease, open or draining skin lesion infected with Staphylococcus aureus or Streptococcus pyogenes or any illness accompanied by diarrhea or vomiting for whom there is a reasonable possibility of contact with marijuana items from having contact with a marijuana item until the condition is corrected;

(b) Require all persons who work in direct contact with marijuana items to conform to hygienic practices while on duty, including but not limited to:

(A) Maintaining adequate personal cleanliness; and

(B) Washing hands thoroughly in an adequate hand-washing area before starting work, prior to having contact with a marijuana item and at any other time when the hands may have become soiled or contaminated;

(c) Provide hand-washing facilities adequate and convenient, furnished with running water at a suitable temperature and provided with effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying device;

(d) Properly remove all litter and waste from the registered premises and maintain the operating systems for waste disposal in an adequate manner so that they do not constitute a source of contamination in areas where marijuana items are exposed;

(e) Provide employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair; and

(f) Hold marijuana items that can support the rapid growth of undesirable microorganisms in a manner that prevents the growth of these microorganisms.

(2) For purposes of this rule "communicable disease" includes but is not limited to: diphtheria, measles, Salmonella enterica serotype Typhi infection, shigellosis, Shiga-toxigenic Escherichia coli (STEC) infection, hepatitis A, and tuberculosis.

Stat. Auth.: ORS 475B.435, 475B.450 & 475B.525
Stats. Implemented: ORS 475B.435 & 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-2160
Foreclosure; Cessation of Operations

In the event that a registrant is foreclosed or otherwise ceases operations as described in ORS chapter 79, a secured party, as defined in ORS 79.0102, may continue operations at the marijuana processing site or dispensary upon submitting to the Authority proof, on a form prescribed by the Authority, that the secured party or, if the secured party is a business entity, any individual who has a financial interest in the secured party, meets the requirements and restrictions set forth in:

(1) For marijuana processing sites, ORS 475B.435 (2)(d) and (4); or

(2) For dispensaries, ORS 475B.450 (2)(d) and (4).

Stat. Auth.: ORS 475B.435, 475B.450, 475B.525
Stats. Implemented: ORS 475B.435, 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-2170
Inspections

(1) The Authority must conduct a routine inspection of every registrant at least every year.

(2) The Authority may conduct a complaint inspection at any time following the receipt of a complaint that alleges a registrant or registrant representative is in violation of ORS 475B.435, ORS 475B.435 to 475B.443, 475B.450 to 475B.453, 475B.555, 475B.605, 475B.615, OAR chapter 333, division 7 or these rules.

(3) The Authority may conduct an inspection at any time if it believes, for any reason, that a registrant or registrant representative is in violation of ORS 475B.435 to 475B.443, 475B.450 to 475B.453, 475B.555, 475B.605, 475B.615, OAR chapter 333, division 7 or these rules.

(4) The Authority may inspect the following to ensure compliance with ORS 475B.435 to 475B.443, 475B.450 to 475B.453, 475B.555, 475B.605, 475B.615, OAR chapter 333, division 7 or these rules:

(a) The premises of a proposed marijuana processing site or dispensary, or registered marijuana processing site or dispensary; and

(b) The records of a registered marijuana processing site or dispensary.

(5) Registrant representatives must cooperate with the Authority during an inspection.

(6) If an individual at a registered dispensary or processing site fails to permit the Authority to conduct an inspection or if the Authority requires access to a dispensary or processing site and cannot obtain permission the Authority may seek an administrative warrant authorizing the inspection pursuant to ORS 431A.010.

(7) The Authority may purchase, possess or seize a marijuana item as necessary for the Authority to determine compliance with ORS 475B.435 to 475B.443, 475B.450 to 475B.453, 475B.555, 475B.605, 475B.615, OAR chapter 333, division 7 or these rules.

Stat. Auth.: ORS 431A.010, 475B.435, 475B.450 & 475B.525
Stats. Implemented: ORS 475B.435 & 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-2180
Violations

(1) It is a violation for an applicant for a registration, registrant or registrant representative to:

(a) Fail to cooperate with an inspection;

(b) Submit false or misleading information to the Authority;

(c) If the registrant is a dispensary, transfer a marijuana item to an individual who is not a patient or a designated primary caregiver;

(d) If the registrant is a processing site, transfer a medical cannabinoid product, concentrate or extract to anyone who is not a dispensary representative or a patient;

(e) Accept the transfer of a marijuana item from an individual who is not registered with the Authority;

(f) Accept the transfer of a marijuana item that was produced or processed in another state;

(g) Possess a mature marijuana plant;

(h) Fail to submit a plan of correction in accordance with OAR 333-008-2190;

(i) Fail to comply with an emergency suspension order or final order of the Authority, including failing to pay a civil penalty;

(j) Fail to comply with ORS 475B.435 to 475B.443, 475B.450 to 475B.453, 475B.555, 475B.605, 475B.615, these rules, or OAR chapter 333, division 7; or

(k) Alter or falsify a laboratory test report or result.

(l) Alter or falsify a receipt issued under OAR 333-008-0023 or 333-008-0040

(2) It is a violation of ORS 475B.450 and these rules to operate a dispensary without being registered by the Authority.

(3) It is a violation of ORS 475B.435 and these rules to operate a processing site without being registered by the Authority unless an exemption applies.

Stat. Auth.: ORS 475B.435, 475B.450 & 475B.525
Stats. Implemented: ORS 475B.435 & 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-2190
Enforcement

(1)(a) Informal Enforcement. If, during an inspection the Authority documents violations of ORS 475B.435 to 475B.443, 475B.450 to 475B.453, 475B.555, 475B.605, 475B.615, any of these rules or OAR chapter 333, division 7, the Authority may issue a written Notice of Violation to a registrant that cites the laws alleged to have been violated and the facts supporting the allegations.

(b) A registrant must submit to the Authority a signed plan of correction within 10 business days from the date the Notice of Violation was mailed by the Authority. A signed plan of correction will not be used by the Authority as an admission of the violations alleged in the Notice.

(c) A registrant must correct all deficiencies within 10 business days from the date of the Notice, unless an extension of time is requested from the Authority. A request for such an extension shall be submitted in writing and must accompany the plan of correction.

(d) The Authority must determine if a written plan of correction is acceptable. If the plan of correction is not acceptable to the Authority it must notify the registrant in writing and request that the plan of correction be modified and resubmitted no later than 10 business days from the date the letter of non-acceptance was mailed.

(e) If the registrant does not come into compliance by the date of correction reflected on the plan of correction, the Authority may propose to suspend or revoke the registrant's registration or impose civil penalties.

(f) The Authority may conduct an inspection at any time to determine whether a registrant has corrected the deficiencies in a Notice of Violation.

(2) Formal Enforcement. If, during an inspection or based on other information the Authority determines that a registrant is in violation of ORS 475B.435 to 475B.443, 475B.450 to 475B.453, 475B.555, 475B.605, 475B.615, any of these rules or OAR chapter 333, division 7 the Authority may issue:

(a) A Notice of Proposed Suspension or Revocation in accordance with ORS 183.411 through 183.470.

(b) A Notice of Imposition of Civil Penalties in accordance with OAR 333-008-2200.

(c) An Order of Emergency Suspension pursuant to ORS 183.430.

(3) The Authority must determine whether to use the informal or formal enforcement process based on the nature of the alleged violations, whether there are mitigating or aggravating factors, and whether the registrant has a history of violations.

(4) The Authority must issue a Notice of Proposed Revocation if the registrant no longer meets the criteria in ORS 475B.450(3)(a) to (d) or ORS 475B.435(3)(a) or (b).

(5) The Authority may issue civil penalties or maintain a civil action against an establishment providing the services of a processing site or dispensary but is not registered in accordance with ORS 475B.450, ORS 475B.435 and these rules.

(6) The Authority may revoke the registration of a registrant for failure to comply with an ordinance adopted by a city or county pursuant to ORS 475B.500, if the city or county:

(a) Has provided the registrant with due process substantially similar to the due process provided to a registration holder under the Administrative Procedures Act, ORS 183.413 to 183.470; and

(b) Provides the Authority with a final order that is substantially similar to the requirements for a final order under ORS 183.470 that establishes the registrant is in violation of the local ordinance.

(7) The Authority must post a final order revoking the registration of a registrant on the Authority's website.

(8) To the extent permitted by law, if the Authority discovers violations that may constitute criminal conduct or conduct that is in violation of laws within the jurisdiction of other state or local governmental entities, the Authority may refer the matter to the applicable agency.

(9) If the registration of a registrant is revoked the owner or an authorized representative of the owner must:

(a) Make arrangements to return the marijuana items still possessed at the location to the person who transferred the marijuana item, document the return, and provide this information in writing within one business day of the transfer, to the Authority; or

(b) Dispose of the marijuana items in a manner specified by the Authority.

(10) The Authority is not required to accept the surrender of a registration and may proceed with an enforcement action even if a registrant has surrendered the registration.

(11) Notwithstanding OAR 333-008-3000 if the Authority suspends or revokes a registration or otherwise takes disciplinary action against the registrant the Authority must provide that information to a law enforcement agency.

(12) The Authority may possess, seize or dispose of marijuana, usable marijuana, medical cannabinoid products, cannabinoid concentrates and cannabinoid extracts as is necessary for the Authority to ensure compliance with and enforce the provisions of ORS 475B.435 to 475B.443, 475B.450 to 475B.453, 475B.555, 475B.605, 475B.615, any of these rules or OAR chapter 333, division 7.

Stat. Auth.: ORS 431A.010, 475B.435, 475B.450 & 475B.525
Stats. Implemented: ORS 475B.435 & 475B.450
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-008-2200
Civil Penalties

(1) In addition to any other liability or penalty provided by law, the Authority may impose, against any person, a civil penalty that does not exceed $500 per day, for each violation of a provision of:

(a) ORS 475B.450, 475B.453, or any rules adopted thereunder;

(b) ORS 475B.435, 475B.440, 475B.443 or any rules adopted thereunder; or

(c) OAR 333-008-1000 to 333-008-2180 or OAR chapter 333, division 7.

(2) The Authority shall impose civil penalties under this section in the manner provided by ORS 183.745.

Stat. Auth.: ORS 431A.010, 475B.435, 475B.450, 475B.495, 475B.525
Stats. Implemented: ORS 475B.435, 475B.450, 475B.495
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

Medical Marijuana Records

333-008-3000
Medical Marijuana Confidentiality

(1) Patient, Designated Primary Caregiver and Grow Site List.

(a) The Authority shall create and maintain a list of patients, designated primary caregivers, and grow site addresses.

(b) Except as provided in subsection (c) of this section, the list is confidential and not subject to public disclosure under ORS 192.410 to 192.505.

(c) Names, addresses and other identifying information made confidential under subsection (1)(b) of this rule may be released to:

(A) Authorized employees of the Authority as necessary to perform official duties of the Authority, including the production of any reports of aggregate (non-identifying) data or statistics;

(B) Authorized employees of state or local law enforcement agencies who provide to the Authority adequate identification but only as necessary to verify:

(i) That a person is or was a lawful possessor of a registry identification card;

(ii) That a person is or was a designated primary caregiver; or

(iii) That the address is or was a registered grow site; or

(C) Other persons (such as, but not limited to, employers, lawyers, family members) upon receipt of a properly executed release of information signed by the patient, the patient's parent or legal guardian, designated primary caregiver or PRMG. The release of information must specify what information the Authority is authorized to release and to whom.

(d) In addition to releasing information to authorized employees of state or local law enforcement agencies for purposes of verifying information under paragraph (1)(c)(B) of this rule, the Authority may release to authorized employees of state or local law enforcement agencies the minimum amount of information necessary to enable an employee to determine whether an individual or location is in compliance with a provision of ORS 475B.400 to 475B.525 or these rules.

(2) Database.

(a) Subject to subsection (2)(b) of this rule the Authority may provide information that is stored in the database to:

(A) A law enforcement agency.

(B) The regulatory agencies of a city or county.

(b) The Authority may not disclose the following information that may be stored in the database:

(A) Any personally identifiable information, as defined in ORS 432.005, related to a patient or a designated primary caregiver.

(B) Any personally identifiable information, as defined in ORS 432.005, submitted to the Authority under ORS 475B.423, 475B.438 or 475B.453 or pursuant to ORS 475B.458.

(C) Any information related to the amount and type of usable marijuana, medical cannabinoid products, or cannabinoid concentrates and extracts transferred to or by a PRMG, medical marijuana processing site or medical marijuana dispensary.

(3) Personally identifiable information in grow site, medical marijuana processor or medical marijuana dispensary applications. Any personally identifiable information, as defined in ORS 432.005, other than a name of an individual or an address submitted with an application under ORS 475B.435 or ORS 475B.450 that the Authority requires to be submitted and maintains for purposes of registering a marijuana grow site, a marijuana processing site or a medical marijuana dispensary is confidential and not subject to public disclosure under ORS 192.410 to 192.505.

(4) Disclosure to designees. The Authority may provide personally identifiable information to a person registered under ORS 475B.400 to 475B.525 if the registrant requests the information and the information is related to a designation made under ORS 475B.400 to 475B.525.

(5) Medical marijuana dispensary security information. Any record that the Authority keeps or maintains for purposes related to the installation or maintenance of a security system by a medical marijuana processing site or dispensary pursuant to OAR 333-008-2080 to 333-008-2120 is confidential and not subject to public disclosure under ORS 192.410 to 192.505.

(6) Disclosure following investigation. Notwithstanding any of the confidentiality provisions of this rule if the Authority determines, after conducting an investigation or receiving a complaint of an alleged violation of a provision of ORS 475B.400 to 475B.525 or any rule adopted thereunder, that a violation of a provision of ORS 475B.400 to 475B.525 or any rule adopted thereunder has occurred, the Authority may provide any information obtained by the Authority, except for information related to a patient's debilitating condition, to:

(a) Authorized employees of state or local law enforcement agencies; or

(b) Another state or local government agency with jurisdiction over the matter.

(7) Subpoenas. Notwithstanding any of the confidentiality provisions of this rule, the Authority may disclose information requested pursuant to a lawfully issued subpoena from a law enforcement agency.

(8) Disclosure following disciplinary action. Notwithstanding section (3) of this rule, if the Authority suspends or revokes the registration of the marijuana grow site, a PRMG, a marijuana processing site or a medical marijuana dispensary, or otherwise takes disciplinary action concerning a medical marijuana grow site, medical marijuana processing site, or a medical marijuana dispensary, the Authority must provide that information to a law enforcement agency.

Stat. Auth.: ORS 475B.458 - 475B.464, 475B.525
Stats. Implemented: ORS 475B.458 - 475B.464, 475B.525
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-3010
System to Allow Verification of Data at All Times

(1) The Authority shall establish an interactive method to allow authorized employees of state and local law enforcement agencies to use the Oregon State Police Law Enforcement Data System (LEDS) to query an OMMP data file in order to verify at any time whether a particular patient, designated primary caregiver, or grow site location is listed or registered with the Authority.

(2) LEDS access will only allow a yes or no answer to the query and the information obtained may not be used for any other purpose other than verification.

(3) The Authority may allow the release of reports related to verification if it is without identifying data.

(4) The Authority shall have staff available by phone to verify law enforcement agency employee questions during regular business hours in case the electronic verification system is down, and in the event the system is expected to be down for more than two business days, the Authority shall ensure program staff are available by phone for verification purposes.

Stat. Auth.: ORS 475B.460 & 475B.525
Stats. Implemented: ORS 475B.460
Hist.: PH 9-2016, f. 2-26-16, cert. ef. 3-1-16

333-008-9900
Waiver of Replacement Card Fee

Notwithstanding OAR 333-008-0021(5) or 333-008-0047(1)(b), until July 1, 2016, the Authority will not impose or collect a $100 replacement card fee if the reason for the replacement card is that the patient is designating a new PRMG or new grow site address.

Stat. Auth.: ORS 475B.415, 475B.420, 475B.525
Stats. Implemented: ORS 475B.415
Hist.: PH 13-2016(Temp), f. 4-13-16, cert. ef. 4-15-16 thru 9-30-16

DIVISION 9

REPORTING REQUIREMENTS OF THE OREGON DEATH WITH DIGNITY ACT

333-009-0000
Definitions

For the purpose of OAR 333-009-0000 through 333-009-0030, the following definitions apply.

(1) "Act" means the "Oregon Death with Dignity Act" or Measure 16 as adopted by the voters on November 8, 1994.

(2) "Adult" means an individual who is 18 years of age or older.

(3) "Attending Physician" means the physician who has primary responsibility for the care of the patient and treatment of the patient's terminal disease.

(4) "Authority" means the Oregon Health Authority.

(5) "Capable" means that in the opinion of a court or in the opinion of the patient's attending physician or consulting physician, psychiatrist or psychologist, a patient has the ability to make and communicate health care decisions to health care providers, including communication through persons familiar with the patient's manner of communicating, if those persons are available.

(6) "Consulting physician" means a physician who is qualified by specialty or experience to make a professional diagnosis and prognosis regarding the patient's disease.

(7) "Counseling" means one or more consultations as necessary between a state licensed psychiatrist or psychologist and a patient for the purpose of determining that the patient is capable and not suffering from a psychiatric or psychological disorder or depression causing impaired judgment.

(8) "Dispensing Record" means a copy of the pharmacy dispensing record form.

(9) "Health Care Facility" shall have the meaning given in ORS 442.015.

(10) "Health Care Provider" means a person licensed, certified or otherwise authorized or permitted by the law of this state to administer health care or dispense medication in the ordinary course of business or practice of a profession and includes a health care facility.

(11) "Patient" means a person who is under the care of a physician.

(12) "Physician" means a doctor of medicine or osteopathy licensed to practice medicine by the Oregon Medical Board.

(13) "Qualified patient" means a capable adult who is a resident of Oregon and has satisfied the requirements of this Act in order to obtain a prescription for medication to end his or her life in a humane and dignified manner.

Stat. Auth.: ORS 127.865
Stats. Implemented: ORS 127.800-127.995
Hist.: HD 15-1997(Temp), f. & cert. ef. 11-6-97; OHD 4-1998, f. & cert. ef. 5-4-98; OHD 12-1999, f. & cert. ef. 12-28-99; PH 24-2006, f. & cert. ef. 10-19-06; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 11-2011, f. & cert. ef. 10-27-11

333-009-0010
Reporting

(1) To comply with ORS 127.865(2), within seven calendar days of writing a prescription for medication to end the life of a qualified patient the attending physician shall send the following completed, signed and dated documentation by mail to the State Registrar, Center for Health Statistics, 800 NE Oregon Street, Suite 205, Portland OR 97232, or by facsimile to (971) 673-1201:

(a) The patient's completed written request for medication to end life, either using the "Written Request for Medication to End My Life in a Humane and Dignified Manner" form prescribed by the Authority or in substantially the form described in ORS 127.897;

(b) One of the following reports prescribed by the Authority:

(A) "Attending Physician's Compliance Form"; or

(B) "Attending Physician's Compliance Short Form" accompanied by a copy of the relevant portions of the patient's medical record documenting all actions required by the Act;

(c) "Consulting Physician's Compliance Form" prescribed by the Authority; and

(d) "Psychiatric/Psychological Consultant's Compliance Form" prescribed by the Authority, if an evaluation was performed.

(2) Within 10 calendar days of a patient's ingestion of lethal medication obtained pursuant to the Act, or death from any other cause, whichever comes first, the attending physician shall complete the "Oregon Death with Dignity Act Attending Physician Interview" form prescribed by the Authority.

(3) To comply with ORS 127.865(1)(b), within 10 calendar days of dispensing medication pursuant to the Death with Dignity Act, the dispensing health care provider shall file a copy of the "Pharmacy Dispensing Record Form" prescribed by the Authority with the State Registrar, Center for Health Statistics, 800 NE Oregon St., Suite 205, Portland, OR 97232 or by facsimile to (971) 673-1201. Information to be reported to the Authority shall include:

(a) Patient's name and date of birth;

(b) Prescribing physician's name and phone number;

(c) Dispensing health care provider's name, address and phone number;

(d) Medication dispensed and quantity;

(e) Date the prescription was written; and

(f) Date the medication was dispensed.

Note: Forms referenced are available from the agency at http://public.health.oregon.gov/ProviderPartnerResources/EvaluationResearch/DeathwithDignityAct/Pages/pasforms.aspx

Stat. Auth.: ORS 127.865
Stats. Implemented: ORS 127.800-127.995
Hist.: HD 15-1997(Temp), f. & cert. ef. 11-6-97; OHD 4-1998, f. & cert. ef. 5-4-98; OHD 12-1999, f. & cert. ef. 12-28-99; PH 24-2006, f. & cert. ef. 10-19-06

333-009-0020
Record Review/Annual Report

(1) The Authority shall annually review records maintained pursuant to this Act.

(2) The Authority shall generate and make available to the public an annual statistical report of information collected under this Act.

Stat. Auth.: ORS 127.800
Stats. Implemented: ORS 127.800 - 127.897
Hist.: HD 15-1997(Temp), f. & cert. ef. 11-6-97; OHD 4-1998, f. & cert. ef. 5-4-98; PH 24-2006, f. & cert. ef. 10-19-06

333-009-0030
Confidentiality/Liability

(1) All information collected pursuant to ORS 127.800 to 127.897 including, but not limited to, the identity of patients, physicians and other health care providers, and health care facilities shall not be a public record and may not be made available for inspection by the public.

(2) All information collected pursuant to ORS 127.800 to 127.897 and the annual statistical report referred to in 333-009-0020(2) shall be considered a special morbidity and mortality study under ORS 432.060. Summary information released in statistical reports shall be aggregated to prevent identification of individuals, physicians, or health care facilities.

(3) Pursuant to ORS 432.060, providing morbidity and mortality information to the Authority does not subject any physician, hospital, health care facility or other organization or person furnishing such information to an action for damages.

(4) Access to death certificate information shall be in accordance with OAR 333-011-0096 pursuant to ORS 432.121.

Stat. Auth.: ORS 127.800
Stats. Implemented: ORS 127.800 - 127.995, 432.060,432.121
Hist.: HD 15-1997(Temp), f. & cert. ef. 11-6-97; OHD 4-1998, f. & cert. ef. 5-4-98; PH 24-2006, f. & cert. ef. 10-19-06

DIVISION 10

HEALTH PROMOTION AND CHRONIC DISEASE PREVENTION

Cancer Reporting Regulations

333-010-0000
Definitions

(1) "Active follow-up program" means a program for contacting a caregiver or cancer patient to determine, at least annually, information including but not limited to the vital status of each case.

(2) "Admitted" means a rendering of any service by the reporting facility to a patient under the authority or auspices of the facility's license under ORS 441.015, including but not limited to routine admission to the hospital, admission to the emergency room, or receiving services in an out-patient clinic.

(3) "Authority" means the Oregon Health Authority.

(4) "Cancer reporting facility" means a hospital or other health care facility in which cancer is diagnosed or treated and is also one of the following:

(a) A facility currently licensed as a hospital as defined under the provisions of ORS 442.015(13); or

(b) A facility currently licensed as an ambulatory surgical center as defined under ORS 442.015(3)(a).

(5) "Central cancer registry" means the Oregon Health Authority, Public Health Division program authorized to collect, receive, and maintain cancer data for the entire state and which maintains the system by which the collected information is reported to the Division.

(6) "Central Registry Cancer Notification Form" means the form required for health care providers to report a case of reportable cancer or reportable non-malignant condition.

(7) "Certified tumor registrar" means an individual who passes the certification examination and is currently certified by the Council on Certification of the National Cancer Registrars Association.

(8) "Clinical laboratory" means a facility where microbiological, serological, chemical, hematological, immunohematological, immunological, toxicological, cytogenetical, exfoliative cytological, histological, pathological or other examinations are performed on material derived from the human body, for the purpose of diagnosis, prevention of disease or treatment of patients by physicians, dentists and other persons who are authorized by license to diagnose or treat humans.

(9) "Date of diagnosis" means the date of initial diagnosis by a health care provider for the cancer being reported.

(10) "Division" means the Public Health Division of Oregon Health Authority.

(11) "First course of treatment" means all methods of treatment recorded in the treatment plan and administered to a person with a case of reportable cancer or reportable non-malignant condition before disease progression or recurrence, as defined in the American College of Surgeons Commission on Cancer Facility Oncology Registry Data Standards Manual, 2011.

(12) "Health care provider" means any person whose professional license allows him/her to diagnose or treat cancer patients.

(13) "Health system cancer registry" means a cancer registry that includes all reportable cancer cases occurring in the population served by a health system, whether or not the cases are diagnosed or treated in the cancer reporting facility.

(14) "OSCaR" means the Oregon State Cancer Registry, Oregon's central cancer registry.

(15) "Quality control system" means operational procedures by which the accuracy, completeness, and timeliness of the information reported to OSCaR can be determined and improved.

(16) "Reportable cancer" means all malignant neoplasms including carcinoma in situ, except basal and squamous cell carcinoma of the skin, carcinoma in situ of the cervix uteri, and CIN III (diagnosed on or after January 1, 1996), and PIN III (diagnosed on or after January 1, 2001).

(17) "Reportable Cancer Data Items List" means the list of variables for reportable cancers and reportable non-malignant conditions reported by cancer reporting facilities following the recommendations of the Centers for Disease Control and Prevention National Program of Cancer Registries ("CDC-NPCR") and further defined by the North American Association of Central Cancer Registries ("NAACCR") Data Standards and Data Dictionary, 2011.

(18) "Reportable non-malignant condition" means benign or borderline tumors of the brain (including the meninges and intracranial endocrine structures) and central nervous system, diagnosed on or after January 1, 2004.

(19) "Reportable pre-malignant condition" means all high-grade squamous intraepithelial lesion (CIN 2,3) and adenocarcinoma in situ (AIS) of the uterine cervix, high-grade squamous intraepithelial lesion of the vagina and vulva (VAIN 2,3/VIN 2,3), and high-grade squamous intraepithelial lesion (AIN 2,3) and carcinoma in situ of the anus.

(20) "Special study" means a Division-sponsored project that explores a particular facet of cancer incidence, morbidity, or mortality including, but not limited to, exploring hypotheses of disease risk, treatment options or cancer control authorized under ORS 432.520.

Stat. Auth.: ORS 432.500, 432.510, 432.540
Stats. Implemented: ORS 432.510, 432.520, 432.540
Hist.: HD 2-1996, f. & cert. ef. 2-29-96; OHD 7-1998, f. 7-14-98, cert. ef. 8-1-98; PH 13-2011, f. 12-28-11, cert. ef. 1-1-12

333-010-0010
General Authority

ORS 432.510 directs the Oregon Health Authority to "establish a uniform, statewide, population-based registry system for the collection of information determining the incidence of cancer and benign tumors of the brain and central nervous system and related data. The purpose of the registry shall be to provide information to design, target, monitor, facilitate, and evaluate efforts to reduce the burden of cancer and benign tumors among the residents of Oregon." ORS 432.510, subsections (a) through (e) further specify that such efforts may include but are not limited to:

(1) Targeting populations in need of screening or other cancer control services;

(2) Supporting the operation of hospital registries and upgrading the care of cancer and benign tumors;

(3) Investigating suspected clusters;

(4) Conducting studies to identify cancer hazards; and

(5) Projecting the benefits or costs of alternative policies regarding the prevention or treatment of benign tumors or cancer.

Stat. Auth.: ORS 432.510
Stats. Implemented: ORS 432.510
Hist.: HD 2-1996, f. & cert. ef. 2-29-96; PH 13-2011, f. 12-28-11, cert. ef. 1-1-12

333-010-0020
Reporting Requirements for Cancer Reporting Facilities

This rule describes the specific requirements for cancer reporting facilities. Such facilities include inpatient facilities, outpatient facilities acting under the license of a hospital, ambulatory surgical centers, and privately owned treatment or diagnostic centers contracted to and acting as a department of a cancer reporting facility.

(1) Cancer reporting facilities must report to OSCaR each case of reportable cancer or reportable non-malignant condition, as defined in OAR 333-010-0000(16) and 333-010-0000(18) respectively, in patients admitted for diagnosis and/or any part of the first course of treatment for that cancer. OSCaR will make lists of reportable cancers and reportable non-malignant conditions available

on the Oregon State Cancer Registry website: www.healthoregon.org/oscar.

(2) Cancer reporting facilities must report cases of reportable cancer or reportable non-malignant conditions to OSCaR as stipulated in OAR 333-010-0020(1) within 180 days of the date the case first receives cancer diagnostic or treatment services at the facility.

(3) Cancer reporting facilities with an active follow-up program must annually report vital status, date of last patient contact, and, if available, cancer or tumor status of reportable cancers and reportable non-malignant conditions to OSCaR.

(4) Cancer reporting facilities must report their cases of reportable cancer or reportable non-malignant conditions and any follow-up information to OSCaR in the electronic data exchange format and codes, Record Type A: Case Abstract, as specified by NAACCR, including the variables specified in the Reportable Cancer Data Items List. The OSCaR Reportable Data Items List will be available on the Oregon State Cancer Registry website: www.healthoregon.org/oscar.

(5) OSCaR shall establish a system of confirmation of receipt of cases submitted by each cancer reporting facility.

(6) Cancer reporting facilities reporting cases of reportable cancer or reportable non-malignant conditions to a health system cancer registry have discharged their reporting responsibilities provided that the health system registry reports those cases to OSCaR according to the requirements for cancer reporting facilities.

(7) Cancer reporting facilities may also elect to contract with a private vendor or contractor to report cases of reportable cancer and reportable non-malignant conditions to OSCaR as outlined above in OAR 333-010-0020(1) through (4).

(8) Any cancer reporting facility designated as a Type A or Type B rural hospital by the Oregon Office of Rural Health, may elect to meet the cancer reporting requirements by conducting their own identification of cases of reportable cancer and reportable non-malignant conditions and mailing a copy of the relevant portions of the medical record for each case to the central registry. The central registry staff will abstract and report such cases and bill the hospital for this service at its cost. Type A or Type B rural hospitals which authorize the central registry to abstract and report cases have fulfilled their abstracting and reporting requirements under these rules.

(9) Upon application to OSCaR by a cancer reporting facility, OSCaR may grant to the facility an extension of time, not to exceed two years, in which to meet the reporting requirements. Such requests must be in writing and directed to the Medical Director of OSCaR. On request, the central registry staff shall provide technical assistance to facilities to meet the reporting requirements.

(10)(a) If cancer reports from a reporting facility do not meet reporting requirements, OSCaR shall inform the facility in writing of the disparity between the facility's reports and the reporting standards. OSCaR will then consult with the facility regarding its options for meeting the reporting standards, as defined in OAR 333-010-0020(1) through (4). Options shall include, but are not limited to:

(A) Further consultation and training;

(B) Referral to contractors for reporting services;

(C) Provision, at cost, of reporting services by OSCaR. By selecting this option, cancer reporting facilities will fulfill all reporting requirements.

(b) If, after a minimum of 30 days from the receipt of the written notification, the facility cannot meet the reporting requirements, OSCaR may activate its reporting service for the facility. When activated, OSCaR may enter the facility, obtain the information and report it in conformance with the appropriate format and standards. In these instances, the facility shall reimburse OSCaR or its authorized representative for the cost of obtaining and reporting the information.

Stat. Auth.: ORS 432.510, 432.520

Stats. Implemented: ORS 432.510, 432.520

Hist.: HD 2-1996, f. & cert. ef. 2-29-96; OHD 7-1998, f. 7-14-98, cert. ef. 8-1-98; PH 13-2011, f. 12-28-11, cert. ef. 1-1-12

333-010-0030

Reporting Requirements for Health Care Providers

(1) Any health care provider diagnosing a case of reportable cancer or a reportable non-malignant condition, as defined in OAR 333-001-0000(16) and 333-010-0000(18) respectively, must notify OSCaR of each such case within 180 days of the diagnosis of the case. OSCaR will make lists of reportable cancers and reportable non-malignant conditions available on the Oregon State Cancer Registry website: www.healthoregon.org/oscar.

(2) Data items required for reporting a case of reportable cancer or reportable non-malignant condition shall include, but not be limited to, cancer diagnosis and treatment information, patient demographics, and health care provider contact information, as specified on the Central Registry Cancer Notification Form. Copies of the Central Registry Cancer Notification Form will be available on the Oregon State Cancer Registry website: www.healthoregon.org/oscar.

(3) Health care providers must comply with one of the following optional notification methods as may be directed by OSCaR:

(a) Completion and submission (by mail or facsimile) of the Central Registry Cancer Notification Form; or

(b) An encrypted electronic communication directed to OSCaR containing the information required by the Central Registry Cancer Notification Form.

(4) Health care providers need not report any case admitted to an Oregon reporting facility for:

(a) A diagnosis of a reportable cancer or reportable non-malignant condition; or

(b) All or any part of the first course of treatment for that case, providing that admission to the facility occurs within 180 days of diagnosis.

(5) Health care providers reporting cases of reportable cancer and reportable non-malignant conditions to a health system cancer registry have discharged their reporting responsibilities provided that the health system cancer registry reports those cases to OSCaR according to the requirements for cancer reporting facilities.

(6) If a health care provider fails to notify OSCaR of cases of reportable cancer and reportable non-malignant conditions according to the standards and format prescribed for health care providers, OSCaR may inform the health care provider in writing of the disparity between the health care provider's reporting performance and the reporting standards and consult with the health care provider regarding methods for bringing the health care provider's reporting performance into compliance with the reporting standards.

(7) If OSCaR does not receive information from another source completing the information required for a case of reportable cancer or reportable non-malignant condition submitted by a health care provider, or if OSCaR learns of an unreported case for which the health care provider has reporting responsibility but of which the central registry has not been notified by the health care provider, OSCaR may notify the health care provider of the missing information or case and the health care provider must, within 30 days, submit requested additional information to OSCaR. In the alternative, OSCaR may contact the health care provider and schedule a time to abstract the necessary data from the health care provider's records. The health care provider must provide access to those portions of a patient's medical record which provide data for the items specified in the Reportable Cancer Data Items List. In these instances, the health care provider must reimburse OSCaR or its authorized representative for the cost of obtaining and reporting the information.

(8) OSCaR shall establish a system of confirmation of receipt of cases submitted by health care providers.

Stat. Auth.: ORS 432.510, 432.520

Stats. Implemented: ORS 432.510, 432.520

Hist.: HD 2-1996, f. & cert. ef. 2-29-96; OHD 7-1998, f. 7-14-98, cert. ef. 8-1-98; PH 13-2011, f. 12-28-11, cert. ef. 1-1-12

333-010-0032
Reporting Requirements for Clinical Laboratories

(1) Clinical laboratories must report to OSCaR all cases with test results indicative of and specific for a reportable cancer or reportable non-malignant condition, as defined in OAR 333-010-0000(16) and 333-010-0000(18) respectively, ("Cancer Pathology Reports") in accordance with the following provisions. Clinical laboratories must submit all Cancer Pathology Reports to OSCaR using the electronic data exchange format and codes set forth in the guidelines for Pathology Laboratory Electronic Reporting issued by the North American Association of Central Cancer Registries ("NAACCR"), unless reported to a health system cancer registry. The NAACCR Guidelines for Pathology Laboratory Electronic Reporting are available from OSCaR.

(2) Clinical laboratories must also report to OSCaR all cases with biopsies (excluding cytologic tests) indicative of and specific for a reportable pre-malignant condition, as defined in OAR 333-010-0000(16), in an electronic format mutually agreed to by OSCaR and the clinical laboratory. These reports must include (if available to the clinical laboratory):

(a) Name, address, and telephone number of the physician listed on the lab order;

(b) Name, address, and telephone number of the reporting laboratory;

(c) Patient name, gender, address (if available), birth date, race/ethnicity;

(d) Primary site and type of cancer-related condition; and

(e) Date of diagnosis.

(3) OSCaR will make lists of reportable cancers, reportable non-malignant conditions, and reportable pre-malignant conditions available on the Oregon State Cancer Registry website: www.healthoregon.org/oscar. If a clinical laboratory fails to submit the required cancer pathology reports or reports of pre-malignant conditions to OSCaR according to the standards and format prescribed, OSCaR may inform the laboratory in writing of the disparity between the laboratory's reporting performance and the reporting standards and consult with the laboratory regarding methods for bringing the clinical laboratory's reporting performance into compliance with the reporting standards.

(4) If a clinical laboratory is not able to submit cancer pathology reports or reports of pre-malignant conditions electronically, OSCaR may authorize the clinical laboratory to report by mail or facsimile for a limited period of time to be specified by OSCaR.

(5) OSCaR shall establish a system of confirmation of receipt of cancer pathology reports and reports of pre-malignant conditions submitted by clinical laboratories.

Stat. Auth.: ORS 432.510, 432.520
Stats. Implemented: ORS 432.510, 432.520
Hist.: PH 13-2011, f. 12-28-11, cert. ef. 1-1-12

333-010-0035
Patient Notification Requirement

This rule describes the process for notifying patients that information about a reportable cancer has been reported to OSCaR.

(1) OSCaR may, but is not required to notify patients that information about a diagnosis of reportable cancer has been included in the registry. OSCaR may make a determination, based on budgeting constraints or otherwise, to curtail patient notification activities.

(2) Information to be provided to patients. The notification to the patient shall include the following information about the purposes of the registry and the protection of confidentiality:

(a) That Oregon statute requires that every cancer newly diagnosed in Oregon, or in an Oregon resident, be reported to the Oregon State Cancer Registry maintained by Oregon Health Authority;

(b) That information reported to the Authority includes the type and characteristics of the cancer, details of the diagnosis and treatment given, and patient demographic information;

(c) That the information is used to understand how cancer affects the population in Oregon, to design and implement prevention and control programs, and for research;

(d) That the information is confidential and no identifiable information about the patient can be released to anyone unless very strict requirements, as provided by law, are met;

(e) If those specific requirements, as provided by law, are met, researchers may be allowed to contact patients to offer them the opportunity to participate in research projects. Any invitation to participate in research is always voluntary and may be freely declined; and

(f) That the researcher shall first notify the patient's physician regarding the patient's participation in a research project, unless the patient specifies to OSCaR that their name never be released for any research purpose.

Stat. Auth.: ORS 432.500
Stats. Implemented: ORS 432.500–432.900
Hist.: OHD 7-1998, f. 7-14-98, cert. ef. 8-1-98; PH 13-2011, f. 12-28-11, cert. ef. 1-1-12

333-010-0040
Quality Standards

The usefulness of OSCaR data is directly dependent upon the accuracy, completeness, and timeliness of the data available in its database. ORS 432.510(5) directs the Oregon Health Authority to establish a quality control program for the data reported to the state registry. In order to assess these aspects of quality for cancer reporting, the central registry will institute a program of continuous quality improvement.

(1) The continuous quality improvement system must include, but is not limited to, coding edits, completeness audits or checks, reabstracting audits, and data analysis techniques to estimate data accuracy, validity, and reliability.

(2) For the purpose of assuring the accuracy and completeness of reported data, OSCaR shall have the right to periodically review all records that would identify cases of reportable cancer and reportable non-malignant conditions or would establish characteristics of the cancer, treatment of the cancer or the medical status of any identified cancer patient. OSCaR will provide advance notification of a minimum of 30 days, to allow time for the reporting sources to prepare records for review.

(3) The collection of cancer data from cancer reporting facilities, including data collection performed by OSCaR staff, must be performed either by certified tumor registrars or by staff knowledgeable about the following, as recommended by the American College of Surgeons, Commission on Cancer:

(a) Cancer as a disease process;

(b) General anatomy and physiology;

(c) Cancer epidemiology and statistics;

(d) Casefinding procedures; and

(e) Basic coding and staging schemes.

(4) A cancer reporting facility must report a minimum of 98 percent of the cases reportable by that facility for any calendar year in order to meet the requirement of these rules.

(5) The item-specific agreement rate of reported data from a cancer reporting facility with the information in the facility's medical record must not be less than 95 percent for those data items identified in the OSCaR Reportable Data Items list as quality control items.

(6) A cancer reporting facility must submit 98 percent of reportable cases to the central cancer registry within 180 days of either:

(a) The date of diagnosis; or

(b) The date of admission for receipt of any part of the first course of treatment provided in that facility, whichever is later.

(7) A health care provider must submit a minimum of 95 percent of reportable cases to the central cancer registry within 180 days of the date of diagnosis.

Stat. Auth.: ORS 432.510
Stats. Implemented: ORS 432.510
Hist.: HD 2-1996, f. & cert. ef. 2-29-96; PH 13-2011, f. 12-28-11, cert. ef. 1-1-12

333-010-0050
Confidentiality and Access to Data

(1) All identifying information regarding individual patients, cancer reporting facilities, clinical laboratories, and health care providers reported pursuant to ORS 432.510 and 432.520, OAR 333-010-0020, 333-010-0030 and 333-010-0032 shall be confidential and privileged. Except as required in connection with the administration or enforcement of public health laws or rules, no public health official, employee, or agent shall be examined in an administrative or judicial proceeding as to the existence or contents of data collected under the cancer registry system.

(2) The information collected and maintained by OSCaR must be stored in secure locations, must be used solely for the purposes stated in ORS 432.510 and 432.520 and must not be further disclosed unless required by law, with the following exceptions:

(a) When OSCaR has entered into reciprocal cooperative agreements with other states to exchange information on resident cases, as provided for in ORS 432.540. Such agreements must provide for obtaining data on Oregon resident cases diagnosed or treated out of state, and for reciprocal rights of other states to receive information on residents of those states diagnosed or treated in Oregon. Before entering into an agreement with any other state, OSCaR must determine that the other state has comparable confidentiality protections;

(b) When disclosure to officers or employees of federal, state, or local government public health agencies is necessary to investigate or avoid a clear and immediate danger to other individuals or to the public generally;

(c) When the Authority elects to contract with another agency for performance of a registry function the Authority will require the contractor to agree to use the information only for the purposes of the central cancer registry, to maintain the information securely, and to protect the information from unauthorized disclosure as referred to in OAR 333-010-0050(1). Before entering into any contract with another agency the Authority must determine the agency has comparable confidentiality protections; and

(d) When the Authority deems that the information is necessary for others to conduct research in conformance with the purposes for which the data are collected.

(3) Cancer reporting facilities shall have access to confidential and privileged data on any case submitted by that facility. When a patient has been seen for care of a case of cancer by multiple cancer reporting facilities, OSCaR may share information on treatment and follow-up among the facilities, provided that all participating facilities have signed agreements with OSCaR to do so.

(4) Health care providers shall have access to confidential and privileged data on any case submitted by that health care provider. When a patient has been seen for care of a case of cancer by multiple health care providers, OSCaR may share information on treatment and follow-up among the health care providers, provided that all participating health care providers have signed agreements with OSCaR to do so.

Stat. Auth.: ORS 432.510, 432.520
Stats. Implemented: ORS 432.530, 432.540
Hist.: HD 2-1996, f. & cert. ef. 2-29-96; OHD 7-1998, f. 7-14-98, cert. ef. 8-1-98; PH 13-2011, f. 12-28-11, cert. ef. 1-1-12

333-010-0055
Research Studies

(1) Requirements for Research Studies. Before any confidential data may be disclosed to a researcher, OSCaR must:

(a) Approve a submitted protocol for the proposed research, which describes how the research will be used to determine the sources of cancer among the residents of Oregon or to reduce the burden of cancer in Oregon, in accordance with ORS 432.510 and OAR 333-010-0010;

(b) Agree that the data requested are necessary for the effective and efficient conduct of the study;

(c) Approve the researcher's submitted protocol and procedures for:

(A) Identifying patients to be contacted;

(B) Protecting against inadvertent disclosure of confidential and privileged data;

(C) Providing secure conditions to use and store the data;

(D) Assuring that the data will only be used for the purposes of the study; and

(E) Assuring that confidential and privileged data will be destroyed upon conclusion of the research;

(d) Determine that the researcher has access to sufficient resources to carry out the proposed research before releasing any confidential data;

(e) Facilitate appropriate review of the research, including peer review for scientific merit, and review by the body used by the Authority as the Committee for the Protection of Human Research Subjects and established in accordance with 45 C.F.R. 46; and

(f) Determine the need for and require the researcher to implement other safeguards which, in the judgment of OSCaR, may be necessary for protecting confidential and privileged data from inadvertent disclosure due to unique or special characteristics of the proposed research.

(2) Contacting Patients for Research. As outlined in OAR 333-010-0035(2)(e) & (f), participation in research is voluntary and patients may choose whether or not they want to participate in research studies.

(a) Before disclosing confidential patient information to a researcher, OSCaR must determine whether any of the patients meeting the criteria for the research study have previously informed OSCaR that they do not wish to participate in research. Such patients will be excluded from the list of patients provided to the researcher or contacted by OSCaR regarding research.

(b) Unless OSCaR determines it to be impracticable, OSCaR and/or the researcher must contact the patient's current treating physician to inform them of the study prior to any contact with a patient. In situations where the treating physician of record is no longer the patient's physician, OSCaR and/or the researcher must make a good faith effort to find the patient's current physician.

(c) When contacted, the patient's physician must be informed of the study and the identity of the eligible patient. Within three weeks the physician must:

(A) Agree that direct contact by the researcher would be appropriate; or

(B) Indicate the presence of a medical, psychological or social situation in the patient's life that would make contact inappropriate at that time. The physician is under no obligation to disclose the specifics of the medical, psychological or social situation.

(d) If a researcher does not receive a response from the physician within one month, the researcher may contact the patient directly.

(e) Researchers are strictly prohibited from redisclosing patient names or other confidential information to other researchers, individuals, or institutions not specifically identified in the approved study protocol as outlined above.

Stat. Auth.: ORS 432.510, 432.530, 432.540
Stats. Implemented: ORS 432.510, 432.530, 432.540
Hist.: OHD 7-1998, f. 7-14-98, cert. ef. 8-1-98; PH 13-2011, f. 12-28-11, cert. ef. 1-1-12

333-010-0060
Special Studies

(1) From time to time, OSCaR may elect to conduct special studies of cancer mortality, morbidity, treatment options and cancer control. OSCaR is specifically authorized to obtain any information which may apply to a patient's reportable cancer or reportable non-malignant condition, and which may be found in the medical record of the patient under ORS 432.510 and 432.520. Upon request, the health care provider or health care facility must provide the requested information to OSCaR or provide OSCaR personnel access to the relevant portions of the medical records. Neither OSCaR nor the record holder shall bill the other for the cost of providing or obtaining this information.

(2) If, in the conduct of a special study, OSCaR identifies a need for access to pathological specimens that have been collected in connection with a case, OSCaR must make a written request to

the clinical laboratory or the cancer reporting facility with which the clinical laboratory is affiliated for the purpose of making arrangements for the procurement of such pathological specimens upon mutually agreeable terms.

Stat. Auth.: ORS 432.510, 432.520
Stats. Implemented: ORS 432.510, 432.520
Hist.: HD 2-1996, f. & cert. ef. 2-29-96; PH 13-2011, f. 12-28-11, cert. ef. 1-1-12

333-010-0070
Advisory Committee

The Authority shall appoint an advisory committee to review the operations of the central registry and to make recommendations regarding registry policy, and to review research protocols for which confidential and privileged data are requested. The composition of the advisory committee must generally represent those with a professional or personal interest in cancer.

Stat. Auth.: ORS 432.510, 432.520
Stats. Implemented: ORS 432.510
Hist.: HD 2-1996, f. & cert. ef. 2-29-96; PH 13-2011, f. 12-28-11, cert. ef. 1-1-12

333-010-0080
Training and Consultation

The Authority shall provide annual continuing education for interested persons involved in cancer registry reporting. Continuing education content must include, but is not limited to, cancer diagnosis and management, epidemiology and statistics, and hardware and software registry applications. The central registry staff must supplement the continuing education with one-on-one consultations to assist cancer reporting facilities and health care providers as needed in meeting the reporting requirements.

Stat. Auth.: ORS 432.510
Stats. Implemented: ORS 432.510
Hist.: HD 2-1996, f. & cert. ef. 2-29-96; PH 13-2011, f. 12-28-11, cert. ef. 1-1-12

333-010-0090
Fees

OSCaR may establish fees, reasonably calculated, to reimburse for its actual cost in making OSCaR records and data available to researchers. Such costs include, but are not limited to, costs for computer programming; consultation; and for summarizing, compiling, analyzing, or tailoring records and data to a researchers' needs.

Stat. Auth.: ORS 432.560
Stats. Implemented: ORS 432.500 - 432.990
Hist.: OHD 11-1999, f. & cert. ef. 12-8-99

ScreenWise Breast and Cervical Cancer Program

333-010-0100
Description of the ScreenWise Breast and Cervical Cancer Program

The mission of the Oregon ScreenWise Program is to reduce breast cancer, cervical cancer, cardiovascular disease and other diseases by promoting early detection through screening, risk reduction counseling, behavior modification support, and referral to medical treatment. ScreenWise includes the Breast and Cervical Cancer Program (ScreenWise BCC), a federal screening and early detection program administered by the Oregon Health Authority to provide screening and diagnostic services to eligible Oregonians statewide. ScreenWise BCC provides coverage for screening and diagnostic services to Oregonians with family incomes up to 250 percent of the Federal Poverty Level through a contract network of qualified providers. OAR 333-010-0100 through 333-010-0197 apply only to providers who have an approved medical services agreement to provide screening and diagnostic services through this program. The program is limited to a finite source of funds which may restrict availability of services on an annual basis.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042
Hist.: PH 9-2008, f. & cert. ef. 6-16-08; PH 1-2012, f. & cert. ef. 1-17-12; PH 28-2014, f. & cert. ef. 10-10-14; PH 20-2015(Temp), f. & cert. ef. 10-12-15 thru 4-8-16; PH 11-2016, f. & cert. ef. 4-1-16

333-010-0105
Definitions

(1) "Agency number" means the administrative number assigned to the service provider by the Center for Prevention and Health Promotion (Center) for identification as a ScreenWise Breast and Cervical Cancer services (ScreenWise BCC) provider.

(2) "Ancillary provider" means a provider that performs services beyond the scope of an enrolling provider. Ancillary providers may include but is not limited to laboratories, imaging centers, surgeons and surgical facilities, and hospitals.

(3) "Approved medical services agreement" means the completed ScreenWise BCC agreement, submitted to and approved by the Center for Prevention and Health Promotion.

(4) "Authority" means the Oregon Health Authority.

(5) "BCCTP" means the Breast and Cervical Cancer Treatment Program. ORS 414.534, 414.536.

(6) "Care coordination or case management" means that a client is provided with services, results, follow-up recommendations, and active tracking of progress towards follow-up recommendations.

(7) "Center" means the Center for Prevention and Health Promotion, the office within the Oregon Health Authority that administers the ScreenWise BCC.

(8) "CLIA" means the federal Clinical Laboratory Improvement Amendments of 1988, establishes quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results, and allows for certification of clinical laboratories operating in accordance with these federal amendments.

(9) "Client" means a person of any age or gender who is enrolled in and receives screening or diagnostic services from the ScreenWise BCC.

(10) "Enrolling provider" means a provider that enrolls a client into the ScreenWise BCC, provides care coordination for the client and timely data submission to ScreenWise BCC.

(11) "FPL" means the federal poverty level guidelines established each year by the Department of Health and Human Services, used to determine eligibility for ScreenWise BCC and other federally funded programs.

(12) "HIPAA" means the Health Insurance Portability and Accountability Act.

(13) "ScreenWise BCC" means the ScreenWise program component that provides statewide breast and cervical cancer screening and diagnostic services to eligible clients, that is administered by the Center for Prevention and Health Promotion within the Oregon Health Authority.

(14) "ScreenWise BCC Provider Network" means the combination of all contracted ScreenWise providers, including enrolling and ancillary providers.

(15) "Service provider" or "provider" means a licensed health care provider operating within a scope of practice, who is authorized by the Center to bill for breast and cervical cancer screening and diagnostic services for eligible clients.

(16) "Site number" means the administrative number assigned to the provider by the Center for identification of the geographic location of each ScreenWise BCC provider.

(17) "Underinsured" means that health insurance does not fully cover breast and cervical cancer screening services or that out-of-pocket cost sharing for diagnostic services would pose a financial hardship.

Stat. Auth.: ORS 413.042
Stats. Implemented: 413.042
Hist.: PH 9-2008, f. & cert. ef. 6-16-08; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 11-2011, f. & cert. ef. 10-27-11; PH 1-2012, f. & cert. ef. 1-17-12; PH 13-2014(Temp), f. & cert. ef. 4-22-14 thru 10-19-14; PH 28-2014, f. & cert. ef. 10-10-14; PH 20-2015(Temp), f. & cert. ef. 10-12-15 thru 4-8-16; PH 11-2016, f. & cert. ef. 4-1-16

333-010-0110
Client Eligibility

In order to be eligible for the ScreenWise BCC a client must meet the following eligibility criteria:

(1) Have an income based on family size that is at or below 250 percent of the Federal Poverty Level at the time of enrollment; and

(2) Reside or declare an intent to reside in Oregon; and

(3) Have no health insurance or be underinsured; and

(4) Meet one of the following criteria:

(a) Be a woman age 21 or over for clinically recommended breast and cervical cancer screening and diagnostic services; or

(b) Be a man of any age who is displaying signs or symptoms that may indicate breast cancer.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042
Hist.: PH 9-2008, f. & cert. ef. 6-16-08; PH 1-2012, f. & cert. ef. 1-17-12; PH 20-2015(Temp), f. & cert. ef. 10-12-15 thru 4-8-16; PH 11-2016, f. & cert. ef. 4-1-16

333-010-0115
Client Enrollment

(1)(a) Clients are determined eligible on a self-declared basis, when they submit a completed and signed ScreenWise BCC enrollment form at the clinic site at the time of service.

(b) Prior to enrolling a client in ScreenWise BCC, providers with access to the Medicaid Management Information System (MMIS) shall check MMIS to verify that applicant is not currently receiving Medicaid. Clients enrolled in Medicaid are ineligible for ScreenWise BCC.

(2) Eligibility is effective for one year unless a client justifiably needs to begin a second breast or cervical cycle, as defined in the program manual, before the end of one year. Justifications include:

(a) The presence of new signs or symptoms; or

(b) The necessity of short-term follow-up, as defined in the program manual.

(3) If breast or cervical services are justifiably initiated again before the end of one year, then eligibility will automatically extend through the end of that cycle, even if the cycle lasts into a new year.

(4) ScreenWise BCC providers must keep a signed enrollment form on file at the clinic for a minimum of four years. Clients enrolled into the program who are found ineligible will be disenrolled.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042
Hist.: PH 9-2008, f. & cert. ef. 6-16-08; PH 1-2012, f. & cert. ef. 1-17-12; PH 28-2014, f. & cert. ef. 10-10-14; PH 20-2015(Temp), f. & cert. ef. 10-12-15 thru 4-8-16; PH 11-2016, f. & cert. ef. 4-1-16

333-010-0120
Covered Services

(1) ScreenWise BCC covers screening and diagnostic services specific to breast and cervical cancer. Contracted providers will only be reimbursed for services related to breast and cervical cancer screening and diagnosis.

(2) Screening and diagnostic services include, but are not limited to:

(a) For breast cancer, both a clinical breast examination and a mammogram;

(b) For cervical cancer, both a pelvic examination and a Pap smear; and

(c) Laboratory tests and medical procedures necessary for detection and diagnosis of breast and cervical cancer.

(3) Information regarding covered services and CPT code lists, including required notice to providers regarding revisions, may be found in the provider's Medical Services Agreement.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042
Hist.: PH 9-2008, f. & cert. ef. 6-16-08; PH 20-2015(Temp), f. & cert. ef. 10-12-15 thru 4-8-16; PH 11-2016, f. & cert. ef. 4-1-16

333-010-0125
Excluded Services

(1) Services and laboratory tests not directly related to breast and cervical cancer screening and diagnosis are not covered by ScreenWise BCC for any eligible client. If the client accepts financial responsibility for a non-covered service that is received during a visit, payment arrangements are between the provider and the client, per OAR 333-010-0140(5)(a).

(2) No payment will be made for any expense incurred for any of the following services or items:

(a) Treatment for cancer or pre-cancerous conditions; or

(b) Any medical service or laboratory tests whose primary purpose is for a reason other than breast or cervical cancer screening or diagnostic testing.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042
Hist.: PH 9-2008, f. & cert. ef. 6-16-08; PH 11-2016, f. & cert. ef. 4-1-16

333-010-0130
Standards of Care for Breast and Cervical Cancer Screening and Diagnostic Services

Participating ScreenWise BCC providers must agree to provide screening and diagnostic services according to the following standards:

(1) Informed Consent. The client's decision to participate in and consent to receive breast and cervical cancer screening and diagnostic services must be voluntary and without bias or coercion.

(a) The informed consent process, provided verbally and supplemented with written materials, must be presented in a language the client understands.

(b) Consent must be obtained from the individual client receiving screening and diagnostic services.

(2) Confidentiality. Services must be provided in a manner that respects the privacy and dignity of the individual.

(a) Providers must inform clients that services and medical records will be kept confidential.

(b) Records cannot be released without written client consent, except as required by law, or otherwise permitted by the Health Insurance Portability and Accountability Act (HIPAA).

(3) Linguistic and Cultural Competence. All services, support and other assistance must be provided in a manner that is responsive to the beliefs, interpersonal styles, attitudes, language, and behaviors of the individuals who are receiving services, and in a manner that has the greatest likelihood of ensuring their maximum participation in the program.

(a) All persons providing interpretation services must adhere to confidentiality guidelines.

(b) The provider must make interpretation services available to all clients needing or requesting such assistance at no cost to the client. The provider must notify clients in need of interpretation services of the availability of such services in accordance with the Civil Rights Act of 1964.

(c) The provider must assure the competency of language assistance provided to limited English proficiency clients by interpreters and bilingual staff. Family and friends should not be used to provide interpretation services, unless requested by the client.

(d) Provider shall make available easily understood client related materials and post signage in the languages of groups commonly encountered in the service area.

(e) All print, electronic, and audiovisual materials must be appropriate according to the client's language and literacy. Providers must accommodate a client's request for alternate formats.

(4) Access to Care. Services covered by ScreenWise BCC must be provided without cost to eligible clients. Providers must inform clients of the scope of services available through the program.

(a) Although not covered by ScreenWise BCC, treatment and supplies for pre-cancerous, cancerous conditions, and sexually transmitted infections must be available at the site, or by referral.

(b) Clients in need of additional medical services beyond the scope of the ScreenWise BCC provider network must be provided with information about available local resources.

(c) Clients with a qualifying breast or cervical cancer diagnosis, including specific pre-cancerous conditions, shall be screened to determine presumptive eligibility for the BCCTP and enrolling providers shall facilitate the application process.

(d) All services must be offered to eligible clients without regard to marital status, race, parity, disability, or sexual orientation.

(5) Clinical and Preventive Services. The scope of breast and cervical cancer screening and diagnostic services offered to clients must include:

(a) A health history, including health risk facts and personal and family medical history as it pertains to breast and cervical cancer screening.

(b) An initial physical examination that includes a breast and pelvic exam with a Pap smear.

(c) Follow-up recommendations.

(d) Care coordination to ensure that appropriate follow-up screening, diagnostic testing and care is provided, including:

(A) An explanation of the results of the physical examination and the laboratory tests; and

(B) The opportunity for questions concerning procedures, methods and results.

Stat. Auth.: ORS 413.042, 414.540
Stats. Implemented: ORS 413.042, 414.534, 414.536
Hist.: PH 9-2008, f. & cert. ef. 6-16-08; PH 1-2012, f. & cert. ef. 1-17-12; PH 20-2015(Temp), f. & cert. ef. 10-12-15 thru 4-8-16; PH 11-2016, f. & cert. ef. 4-1-16

333-010-0135
Provider Enrollment

(1) This rule applies only to providers participating in ScreenWise BCC through an approved provider agreement with the Center.

(2) An individual or organization must meet applicable licensing or regulatory requirements set forth by federal and state statutes, regulations, and rules to be enrolled and to bill as a provider. In addition, all providers of services within the State of Oregon must have a valid Oregon business license if such a license is a requirement of the state, federal, county or city government to operate a business or to provide services.

(3) An individual or organization that is currently subject to sanctions by the Authority or the federal government is not eligible for enrollment.

(4) A ScreenWise BCC agency number will be issued to an individual or clinic upon:

(a) Completion of the application and submission of the required documents;

(b) The signing of the provider agreement by the provider or person authorized by the provider to bind the organization or individual to comply with these rules;

(c) Verification of licensing or certification; and

(d) Approval of the application by the Center.

(5) Issuance of an agency number establishes enrollment of an individual or organization as a provider for ScreenWise BCC services.

(6) If a provider changes address, business affiliation, licensure, ownership, certification, billing agents, registered name, or Federal Tax Identification Number (TIN), the Center must be notified in writing within 30 days of the change. Failure to notify the Center of a change of TIN may result in the imposing of a fine. Changes in business affiliation, ownership, registered name, and TIN may require the submission of a new application. Payments made to providers who have not furnished such notification may be recovered.

(7) Providers of services outside the state of Oregon will be enrolled under the following conditions:

(a) The provider is appropriately licensed or certified by the provider's state;

(b) The provider lives in a state contiguous to Oregon, and is within seventy-five miles of the Oregon border.

(8) Provider termination:

(a) The provider may terminate enrollment at any time. The request must be sent to the Center in writing, via certified mail, return receipt requested. The notice shall specify the agency number to be terminated and the effective date of termination. Termination of the provider enrollment does not terminate any obligations of the provider for dates of services during which the enrollment was in effect.

(b) ScreenWise BCC provider terminations or suspensions and subsequent recovery of any payments made by the Center may be for, but are not limited to, the following reasons:

(A) Breaches of the medical services agreement;

(B) Failure to comply with the statutes, regulations and policies of the Authority, and federal or state regulations that are applicable to the provider;

(C) Loss of the appropriate licensure or certification.

(9) The provider is entitled to a contested case hearing to determine whether the provider's agency number will be revoked.

(10) In the event of bankruptcy proceedings, the provider must notify the Center in writing within 15 days.

(11) Providers must receive information about administering the ScreenWise BCC from a ScreenWise BCC representative before services are initiated.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042
Hist.: PH 9-2008, f. & cert. ef. 6-16-08; PH 11-2016, f. & cert. ef. 4-1-16

333-010-0140
Billing

(1) Only clinics providing breast and cervical cancer screening and diagnostic services pursuant to an approved medical services agreement, and who have been assigned an agency number may submit claims for ScreenWise BCC services.

(2) All services must be billed by submitting claim information in the method specified by the ScreenWise BCC.

(3) A primary diagnosis code is required on all claims. All billings must be coded with the most current and appropriate International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM), incorporated by reference and the most appropriate Current Procedural Terminology (CPT) codes. Information regarding CPT code lists, including required notice to providers regarding CPT code list revisions, may be found in the provider's Medical Services Agreement. Claims including primary diagnosis codes that are not listed on the approved CPT code list will not be paid without program approval.

(4) The provider must use CLIA certified laboratories for all tests whether done at the clinic site or by an outside clinic.

(5) Enrolled providers with ScreenWise BCC must not seek payment from an eligible client, or from a financially responsible relative or representative of that individual, for any services covered by ScreenWise BCC.

(a) A client may be billed for services that are not covered by ScreenWise BCC. However, the provider must inform the client in advance of receiving the specific service that it is not covered, the estimated cost of the service, and that the client or client's representative is financially responsible for payment for the specific service. Providers must document in writing that the client was provided this information and the client knowingly and voluntarily agreed to be responsible for payment. The client or client's representative must sign the documentation.

(b) Services not covered by ScreenWise BCC are those outside of the scope of standard breast and cervical cancer screening and diagnosis, or those not included in the ICD-10 list, incorporated by reference and approved CPT code lists.

(6) Prior to submission of a claim to the Center for payment, an approved provider agreement must be in place.

(7) All claims must be submitted with data, as described in the claims section of the rules.

(a) Except for services performed by a CLIA certified laboratory outside of the clinic, all billings must be for services provided within the provider's licensure or certification.

(b) Providers must submit true and accurate information when billing the Center.

(c) A claim may not be submitted prior to providing services.

(8) Diagnosis Code Requirement:

(a) A primary diagnosis code is required on all claims.

(b) Use the highest degree of specificity within the diagnosis codes listed in the ICD-10-CM codes, incorporated by reference, for breast and cervical screening or diagnostic testing.

(9) No provider shall submit to the Center:

(a) Any false claim for payment;

(b) Any claim altered in such a way as to result in a payment for a service that has already been paid;

(c) Any claim upon which payment has been made by another source unless the amount paid is clearly entered on the claim form;

(10) The provider must submit a billing error edit correction, or refund the amount of the overpayment, on any claim where the provider identifies an overpayment made by the Center.

(11) A provider who, after having been previously warned in writing by the Authority or the Department of Justice about improper billing practices, is found to have continued such improper billing practices and has had an opportunity for a contested case hearing, shall be liable to the Center for up to triple the amount of the established overpayment received as a result of such violation.

(12) Third Party Resources:

(a) Providers must make all reasonable efforts to ensure that ScreenWise BCC will be the payor of last resort with the exception of clinic or offices operated by the Indian Health Service (IHS) or individual American Indian tribes;

(b) Providers must make all reasonable efforts to obtain payment first from other resources. For the purposes of this rule reasonable efforts include:

(A) Determining the existence of insurance coverage or other resource by asking the client;

(B) Except in the case of the underinsured, when third party coverage is known to the provider, by any other means available:

(i) The provider must bill the third party resource;

(ii) Comply with the insurer's billing and authorization requirements.

(C) Providers are required to submit a billing error edit correction showing the amount of the third party payment or to refund the amount received from another source within 30 days of the date the payment is received. Failure to submit a billing error edit correction within 30 days of receipt of the third party payment or to refund the appropriate amount within this time frame is considered concealment of material facts and grounds for recovery or sanction.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042
Hist.: PH 9-2008, f. & cert. ef. 6-16-08; PH 17-2015, f. 9-30-15, cert. ef. 10-1-15; PH 20-2015(Temp), f. & cert. ef. 10-12-15 thru 4-8-16; PH 11-2016, f. & cert. ef. 4-1-16

333-010-0145
Claims and Data Submission

(1) In addition to submitting standard claims information, enrolling providers are required to submit client data in order to receive payment for the claim. The data is used to collect information pertaining to breast and cervical cancer prevention, diagnosis, and treatment and is used by the National Breast and Cervical Cancer Early Detection Program and the ScreenWise BCC primarily to monitor the delivery of services and clinical outcomes of the program.

(2) Although data requirements may require more information than necessary for payment of a specific claim, all related fields must be completed and submitted.

(3) Data requirements for enrolling providers and ancillary providers are as follows:

(a) Enrolling providers must provide required information on client data forms, as defined by the program and posted on the Program website: www.healthoregon.org/screenwise.

(b) Ancillary providers must provide results of services to enrolling providers. Ancillary providers are not required to provide data to the ScreenWise BCC directly.

(4) If a provider terminates the medical services agreement all data must be submitted through the completion of each client's cycle.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042
Hist.: PH 9-2008, f. & cert. ef. 6-16-08; PH 20-2015(Temp), f. & cert. ef. 10-12-15 thru 4-8-16; PH 11-2016, f. & cert. ef. 4-1-16

333-010-0150
Timely Submission of Claims and Data

(1) All claims for services must be submitted within 120 days of the date of service. Claims older than 120 days from the date of service will not be paid, except as provided for in section (2) and (3) of this rule.

(2) If a claim is denied, the claim must be resolved within 120 days of the date of the denial. Claims older than 120 days from the date of denial will not be paid, except as provided for in section (3) of this rule.

(3) When the Center has made an error that caused the provider not to be able to bill within 120 days of the date of service, then the claim may be submitted to the Center. The error must be confirmed by the Center.

(4) Client data not related to payment of the claim may be updated or corrected at any time after the date of service.

(5) Ancillary providers must provide results of services to enrolling providers within 14 calendar days from the date of service.

(6) Enrolling providers must provide the ScreenWise BCC with enrollment and eligibility information immediately or within five calendar days from the date of enrollment. All other data must be submitted within 90 days from the date of enrollment. In the event that a case requires additional diagnostic procedures that exceed 90 days from the date of enrollment, the data must be submitted immediately upon receipt.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042
Hist.: PH 9-2008, f. & cert. ef. 6-16-08; PH 28-2014, f. & cert. ef. 10-10-14; PH 11-2016, f. & cert. ef. 4-1-16

333-010-0155
Payment

(1) The Center will make payment only to providers that have a medical services agreement with the ScreenWise BCC and are billing for an eligible client.

(2) The ScreenWise BCC reimbursement amount will be up to the Medicare reimbursement rate for the Portland metropolitan area for ScreenWise BCC approved CPT codes, on a fee-for-service basis.

(3) Federally qualified health centers or rural health centers are not paid at their Prospective Payment System (PPS) rate; they will receive up to the Medicare reimbursement rate for ScreenWise BCC approved CPT codes, on a fee-for-service basis.

(4) Center payments for ScreenWise BCC provider services, unless in error, constitute payment in full.

(5) The Center will not make payment on claims that have been assigned, sold, or otherwise transferred, or on which a provider of billing services receives a percentage of the amount billed or payment authorized. This includes, but is not limited to, transfer to a collection agency or individual who advances money to a provider for accounts receivable.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042
Hist.: PH 9-2008, f. & cert. ef. 6-16-08; PH 13-2014(Temp), f. & cert. ef. 4-22-14 thru 10-19-14; PH 28-2014, f. & cert. ef. 10-10-14; PH 11-2016, f. & cert. ef. 4-1-16

333-010-0160
Requirements for Financial, Clinical and Other Records

(1) The Center is responsible for analyzing and monitoring the operation of ScreenWise BCC and for auditing and verifying the accuracy and appropriateness of payment, utilization of services, the quality of care, and access to care. The provider shall:

(a) Develop and maintain adequate financial and clinical records and other documentation which supports the services for which payment has been requested. Payment will be made only for services that are adequately documented.

(b) All medical records must document the service provided, primary diagnosis code for the services, the date on which the service was provided, and the individual who provided the services. Patient account and financial records must also include documentation of charges, identify other payment resources pursued,

indicate the date and amount of all debit or credit billing actions, and support the appropriateness of the amount billed and paid. The records must be accurate and in sufficient detail to substantiate the data reported.

(2) Clinical records must sufficiently document that the client's services were primarily for breast or cervical cancer screening or diagnosis of breast or cervical cancer. The client's record must be annotated each time a service is provided and signed or initialed by the individual who provided the service or must clearly indicate the individual who provided the service. Information contained in the record must meet the standards of care for breast and cervical cancer screening and diagnosis, and must be appropriate in quality and quantity to meet the professional standards applicable to the provider or practitioner and any additional standards for documentation set forth in this rule.

(3) The provider must have policies and procedures to ensure the maintenance of the confidentiality of medical record information. These procedures ensure that the provider may release such information in accordance with federal and state statutes, ORS 179.505, 411.320, 45 CFR 205.50.

(4) The provider must retain clinical, financial and other records described in this rule for at least four years from the date of last activity.

(5) Upon written request from the Center, the Authority, the Oregon Department of Justice Medicaid Fraud Unit, the Oregon Secretary of State, or their authorized representatives (Requestor), the provider must furnish requested documentation, without charge, immediately or within the time-frame specified in the written request. Copies of the documents may be furnished unless the originals are requested. At their discretion, representatives of the Requestor may review and copy the original documentation in the provider's place of business. Upon the written request of the provider, the Requestor may, at their sole discretion, modify or extend the time for provision of such records if, in the opinion of the Center, good cause for such extension is shown. Factors used in determining whether good cause exists include:

(a) Whether the written request was made in advance of the deadline for production;

(b) If the written request is made after the deadline for production, the amount of time elapsed since that deadline;

(c) The efforts already made to comply with the request;

(d) The reasons the deadline cannot be met;

(e) The degree of control that the provider had over its ability to produce the records prior to the deadline; and

(f) Other extenuating factors.

(6) Access to records, inclusive of medical charts and financial records, does not require authorization or release from the client if the purpose of such access is to:

(a) Perform billing review activities;

(b) Perform utilization review activities;

(c) Review quality, quantity and services provided;

(d) Facilitate payment authorization and related services;

(e) Investigate a client's fair hearing request;

(f) Facilitate investigation by the Authority;

(g) Where review of records is necessary to the operation of the program.

(7) Failure to comply with requests for documents and within the specified time-frames means that the records subject to the request may be deemed by the Authority not to exist for purposes of verifying appropriateness of payment, medical appropriateness, the quality of care, and the access to care in an audit or overpayment determination, and accordingly subjects the provider to possible denial or recovery of payments made by the Authority, or to sanctions.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042
Hist.: PH 9-2008, f. & cert. ef. 6-16-08; PH 11-2016, f. & cert. ef. 4-1-16

333-010-0165
Compliance with Federal and State Statutes

(1) Submission of a claim for medical services or supplies provided to a ScreenWise BCC client shall be deemed a representation by the medical provider to the Center of the medical provider's compliance with the applicable sections of the federal and state statutes referenced in this rule:

(a) 45 CFR Part 84 which implements Title V, Section 504 of the Rehabilitation Act of 1973;

(b) Title II and Title III of the Americans with Disabilities Act of 1991;

(c) Title VI of the Civil Rights Act of 1964;

(d) 42 CFR Part 493 Laboratory Requirements and ORS chapter 438 (Clinical Laboratories).

(2) Providers are required to comply with HIPAA regarding the confidentiality of client records.

(3) CLIA requires all entities that perform even one laboratory test, including waived tests on, "materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings" to meet certain federal requirements. If an entity performs tests for these purposes, it is considered under CLIA to be a laboratory.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042
Hist.: PH 9-2008, f. & cert. ef. 6-16-08; PH 11-2016, f. & cert. ef. 4-1-16

333-010-0170
Denial or Recovery of Reimbursement Resulting from Review or Audit

(1) The Center's staff, contractor or auditor may review a claim for assurance that the specific medical service was provided in accordance with the program's policies and rules and the generally accepted standards of a provider's scope of practice or specialty.

(2) Payment may be denied or subject to recovery if review or audit determines the service does not meet the program's policies, rules or the Standards of Care for Breast and Cervical Cancer Screening and Diagnostic Services set forth in OAR 333-010-0130.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042
Hist.: PH 9-2008, f. & cert. ef. 6-16-08

333-010-0175
Recovery of Overpayments to Providers Resulting from Review or Audit

(1) When the Center determines that an overpayment has been made to a provider, the amount of overpayment is subject to recovery:

(a) To determine the overpayment amount, the Center may use a statistically valid random sampling, with sufficient sample size allowing a confidence interval of 95 percent.

(b) After the Center determines an overpayment amount by the random sampling method set forth in section (1) of this rule, the provider may request a 100 percent audit of all billings submitted to the Center for breast and cervical cancer screening and diagnostic services provided during the period in question. If a 100 percent audit is requested:

(A) Payment and arrangement for a 100 percent audit is the responsibility of the provider requesting the audit; and

(B) The audit must be conducted by a certified public accountant that is knowledgeable about the Oregon Administrative Rules covering the payments in question, and must be conducted within 120 calendar days of the request to use such audit in lieu of the Center's random sample.

(2) The amount of the review or audit overpayment to be recovered:

(a) Will be the entire amount determined or agreed to by the Center;

(b) Is not limited to amounts determined by criminal or civil proceedings; and

(c) Will include interest to be charged at allowable state rates.

(3) The Center will deliver to the provider by registered or certified mail or in person a request for repayment of the overpayment and the documentation to support the alleged amount.

(4) If the provider disagrees with the Center's determination or the amount of overpayment the provider may appeal the decision by requesting a contested case hearing:

(a) A written request for hearing must be submitted to the Center by the provider within 30 calendar days of the date of the decision affecting the provider. The request must specify the areas of disagreement.

(b) Failure to request a hearing or administrative review in a timely manner constitutes acceptance by the provider of the amount of the overpayment.

(5) The overpayment is due and payable 30 calendar days from the date of the decision by the Center:

(a) An additional 30 day grace period may be granted the provider upon request to the Center;

(b) A request for a hearing does not change the date the repayment of the overpayment is due.

(6) The Center may extend the reimbursement period or accept an offer of repayment terms. Any change in reimbursement period or terms must be made in writing by the Center.

(7) If the provider refuses to reimburse the overpayment or does not adhere to an agreed upon payment schedule, the Center may:

(a) Recoup future provider payments up to the amount of the overpayment; or

(b) Pursue civil action to recover the overpayment.

(8) As the result of a hearing the amount of the overpayment may be reduced in part or in full.

(9) The Center may, at any time, change the amount of the overpayment upon receipt of additional information. Any changes will be verified in writing by the Center. Any monies paid to the Center that exceed an overpayment will be refunded to the provider.

(10) If a provider is terminated or sanctioned for any reason, the Center may pursue civil action to recover any amounts due and payable to ScreenWise BCC.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042
Hist.: PH 9-2008, f. & cert. ef. 6-16-08; PH 11-2016, f. & cert. ef. 4-1-16

333-010-0180
Provider Sanctions

The following are conditions that may result in the imposition of a sanction on a provider.

(1) Basis for Sanction:

(a) Conviction of a provider of a felony or misdemeanor related to a crime or violation of Title XVIII, XIX, or XX of the Social Security Act or related state laws (or entered a plea of nolo contendere);

(b) Conviction of fraud related to any federal, state, or locally financed health care program;

(c) Conviction of interference with the investigation of health care fraud;

(d) Conviction of unlawfully manufacturing, distributing, prescribing, or dispensing a controlled substance;

(e) Failure to comply with the state and federal statutory requirements set forth in OAR 333-010-0165;

(f) By actions of any state licensing authority for reasons relating to the provider's professional competence, professional conduct, or financial integrity, the provider either:

(A) Had a health care license suspended or revoked, or has otherwise lost such license; or

(B) Surrendered the license while a formal disciplinary proceeding was pending before a licensing authority.

(g) Suspension or exclusion from participation in a federal or state health care program for reasons related to professional competence, professional performance, or other reason;

(h) Improper billing practices, including billing for excessive charges or visits;

(i) Failure to furnish services as required by law or contract with the Center, if the failure has adversely affected (or has a substantial likelihood of adversely affecting) the client;

(j) Failure to supply requested information on subcontractors and suppliers of goods or services;

(k) Failure to supply requested payment information;

(l) Failure to grant access to facilities or provide records upon request of the Center or a designated Requestor;

(m) Receiving payments for services provided to persons who were not eligible;

(n) Establishing multiple claims using procedure codes that overstate or misrepresent the level, amount or type of health care provided;

(o) Failure to develop, maintain, and retain in accordance with relevant rules and standards adequate clinical or other records that document the medical appropriateness, nature, and extent of the health care provided;

(p) Failure to develop, maintain, and retain in accordance with relevant rules and standards adequate financial records that document charges incurred by a client and payments received from any source;

(q) Failure to follow generally accepted accounting principles or accounting standards or cost principles required by federal or state laws, rule, or regulation;

(r) Submission of claims or written orders contrary to generally accepted standards of medical practice;

(s) Submission of claims for services that exceed that requested or agreed to by the client or the responsible relative or guardian or requested by another medical practitioner;

(t) Breach of the terms of the medical services agreement;

(u) Failure to correct deficiencies in operations after receiving written notice of the deficiencies from the Center;

(v) Submission of any claim for payment for which payment has already been made by the Center; or

(w) Provision of or billing for services provided by ineligible or unsupervised staff.

(2) A provider who has been suspended or terminated from participation in a federal or state medical program, such as Medicare or Medicaid, or whose license to practice has been suspended or revoked by a state licensing board, shall not submit claims for payment, either personally or through claims submitted by any billing provider or other provider, for any services or supplies provided under ScreenWise BCC, except those services provided prior to the date of suspension or termination.

(3) When the provisions of section (2) of this section are violated, the Center may suspend or terminate the provider who is responsible for the violation.

(4) Provider sanctions will be imposed at the discretion of the Authority or the administrator of the office whose budget includes payment for the services involved.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042
Hist.: PH 9-2008, f. & cert. ef. 6-16-08; PH 11-2016, f. & cert. ef. 4-1-16

333-010-0185
Provider Appeals

A provider may appeal certain decisions affecting the provider made by the Center. There are two levels of appeal. Level 1 is a reconsideration on a claim. Level 2 is a contested case hearing.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042
Hist.: PH 9-2008, f. & cert. ef. 6-16-08

333-010-0190
Provider Appeals (Level 1) — Claims Reconsideration

A provider disputing the Center's claim decision may request reconsideration. The provider must submit the request in writing to the Center. The request must include the reason for the dispute, and any information pertinent to the outcome of the dispute. The Center will complete an additional review and respond back to the provider in writing. If the provider is not satisfied with the review, the provider may request a contested case hearing.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042
Hist.: PH 9-2008, f. & cert. ef. 6-16-08

333-010-0195
Provider Appeals (Level 2) — Contested Case Hearing

Contested case hearings will be held in accordance with ORS 183.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042
Hist.: PH 9-2008, f. & cert. ef. 6-16-08

333-010-0197
Presumptive Eligibility for BCCTP

(1) Any licensed health care provider who can diagnose breast or cervical cancer may presumptively enroll a client into BCCTP and refer the client to the Oregon Health Plan if she meets the presumptive eligibility criteria as described in section (2) of this rule.

(2) In order to be presumptively enrolled into BCCTP a client must meet the eligibility criteria in OAR 333-010-0110 and 410-200-0400.

Stat. Auth.: ORS 413.042, 414.540
Stats. Implemented: ORS 414.534, 414.536
Hist.: PH 1-2012, f. & cert. ef. 1-17-12; PH 20-2015(Temp), f. & cert. ef. 10-12-15 thru 4-8-16; PH 11-2016, f. & cert. ef. 4-1-16

WISEWOMAN Program

333-010-0200
Description of the WISEWOMAN Program

The WISEWOMAN (WW) Program is a federal program, administered by the Oregon Health Authority, that provides heart disease, stroke and diabetes screening support to develop and maintain healthy behaviors, and referral services in an effort to prevent cardiovascular disease to eligible women statewide. The WW Program provides these services through a contract network of qualified providers. These rules (OAR 333-010-0200 through 333-010-0290) apply only to providers who have an approved medical services agreement to provide screening and services through this program. The program is limited to a finite source of funds, which may restrict availability of services on an annual basis.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042, 431.250
Hist.: PH 1-2009, f. & cert. ef. 2-13-09; PH 27-2014, f. & cert. ef. 10-10-14

333-010-0205
Definitions

(1) "Agency number" means the administrative number assigned to the service provider by the Center for Prevention and Health Promotion (Center) for identification as a BCCP/WW provider.

(2) "Ancillary provider" means an individual or entity that has met the eligibility requirements for enrollment in the WW Program, has executed a medical services agreement with the Center, has been assigned a BCCP/WW Program agency number, and performs services beyond the scope of an enrolling provider, such as laboratory, imaging, or surgical services.

(3) "Approved medical services agreement" means the completed WW Program agreement, submitted to and approved by the Center for Prevention and Health Promotion.

(4) "Authority" means the Oregon Health Authority.

(5) "BCCP" means the Oregon Breast and Cervical Cancer Program.

(6) "Care coordination" or "case management" means that a client is provided with services, results, follow-up recommendations, and active tracking of progress towards follow-up recommendations.

(7) "Center" means the Center for Prevention and Health Promotion, within the Oregon Health Authority, Public Health Division.

(8) "CLIA" means the federal Clinical Laboratory Improvement Amendments of 1988 (P.L. 100-578, 42 U.S.C. 201 and 263a)

(9) "Client" means a woman 40 to 64 years of age who is enrolled in and receives screening or services from the WW Program.

(10) "Enrolling provider" means an individual or entity that has met the eligibility requirements for enrollment in the WW Program, has executed a medical services agreement with the Center, has been assigned a BCCP/WW Program agency number, and provides screening, services, or care coordination for WW Program clients.

(11) "FPL" means the federal poverty level guidelines established each year by the United States Department of Health and Human Services, used to determine eligibility for the WW Program and other federally funded programs.

(12) "HIPAA" means the Health Insurance Portability and Accountability Act.

(13) "Site number" means the administrative number assigned to the family planning service provider by the Center for identification of the geographic location of each WW provider.

(14) "WISEWOMAN Program" or "WW Program" means the program that provides statewide heart disease, stroke and diabetes screening and services to eligible clients, that is administered by the Center.

(15) "WW Program provider network" means the combination of all contracted WW Program providers, including enrolling and ancillary providers.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042, 431.250
Hist.: PH 1-2009, f. & cert. ef. 2-13-09; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 11-2011, f. & cert. ef. 10-27-11; PH 12-2014(Temp), f. & cert. ef. 4-18-14 thru 10-15-14; PH 27-2014, f. & cert. ef. 10-10-14

333-010-0210
Client Eligibility

A person must meet the following WW Program eligibility criteria in order to be enrolled in the WW Program:

(1) Be a woman 40 to 64 years of age; and

(2) Be enrolled in the BCCP program.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042, 431.250
Hist.: PH 1-2009, f. & cert. ef. 2-13-09; PH 27-2014, f. & cert. ef. 10-10-14

333-010-0215
Client Enrollment

(1) A person is determined eligible for the WW Program after submitting a completed and signed BCCP/WW Program enrollment form.

(2) Eligibility is effective for one year.

(3) A person who enrolled in the WW Program but who is later found to be ineligible shall be notified by the Center or her enrolling provider in writing of such disenrollment and may be responsible for the payment of services received from her provider.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042, 431.250
Hist.: PH 1-2009, f. & cert. ef. 2-13-09; PH 12-2014(Temp), f. & cert. ef. 4-18-14 thru 10-15-14; PH 27-2014, f. & cert. ef. 10-10-14

333-010-0220
Provider Enrollment

(1) An individual or organization that wishes to be an enrolling provider or an ancillary provider with the WW Program shall apply to the Center on a form prescribed by the Center.

(2) In order to be eligible for enrollment, an individual or organization shall:

(a) Have a valid Oregon business license if such a license is a requirement of the state, federal, county or city government to operate a business or to provide services; and

(b) Meet applicable licensing or regulatory requirements set forth by federal and state statutes, regulations, and rules to be enrolled and to bill as a health care provider.

(3) A laboratory or any other entity that does laboratory tests must provide evidence that it is CLIA certified in order to be a provider or an ancillary provider.

(4) An individual or organization that is currently subject to sanctions by the Authority or the federal government is not eligible for enrollment.

(5) Upon receipt of an application the Center shall verify the information and determine if the individual or organization is eligible to be an enrolling or ancillary provider.

(6) If the Center approves an application, an individual or organization shall:

(a) Sign a medical services agreement that requires the provider to comply with these rules; and

(b) Be issued a BCCP/WW Program agency number.

(7) An enrolling or ancillary provider may not offer services to a client prior to receiving information from a Center WW Program representative about administering the WW Program.

(8) An enrolling provider or ancillary provider shall notify the Center in writing within 30 days of the change if it changes its address, business affiliation, licensure, ownership, certification, billing agents, registered name, or Federal Tax Identification Number (TIN). Changes in business affiliation, ownership, registered name, and TIN may require the submission of a new application. Payments made to an enrolling provider or an ancillary provider who has not furnished such notification may be recovered by the Center.

(9) An enrolling provider or an ancillary provider shall notify the Center in writing of a bankruptcy proceedings within 15 days.

(10) An individual or organization outside the state of Oregon may be eligible for enrollment if the individual or organization:

(a) Is appropriately licensed or certified in its state; and

(b) Is located in a state contiguous to Oregon, and is within 75 miles of the Oregon border.

(11) An enrolling provider or an ancillary provider may terminate enrollment at any time by sending a written termination notice to the Center, via certified mail, return receipt requested. The notice shall specify the agency number to be terminated and the effective date of termination. Termination of a provider enrollment does not terminate any obligations of the provider for services provided to a client prior to the effective date of the termination.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042, 431.250
Hist.: PH 1-2009, f. & cert. ef. 2-13-09; PH 12-2014(Temp), f. & cert. ef. 4-18-14 thru 10-15-14; PH 27-2014, f. & cert. ef. 10-10-14

333-010-0225
Standards of Care for WISEWOMAN Program Screening and Services

An enrolling provider shall:

(1) Inform each client, verbally and with supplementary written materials in a language the client understands, without bias or coercion, that the client's decision to participate in the WW Program screening and services is voluntary;

(2) Inform clients of the scope of services available through the program;

(3) Obtain informed consent from each client receiving WW screening and services;

(4) Provide services within the scope by the WW Program without cost to eligible clients;

(5) Offer clients with abnormal or ALERT values additional medical support even though treatment is not covered by the WW Program. The WW Program Manual, October 2014, incorporated by reference, includes a complete list of abnormal and ALERT values and medical support services approved for reimbursement.

(6) Provide information to clients in need of additional medical services beyond the scope of the WW Program provider network with information about available local resources;

(7) Provide all services to eligible clients without regard to marital status, race, parity, disability, or sexual orientation;

(8) Take a health history for all clients, including health risk facts and personal and family medical history as it pertains to heart disease, stroke and diabetes screening;

(9) Provide follow-up recommendations for each client;

(10) Provide care coordination to ensure that appropriate follow-up screening, diagnostic testing and care is provided, including:

(a) An explanation of the results of the screening and laboratory tests; and

(b) The opportunity for questions concerning procedures, methods and results.

(11) Submit enrollment and eligibility information immediately or within five calendar days from the date of enrollment to the Center;

(12) Submit all client data to the WW Program, including required information about client history and screening results;

(13) Provide services to each client in a manner that respects the privacy and dignity of the individual;

(14) Inform clients that services and medical records will be kept confidential and that records cannot be released without written client consent, except as required by law, or otherwise permitted by HIPAA;

(15) Provide all services, support and other assistance in a manner that is responsive to the beliefs, interpersonal styles, attitudes, language, and behaviors of the clients receiving services, and in a manner that has the greatest likelihood of ensuring a client's maximum participation in the program;

(16) Notify clients of the availability of interpretation services in accordance with the Civil Rights Act of 1964, and make interpretation services available to all clients needing or requesting such assistance at no cost to the client;

(a) A provider shall ensure that all persons providing interpretation services adhere to confidentiality guidelines;

(b) A provider must assure the competency of language assistance provided to clients by interpreters and bilingual staff. Family and friends should not be used to provide interpretation services, unless requested by the client;

(17) Make available easily understood client related materials and post signage in the languages of groups commonly encountered in the service area;

(18) Ensure that all print, electronic, and audiovisual materials are appropriate according to the client's language and literacy level, including accommodating a client's request for alternate formats; and

(19) Use only CLIA certified laboratories for all tests, whether done at the clinic site or by an outside clinic.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042, 431.250
Hist.: PH 1-2009, f. & cert. ef. 2-13-09; PH 12-2014(Temp), f. & cert. ef. 4-18-14 thru 10-15-14; PH 27-2014, f. & cert. ef. 10-10-14

333-010-0230
Submission of Information by Ancillary Providers

Ancillary providers shall provide results of services to enrolled providers within 14 calendar days from the date of service.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042, 431.150
Hist.: PH 1-2009, f. & cert. ef. 2-13-09

333-010-0235
Covered Services

The WW Program Manual, October 2014, incorporated by reference, includes a complete list of covered services.

[Publications: Publications referenced are available from the Oregon WW Program].

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042, 431.250
Hist.: PH 1-2009, f. & cert. ef. 2-13-09; PH 12-2014(Temp), f. & cert. ef. 4-18-14 thru 10-15-14; PH 27-2014, f. & cert. ef. 10-10-14

333-010-0240
Excluded Services

(1) Services and laboratory tests not directly related to heart disease, stroke and diabetes, or not included in the ICD-10 and CPT code lists provided in the WW Program Manual are not covered by the WW Program.

(2) No payment will be made for any expense incurred for any other medical service or laboratory tests whose primary purpose is for a reason other than heart disease, stroke, or diabetes screening and prevention.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042, 431.250
Hist.: PH 1-2009, f. & cert. ef. 2-13-09; PH 17-2015, f. 9-30-15, cert. ef. 10-1-15

333-010-0245
Claims and Billing

(1) Only an enrolling or ancillary provider providing WW Program covered services pursuant to a fully executed medical ser-

vices agreement, and who has been assigned an agency number may submit claims for payment to the Center for providing WW Program covered services.

(2) An enrolling or ancillary provider shall, as applicable:

(a) Submit claim information in the manner specified by the WW Program;

(b) Include a primary diagnosis code on all claims;

(c) Code all claims with the most current and appropriate International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) diagnosis codes and the most appropriate Current Procedural Terminology (CPT) codes as noted in the WW Program Manual;

(d) Submit to the Center all claims for services within 12 months of the date of service;

(e) Submit a billing error edit correction, or refund the amount of the overpayment, on any claim where a provider identifies an overpayment made by the Center;

(f) Make all reasonable efforts to ensure that the WW Program is the payor of last resort with the exception of clinics or offices operated by the Indian Health Service (IHS) or individual American Indian tribes. For the purposes of this rule "reasonable efforts" include:

(A) Determining the existence of insurance coverage or other resource by asking the client; and

(B) Except in the case of the underinsured, billing any known insurer in compliance with that insurer's billing and authorization requirements.

(g) Submit to the Center a billing error edit correction if it receives a third party payment and refund to the Center the amount received from the other source within 30 days of the date the payment is received.

(3) The Center may not pay a claim older than 12 months, except as provided for in section (4) of this rule. An enrolling or ancillary provider that has a claim rejected because of an error must resolve the error within 12 months of the date of service.

(4) If the Center makes an error that makes it impossible for an enrolling or ancillary provider to bill within 12 months of the date of service, the enrolling or ancillary provider shall notify the Center of the alleged error and submit the claim to the Center. The Center shall confirm that it made an error prior to payment being made.

(5) The Center may not pay a claim that includes a primary diagnosis code that is not in the WW Program Manual.

(6) An enrolling or ancillary provider with the WW Program may not seek payment from a client, or from a financially responsible relative or representative of that client for any services covered by the WW Program.

(7) An enrolling or ancillary provider may bill a client for services that are not covered by the WW Program. However, the provider must inform the client in advance of receiving the specific service that it is not covered, the estimated cost of the service, and that the client or client's representative is financially responsible for payment for the specific service. Providers must document in writing that the client was provided this information and the client knowingly and voluntarily agreed to be responsible for payment. The client or client's representative must sign the documentation.

(8) Except for services performed by a CLIA certified laboratory outside of the clinic, all billings by an enrolling provider must be for services provided within the provider's licensure or certification.

(9) A provider who has been suspended or terminated from participation in a federal or state medical program, such as Medicare or Medicaid, or whose license to practice has been suspended or revoked by a state licensing board, may not submit claims for payment, either personally or through claims submitted by any billing provider or other provider, for any services or supplies provided under the WW Program, except those services provided prior to the date of suspension or termination.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042, 431.250
Hist.: PH 1-2009, f. & cert. ef. 2-13-09; PH 12-2014(Temp), f. & cert. ef. 4-18-14 thru 10-15-14; PH 27-2014, f. & cert. ef. 10-10-14; PH 17-2015, f. 9-30-15, cert. ef. 10-1-15

333-010-0250
Payment

(1) The Center shall only pay claims submitted by an enrolling or ancillary provider for a client.

(2) The Center shall reimburse an enrolling or ancillary provider an amount up to the Medicare reimbursement rate for the Portland metropolitan area for WW Program approved CPT codes, on a fee-for-service basis.

(3) A federally qualified health center or rural health center shall not be paid at their Prospective Payment System (PPS) rate, but will be paid at the reimbursement rate described in section (2) of this rule.

(4) The Center payments for WW Program provider services, unless in error, constitute payment in full.

(5) The Center may not make payment on claims that have been assigned, sold, or otherwise transferred, or on which a provider of billing services receives a percentage of the amount billed or payment authorized, including claims that have been transferred to a collection agency or individual who advances money to a provider for accounts receivable.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042, 431.250
Hist.: PH 1-2009, f. & cert. ef. 2-13-09; PH 12-2014(Temp), f. & cert. ef. 4-18-14 thru 10-15-14; PH 27-2014, f. & cert. ef. 10-10-14

333-010-0255
Denial or Recovery of Reimbursement Resulting from Review or Audit

(1) The Center's staff, contractor or auditor may review a claim for assurance that the specific medical service was provided in accordance with the WW Program's rules or the generally accepted standards of a provider's scope of practice or specialty.

(2) Payment may be denied or subject to recovery if a review or audit determines the service was not provided in accordance with the WW Program's rules or the generally accepted standards of a provider's scope of practice or specialty.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042, 431.250
Hist.: PH 1-2009, f. & cert. ef. 2-13-09

333-010-0260
Recovery of Overpayments to Providers Resulting from Review or Audit

(1) If the Center determines that an overpayment has been made to an enrolling or ancillary provider, the Center shall seek to recover the amount of overpayment. The Center may use a statistically valid random sampling, with sufficient sample size allowing a confidence interval of 95 percent to determine if an overpayment has been made.

(2) The amount of the review or audit overpayment to be recovered:

(a) Will be the entire amount determined by the Center;

(b) Is not limited to amounts determined by criminal or civil proceedings; and

(c) Will include interest to be charged at allowable state rates.

(3) The Center shall provide an enrolling provider in writing, by registered or certified mail or in person, notice of an overpayment and a request for repayment of the overpayment, along with documentation to support the amount owed.

(4) An enrolling or ancillary provider shall pay the overpayment amount within 30 calendar days from the date the Center mails the notice of overpayment. A request for a hearing does not change the date the repayment of the overpayment is due.

(5) The Center may extend the 30-day repayment period or accept an offer of repayment terms. Any change in reimbursement period or terms must be documented in writing by the Center.

(6) If the provider disagrees with the Center's determination or the amount of overpayment the provider may:

(a) Appeal the decision by requesting a contested case hearing; or

(b) Request a 100 percent audit of all billings submitted to the Center for heart disease, stroke, and diabetes screenings and services provided during the period in question.

(7) A written request for hearing must be submitted to the Center by the provider within 30 calendar days of the date of the decision affecting the provider. The request must specify the areas of disagreement. Failure to request a hearing or administrative review in a timely manner constitutes acceptance by the provider of the amount of the overpayment.

(8) If a 100 percent audit is requested:

(a) An enrolling or ancillary provider is responsible for arranging and paying for the audit; and

(b) The audit must be conducted by a certified public accountant that is knowledgeable about the Oregon Administrative Rules covering the payments in question, and must be conducted within 120 calendar days of the request to use such an audit in lieu of the Center's random sample.

(9) If the provider refuses to reimburse the overpayment or does not adhere to an agreed upon payment schedule, the Center may:

(a) Recoup future provider payments up to the amount of the overpayment; or

(b) Pursue civil action to recover the overpayment.

(10) The Center may, at any time, change the amount of the overpayment upon receipt of additional information from an enrolling provider. If the Center changes an overpayment amount it will provide written notice to the enrolling provider. Any monies paid to the Center that exceed an overpayment will be refunded to the provider.

(11) The Center may pursue civil action to recover any amounts due and payable to the WW Program.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042, 431.250
Hist.: PH 1-2009, f. & cert. ef. 2-13-09; PH 12-2014(Temp), f. & cert. ef. 4-18-14 thru 10-15-14; PH 27-2014, f. & cert. ef. 10-10-14

333-010-0265
Client Data Submission

(1) In addition to submitting the claim information required in OAR 333-010-0225, in order to receive payment an enrolling provider shall submit client data to the Center. The data shall be used by the WW Program to monitor the delivery of services and clinical outcomes of the program.

(2) An enrolling provider shall submit client data to the Center, in a manner specified by the Center, on the Enrollment Form, Assessment Form and the Screening Form, included in the WW Program Manual within 90 days from the date of enrollment. In the event that a client requires additional diagnostic procedures and the information is not available within 90 days from the date of enrollment, the data shall be submitted to the Center immediately once it is received by the provider.

(3) An ancillary provider shall report data to an enrolling provider and is not required to provide data to the Center directly.

(4) An enrolling provider may update or correct client data not related to payment of the claim at any time after the date of service.

(5) If an enrolling provider or the Center terminates the medical services agreement, data are still required to be submitted for each client that was provided services while the agreement was in effect.

[Publications: Publications referenced are available from the agency]
Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042, 431.250
Hist.: PH 1-2009, f. & cert. ef. 2-13-09; PH 12-2014(Temp), f. & cert. ef. 4-18-14 thru 10-15-14; PH 27-2014, f. & cert. ef. 10-10-14

333-010-0270
Requirements for Financial, Clinical and Other Records

(1) An enrolling provider shall:

(a) Develop and maintain adequate financial and clinical records and other documentation that supports the services for which payment has been requested;

(b) Ensure that all medical records document the service provided, primary diagnosis code for the services, the date on which the service was provided, and the individual who provided the services;

(c) Ensure that patient account and financial records include documentation of charges, identify other payment resources pursued, indicate the date and amount of all debit or credit billing actions, and support the appropriateness of the amount billed and paid in accurate and sufficient detail to substantiate the data reported;

(d) Ensure that clinical records sufficiently document that the client's services were primarily for heart disease, stroke and diabetes;

(e) Ensure that each time a service is provided to a client, the client's record is signed or initialed by the individual who provided the service or otherwise clearly indicates who provided the service;

(f) Ensure that the information contained in the record reflects that the standard of care for heart disease, stroke and diabetes screening and services were met;

(g) Have policies and procedures to ensure the confidentiality of medical records and that address the circumstances under which information may be released in accordance with federal and state law; and

(h) Retain client enrollment forms, clinical, financial and other records described in this rule for at least four years from the date of last activity.

(2) The Center, the Authority, the Oregon Department of Justice Medicaid Fraud Unit, the Oregon Secretary of State, or their authorized representatives (requestor) may request, in writing, any records related to an enrolling or ancillary provider's participation in the WW Program, including client medical records. An enrolling or ancillary provider shall furnish requested records, without charge, immediately or within the time frame specified in the written request. Copies of the documents may be furnished unless the originals are requested. At the requestor's discretion, representatives of the requestor may review and copy the original documentation in the provider's place of business. Upon the written request of the provider, the requestor may, at its sole discretion, modify or extend the time for provision of such records for good cause shown.

(3) Failure to comply with requests for documents within the specified time frames means that the records subject to the request may be deemed by the Authority not to exist for purposes of verifying appropriateness of payment, medical appropriateness, the quality of care, and the access to care in an audit or overpayment determination, and accordingly subjects the provider to possible denial or recovery of payments made by the Authority, or to sanctions.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042, 431.250
Hist.: PH 1-2009, f. & cert. ef. 2-13-09; PH 12-2014(Temp), f. & cert. ef. 4-18-14 thru 10-15-14; PH 27-2014, f. & cert. ef. 10-10-14

333-010-0275
Compliance with Federal and State Statutes

(1) Submission of a claim for medical services or supplies provided to a client shall be deemed a representation by the enrolling or ancillary provider to the Center of the provider's compliance with the applicable sections of the following federal and state statutes:

(a) 45 CFR Part 84 which implements Title V, Section 504 of the Rehabilitation Act of 1973;

(b) Title II and Title III of the Americans with Disabilities Act of 1991;

(c) Title VI of the Civil Rights Act of 1964; and

(d) 42 CFR Part 493 Laboratory Requirements and ORS Chapter 438 (Clinical Laboratories).

(2) Enrolling and ancillary providers are required to comply with HIPAA regarding the confidentiality of client records.

(3) A provider that performs even one laboratory test, including waived tests on "materials derived from the human body for the purpose of providing information for the diagnosis, preven-

tion or treatment of any disease or impairment of, or the assessment of the health of human beings" is considered a laboratory under CLIA and therefore CLIA certification may be required.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042, 431.250
Hist.: PH 1-2009, f. & cert. ef. 2-13-09; PH 12-2014(Temp), f. & cert. ef. 4-18-14 thru 10-15-14; PH 27-2014, f. & cert. ef. 10-10-14

333-010-0280
Provider Sanctions

(1) The Center may sanction an enrolling provider if the provider:

(a) Is convicted of a felony or misdemeanor related to a crime or violation of Title XVIII, XIX, or XX of the Social Security Act or related state laws (or entered a plea of nolo contendere);

(b) Is convicted of fraud related to any federal, state, or locally financed health care program;

(c) Is convicted of interference with the investigation of health care fraud;

(d) Is convicted of unlawfully manufacturing, distributing, prescribing, or dispensing a controlled substance;

(e) Fails to comply with the state and federal statutory requirements set forth in OAR 333-010-0275;

(f) By actions of any state licensing authority for reasons relating to the provider's professional competence, professional conduct, or financial integrity:

(A) Has a health care license suspended or revoked, or has otherwise lost such license; or

(B) Surrenders a health care license during a pending formal disciplinary proceeding;

(g) Is suspended or excluded from participation in a federal or state health care program for reasons related to professional competence, professional performance, or other reason;

(h) Engages in improper billing practices, including:

(A) Billing for excessive charges or visits;

(B) Submitting a false claim for payment;

(C) Altering a claim in such a way as to result in a payment for a service that has already been paid; or

(D) Making a claim upon which payment has been made by another source unless the amount paid is clearly entered on the claim form;

(i) Fails to furnish services as required by law or contract with the Center, if the failure has adversely affected (or has a substantial likelihood of adversely affecting) the client;

(j) Fails to supply requested information on subcontractors and suppliers of goods or services;

(k) Fails to supply requested payment information;

(l) Fails to grant access to facilities or provide records upon request of the Center or a designated requestor;

(m) Receives payments for services provided to persons who were not eligible;

(n) Establishes multiple claims using procedure codes that overstate or misrepresent the level, amount or type of health care provided;

(o) Fails to develop, maintain, and retain, in accordance with relevant rules and standards adequate clinical or other records that document the medical appropriateness, nature, and extent of the health care provided;

(p) Fails to develop, maintain, and retain, in accordance with relevant rules and standards, adequate financial records that document charges incurred by a client and payments received from any source;

(q) Fails to follow generally accepted accounting principles or accounting standards or cost principles required by federal or state laws, rules, or regulation;

(r) Submits claims for services provided that were contrary to generally accepted standards of medical practice;

(s) Submits claims for services that exceed that requested or agreed to by the client or the responsible relative or guardian or requested by another medical practitioner;

(t) Breaches the terms of the medical services agreement;

(u) Fails to correct deficiencies in operations after receiving written notice of the deficiencies from the Center;

(v) Fails to submit a billing error edit correction within 30 days of receipt of the third party payment or to refund the appropriate amount within this time frame;

(w) Provides or bills for services provided by ineligible or unsupervised staff;

(x) Submits claims for payment, either personally or through claims submitted by any billing provider or other provider, for any services or supplies provided under the WW Program for services provided after being suspended or terminated from participation in a federal or state medical program, such as Medicare or Medicaid, or after his or her license to practice has been suspended or revoked by a state licensing board;

(y) Fails to notify the Center of a change of TIN within 30 days; or

(z) Fails to respond to a request for records under OAR 333-010-0270.

(2) Sanctions may include:

(a) Termination from participation in the WW Program;

(b) Suspension from participation in the WW Program for a specified length of time, or until specified conditions for reinstatement are met and approved by the Center;

(c) Withholding payments to an enrolling or ancillary provider;

(d) A requirement to attend provider education sessions at the expense of the sanctioned enrolling or ancillary provider;

(e) A requirement that payment for certain services are made only after the Center has reviewed documentation supporting the services;

(f) The recovery of investigative and legal costs;

(g) Reduction of any amount otherwise due the enrolling or ancillary provider; and the reduction may be up to three times the amount a provider sought to collect from a client;

(h) Any other sanction reasonably designed to remedy or compel future compliances with federal, state or Center regulations.

(3) An enrolling or ancillary provider who has been the subject of repeat sanctions regarding improper billing practices may be liable to the Center for up to triple the amount of the established overpayment received as a result of such violation.

(4) When an enrolling or ancillary provider fails to meet one or more of the requirements identified in this rule the Center, at its sole discretion, may immediately suspend the provider's BCCP/WW Program assigned billing number to prevent public harm or inappropriate expenditure of public funds.

(a) An enrolling or ancillary provider subject to immediate suspension is entitled to a contested case hearing as outlined in OAR 333-010-0290 to determine whether the provider's BCCP/WW Program assigned number will be revoked.

(b) The notice requirements described in section (5) of this rule does not preclude immediate suspension at the Center's sole discretion to prevent public harm or inappropriate expenditure of public funds. Suspension may be invoked immediately while the notice and contested case hearing rights are exercised.

(5) If the Center decides to sanction an enrolling or ancillary provider, the Center shall notify the provider by certified mail or personal delivery service of the intent to sanction. The notice of immediate or proposed sanction will identify:

(a) The factual basis used to determine the alleged deficiencies;

(b) Explanation of actions expected of the provider;

(c) Explanation of subsequent actions the Center intends to take;

(d) The provider's right to dispute the Center's allegations, and submit evidence to support the provider's position; and

(e) The provider's right to appeal the Center's proposed actions pursuant to OAR 333-010-0285 through 333-010-0290.

(6) If the Center makes a final decision to sanction an enrolling or ancillary provider, the Center shall notify the provider in writing at least 15 days before the effective date of action, except

in the case of immediate suspension to avoid public harm or inappropriate expenditure of funds.

(7) An enrolling or ancillary provider must appeal an immediate or proposed sanction separately from any appeal of audit findings and overpayments.

Stat. Auth.: ORS 413.042

Stats. Implemented: ORS 413.042, 431.250

Hist.: PH 1-2009, f. & cert. ef. 2-13-09; PH 12-2014(Temp), f. & cert. ef. 4-18-14 thru 10-15-14; PH 27-2014, f. & cert. ef. 10-10-14

333-010-0285
Provider Appeals (Level 1) — Claims Reconsideration

An enrolling or ancillary provider disputing a claim or sanction decision by the Center may request reconsideration. The provider must submit the request for reconsideration in writing to the Center. The request must include the reason for the dispute, and any information pertinent to the outcome of the dispute. The Center will complete an additional review and respond back to the provider in writing. If the provider is not satisfied with the review, the provider may request a contested case hearing.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042 & 431.250
Hist.: PH 1-2009, f. & cert. ef. 2-13-09; PH 12-2014(Temp), f. & cert. ef. 4-18-14 thru 10-15-14; PH 27-2014, f. & cert. ef. 10-10-14

333-010-0290
Provider Appeals (Level 2) — Contested Case Hearing

An enrolling or ancillary provider may request a contested case hearing within 30 calendar days of the date of a decision affecting the provider. Contested case hearings will be held in accordance with ORS Chapter 183 and the Attorney General's model rules, OAR 137-003-0501 through 137-003-0700.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 413.042 & 431.250
Hist.: PH 1-2009, f. & cert. ef. 2-13-09; PH 12-2014(Temp), f. & cert. ef. 4-18-14 thru 10-15-14; PH 27-2014, f. & cert. ef. 10-10-14

Tobacco Prevention and Education Program

333-010-0300
Definitions

(1) "Centers for Disease Control and Prevention" means the federal agency of the Department of Health and Human Services responsible for promoting health and quality of life through the prevention and control of disease, injury and disability.

(2) "Conference of Local Health Officials" means All local health officers and public health administrators, appointed pursuant to ORS 431.418 and such other local health personnel as may be included by the rules of the conference.

(3) "Contractor" means an independent contractor or corporation that performs a service(s) for an Agency, when an Agency has no right to and does not control the means and manner of performing the contract, except as to the delivery schedule, determining compliance with the Statement of Work, and accepting or rejecting the deliverables or results required under the contract.

(4) "Director" means the Assistant Director of the Oregon Public Health Division or his/her designee.

(5) "Environmental Tobacco Smoke" means the mixture of smoke from the burning end of a cigarette, pipe, or cigar, and the smoke exhaled from the lungs of smokers. It is also referred to as "second-hand smoke."

(6) "Governor's Tobacco Reduction Advisory Committee" has the meaning given that term in Executive Order 97-10.

(7) "Local Coalition" means an organization of individuals representing diverse groups, factions, or constituencies from a community who agree to work together to achieve the common goal of reducing tobacco use and its impact on the health and economic well-being of the community.

(8) "Local Health Department" means the county or district public health agency or the provider of public health services authorized by the county or district.

(9) "Local Lead Agency" means a local health department, local governmental, or not-for-profit health-related organization designated by a local health department within a county, that submits a proposal to the Oregon Public Health Division for a grant under the "Local Coalition and Community-Based Programs" section of these rules.

(10) "Proposal" means a written response submitted in application to the Oregon Public Health Division's Tobacco Prevention and Education Program Request for Proposals.

(11) "Request for Proposals (RFP)" means a written document issued by the Public Health Division calling for proposals for ser-

vices or activities to be performed by a grantee or contractor under the terms of these rules.

(12) "School district" means a taxing disctrict within the state that provides public elementary and secondary education K-12, or an education service district (ESD), or a state operated school, or any legally constituted combination of such entities.

(13) "Superintendent" means the State Superintendent of Public Instruction of the Department of Education or his or her designee.

(14) "Tobacco-Free Coalition of Oregon" (TOFCO) means the broad-based alliance of people and organizations that created the Oregon Statewide Tobacco Prevention Plan, and whose goal is to reduce tobacco use and decrease the human and economic costs of tobacco use among Oregonians.

Stat. Auth.: ORS 431.834
Stats. Implemented: ORS 431.831 - 431.836
Hist.: HD 11-1997, f. & cert. ef. 9-12-97

333-010-0310
Purpose and Intent

The purpose of this rule is to implement Chapter 2 of Oregon Laws of 1997, approved by the people as Ballot Measure 44, at the November 5, 1996 General Election, which:

(1) Authorizes 5.77% of the money received by the Department of Revenue under the Tobacco Products Tax Act to be credited to the Tobacco Use Reduction Account; and

(2) Requires the Public Health Division to adopt rules for awarding grants to programs for educating the public on the risk of tobacco use, including but not limited to, educating children on the health hazards and consequences of tobacco use, and promoting enrollment in smoking cessation programs.

Stat. Auth.: ORS 431.834
Stats. Implemented: ORS 431.831 - 431.836
Hist.: HD 11-1997, f. & cert. ef. 9-12-97

333-010-0320
Framework for Grant Awards

(1) These rules describe provisions for awarding grants and contracts for local, regional, and statewide activities in four program areas. The program areas are:

(a) Local Coalitions and Community-Based Programs;

(b) School-Based Prevention Programs;

(c) Statewide Public Awareness and Education Programs; and

(d) Statewide and Regional Special Programs.

(2) Proposals shall support the following goals of Oregon's Statewide Tobacco Prevention Plan:

(a) Decrease tobacco use by youth;

(b) Treat tobacco dependence;

(c) Protect children from exposure to tobacco; and

(d) Protect workers and the public from second-hand smoke.

(3) Proposals must contain a statement disclosing any and all direct and indirect organizational or business relationships between the applicant or its subcontractors, including its owners, parent company or subsidiaries, and companies involved in any way in the production, processing, distribution, promotion, sale or use of tobacco.

Stat. Auth.: ORS 431.834
Stats. Implemented: ORS 431.831 - 431.836
Hist.: HD 11-1997, f. & cert. ef. 9-12-97

333-010-0330
Local Coalitions and Community-Based Programs

The goal of the Oregon Public Health Division under this section is to fulfill the purpose and intent of Chapter 2 of Oregon Laws of 1997, approved by the people as Ballot Measure 44, at the November 5, 1996 General Election, by having a tobacco prevention and education program serving every county.

(1) Eligibility for Grant Awards:

(a) The Oregon Public Health Division shall accept for funding a maximum of one proposal per county or consortium of counties;

(b) For the purposes of this program the local health department shall be considered the Local Lead Agency in each county for submitting a proposal, except as provided under (c) or (d) below;

(c) Any local health department that elects not to submit a proposal under this section may form a consortium with one or more health department(s) and jointly submit one proposal;

(d) Any local health department electing not to submit a proposal by itself or in consortium with another county(s) shall designate an appropriate local governmental or not-for-profit health-related organization and shall send a letter to the Director identifying such organizations as the Local Lead Agency for that county;

(e) Any Local Lead Agency designated under subsection (d) above shall be eligible to submit a proposal for that county directly to the Oregon Public Health Division;

(f) A local health department may revoke the designated Local Lead Agency under subsection (d) upon mutual agreement of both the local health department and the Local Lead Agency. The health department and the Local Lead Agency shall jointly notify the Director of the agreement. If the local health department and the Local Lead Agency do not reach an agreement on the revocation of the designation under subsection (d) above the Director may determine whether the revocation is in the best interest of the public health.

(2) Development of the Request for Proposals (RFP) Document. The RFP document for local coalitions and community-based programs shall be developed by the Director in consultation with representatives from appropriate groups, including but not limited to the Governor's Tobacco Reduction Advisory Committee, the Tobacco-Free Coalition of Oregon, the Conference of Local Health Officials, the Oregon Department of Education, the Oregon Office on Alcohol and Drug Abuse Programs, and the Centers for Disease Control and Prevention.

(3) Grant Application Process. Proposals shall be submitted in a format and within a time frame prescribed by the Director, and shall include, but are not limited to:

(a) A list of local coalition members and a description of their roles;

(b) Specific local program goals, objectives, activities and evaluation plans; and

(c) A detailed budget for use of grant funds.

(4) Review of Proposals:

(a) Proposals shall be evaluated by a review committee appointed by the Director. The Director has the authority to include on the review committee persons not employed by the Oregon Public Health Division, including experts in the field of tobacco use reduction;

(b) The Director may reject any application not in compliance with the RFP's instructions;

(c) Proposals shall be evaluated according to the criteria described in the RFP;

(d) The Director may request additional information from an applicant prior to and during the review of a proposal.

(5) Awarding of Funds:

(a) Funds shall be awarded based on the quality of proposals in addressing the RFP requirements;

(b) The Director may negotiate modifications of the applicant's proposal on the basis of availability of funds, and merit of application. In these cases funds shall be awarded only after such modifications have been agreed upon by both the Director and the Local Lead Agency;

(c) The Director shall determine final funding levels.

Stat. Auth.: ORS 431.834
Stats. Implemented: ORS 431.831 - 431.836
Hist.: HD 11-1997, f. & cert. ef. 9-12-97

333-010-0350
Statewide Public Awareness and Education Programs

The goal of the Oregon Public Health Division under this section is to fulfill the purpose and intent of Chapter 2 of Oregon Laws of 1997, approved by the people as Ballot Measure 44, at the

November 5, 1996 General Election, by developing a statewide tobacco public awareness and education program.

(1) Eligibility for Grant Awards. Under this section the Director may award one or more contracts to providers of public relations, public awareness, public education or communications services.

(2) Development of the Request for Proposals (RFP) Document. The RFP for Statewide Public Awareness and Education Programs shall be developed by the Director in consultation with representatives from appropriate groups, which may include, but are not be limited to, the Governor's Tobacco Reduction Advisory Committee, the Tobacco-Free Coalition of Oregon, the Oregon Department of Education, the Office of Alcohol and Drug Abuse Programs, and the Centers for Disease Control and Prevention.

(3) Grant Application Process:

(a) The Director may award one or more contracts using the RFP process provided for in OAR, chapter 125;

(b) Proposals responding to the RFP must contain, but shall not be limited to:

(A) A plan to develop and utilize educational messages about the dangers of tobacco use, the harm of second-hand smoke and the benefits of cessation;

(B) Detailed budget for proposed use of funds;

(C) Plans for evaluating effectiveness of contract services.

(c) The RFP shall include but is not limited to the following elements:

(A) Minimum standards and qualifications required from the contractor(s) to be eligible to provide the service;

(B) The evaluation process and criteria to be used to select the contractor(s), including weights or points applicable to each criterion;

(C) The manner in which the proposers cost and pricing proposal will be evaluated;

(D) A requirement to provide a list of similar services completed, with references addressing past performance;

(E) The closing date and time and place of delivery for the proposal;

(F) Reservation about the right to seek clarification of each proposal, and the right to negotiate a final contract within the scope of the work described in the RFP;

(G) Reservation of the right to reject any or all proposals, if rejection would be in the public interest;

(H) Reservation of the right to cancel the solicitation, if such cancellation would be in the public interest;

(I) A sample of the standard contract provisions;

(J) The possibility of pre-proposal meetings and post-proposal interviews and presentations; and

(K) Any other information appropriate to, evaluate, rank, and select the best proposal(s).

(4) Review of Proposals:

(a) Proposals shall be evaluated by a review committee appointed by the Director. The Director may include on the review committee persons not employed by the Oregon Public Health Division, including experts in the field of tobacco use reduction;

(b) The Director may reject any application not in compliance with the RFP's instructions;

(c) Evaluation criteria may include, but not be limited to, the following:

(A) Availability and capability to perform the work;

(B) Staff experience on comparable projects and services;

(C) Demonstrated ability to complete similar projects and services on time and within budget;

(D) References from clients, public and private;

(E) Performance history in meeting deadlines, submitting accurate estimates, producing quality work, and meeting financial obligations;

(F) Status and quality of any required licensing or certification;

(G) Knowledge and understanding of the required services as shown through the proposed approach to staffing and scheduling needs;

(H) Fees or costs;

(I) Results from oral interviews, if conducted;

(J) Availability of any required specific resources or equipment;

(K) Geographic proximity to the project or the area where the services will be performed;

(L) Identity of proposed subcontractors and their qualifications; and

(M) Any other criteria deemed relevant to the provision of services.

(5) Awarding of Funds:

(a) Ranking of proposals shall be based on all information obtained by the reviewers during the evaluation process. Budget shall be considered, but shall not necessarily govern selection of the contractor(s);

(b) Contracts entered into under the formal selection procedure may be amended, provided the original contract allows for the particular amendment and the services to be provided under the amendment are included within, or directly related to, the scope of the project or the scope of the services described in the RFP;

(c) The Director may negotiate modifications of the applicant's proposal and award funds only after such modifications have been agreed upon by the Director and the applicant;

(d) The Director shall determine the final contract awards and funding levels.

Stat. Auth.: ORS 431.834
Stats. Implemented: ORS 431.831 - 431.836
Hist.: HD 11-1997, f. & cert. ef. 9-12-97

333-010-0360
Statewide and Regional Projects Programs

The goal of the Oregon Public Health Division under this section is to fulfill the purpose and intent of Chapter 2 of Oregon Laws of 1997, approved by the people as Ballot Measure 44, at the November 5, 1996 General Election, by developing various programs serving special populations through innovative projects for tobacco prevention and education.

(1) Eligibility for Grant Awards:

(a) The Director may award grants under this section to public and/or private agencies using the process specified in OAR, chapter 125;

(b) Agencies eligible to apply for grants under this section shall be those capable of developing and implementing special statewide or regional projects, including but not limited to those:

(A) Serving multi-cultural populations, including, but not limited to, Indian Tribes;

(B) Developing and implementing a toll-free telephone service, which includes counseling, referral to cessation resources, and follow-up;

(C) Developing and implementing regional and statewide training, and technical assistance on the best practices for effective tobacco prevention programs; and

(D) Developing other innovative, demonstration, and research projects to decrease tobacco initiation by youth, promote cessation for youth and adults, and promote smoke-free communities.

(2) Development of the Request for Proposals (RFP) Document. The RFP for Statewide and Regional Special Projects shall be developed by the Director in consultation with representatives from appropriate groups, which may include, but are not limited to, the Governor's Tobacco Reduction Advisory Committee, the Tobacco-Free Coalition of Oregon, the Oregon Department of Education, the Office of Alcohol and Drug Abuse Programs, and the Centers for Disease Control and Prevention.

(3) Grant Application Process:

(a) The Director may award one or more grants using a RFP process provided for in OAR, chapter 125;

(b) Under this section, proposals shall be requested for programs that serve special populations, and for regional or statewide innovative and unique tobacco prevention and education projects;

(c) Grants may be awarded for, but are not limited to, the following: a toll-free telephone service, training and technical assistance, special projects to decrease tobacco initiation by youth, to

promote cessation for youth and adults, and to promote smoke-free communities;

(d) The RFP shall address but not be limited to the following elements:

(A) Minimum standards and qualifications required from the proposer(s) to be eligible to provide the service;

(B) Statement of work, tied to measurable objectives;

(C) Detailed budget;

(D) Plan for evaluating effectiveness and impact of proposed activities;

(E) The evaluation process and criteria to be used to select the contractor(s), including weights or points applicable to each criterion;

(F) The manner in which the proposers cost and pricing proposal will be evaluated;

(G) A requirement to provide a list of similar services completed, with references addressing past performance;

(H) The closing date and time and place of delivery for the proposal;

(I) Reservation about the right to seek clarification of each proposal, and the right to negotiate a final contract within the scope of the work described in the RFP;

(J) Reservation of the right to reject any or all proposals, if rejection would be in the public interest;

(K) Reservation of the right to cancel the solicitation, if such cancellation would be in the public interest;

(L) A sample of the standard contract provisions;

(M) The possibility of pre-proposal meetings and post-proposal interviews and presentations; and

(N) Any other information appropriate to evaluate, rank, and select the best proposal(s).

(4) Review of Proposals:

(a) Proposals shall be evaluated by a review committee appointed by the Director. The Director has the authority to include on the review committee persons not employed by the Oregon Public Health Division, including experts in the field of tobacco use reduction;

(b) Evaluation criteria may include, but not be limited to, the following:

(A) Availability and capability to perform the work;

(B) Staff experience on comparable projects and services;

(C) Demonstrated ability to complete similar projects and services on time and within budget;

(D) References from clients, public and private;

(E) Performance history in meeting deadlines, submitting accurate estimates, producing quality work, and meeting financial obligations;

(F) Status and quality of any required licensing or certification;

(G) Knowledge and understanding of the required services as shown through the proposed approach to staffing and scheduling needs;

(H) Fees or costs;

(I) Results from oral interviews, if conducted;

(J) Availability of any required specific resources or equipment;

(K) Geographic proximity to the project or the area where the services will be performed;

(L) Identity of proposed subcontractors and their qualifications; and

(M) Any other criteria deemed relevant to the provision of services.

(5) Awarding of Funds:

(a) The final ranking of proposals will be based on all information obtained by the reviewers during the evaluation process. Price will be considered, but will not necessarily govern selection of the contractor(s);

(b) Contracts entered into under the formal selection procedure may be amended, provided the original contract allows for the particular amendment and the services to be provided under the amendment are included within, or directly related to, the scope of the project or the scope of the services described in the RFP;

(c) The Director may negotiate a modification of the applicant's proposal, and award funds only after such modification has been agreed upon by the Director and the applicant;

(d) The Director shall determine final grant awards and funding levels.

Stat. Auth.: ORS 431.834
Stats. Implemented: ORS 431.831 - 431.836
Hist.: HD 11-1997, f. & cert. ef. 9-12-97

333-010-0370
Reporting

(1) During each biennium the Director shall prepare a report regarding the awarding of grants from the Tobacco Use Reduction Account and the formation of public-private partnerships in connection with the receipt of funds from the account. The report shall include an evaluation of the effectiveness of the program funded by the Tobacco Use Reduction Account.

(2) The Public Health Division shall present the report to the Governor and to those committees of the Legislative Assembly to which matters of public health are assigned.

Stat. Auth.: ORS 431.834
Stats. Implemented: ORS 431.831 - 431.836
Hist.: HD 11-1997, f. & cert. ef. 9-12-97

Dental Pilot Projects

333-010-0400
Description of Dental Pilot Projects

The Dental Pilot Projects are intended to evaluate the quality of care, access, cost, workforce, and efficacy by teaching new skills to existing categories of dental personnel; developing new categories of dental personnel; accelerating the training of existing categories of dental personnel; or teaching new oral health care roles to previously untrained persons. The oral health status of Oregonians is poor and the most vulnerable are those with the least access to services. OAR 333-010-0400 through 333-010-0470 provides administrative guidance to the required content of Dental Pilot Project applications, process for review, approval and monitoring of Dental Pilot Projects, and steps to terminate or conclude a Dental Pilot Project.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

333-010-0405
Definitions

For purposes of OAR 333-010-0400 through 333-010-0470, the following definitions apply:

(1) "Authority" means the Oregon Health Authority.

(2) "Clinical phase" means instructor supervised experience with a patient during which a trainee applies knowledge presented by an instructor.

(3) "Didactic phase" means an organized body of knowledge presented by an instructor.

(4) "Director" means the Public Health Director within Oregon Health Authority, or his or her designee.

(5) "Employment/Utilization Phase" means ongoing application of didactic and clinical knowledge and skills in an employment setting under the supervision of a supervisor.

(6) "Employment/Utilization Site" means a health facility, any clinical setting where health care services are provided, and the facilities or programs described in ORS 680.205(1).

(7) "Instructor" means a person qualified to practice or teach the knowledge or skills a trainee is to learn.

(a) "Clinical instructor" is a person who is certified or licensed in the field for which clinical instruction is occurring.

(b) "Non-clinical instructor" is a person with specific training or expertise as demonstrated through a degree or years of experience relevant to the content of instruction.

(8) "Program" means the Dental Pilot Projects program administered by the Authority.

(9) "Program staff" means the staff of the Authority with responsibility for the program.

(10) "Project" means a Dental Pilot Project approved by the director or delegate.

(11) "Project director" means the individual designated by the sponsor to have responsibilities for the conduct of the project staff, instructors, supervisors, and trainees.

(12) "Reviewer" means an individual designated by program staff to review and comment on all or portions of a project application.

(13) "Sponsor" means an entity putting forth an application for a dental pilot project.

(14) "Training program" means an organized educational program that includes at least a didactic phase, clinical phase, and usually an employment/utilization phase.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

333-010-0410
Minimum Standards

A dental pilot project shall:

(1) Provide for patient safety as follows:

(a) Provide treatment which does not expose a patient to risk of harm when equivalent or better treatment with less risk to the patient is available;

(b) Seek consultation whenever the welfare of a patient would be safeguarded or advanced by having recourse to those who have special skills, knowledge and experience;

(c) Provide or arrange for emergency treatment for a patient currently receiving treatment;

(d) Comply with ORS 453.605 to 453.755 or rules adopted pursuant thereto relating to the use of x-ray machines;

(e) Not attempt to perform procedures which the trainee is not capable of performing due to physical or mental disability; and

(f) Comply with the infection control procedures in OAR 818-012-0040.

(2) Provide appropriately qualified instructors to prepare trainees;

(3) Assure that trainees have achieved a minimal level of competence before they enter the employment/utilization phase;

(4) Inform trainees in writing that there is no assurance of a future change in law or regulations to legalize their role;

(5) Demonstrate that the project has sufficient staff to monitor trainee performance and to monitor trainee supervision during the employment/utilization phase;

(6) Demonstrate the feasibility of achieving the project objectives;

(7) Comply with the requirements of the Dental Pilot Projects statute, Oregon Laws 2011, chapter 716 and rules adopted thereunder;

(8) Evaluate quality of care, access, cost, workforce, and efficacy;

(9) Achieve at least one of the following:

(a) Teach new skills to existing categories of dental personnel;

(b) Accelerate the training of existing categories of dental personnel;

(c) Teach new oral health care roles to previously untrained personnel; or

(d) Develop new categories of dental personnel.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

333-010-0415
Application Procedure

(1) A sponsor may submit an application for a dental pilot project on a form prescribed by the Authority.

(2) The application must demonstrate how the pilot project will comply with the requirements of these rules.

(3) An application must include, but is not limited to the following information:

(a) Sponsors:

(A) A description of the sponsor, including a copy of an organizational chart that identifies how the project relates organizationally to the sponsor;

(B) A copy of a document verifying the sponsor's status as a non-profit educational institution, professional dental organization, or community hospital or clinic;

(C) A description of the functions of the project director, instructors, and other project staff;

(D) The funding sources for the project; and

(E) Documentation of liability insurance relevant to services provided by trainees.

(b) Trainee information:

(A) The criteria that will be used to select trainees; and

(B) The number of proposed trainees.

(c) Instructor/Supervisor information:

(A) The criteria used to select instructors and supervisors;

(B) Instructor-to-trainee ratio;

(C) The background of instructors in training techniques and methodology;

(D) The number of proposed supervisors; and

(E) The criteria used to select an employment/utilization site.

(d) Costs:

(A) The average cost of preparing a trainee, including but not limited to the cost information related to instruction, instructional materials and equipment, space for conducting didactic and clinical phases, and other pertinent costs;

(B) The predicted average cost per patient visit for the care rendered by a trainee; and

(C) A budget narrative that lists costs associated with key project areas, including but not limited to:

(i) Personnel and fringe benefits for project director, instructors, and staff associated with the project;

(ii) Contractors and consultants to the project;

(iii) Materials and supplies used in the clinical, didactic, and employment/utilization phases of the project;

(iv) Equipment and other capital costs associated with the project; and

(v) Travel required for implementing and monitoring the project.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

333-010-0420
Trainees

(1) A dental pilot project must have a plan to inform trainees of their responsibilities and limitations under Oregon Laws 2011, chapter 716 and these rules.

(2) A project must provide notice to program staff within 14 days of a trainee entering the employment/utilization phase. The notice shall include, but is not limited to the following:

(a) Name, work address and telephone number of the trainee; and

(b) Name, work address, telephone number and license number of the supervisor.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

333-010-0425
Instructor and Supervisor Information

A dental pilot project must have:

(1) Instructors:

(a) A number and distribution of instructors sufficient to meet project objectives; and

(b) Instructors with current knowledge and skill in topics they will teach.

(2) A plan to orient supervisors to their roles and responsibilities.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

333-010-0430
Curriculum

A sponsor of a dental pilot project must have a curriculum plan that includes but is not limited to a description of:

(1) The level of competence the trainee shall have before entering the employment/utilization phase of the project;

(2) The instructional content required to meet the level of competence;

(3) The skills trainees are to learn;

(4) The methodology utilized in the didactic and clinical phases;

(5) The evaluation process used to determine when trainees have achieved the level of competence; and

(6) The hours and months of the time required to complete the didactic and clinical phases.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

333-010-0435
Evaluation and Monitoring

(1) Evaluation Plan. A sponsor of a dental pilot project must have an evaluation plan that includes, but is not limited to the following:

(a) A description of the baseline data and information collected about the availability or provision of oral health care delivery, or both, prior to utilization of the trainee;

(b) A description of baseline data and information to be collected about trainee performance, acceptance among patient and community, and cost effectiveness;

(c) A description of methodology to be used in collecting and analyzing the data about trainee performance, acceptance, and cost effectiveness; and

(d) A provision for reviewing and modifying objectives and methodology at least annually.

(2) Monitoring Plan. A sponsor of a dental pilot project must have a monitoring plan that ensures at least quarterly monitoring and describes how the sponsor will monitor and ensure:

(a) Patient safety;

(b) Trainee competency;

(c) Supervisor fulfillment of role and responsibilities; and

(d) Employment/utilization site compliance.

(3) Data. A sponsor's evaluation and monitoring plans must describe:

(a) How data will be collected;

(b) How data will be monitored for completeness; and

(c) How data will be protected and secured.

(4) A sponsor must permit project staff or their designees to visit each employment/utilization site at least monthly during the first six month period and at least quarterly thereafter.

(5) A sponsor must provide a report of information requested by the program in a format and timeframe requested.

(6) A sponsor must report adverse events to the program the day they occur.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

333-010-0440
Informed Consent

(1) A sponsor must ensure that informed consent for treatment is obtained from each patient or a person legally authorized to consent to treatment on behalf of the patient.

(2) A sponsor must submit an informed consent form and any accompanying information to program staff for review. Informed consent must include but is not limited to the following:

(a) An explanation of the role and status of the trainee, including the ready availability of the trainee's supervisor for consultation;

(b) Assurance that the patient can refuse care from a trainee without penalty for such a request; and

(c) Identification that consenting to treatment by a trainee does not constitute assumption of risk by the patient.

(3) Informed consent shall be provided in a language in which the patient is fluent.

(4) Dental pilot project staff or trainees must document informed consent in the patient record prior to providing care to the patient.

(5) Informed consent needs to be obtained specifically for those tasks, services, or functions to be provided by a pilot project trainee.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

333-010-0445
Application Review Process

(1) The program staff shall review an application to determine if it is complete within 45 calendar days from the date the application was received.

(a) If an applicant does not provide all the information required and the application is considered incomplete, the program shall notify the applicant of the information that is missing, and shall allow the applicant 15 days to submit the missing information.

(b) If an applicant does not submit the missing information within the timeframe specified in the notice the application shall be rejected as incomplete. An applicant whose application is rejected as incomplete may reapply at any time.

(2) An application deemed complete will continue through a review process.

(3) The program may have individuals outside the program review applications but no individual who has contributed to or helped prepare an application will be permitted to do a review.

(4) Program staff may request additional information from an applicant during the review process.

(5) Once project staff have completed an application review a Notice of Intent to approve or deny an application will be provided to the applicant and the Notice and application will be posted for public comment for a period of 10 business days. The Notice will be sent to interested parties.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

333-010-0450
Project Approval

(1) Once the public comment period described in OAR 333-010-0445(5) has closed the director or his or her designee shall grant or deny approval of a pilot project applicant within 30 calendar days of receiving the application from the program.

(2) If the director grants approval, he or she will specify the length of time the project can operate.

(3) The director's decision shall be transmitted in writing to the applicant.

(4) A sponsor whose project has been denied may not submit a new application within six months from the date the director denied the application.

(5) The program staff shall notify the Oregon Board of Dentistry when a project is approved.

(6) The director or his or her designee may extend the length of time a project can operate at his or her discretion.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

333-010-0455
Program Responsibilities

(1) Project evaluation. Program staff shall evaluate approved projects and the evaluation shall include but is not limited to:

(a) Periodically requesting written information from the project, at least annually to ascertain the progress of the project in meeting its stated objectives and in complying with program statutes and regulations; and

(b) Periodic, but at least annual, site visits to project offices, locations, or both, where trainees are being prepared or utilized.

(2) Site visits.

(a) Site visits shall include, but are not limited to:

(A) Determination that adequate patient safeguards are being utilized;

(B) Validation that the project is complying with the approved or amended application; and

(C) Interviews with project participants and recipients of care.

(b) An interdisciplinary team composed of representatives of the dental boards, professional organizations, and other state regulatory bodies may be invited to participate in the site visit.

(c) Written notification of the date, purpose, and principal members of the site visit team shall be sent to the project director at least 14 calendar days prior to the date of the site visit.

(d) Plans to interview trainees, supervisors, and patients or to review patient records shall be made in advance through the project director.

(e) An unannounced site visit may be conducted by program staff if program staff have concerns about patient or trainee safety.

(f) A report of findings and an indication of pass or fail for site visits shall be prepared by program staff and provided to the project director in written format within 60 calendar days following a site visit.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

333-010-0460
Modifications

(1) Any modifications or additions to an approved project shall be submitted in writing to program staff. Modifications include, but are not limited to the following:

(a) Changes in the scope or nature of the project. Changes in the scope or nature of the project require program staff approval;

(b) Changes in selection criteria for trainees, supervisors, or employment/utilization sites; and

(c) Changes in project staff or instructors.

(2) Changes in project staff or instructors do not require prior approval by program staff, but shall be reported to the program staff within two weeks after the change occurs along with the curriculum vitae for the new project staff and instructors.

(3) All other modifications require program staff approval prior to implementation.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

333-010-0465
Completion of Project

(1) An approved project must notify the Authority in writing if it intends to discontinue its status as a Dental Pilot Project, at least 60 calendar days prior to discontinuation. Notification must include a closing report that includes but is not limited to:

(a) The reasons for discontinuation as a pilot project;

(b) A summary of pilot project activities including the number of persons who entered the employment/utilization phase; and

(c) A description of the plan to inform trainees of the project's discontinuation, and that they are precluded from performing the skills authorized under the pilot project after discontinuation unless the role has been legalized.

(2) The project must obtain written acknowledgement from trainees regarding notification of the project's discontinuation and preclusion from performing skills authorized under the pilot project after discontinuation unless the role has been legalized and the trainee has met necessary licensure requirements.

(3) The project must inform the Oregon Board of Dentistry that the project is completed and provide a list of trainee names associated with the project at least 14 calendar days prior to discontinuation.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

333-010-0470
Suspension or Termination of Project

(1) A pilot project may be suspended or terminated during the term of approval for violation of 2011 Oregon Laws, chapter 716 or any of these rules.

(2) If the Authority determines that a dental pilot project is in violation of 2011 Oregon Laws, chapter 716 or these rules, the Authority may issue a Notice of Proposed Suspension or Notice of Proposed Termination in accordance with ORS 183.411 through 183.470. A sponsor who receives a Notice may request an informal meeting with the director and program staff. A request for an informal meeting does not toll the time period for requesting a hearing as described in section (3) of this rule.

(3) If the Authority issues a Notice of Proposed Suspension or Notice of Proposed Termination the sponsor is entitled to a contested case hearing as provided under ORS Chapter 183. The sponsor has 30 days to request a hearing.

(4) If the Authority terminates a dental pilot project the order shall specify when, if ever, the sponsor may reapply for approval of a dental pilot project.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

Childhood Diabetes Database

333-010-0600
Definitions

(1) "Case" means a reportable case of type 1 or type 2 diabetes in an individual who is 18 years of age or younger, and a resident of Oregon.

(2) "Diabetes Program" means the Oregon Diabetes Prevention and Control Program of Oregon Health Authority, Public Health Division, the program authorized to collect, receive, and maintain a childhood diabetes database under ORS 444.300.

(3) "Date of diagnosis" means the date of initial diagnosis by a practitioner of a case of diabetes being reported to the Diabetes Program.

(4) "Effective Date" means the date after which reporting by schools and physicians shall be required.

(5) "Identifying information" includes, but is not limited to the student's name, address, date of birth, and information that identifies the individual or could be used to identify the individual, and relates to the individual's past, present or future health, and the provision of healthcare to the individual. "Identifying information" also includes "Individually Identifiable Health Information" as that is defined in the 1996 Health Insurance Portability and Accountability Act and "Directory Information" as that is defined in the Federal Family Educational Right to Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99).

(6) "Practitioner" means any person whose professional license allows him or her to diagnose or treat diabetes patients.

(7) "Reportable childhood diabetes" means a medical condition, occurring in a person aged 18 years or younger, and meeting the criteria for diagnosis of diabetes in a child as outlined by the American Diabetes Association. (Reference: **American Diabetes Association. Standards of Medical Care in Diabetes**. **Diabetes Care 2005**; 28: S4-S36.)

(8) "School" means any public, public charter, or registered private school in Oregon.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 444.300
Stats. Implemented: ORS 444.300-444.330
Hist.: PH 6-2007, f. & cert. ef. 4-13-07

333-010-0610
General Authority and Purpose

According to ORS 444.300(1), subject to available funding, including gifts, grants or donations, the Diabetes Program shall establish a uniform, statewide database for the collection of information on type 1 and type 2 diabetes occurring in children in Oregon. The purposes of the database shall be to collect and serve as a repository for data about the prevalence and incidence of dia-

betes occurring in the pediatric population of this state and to make the data available for scientific and medical research and for assistance in making decisions about the allocation of public resources.

Stat. Auth.: ORS 444.300
Stats. Implemented: ORS 444.300-444.330
Hist.: PH 6-2007, f. & cert. ef. 4-13-07

333-010-0620
Reporting Requirements for Schools

(1) The Diabetes Program shall conduct an annual survey to collect information about diabetes occurring in students age 18 years or younger. Preferably the survey will be completed and returned to the Diabetes Program within 30 days of the date the survey or electronic survey link is sent out, but in no event, later than June 15 of each year.

(2) Each school surveyed, upon receipt of written consent of the parent, guardian (or of the student if age18 years) shall report to the Diabetes Program for each student enrolled at the school, during the academic year, who has type 1 or type 2 diabetes, the following information:

(a) The name and address of the student;
(b) The sex of the student;
(c) The date of birth of the student;
(d) The type of diabetes diagnosed (if known);
(e) The date of diagnosis; (if known); and
(f) The name of the child's practitioner (if known).

Stat. Auth.: ORS 444.300
Stats. Implemented: ORS 444.300-444.330
Hist.: PH 6-2007, f. & cert. ef. 4-13-07

333-010-0630
Reporting Requirements for Practitioners

(1) Upon diagnosing or first treating a case of type 1 or type 2 diabetes in an Oregon child, a practitioner shall report the following information to the Diabetes Program:

(a) The name and address of the child;
(b) The sex of the child;
(c) The date of birth of the child;
(d) The type of diabetes diagnosed;
(e) The date of diagnosis or first treatment by the reporting practitioner; and
(f) The measured height and weight of the child.

(2) The practitioner shall report the case to the Diabetes Program within 30 days of diagnosing or first treating the child.

(a) The practitioner shall report the case using the Diabetes Program's Practitioner Childhood Diabetes Report Form. The report may be sent to the Diabetes Program by mail, electronically, or by fax. Copies of the form, and directions for submission may be obtained from the Diabetes Program, 800 NE Oregon Street, Portland, Oregon 97232; or may be downloaded through the Diabetes Program's website.

(b) The Diabetes Program may elect to supplement passive reporting from practitioners with active solicitation of reporting through periodic contacts with certain practitioners.

Stat. Auth.: ORS 444.300
Stats. Implemented: ORS 444.300-444.330
Hist.: PH 6-2007, f. & cert. ef. 4-13-07

333-010-0640
Confidentiality and Access to Data

(1) All identifying information regarding individual patients, reporting schools, and practitioners reported pursuant to OAR 333-010-0620 and 333-010-0630 shall be confidential and privileged. Except as required in connection with the administration or enforcement of public health laws or rules, no public health official, employee or agent shall be examined in an administrative or judicial proceeding as to the existence or contents of data collected under the childhood diabetes database.

(2) The information collected and maintained by the diabetes database shall be stored in physically secure locations and in a technologically secure manner, and shall be used solely for the purposes stated in ORS 444.330

Stat. Auth.: ORS 444.300
Stats. Implemented: ORS 444.300-444.330
Hist.: PH 6-2007, f. & cert. ef. 4-13-07

333-010-0650
Research Studies

(1) Prior to any confidential data from the database being released to a researcher, the researcher must:

(a) Obtain approval from Oregon Health Authority, Public Health Division Institutional Review Board, established in accordance with 45 C.F.R. 46.

(b) Obtain approval from the Diabetes Program.

(2) In reviewing research proposals for approval under section (1)(b) of this rule, the Diabetes Program, with input from its advisory committee, shall consider whether the research will:

(a) Further knowledge of the prevalence and incidence of diabetes occurring in the pediatric population;

(b) Better define causes of and treatment for childhood diabetes; or

(c) Inform decision-making about the allocation of public resources.

(3) The Diabetes Program shall also ensure that the research proposal has been reviewed for scientific excellence by a nationally recognized peer review group.

(4) Prior to confidential information being released to a researcher, the Diabetes Program will contact the family and offer the option to decline contact regarding research opportunities.

Stat. Auth.: ORS 444.300
Stats. Implemented: ORS 444.300-444.330
Hist.: PH 6-2007, f. & cert. ef. 4-13-07

333-010-0660
Advisory Committee

(1) The Diabetes Program may convene an advisory committee to make recommendations regarding the Diabetes Program's use of the database, and to assist in reviewing research proposals under OAR 333-010-0650.

(2) Advisory committee members may not have access to confidential information provided to the program under ORS 444.300 to 444.320.

(3) The advisory committee shall be composed of persons with a professional or personal interest in childhood diabetes.

Stat. Auth.: ORS 444.300
Stats. Implemented: ORS 444.300-444.330
Hist.: PH 6-2007, f. & cert. ef. 4-13-07

ADMINISTRATION

DIVISION 11

VITAL STATISTICS

333-011-0205
County Vital Records Services

(1) A county registrar may only sell certified copies of records with authorization by the state registrar. A county registrar may apply to the state registrar for authorization to sell certified copies of death records or certified copies of birth records and death records. The application shall specify the county need and interests that the sale of certified copies would serve, types of records to be issued, and hours of service available. The state registrar shall review the application and authorize the county registrar to sell certified copies if such action is supported by local needs and resources.

(2) If approved for birth records, the county registrar may issue certified copies of registered birth records from the state vital records system for a period not to exceed six months from the date of birth.

(3) If approved for death records, the county registrar may accept after review paper death records for deaths occurring in the county prior to registration at the state office. The county registrar shall forward death records that have been filed at the county to the state registrar within three business days of the date filed by the county registrar.

(a) County registrars may issue certified copies of a death record from the original record while the original record is in the possession of the county. County registrars may maintain a copy of the completed death record for a period up to 14 calendar days from the date the record is forwarded to the state and within that time period may issue from that copy until the record is registered in the state vital records system.

(b) After the death record is registered in the state vital records system, whether originally a paper record or an electronic record, the county registrar may issue only from the state vital records system for a period not to exceed six months from the date of death.

(4) County registrars shall collect fees in the amounts authorized under OAR 333-011-0340 for services provided at a county vital records office.

Stat Auth: ORS 432.035
Stats. Implemented: ORS 432.035
Hist.: PH 17-2013, f. 12-26-13, cert. ef. 1-1-14; PH 21-2015, f. 10-30-15, cert. ef. 1-1-16

333-011-0210
Prenatal Care Information

(1) The physician, institution or other person providing prenatal care shall transfer the prenatal care information including but not limited to pregnancy history, date of first visit, number of visits, pregnancy risk factors, and cigarette use as required in ORS 432.088 to the institution where the delivery is expected to occur not less than 30 calendar days and not more than 45 calendar days prior to the expected delivery date.

(2) If the institution where the delivery is expected to occur has direct access to the prenatal care information, the physician, institution or other person providing prenatal care may authorize direct access to the information.

(3) If the institution where the delivery is expected to occur does not have direct access to the prenatal care information or direct access is not authorized by the physician, institution or other person providing prenatal care, the prenatal care provider shall send by facsimile or otherwise electronically transmit in a secure manner the prenatal care information on a form prescribed by the State Registrar of the Center for Health Statistics.

Stat Auth: ORS 432.088
Stats. Implemented: ORS 432.088
Hist.: PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0215
Registering Live Births that Occur Outside of a Facility with a Licensed Birth Attendant or Non-licensed Midwife within One Year of the Date of Birth

(1) For purposes of this rule, attendant means:

(a) A physician;

(b) A nurse practitioner as defined in ORS 678.010;

(c) A direct entry midwife licensed under ORS 687.405 to 687.495; or

(d) A person not required by law to be licensed to practice midwifery who is registered with the Center for Health Statistics to submit reports of live birth.

(2) Any individual listed in subsections (1)(a) through (d) of this rule who attends a birth that occurred outside a health care facility must register the birth with the Center for Health Statistics.

(a) Information regarding the birth may be submitted through the state electronic vital records system or through a paper report of live birth. All information required in the report of live birth must be received by the Center for Health Statistics prior to registration.

(b) Reports of live birth submitted within one year from the date of birth shall not be marked "Delayed."

(c) The attendant may submit the report of live birth based on existing medical records.

(A) Personal information, such as the name of the child, can be completed from information provided by the parent at the time of birth.

(B) If the birth cannot be confirmed through other public health sources including but not limited to newborn metabolic screening, first dose immunization records, or early hearing test, the state registrar may require the parents to submit additional documents that support the birth of the child in Oregon or present the child at the county vital records office.

(d) The state registrar may request additional documentation from the attendant or explanation of the delay in submitting the report of live birth for reports submitted more than 10 days after the date of birth.

(e) The state registrar shall review and register reports of live birth submitted within one year from the date of birth using the same process for reviewing and registering reports of births submitted within five days from the date of birth.

(3) An attendant who attends the birth of their own child, grandchild, niece or nephew must submit the application and documentation required under OAR 333-011-0220 if the birth does not occur in a licensed medical facility.

Stat Auth: ORS 432.088
Stats. Implemented: ORS 432.088
Hist.: PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0220
Registering Live Births that Occur Outside of a Facility and Without a Licensed Attendant within One Year of the Date of Birth

When a birth occurs outside a licensed health care facility, the birth attendant is not an attendant described in OAR 333-011-0215 and a report of live birth has not been submitted to the state registrar, the mother, the father if the father's relationship to the child is legally established, the legal guardian, or a state agency with physical custody shall fill out a form prescribed by the state registrar to report the live birth and provide additional evidence to the state register if the birth occurred within one year of the report being submitted to the Center for Health Statistics.

(1) The individual submitting the report of live birth must also submit evidence to establish the following facts:

(a) The mother was pregnant at the time relevant to the birth. If the birth cannot be confirmed through other public health sources, the parents must submit additional documents that support the birth of the child in Oregon. Evidence of the pregnancy can include but is not limited to:

(A) Prenatal record or a statement from a physician or other health care provider qualified to determine pregnancy who examined the mother during the pregnancy; or

(B) Chart notes from a home visit by a public health nurse or other health care provider that include observation of the pregnancy.

(b) A live birth resulted from the pregnancy. Evidence that the infant was born alive can include but is not limited to:

(A) A statement from a physician, naturopathic doctor, nurse practitioner, or registered nurse who saw or examined the infant within three months of the birth; or

(B) Chart notes of an observation of the infant during a home visit by a public health nurse within three months of the birth; or

(C) Presentation of the child at the state or county vital records office.

(c) The mother was present in Oregon at the time of birth. Evidence of the mother's presence in this state within 30 days of the date of the live birth and inclusive of the date of birth can include but is not limited to:

(A) A rent receipt that includes the mother's name and address; or

(B) A utility, telephone, or other bill that includes the mother's name and address.

(d) Information on the identity of the mother and information on the identity of the father if the father is to be listed on the record of live birth. Evidence of the identity of the mother or the father shall include:

(A) An official identification document from a government agency that includes a photograph of the mother or of the father; and

(B) A certified copy of the mother's or father's birth record; or

(C) Other official documents acceptable to the state registrar.

(2) If a parent's current legal name does not match the name on his or her birth record, evidence of the legal name change

through court order, marriage or other legal process must be provided.

(3) If the father is listed on the record of live birth because the mother and father are married, a certified copy of a marriage record for the mother and the father must be submitted.

(4) After the application is received and evidence has been submitted, the state registrar shall review the documents and application, and verify any documentation at the state registrar's discretion.

(5) The state registrar shall determine if a previously registered record of live birth exists for the registrant. If no previously registered record is identified and the submitted application and evidence appear valid, the record may be registered.

(6) Reports of live birth filed within one year from the date of birth shall not be marked "Delayed."

Stat Auth: ORS 432.088
Stats. Implemented: ORS 432.088
Hist.: PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0225
Registering Live Births that Occur in a Licensed Medical Facility More Than One Year after the Date of Birth

All reports of live birth for births occurring in licensed medical facilities certified more than one year from the date of live birth are to be submitted by hospital staff through the electronic system and registered on the current form in use.

(1) Births may be matched to newborn screening records for the purpose of confirming the birth occurred.

(2) Reports of live birth submitted more than one year from the date of birth shall be marked "Hospital Delayed" and include a footnote that the record was filed based on the medical facility's record of the live birth.

(3) The facility administrator or designee shall submit the report of live birth based on existing medical or business records related to the birth if all facts of birth appear in the medical or business records. Personal information, such as the name of the child, can be completed from information provided by the parent at the time of birth.

(4) The facility administrator or designee shall include an explanation of the delay in submitting the report of live birth and the facility records on which the report of live birth is based.

(5) The state registrar shall determine if a previously registered record of live birth exists for the registrant and may inspect the medical facility's medical and business records prior to registration. If no previously registered record is identified and the submitted record appears valid, the record may be registered.

Stat Auth: ORS 432.113
Stats. Implemented: ORS 432.113
Hist.: PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0230
Registering Live Births that Occur Outside a Facility More Than One Year after the Date of Birth

(1) When a live birth that occurred outside a licensed medical facility has not been registered within one year from the date of birth, an application for a delayed registration of live birth may be submitted. The applicant shall complete a delayed report of live birth application form prescribed by the state registrar, pay the delayed filing fee, and shall provide additional documentation described in this rule.

(a) If the proposed registrant is age 18 or older, the proposed registrant must file the application unless the proposed registrant has a legal guardian due to incapacity. If the proposed registrant is age 18 or older and has a legal guardian due to incapacity, the legal guardian may file the application on behalf of the proposed registrant.

(b) If the proposed registrant is less than age 18, the mother, the father if legal relationship is established, the legal guardian, or a state agency with physical custody may file the application.

(c) No delayed report of live birth shall be registered for a deceased person.

(2) A delayed registration of birth application form shall be signed by the person authorized to request a delayed registration of birth as described in subsections (1)(a) and (b) of this rule and sworn to before an official authorized to administer oaths, swearing to the accuracy of the facts stated therein.

(3) In addition to completing the delayed registration of live birth application, the applicant must submit documents to establish the facts of birth including:

(a) The full name of the proposed registrant at the time of birth;

(b) The date of birth;

(c) The place of birth within Oregon;

(d) The mother's full name at birth and current full legal name; and

(e) Proof that a record does not currently exist in Oregon.

(4) If the mother was not married either at the time of conception or birth or within 300 days prior to the birth, the state registrar shall not enter the name of the father on the delayed record of live birth for a minor child except upon receipt of a voluntary acknowledgment of paternity as provided in OAR 333-011-0270 or upon receipt of a court order establishing paternity.

(5) A delayed registration of birth application completed and submitted to the state registrar within 10 years of the birth of the proposed registrant must include three pieces of documentary evidence that support the facts of birth.

(a) One of the three documents must establish the mother's residence address in Oregon within 30 days of the date of the live birth and inclusive of the date of birth. A personal affidavit cannot be used to establish residence.

(b) One document other than a personal affidavit must have the full name at birth of the proposed registrant, the date of birth, and the full legal name or the full name at birth of the mother. This document must be dated either:

(A) Before the first birthday of the proposed registrant; or

(B) At least one year prior to the date of the application.

(c) One of the documents may be a personal affidavit. To be accepted, a personal affidavit must be signed by a person who is at least 18 years of age and is at least 10 years older than the proposed registrant. That person must have personal knowledge of the facts of birth and not be a family member of either parent.

(d) In addition to the facts of birth, information on the identity of the mother and father is required.

(A) Evidence of the identity of the mother shall include:

(i) An official identification document from a government agency that includes a photograph of the mother; and

(ii) A certified copy of the mother's record of birth; or

(iii) Other official documents acceptable to the state registrar.

(B) Evidence of the identity of the father if the father is to be listed on the record of live birth shall include:

(i) An official identification document from a government agency that includes a photograph of the father; and

(ii) A certified copy of the father's record of birth; or

(iii) Other official documents acceptable to the state registrar.

(C) If a parent's current legal name does not match the name on his or her record of birth, evidence of the legal name change through court order, marriage or other legal process must be provided.

(e) If the father is listed on the birth report because the mother and father are married, a certified copy of a marriage record for the mother and the father must be submitted.

(6) If a delayed registration of live birth application is completed and submitted to the state registrar 10 years or later after the date of birth of the proposed registrant, at least three pieces of documentary evidence shall be submitted with the application for delayed record of live birth.

(a) All documents must have been established:

(A) Prior to the proposed registrant's 10th birthday and at least one year prior to the date of application; or

(B) At least 10 years prior to the date of application.

(b) One document must have the full name at birth of the proposed registrant, the date of birth or age, the place of birth within Oregon, and the mother's first and last name prior to marriage.

(c) The remaining two documents must have the name of the proposed registrant, the date of birth or age, and place of birth. One document of the three must include the registrant's first and last name, date of birth and place of birth within Oregon.

(d) The father will be included on the record of live birth if the proposed registrant is age 18 or older and the evidence submitted documents the identity and relationship.

(e) Documents in addition to the three required may include first and last names only and do not need to include the date of birth and place of birth if sufficient information appears in the document to clearly identify the proposed registrant as the subject of the document. These documents may be used to correct the spelling of a name or to add information missing from the three documents required, such as a parent's place of birth.

Stat Auth: ORS 432.113
Stats. Implemented: ORS 432.113
Hist.: PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0235
Documentation in Support of an Application to Register a Delayed Report of Live Birth

(1) The following documents shall be considered by the state registrar to meet the documentation requirements for delayed registration of live birth described in OAR 333-011-0230 if the documents contain sufficient information to identify the proposed registrant as the subject of the document and support the facts of birth as reported by the applicant. Documents may include:

(a) Licensed medical facility records of the proposed registrant;

(b) A certified copy of an accepted application for a Social Security card for the proposed registrant;

(c) The proposed registrant's mother's medical record if the proposed registrant's name, date of birth and place of birth are included in the record;

(d) A certified copy of school records of the proposed registrant;

(e) A certified copy of census records;

(f) Military records of the proposed registrant;

(g) A certified copy of marriage record;

(h) A certified copy of birth record of the proposed registrant's child;

(i) Voter registration records for the proposed registrant; or

(j) Other official documents acceptable to the state registrar.

(2) All documents submitted in support of an application for delayed registration of live birth must be original documents or certified copies of original documents. Certified copies must be authenticated by the official custodian of the record.

Stat Auth: ORS 432.113
Stats. Implemented: ORS 432.113
Hist.: PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0240
Review and Filing of Delayed Registration of Live Birth

(1) The state registrar shall review the application for delayed registration of birth and documents in support of the application for authenticity, relevance and content required by OAR 333-011-0230. If the application cannot be approved as submitted, the applicant will be notified by correspondence or electronic mail of the deficiencies and provided an opportunity to submit additional documentation.

(2) The state registrar shall review the delayed registration of live birth application and the documents submitted, and shall search to confirm there is no existing birth record for the proposed registrant in Oregon. If the state registrar finds no such records and finds that the documents submitted are adequate to establish that the proposed registrant was born in Oregon on the date specified, the state registrar or the state registrar's designated representative shall register the record and include on the record of delayed registration of live birth an abstract of the evidence supporting the delayed report of live birth.

(3) If the application and evidence is accepted, the state registrar shall send the delayed report of live birth, including the abstract of evidence, to the applicant for notarized signature.

(4) When the notarized delayed report of live birth with the applicant's notarized signature is received, the state registrar shall create the delayed record of live birth. The record of live birth shall be marked 'Delayed' and shall include a description of each document submitted to support the facts shown on the delayed birth record. This description shall include:

(a) The title or description of the document;

(b) The name of the affiant, if the document is an affidavit of personal knowledge, or of the custodian, if the document is an original or certified copy of a record or a signed statement from the custodian;

(c) The date of the original filing of the document being abstracted; and

(d) The information regarding the birth facts contained in the document.

(5) The state registrar shall return all original documents other than personal affidavits submitted in support of the application for delayed registration of live birth and received directly from the applicant to the applicant after review. A copy of the personal affidavit shall be provided to the applicant. Copies of documents and application will be maintained for delayed registrations of live birth that are accepted for registration.

Stat Auth: ORS 432.113
Stats. Implemented: ORS 432.113
Hist.: PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0245
Denial of Application for Delayed Registration of Live Birth after Two Years

(1) An application for an out of facility record of live birth or delayed record of live birth which is not completed through the submission of required evidence of all facts to be established as identified in rule within two years of application shall be denied. The applicant shall be notified of the right to appeal the decision of the state registrar under ORS 183.484. The applicant may request denial for the purpose of seeking a court order prior to two years.

(2) Any applicant that has had a previous application denied must file a new application for the proposed registrant including the fee if choosing to submit a new application for delayed registration of birth.

(3) Copies of the application and submitted documentation will be maintained according to the agency's retention schedule and may be used if a subsequent application indicates contradictory information.

Stat Auth: ORS 432.113
Stats. Implemented: ORS 432.113
Hist.: PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0250
Court Ordered Birth Records

A certified copy of each order to establish a record of birth shall be forwarded to the State Registrar from the court clerk by the 5th and 15th working day of each month. The order shall be in the form specified by the State Registrar and shall be suitable for issuing certified copies of the birth record on a single sheet.

Stat Auth: ORS 432.188
Stats. Implemented: ORS 432.188
Hist.: PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0255
Infants of Unknown Parentage

(1) A report for a minor child of unknown parentage found in Oregon shall be registered in the current format for births.

(2) If the minor child is less than one year of age, the hospital where the child is examined shall submit the report of live birth in the state's electronic reporting system.

(3) If the minor child is more than one year of age, the agency who has assumed custody of the child shall submit a request to locate birth record to the state registrar. The request shall include:

(a) A statement that the child is a possible foundling;

(b) All information available on the identity of the child and parents for the purpose of identifying the birth record;

(c) Whether the agency will be able to locate evidence to support a delayed record of birth if a birth record is not identified;

(d) Whether an expedited denial is requested for the purpose of obtaining a court order to register the birth.

(4) If the agency requests expedited denial, the state registrar shall review the information available and determine whether a birth record can be identified. If no birth record can be identified based on the information provided by the agency and the agency cannot provide additional documentation to support a delayed record of birth, the state registrar shall issue a denial of the request.

(5) If the agency later identifies the child's parents, the agency shall notify the state registrar within 10 days of the additional information. If a previously registered record is identified with the child's information, the record registered under this rule shall be voided. If no registered record with the parent information is found, the agency shall amend the court order to register the birth to include the names, dates of birth and places of birth of the parents.

Stat Auth: ORS 432.108
Stats. Implemented: ORS 432.108
Hist.: PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0260
Amendment of the Same Item More than Once

Once an amendment of an item is made on a vital record, except for cause and manner of death to be amended by the medical certifier or Medical Examiner or clerical error on the part of the reporting source or the state registrar, that item shall not be amended again except upon receipt of an appropriate order which, depending on the nature of the order, shall be from either a court of competent jurisdiction or a court with competent jurisdiction over the state agency.

Stat Auth: ORS 432.235
Stats. Implemented: ORS 432.235
Hist.: PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0265
Amending Birth Records

(1) All amendments. Unless otherwise provided in these rules or in statute, all amendments to vital records shall be supported by:

(a) An affidavit setting forth:

(A) Information to identify the record;

(B) The incorrect data as it is listed on the record; and

(C) The correct data as it should appear.

(b) One or more original items of documentary evidence which support the alleged facts and which were established at least five years prior to the date of application for amendment or within seven years of the date of the event and one year prior to the date of the requested amendment.

(2) The state registrar shall evaluate the evidence submitted in support of any amendment, and when the state registrar finds reason to doubt its validity or adequacy the amendment may be rejected and the applicant advised of the reasons for this action.

(3) Who may apply:

(a) To change the date of birth, time of birth or sex of the registrant, only the facility where the birth occurred or the individual who submitted the report of birth may apply to amend unless the medical record is no longer available at the facility. If the medical record is no longer available, other individuals, including the parents and the registrant, shall submit an application for amendment under section (1) of this rule. If the evidence is not sufficient, the applicant must present a certified copy of a court order ordering such amendment.

(b) To amend a record of live birth for items other than date of birth, time of birth or sex, application may be made by one of the parents, the legal guardian, the registrant if 18 years of age or over, or the individual responsible for filing the report of live birth.

(c) To amend the sex of a registrant on a record of live birth following the completion of sexual reassignment, an individual must submit documentation under OAR 333-011-0275.

(4) Amendment of registrant's first, middle or last names on records of live birth within the first year. Until the registrant reaches the age of one year, first, middle, or last names of the registrant may be amended upon written request of:

(a) Both parents; or

(b) The mother if no father or second parent appears on the record or if the father or second parent is deceased or incapacitated; or

(c) The father or second parent if the mother is deceased or incapacitated; or

(d) The legal guardian or agency having legal custody of the registrant.

(5) Amendment of registrant's first, middle or last names on records of live birth after the first year:

(a) After one year from the date of birth the provisions of section (1) of this rule must be followed to amend a first, middle or last name if the name was misspelled on the birth record.

(b) A legal change of name order must be submitted from a court of competent jurisdiction to change a first, middle or last name that appears on the birth record after one year from date of birth.

(6) Addition of first, middle or last name of a registrant on a record of live birth:

(a) Until the registrant's seventh birthday, first, middle and last names, for a child whose birth was registered without such names, may be added to the record of live birth upon written request of:

(A) Both parents; or

(B) The mother if no father appears on the record or if the father is deceased or incapacitated; or

(C) The father if the mother is deceased or incapacitated; or

(D) The legal guardian or agency having legal custody of the registrant.

(b) After seven years the provisions of section (1) of this rule must be followed to add a first, middle or last name.

(7) Amendment of parents' information on birth records. When a requested amendment to an item, in combination with previous amendments or concurrent requests for amendment, would appear to change the identity of the parent through cumulative changes to name, date of birth, or place of birth, the state registrar shall only make such an amendment upon receipt of a court order from a court of competent jurisdiction.

(8) Original evidence documents submitted to correct errors in the spelling of a parent name, parent date of birth, or parent place of birth must be dated prior to the birth of the child.

(9) Birthing facilities may correct typographical errors on birth records within the first year. After one year, only errors in the child's date of birth, time of birth or sex will be accepted directly from the birthing facility. The birthing facility must have access to the medical record when submitting the correction.

(10) For births occurring outside a birthing facility, medical certifiers may only correct typographical errors within the first year with evidence from the medical record or the birth worksheet.

(11) Amendment of minor errors on birth records. Amendment of obvious errors, transposition of letters in words of common knowledge, or omissions may be made by the state registrar either upon the state registrar's observation or upon request of one of the parents, the legal guardian, or the birthing facility or by the individual responsible for filing the report of live birth. The record shall not be marked "Amended". Corrections to names will not be considered minor errors.

(12) In all cases where the record is amended, there shall be inserted on the record a statement identifying the affidavit or documentary evidence used as proof of the correct facts, the date the amendment was made, and the initials of the person making the change. As required by statute or rule, the record shall be marked "Amended".

Stat Auth: ORS 432.235
Stats. Implemented: ORS 432.235
Hist.: PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0270
Voluntary Acknowledgment of Paternity

(1) Any voluntary acknowledgment paternity form establishes paternity, and the establishment of paternity shall be a rebuttable presumption. Forms must contain all information necessary to comply with existing federal and state laws and regulations for determination and recording of paternity including but not limited to:

(a) The current full names of mother, father and child;

(b) The social security numbers of mother and father if available;

(c) The dates of birth for mother, father and child;

(d) The address(es) of the mother and of the father;

(e) The birthplace of the child;

(f) A brief explanation of the legal significance of signing a voluntary paternity affidavit and a statement that both parents have 60 days to rescind the paternity acknowledgment affidavit;

(g) A statement signed by both parents indicating they understand that signing the paternity acknowledgment is voluntary and that they understand the rights, responsibilities, alternatives to signing, and consequences of signing;

(h) Signature lines for the mother and the father; and

(i) Signature lines for witnesses or notaries.

(2) The witnessed voluntary acknowledgment of paternity form is established for completion in a health care facility where births occur. This form can be used by unwed biological parents if:

(a) The mother was not married at conception, at birth, or within 300 days prior to the birth;

(b) The form is completed:

(A) After the birth; and

(B) While the mother is admitted for this birth; and

(c) The form is witnessed by a member of the hospital staff; and

(d) The form is submitted to the Center for Health Statistics within five days after the birth.

(e) This form will not be accepted and the father's information will not be placed on this record of live birth if any of these conditions are not met.

(3) Completion of a voluntary acknowledgment of paternity form and returning the form to the hospital staff for submission is the responsibility of the biological parents.

(4) The notarized voluntary acknowledgment of paternity form can be used by unwed biological parents if:

(a) The mother was not married at conception, at birth, or within 300 days prior to the birth;

(b) The form is completed after the birth; and

(c) Signatures of each biological parent are notarized.

(d) This form will not be accepted and the father's information will not be placed on this record of live birth if any of these conditions are not met.

(5) The State Registrar of the Center for Health Statistics shall consult the Division of Child Support on the language in the rights and responsibility statement for voluntary acknowledgment of paternity forms to ensure compliance with state and federal law and regulations.

(6) All questions regarding acceptability of a completed form are determined by the State Registrar for the Center for Health Statistics. Appeals of decisions of determination of the state registrar will be made under ORS 183.484.

Stat Auth: ORS 432.098
Stats. Implemented: ORS 432.098
Hist.: PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0275
New Record of Birth Following Adoption, Legitimation, Paternity Determination, and Paternity Acknowledgement or Sexual Reassignment

(1) The state registrar shall amend a record of live birth and establish a replacement record of live birth for a person born in this state upon receipt of the following:

(a) Legitimation. If the mother is unmarried at the time of birth and the biological parents marry after the birth of a child, a new record of live birth shall be prepared by the state registrar for a child born in this state upon receipt of a sworn acknowledgement of paternity signed by the biological parents of said child together with a certified copy of the parents' marriage record. The mother's legal name can be amended to the name taken at marriage on the child's record of live birth if requested.

(b) Determination of paternity. A new record of live birth shall be prepared by the State Registrar for a child born in this state upon receipt of a certified copy of a court determination of paternity. If the mother's marital status was not unmarried at the time of birth or if another man is listed as the father, the court order must disestablish paternity as well as establish the new father. If the surname of the child is not decreed by the court, the request for the new record received with the certified copy of the court determination shall specify the surname requested by both parents to be placed on the record.

(c) Acknowledgement of paternity. A new record of live birth shall be prepared by the state registrar for a child born to an unmarried mother in this state upon acceptance of a notarized voluntary acknowledgement of paternity signed by both parents if no father appears on the record. The child's surname may be changed through the voluntary acknowledgment of paternity.

(d) Adoption. A certified copy of a report of adoption as provided in ORS 432.223 or a certified copy of the decree of adoption, together with the information necessary to identify the original record of live birth and to establish a replacement record of live birth, except that a replacement record of live birth shall not be established if so requested by the court decreeing the adoption.

(e) Sexual reassignment. A certified copy of an order of a court of competent jurisdiction indicating that an individual born in this state has completed sexual reassignment and that the sex on the record of live birth shall be changed.

(2) The mother's marital status is unmarried at the time of birth if she was not married at conception, at birth, or within 300 days prior to the birth.

(3) New record:

(a) The new record of live birth prepared after adoption, legitimation, determination of paternity, or acknowledgment of paternity, or sexual reassignment shall be on the form in use at the time of its preparation and shall include the following items and such other information necessary to complete the certification:

(A) The name of the child;

(B) The date and place of birth as transcribed from the original record;

(C) The full names, dates of birth and places of birth of the adoptive parents or the biological parents whichever is appropriate;

(D) The name of the attendant;

(E) The state file number assigned to the original birth record; and

(F) The original filing date.

(b) The information necessary to locate the existing record and to complete the new record shall be submitted to the state registrar on forms prescribed or approved by the state registrar.

(4) Existing record to be placed in a special file. After preparation of the new record, the existing record and the evidence upon which the new record was based are to be placed in a special file. Such file shall not be subject to inspection except upon order of a court of competent jurisdiction or by the state registrar for purposes of properly administering the vital statistics program. A court order is not required before the release of a Voluntary Acknowledgment of Paternity form to any government agency responsible for the administration of child support enforcement programs created under Title IV-D of the Social Security Act, to a parent who signed the form or to the registrant if age 18 or older.

Stat. Auth.: ORS 432.245, 432.098 & 432.289
Stats. Implemented: ORS 432.245, 432.098 & 432.289
Hist.: HD 24-1981, f. & ef. 11-17-81; PH 2-2003(Temp), f. & cert. ef. 2-20-03 thru 8-19-03; PH 11-2003, f. & cert. ef. 7-31-03; Renumbered from 333-011-0047 by PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0280
Extension of Time for Submission of Report of Death or Fetal Death

(1) Upon written request by the funeral service practitioner, person acting as a funeral service practitioner, or Medical Examiner, the state registrar may extend the period to file a report of death, not to exceed 60 days.

(2) Upon written request by the facility administrator or the Medical Examiner, the state registrar may extend the period to file a report of fetal death, not to exceed 60 days.

(3) The request shall include the date of event, name of the decedent if a report of death or name of the mother if a report of fetal death, and an explanation of why the extension of time is required.

(4) The state registrar shall respond to such request within two business days of receipt. The request may be faxed or otherwise transmitted electronically, but must include a signature of the person requesting the extension.

Stat Auth: ORS 432.163
Stats. Implemented: ORS 432.163
Hist.: PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0285
Report of Fetal Death Which Occurred Outside a Licensed Medical Facility

When a fetal death occurs outside a licensed medical facility, the report of fetal death must be submitted by the Medical Examiner or physician who attended at or immediately after the delivery through the electronic reporting system.

Stat Auth: ORS 432.143
Stats. Implemented: ORS 432.143
Hist.: PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0290
Commemorative Certificate of Stillbirth

(1) The Certificate of Stillbirth shall be suitable for display and shall feature an attractive design with calligraphy-like font, high quality paper, a State of Oregon seal, and signature of the state registrar.

(2) Information on the Certificate of Stillbirth shall be prepared using information from the "Report of Fetal Death" submitted to the Center for Health Statistics. The text of the certificate shall contain the name of the child, date and place of birth, names of parent(s), date of issuance, state file number from the fetal death record, and a statement that the certificate is not proof of a live birth. The word deceased would be included after the name of the child.

Stat Auth: ORS 432.148
Stats. Implemented: ORS 432.148
Hist.: PH 27-2006, f. 11-30-06, cert. ef. 12-1-06; Renumbered from 333-011-0200 by PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0295
Authorization for Final Disposition

(1) Removal of body. Before removing a dead body or fetus from the place of death, the funeral director or person acting as such shall:

(a) Obtain assurance from the attending physician that death is from natural causes and that the physician will assume responsibility for certifying to the cause of death or fetal death and receive permission to remove the body from the place of death; or

(b) Notify the medical examiner, if the case comes within the medical examiner's jurisdiction and obtain authorization to remove the body.

(2) Authorization for disinterment and reinterment. An authorization for disinterment and reinterment of human remains shall be issued by the state registrar upon receipt of a written application signed by the next of kin and the person who is in charge of the disinterment or upon receipt of an order of a court of competent jurisdiction directing such disinterment:

(a) Upon receipt of such a court order or signed permission of the next of kin, the state registrar may issue one authorization to permit disinterment and reinterment of all human remains in a mass disinterment provided that, insofar as possible, the remains of each body be identified and the place of disinterment and reinterment specified. The authorization shall be permission for disinterment, transportation, and reinterment;

(b) Human remains properly prepared by an embalmer and deposited in a receiving vault shall not be considered a disinterment when removed from the vault for final reinterment within the same cemetery.

Stat. Auth.: ORS 432.158
Stats. Implemented: ORS 432.158
Hist.: HB 169, f. & ef. 10-16-63; HD 24-1981, f. & ef. 11-17-81; Renumbered from 333-011-0076 by PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0300
Amendments to Death Records

(1) To amend a death record, application may be made by the informant, the next of kin of the decedent, person acting as the funeral service practitioner who signed the report of death, or a funeral service practitioner employed by the licensed funeral establishment that submitted the report of death.

(a) Next of kin is, in order of preference:

(A) Spouse of the decedent;

(B) A son or daughter age 18 or older of the decedent;

(C) The mother or the father of the decedent;

(D) A brother or sister age 18 or older of the decedent;

(E) The guardian of the decedent at the time of death;

(F) The personal representative of the estate of the decedent; or

(G) The person nominated as the personal representative of the decedent in the decedent's will.

(b) Applications to amend the medical certification of cause of death shall be made only by the physician who signed the medical certification or the medical examiner.

(c) A completed and signed affidavit in a format prescribed by the state registrar is required for all amendments.

(2) When the marital/partnership status is shown as married/partnered and a surviving spouse/partner is listed on the death record of the decedent then the marital/partnership status shall be changed to:

(a) Widowed and the spouse/partner removed if a certified copy of a death record for the spouse/partner documenting that the spouse/partner died prior to the death of the decedent is submitted by the informant.

(b) Divorced or never married and the spouse/partner removed if a certification of divorce/dissolution/annulment documenting that the event occurred prior to the death of the decedent is submitted by the informant.

(3) If the marital/partnership status is shown as married/partnered and surviving spouse/partner is listed as unknown or is blank on the death record, then a certified copy of the record of marriage/partnership must be provided to add the name of the surviving spouse/partner.

(4) If the marital/partnership status is shown as married/partnered and the surviving spouse/partner is listed on the death record then an order from a court of competent jurisdiction will be needed to change that spouse/partner to a different person.

(5) When the marital/partnership status is shown as divorced, widowed, or never married and no surviving spouse/partner is listed on the death record of the decedent then the marital/partnership status shall be amended to married/partnered and the surviving spouse/partner added upon receipt of notarized affidavits from both the informant and from the alleged surviving spouse/partner stating that an error was made and stating the correct information, and either:

(a) A certified copy of the marriage/partnership record showing that the person to be listed as the surviving spouse/partner was married to/partnered with the decedent prior to death is submitted by the informant; or

(b) An order from a court of competent jurisdiction issued in a legal action indicating that the person was in a common-law marriage with the decedent at the time of the decedent's death.

(6) Other changes to marital/partnership status and surviving spouse/partner will be made only upon the finding of a court of

competent jurisdiction in an order that determined the marital/partnership status of the decedent and identifies the surviving spouse/partner, if appropriate.

(7) For sections (2) through (5) of this rule, in addition to documentation required, the informant listed on the death record shall be notified of the requested change and given the opportunity to respond prior to the state registrar amending the death record. If the informant disagrees with the change, marital status and surviving spouse can only be changed upon receipt of an order from a court of competent jurisdiction.

(8) Amendment to other items on the death record:

(a) Signatures may not be amended.

(b) Other personal and statistical items on the death record may be amended by the funeral services practitioner based on a correction affidavit.

(c) Other personal and statistical items on the death record shall be amended by the informant or next of kin only if supported by an affidavit and documentary evidence that is acceptable to the state registrar.

(d) An order from a court of competent jurisdiction may be used to amend any item except signatures, the date of registration, or to amend the date of death to a date that is after the date of registration.

(9) Notwithstanding sections (2) through (7) of this rule, any item may be amended except signatures if the amendment is required because of clerical error by the facility, institution or individual responsible for submitting the report. The request for amendment shall be supported by a written statement explaining the error.

Stat Auth: ORS 432.235
Stats. Implemented: ORS 432.235
Hist.: PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0305
Marriage and Oregon Registered Domestic Partnership Records

(1) The state registrar shall register Declaration of Oregon Registered Domestic Partnership forms that have been completed, notarized, and filed with an Oregon county clerk.

(a) The form shall be considered complete when all items not identified as optional or statistical have been completed.

(b) If the item "legal name taken after domestic partnership" is not completed, the form may be accepted for registration. A partner not completing the item will retain the legal name prior to the declaration as their sole legal name.

(2) The state registrar shall register the Application, License, and Record of Marriage forms that have been completed by the officiant and filed with the Oregon county clerk who issued the license.

(a) The form shall be considered complete when all items not identified as statistical have been completed. Affidavit of age may be blank if not required by the county clerk under ORS 109.050.

(b) If the item "legal name taken after marriage" is not completed, the form may be accepted for registration. A party not completing the item will retain the legal name prior to the marriage as their sole legal name.

Stat Auth: ORS 432.173
Stats. Implemented: ORS 432.173
Hist.: PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0310
Record of Dissolution

(1) The state registrar shall register Record of Dissolution of Marriage, Annulment or Domestic Partnership forms that have been completed and certified by an Oregon clerk of the court. The form shall be considered complete when the following minimal information has been completed:

(a) Husband/Partner A legal name, date of birth and birthplace;

(b) Wife/Partner B legal name, date of birth and birthplace;

(c) Date of marriage or filing of registered domestic partnership, place of marriage or registered domestic partnership;

(d) Date marriage or registered domestic partnership was dissolved, date judgment becomes effective, county of decree; and

(e) Signature, either physical or electronic, of court official, title of official and date signed.

(2) The clerk of the court shall complete and submit reports of dissolution of marriage or dissolution of domestic partnership for cases where final judgment has been entered on the 5th working day and the 15th working day of each month.

Stat Auth: ORS 432.183
Stats. Implemented: ORS 432.183
Hist.: PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0315
Disposition of Reports of Induced Termination of Pregnancy

(1) Reports of induced termination of pregnancy are statistical reports only and are not to be incorporated into the official records of the Vital Statistics Section. The state registrar is authorized to dispose of such reports when all statistical processing of the records has been accomplished. However, the state registrar may establish a file of such records so they will be available for future statistical and research projects provided such file is not made a part of the official records and the reports are not made available for the issuance of certified copies. Such file shall be retained for as long as the state registrar deems necessary and it shall then be destroyed. The file may be maintained by photographic, electronic, or other means as determined by the state registrar, in which case the original report from which the photographic, electronic, or other file was made shall be destroyed.

(2) The provisions of this regulation shall also apply to all records of induced termination of pregnancy filed prior to the adoption of this regulation.

Stat. Auth.: ORS 432.153
Stats. Implemented: ORS 432.153
Hist.: HB 228, f. 11-5-69; HD 24-1981, f. & ef. 11-17-81; Renumbered from 333-011-0110 by PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0320
Preservation of Vital Records

(1) When an authorized reproduction of a vital record has been properly prepared by the state registrar and when all steps have been taken to provide for the continued preservation of the information, the record from which such authorized reproduction was made may be disposed of by the state registrar. Such record may not be disposed of until:

(a) The quality of the authorized reproduction has been tested to ensure that acceptable certifications can be issued;

(b) A permanent copy of such record has been placed in a secure location removed from the building where the authorized reproduction is housed; and

(c) The original records have been offered to the State Archives.

(2) Such permanent copy described in section (1) shall be maintained in such a manner to ensure that it can replace the authorized reproduction should the authorized reproduction be lost or destroyed.

(3) The state registrar shall offer the original documents from which the authorized reproductions are made to the State Archives. The State Archives shall retain permanently such records and shall adhere to the restrictions in the vital statistics law related to access to such records. If the State Archives declines to place such records in its files the state registrar shall be authorized to destroy the documents. Such destruction shall be in accordance with generally accepted methods for disposition of confidential or sensitive documents.

(4) Microfilm used for preservation shall be manufactured and stored in accordance with the standards established by the State Archives by rule. Redundant copies shall be stored at one or more sites distant from the master copies. Mechanisms for retrieving copies from distant sites shall be documented and periodically tested.

(5) Electronic images of vital record documents shall be indexed for ease of retrieval. Long-term archiving of electronic documents shall follow standards established by the State Archives by rule. The index shall allow for linking of amended or corrected images to the original image. The images shall be stored in a

tamper resistant manner and media. The preservation management program shall include the refreshment of storage media to assure integrity and prevent obsolescence on a periodic basis into new formats as they become accepted.

(6) Vital event information stored as electronic data shall be stored in a manner that is both tamper resistant and tamper evident. All changes to information shall be tracked, including the item changed, the user who made the change, the date of the change, and the justification for the change. Back-ups of electronic data shall be made at regular intervals, and copies shall be stored at one or more sites distant from the master copy. Mechanisms and procedures for retrieving copies from distant sites shall be documented and periodically tested.

(7) The preservation management program shall provide for the periodic refreshment of electronic data, to include hardware, software, and coding standards. The program must include documentation of changes in coding structures, provide for testing of converted files to assure data quality, and address associated costs.

Stat Auth: ORS 432.295
Stats. Implemented: ORS 432.295
Hist.: PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0325
Confidentiality and Disclosure of Information from Vital Records or Vital Reports

To protect the confidentiality and security of vital records and vital reports:

(1) The state registrar shall not permit access to or disclosure of personally identifiable information contained in vital records, or issue a copy of all or part of any such record unless the applicant is authorized to obtain such record for a proper purpose under ORS 432.350, or is authorized to obtain such record under 432.380.

(a) Access to or disclosure of information contained in vital records for sale or release to the public, for direct or indirect marketing of goods or services, for other non-research solicitation of registrants or families of registrants, or for other commercial or speculative purposes shall not be deemed a proper purpose.

(b) The state registrar may impose reasonable conditions as to the use and re-disclosure of information, and may limit access to the minimum necessary to fulfill the purpose for which information is requested.

(2) Requests for personally identifiable information contained in vital records for health research purposes shall be submitted in writing to the state registrar.

(a) Each request shall contain at a minimum:

(A) Name, title, organizational affiliation and contact information (mailing address, telephone number, and electronic mail address) of the requestor and the organizational official authorized to execute agreements;

(B) Title, objectives and description of the proposed research study;

(C) Institutional Review Board approval of study protocol if any contact with study subjects including children or parents listed on live birth records or next-of-kin or informants of decedents is proposed;

(D) Physical and electronic storage and security measures to be taken to assure confidentiality and security of identifying information, and provision for return or destruction of the information at the conclusion of the research study;

(E) Time frame of the research study;

(F) Names of all persons on the research study team who will have access to the personally identifiable information;

(G) Plan for dissemination of the results.

(b) Each request for personally identifiable information from vital records to be used for health research purposes shall be reviewed to determine compliance with at least the following:

(A) Contains all elements required by this rule;

(B) Adequately justifies the need for the requested information;

(C) Compliance with past data use agreements;

(D) The requested information can be provided within the time frame set forth in the request; and

(E) The state registrar has adequate resources with which to comply with the request.

(3) Requests by government agencies for any identifiable information contained in the state's vital records maintained pursuant to ORS Chapter 432, or for verifications thereof, shall specify in writing the official use to which the requested information will be put and why the information is necessary in accordance with ORS 432.350. The request may be granted only if the state registrar agrees that the requested information is necessary for a proper purpose.

(a) Each request shall contain at a minimum:

(A) Name, title, agency, and contact information (mailing address, telephone number, and electronic mail address) of the requestor and the agency official authorized to execute agreements;

(B) Purpose or intended use of the data or vital records being requested;

(C) Physical and electronic storage and security measures to be taken to assure confidentiality and security of identifying information, and provision for return or destruction of the information at the conclusion of the intended use;

(D) Time frame of intended use; and

(E) Names of all persons who will have access to the personally identifiable information being requested.

(b) Each request from a government agency for personally identifiable information from vital records shall be reviewed to determine compliance with at least the following:

(A) Contains all elements required by this rule;

(B) Adequately justifies the need for the requested information;

(C) Compliance with past data use agreements;

(D) The requested information can be provided within the time frame set forth in the request; and

(E) The state registrar has adequate resources with which to comply with the request.

(4) The state registrar shall enter into data use agreements for all approved health research and government agency requests for personally identifiable information from vital records. Each data use agreement shall include but not be limited to:

(a) Specification of exactly what information will be disclosed to the requestor, the purpose for which it is provided, and the manner in which the data will be used;

(b) The charges or fees, if any, to be paid by the requestor to the state registrar for use of the data;

(c) A prohibition of re-release by the requestor of any information that may identify any person or any individual case record, whether identifiable or not, without the prior written approval of the state registrar;

(d) The requestor's acknowledgment and agreement that ownership of all information provided by the state registrar shall remain exclusively that of the state registrar and that the data use agreement constitutes a license to use the data provided only for the purpose and in the manner set forth in the agreement;

(e) The requestor's agreement neither to attempt to link nor to permit others to attempt to link the data set with individually identifiable records from any other data set without the prior written approval of the state registrar;

(f) The requestor's agreement neither to use nor to allow anyone else to use the information to attempt to learn the identity of any person included from the information provided without the prior written approval of the state registrar;

(g) Agreement that if the identity of any person is discovered inadvertently, the recipient:

(A) Will not make use of this knowledge;

(B) Will immediately notify the state registrar; and

(C) Will safeguard or destroy the information which led to the identification of the individual as requested by the state registrar;

(h) Acknowledgment and agreement that the requestor shall be responsible for any breach of security, including but not limited to any notifications to affected persons required by law or by the state registrar, and any fines, penalties or other sanctions that may be imposed pursuant to applicable law.

(i) Agreement to prohibit the use of data provided for any purpose not explicitly identified and approved in the signed data use agreement.

Stat Auth: ORS 432.350
Stats. Implemented: ORS 432.350
Hist.: PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0330
Authentication of Applicant

(1) An authentication quiz shall be used for each application received by telephone, Internet, or through a kiosk. The authentication quiz shall be based on publicly available information and must be information requiring personal knowledge not available from reviewing current information typically found in a wallet.

(a) For applications received by telephone or Internet, successful completion of the authentication quiz shall serve as identification of the applicant and additional documentation shall not be required.

(b) For applications received by telephone or Internet and the authentication quiz is not successfully completed, the applicant shall be instructed to send additional identity documentation to support the application.

(c) For applications received by kiosk and the authentication quiz is not successfully completed, the applicant must show identification documents before receiving a certified copy in person or by mail.

(2) All applicants applying in person must show identification regardless of authentication quiz completion.

(3) Applicants for records for events occurring more than 50 years for death, fetal death, marriage, Oregon registered domestic partnerships or dissolution of marriage or registered domestic partnerships or 100 years for birth, shall be submitted on the same form and in the same manner, including the authentication quiz, as records for current events.

Stat Auth: ORS 432.380
Stats. Implemented: ORS 432.380
Hist.: PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0335
Copies of Vital Records

(1) Full or short form certified copies of vital records may be made by mechanical, electronic, or other reproductive processes, except that the information contained in the "Information for Medical and Health Use Only" section of the record of live birth shall not be included.

(2) When a certified copy is issued, it shall be certified as a true representation of the facts of the event by an authorized agent and shall include the date issued, the name of the state registrar, the state registrar's signature or an authorized facsimile thereof, and the seal of the state and agency authorized under ORS 432.010.

(3) Confidential verification of the facts contained in a vital record may be furnished by the state registrar to any federal, state, county, or municipal government agency or to any other agency representing the interest of the registrant, subject to the limitations as indicated in section (1) of this rule. Such confidential verifications shall be on forms prescribed and furnished by the state registrar or on forms furnished by the requesting agency and acceptable to the state registrar; or, the state registrar may authorize the verification in other ways when it shall prove in the best interests of his or her office.

(4) The state registrar may authorize certification or verification of fact of death to an institution when the institution has demonstrated to the satisfaction of the state registrar that such information is necessary for a determination of or protection of a personal or property right of the institution.

(5) When the state registrar finds evidence that a record was registered through misrepresentation or fraud, he or she shall have authority to withhold the issuance of a certified copy of such record until a court determination of the facts has been made.

(6) The state registrar shall determine the minimum information needed to locate and identify a particular record within the files.

(7) Subject to the penalties of ORS 432.993, no person is authorized to photograph, photostat, duplicate, or issue what purports to be a certified copy, certification, or record of birth, death, or fetal death except authorized employees of the Public Health Division, county registrars, or their deputies, acting in accordance with directives, regulations, or law governing their official duties.

(8) Certified copies of records of death or records of fetal death issued to an employee or agent of a funeral home or a person acting as a funeral service practitioner shall be transferred only to persons eligible to receive certified copies if applying individually.

(9) The county registrar shall forward any completed original birth records received to the state registrar immediately for registration at the state.

(10) Certified copies of death records used to record the transfer of property in Oregon must not include cause of death information if:

(a) The death occurred after 1977;

(b) The death occurred in Oregon; and

(c) The certified copy is issued after January 1, 2014.

Stat. Auth.: ORS 432.010, 432.085, 432.121 & 432.180
Stats. Implemented: ORS 432.010, 432.085, 432.121 & 432.180
Hist.: HB 169, f. & ef. 10-16-63; HD 24-1981, f. & ef. 11-17-81; HD 3-1986, f. & ef. 2-5-86; PH 16-2011, f. 12-28-11, cert. ef. 1-1-12; Renumbered from 333-011-0101 by PH 17-2013, f. 12-26-13, cert. ef. 1-1-14

333-011-0340
Fees

(1) The fee for any search of the files and vital statistics records is $25.

(a) The $25 search fee includes the issuance of one certified copy if the record is located and matched to the request. If no matching record is found, a statement to this effect will be issued in lieu of a record.

(b) The $25 fee covers the cost of a five year search for death, fetal death, marriage, divorce, domestic partnership and dissolution of domestic partnership records. If more than a five year search is requested, an additional fee of $1 per year shall be charged.

(2) The fee for the first certified copy of a death, fetal death, marriage, divorce, domestic partnership, or dissolution of domestic partnership vital statistics record is $25. Additional certified copies of the same record ordered at the same time is $20 for each certified copy through December 31, 2017. Effective January 1, 2018, additional certified copies of the same record ordered at the same time shall be $25 for each certified copy.

(3) The fee for a certified copy of a birth vital statistics record is:

(a) $25 when a computerized version of the record is issued. Additional certified copies of the same record ordered at the same time shall be $20 for each certified copy through December 31, 2017. Effective January 1, 2018, additional certified copies of the same record ordered at the same time shall be $25 for each certified copy.

(b) $30 for each certified copy when an image of the original record is requested by the applicant.

(4) The fee for a certified copy of a recorded court order registering an unrecorded birth under ORS 432.118 is $25.

(5) The fee for a Commemorative Certificate of Stillbirth is $25.

(6) A fee of $35 shall be paid to the state registrar for the preparation of a new or updated record of live birth for amendment, correction, adding the father's name to the birth record or filing of adoption orders and delayed and court registered birth records. This fee does not include a certified copy of the amended record.

(a) The $35 fee may be waived to correct an error or omission by a reporting source if a birth record is corrected within the first year from the date of the event.

(b) The $35 fee may be waived at any future time to correct an error on a record of live birth by a reporting source for date of birth, time of birth or sex of registrant.

(c) An additional service to expedite an amendment within three business days may be available for an additional fee of $30 if the request is matched to a registered record and all required documentation under ORS 432.223 & 432.245, OAR 333-011-0260

through 0275, or OAR 333-011-0300 has been received and approved. This fee does not include a certified copy of the amended record and is in addition to the amendment fee.

(7) A fee of $35 shall be paid to the state registrar for the preparation of an amended death record, if amendments are filed more than one year after the date of death. However, no fee shall be paid for amendments to the cause of death filed by the physician or medical examiner that signed the report of death. This fee does not include a certified copy of the amended record.

(8) A fee of $5 for each certified copy shall be paid for the replacement of certified copies of a death record when the original documents are returned within a year of issuance with an acceptable correction document and appropriate amendment fee. This fee may be waived when the replacement of certified copies is required solely due to an amendment or correction by the medical certifier on the record or a Medical Examiner.

(9) A fee of $5 for each certified copy shall be paid for the replacement of certified copies of a birth record when the original documents are returned within a year of issuance and an acceptable correction document and appropriate amendment fee has been received. The $5 fee may be waived for the replacement of one certified copy of the record of live birth when an amendment is made.

(10) A fee of $7 shall be paid to expedite the search and filling of an order for a certified copy when the order is placed by telephone or the Internet, billed to a credit card and processed within three working days upon receipt of the order. This fee is in addition to the fee charged by a subcontractor providing computer, prepayment, billing and collection services for orders processed using the subcontractor's services.

(11) A fee of $45 shall be paid for heirloom birth certificates under ORS 432.445.

(12) A fee of $30 shall be paid for a certified copy of a person's original record of live birth prior to adoption under ORS 432.228(1).

(13) A fee of $25 shall be paid when submitting a Contact Preference Form to match with an adopted person's record of live birth.

(14) Persons requesting special services or specific data sets shall be charged actual time and material costs of producing the data.

(15) The fee for copies of vital statistics records issued for research approved by the state registrar under ORS 432.350 is $25 for each record. Records for research purposes are issued as uncertified copies.

(16) A fee of $24 shall be paid for making certified copies of documents from sealed files, special files and affidavits and supplemental reports authorized by statute or rule.

(17) A fee of $4 per page shall be charged for uncertified copies of documents from sealed files, special files and affidavits or supplemental reports authorized by statute or rule.

(18) A fee of $10 shall be paid for each manual verification of a vital event for each government agency or subdivision of a government agency requesting over 5 verifications per month.

(19) A fee not to exceed $4 shall be paid for each electronic verification of a vital event. This fee is in addition to the fee charged by a subcontractor providing computer system, billing and collection services for verifications processed using the subcontractor's services.

(20) Overpayment of a required fee received in the office of the state registrar shall be refunded if in excess of $6 and any overpayment less than $6 shall be refunded upon written request of the applicant within one year.

Stat. Auth.: ORS 432.015, 432.350, 432.435 & 432.148
Stats. Implemented: ORS 432.435 & 432.148
Hist.: HB 169, f. & ef. 10-16-63; HD 13-1979(Temp), f. & ef. 10-1-79; HD 18-1979, f. & ef. 12-12-79; HD 2-1985, f. & ef. 2-19-85; HD 1-1987, f. 1-20-87, ef. 2-2-87; HD 10-1990, f. 5-3-90, cert. ef. 7-1-90; HD 4-1992(Temp), f. & cert. ef. 4-28-92; HD 8-1992, f. & cert. ef. 6-22-92; HD 19-1993(Temp), f. & cert. ef. 10-27-93; HD 21-1994, f. & cert. ef. 8-15-94; PH 17-2003, f. 10-31-03, cert. ef. 12-1-03; PH 3-2010, f. & cert. ef. 2-3-10; Renumbered from 333-011-0106 by PH 17-2013, f. 12-26-13, cert. ef. 1-1-14; PH 21-2015, f. 10-30-15, cert. ef. 1-1-16

DIVISION 12

PROCEDURAL RULES

County Performance of the Authority, Responsibilities, and Functions of the Administrator of the Health Division Relating to Traveler's Accommodations, Recreation Parks, Organizational Camps, Swimming Pools, Bath Houses, Food Service Facilities, Mobile Units, and Vending Machines

333-012-0050
General Rules Applicable to All Programs

(1) The purpose of these rules is to establish standards under which local public health authorities shall provide environmental health services to establishments and facilities licensed under ORS Chapters 446, 448 and 624.

(2) Definitions:

(a) "Administrative Costs" means those costs that are over the direct costs of providing delegated program services. These include actual departmental, agency or central government charges such as, but not limited to, accounting, purchasing, human resources, data management, legal council and central mail functions;

(b) "Administrator" means the assistant director for the Public Health Division of the Authority or an authorized representative;

(c) "Authority" means the Oregon Health Authority.

(d) "Complete Inspection" means the evaluation of a licensed establishment or facility conducted at the election of the local public health authority for compliance with all applicable regulations;

(e) "Consultation Services Remittance" means the biennial assessment of the Authority for consultation services and maintenance of the Foodborne Illness Prevention, Public Swimming Pool and Tourist Facility Programs;

(f) "Direct Costs" mean those costs for salaries and benefits of field and support staff and their associated costs including, but not limited to, rent, vehicles and travel, equipment, data management, training, phone, office supplies and the pro-rated portion of direct costs relating to supervision;

(g) "Fiscal Audit" means a comprehensive audit using standard audit procedures of the financial records of the local public health authority related to licenses and fees;

(h) "Local Public Health Authority" means county governments or health districts established under ORS 431.414 that are responsible for management of local public health services;

(i) "Recheck Inspection" means an inspection to determine whether specified corrections have been made or alternative procedures maintained for violations identified in previous inspections. In food service establishments, a recheck inspection also means an inspection to determine whether specific corrections have been maintained for violations creating a significantly increased risk for foodborne illness. Recheck inspections may be conducted either on pre-announced dates or unannounced.

Stat. Auth.: ORS 446.425, 448.100 & 624.510
Stats. Implemented: ORS 446.425, 448.100 & 624.510
Hist.: HD 105, f. & ef. 2-5-76; HD 1-1979, f. & ef. 1-18-79; HD 9-1994, f. & cert. ef. 4-1-94; HD 16-1995, f. 12-28-95, cert. ef. 1-1-96; HD 4-1996, f. & cert. ef. 9-17-96; PH 13-2004, f. & cert. ef. 4-9-04; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 11-2011, f. & cert. ef. 10-27-11; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-012-0053
Licensing and Fees

(1) License applications and licenses issued must be on forms provided or approved by the Authority.

(2) The Local Public Health Authority must establish a single license fee per establishment or facility type. There may not be added fees based on local determination of unique features of an establishment or facility.

(3) Licensing categories must be based upon those specified in ORS 446.310, 448.035 and 624.490. The Local Public Health Authority may not create additional licensing categories.

(4)(a) Annual work hours available for a dedicated full time equivalent (FTE) for field staff in the food service program based

on a 40-hour week is 1640 hours, of which 25 percent is allocated for office and administrative duties and consultation, and 75 percent is for field inspection activities;

(b) Standards for complete inspection functions, on average, including travel time, relative to facility size are as follows:

(A) 0–15 seats, 1-1/2 hours;

(B) 16–50 seats, 1-3/4 hours;

(C) 51–150 seats, 2 hours;

(D) Over 150 seats, 2-1/2 hours.

(c) An average recheck inspection rate of 40 percent with an average priority or priority foundation item recheck inspection taking 45 minutes including travel.

(5) The following standards are established to reflect the levels of effort and resources needed to carry out the delegated functions and provisions of ORS Chapter 624:

(a) Workload indicators established in section (4) of this rule must be used to determine staffing levels budgeted for field inspection activities;

(b) Administrative costs must be limited to 15 percent of direct costs;

(c) A ratio of up to 0.35 FTE for clerical support and up to 0.25 FTE for supervision to field staff FTE respectively, must be observed;

(d) Charges for services and supplies may not exceed a ratio of 0.25 of personnel salary for direct program costs;

(e) In lieu of the administrative standards outlined in this rule, the Local Public Health Authority may determine staffing standards and actual costs of providing program services. The Local Public Health Authority must document and report to the Authority actual time spent and expenses incurred and may be subject to a fiscal audit as specified in OAR 333-012-0070(3).

(6) The Local Public Health Authority may:

(a) Adopt a fee schedule for facilities that require more than two recheck inspections per year;

(b) Adopt a fee schedule for seasonal temporary restaurants and intermittent temporary restaurants that require a recheck inspection;

(c) Set a fee for costs associated with conducting an operational review in accordance with guidelines established by the Authority.

(d) Set a fee for costs associated with plan review conducted under guidelines established by the Authority;

(e) Set a reinstatement fee for late license reinstatement;

(f) Recover the cost of the extra inspections required under OAR 333-157-0027, Increased Inspection Schedule, by charging a fee of up to one-half of the annual licensing fee otherwise assessable to the restaurant for each additional inspection; and

(g) Pro-rate fees for partial year operation as follows:

(A) From January 1 through September 30, a full license fee is required;

(B) From October through December 31, one-half the annual fee must be assessed.

(7) A license may be issued only after the Local Public Health Authority has received the fee and determined that the facility meets the requirements of the statutes and rules.

(8) If license fees assessed by the Local Public Health Authority are more than 20 percent above or below the fees established in ORS 624.490, the Local Public Health Authority must document and report to the Authority actual time spent and expenses incurred on program services and may be subject to a fiscal audit as specified in OAR 333-012-0070(3).

(9) All license fees collected by the Local Public Health Authority pursuant to ORS 446.425, 448.100 and 624.510 must be paid into the county treasury and placed in a special revenue fund or the general fund of the county treasury and placed to the credit of the Local Public Health Authority. Such monies must be used only for program services pursuant to ORS 446.425, 448.100 and 624.510. The Local Public Health Authority must assure on an annual basis that all fees collected are used solely for the purposes of administering the programs as described in this section.

(10) If the Local Public Health Authority requests a fiscal audit required in OAR 333-012-0070(3) be conducted by a private auditing agency, the Local Public Health Authority must pay the costs and a copy of audit report must be provided to the Authority.

Stat. Auth.: ORS 446.425, 448.100 & 624.510
Stats. Implemented: ORS 446.425, 448.100 & 624.510
Hist.: PH 13-2004, f. & cert. ef. 4-9-04; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06; PH 3-2012, f. 2-29-12, cert. ef. 3-1-12; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-012-0055
Inspection Standards

(1) All licensed establishments and facilities, except bed and breakfast facilities, travelers' accommodations, hostels and temporary restaurants, must receive a minimum of one complete inspection for every six months of operation or fraction thereof by the Local Public Health Authority. For vending machines, the Local Public Health Authority shall evaluate at least 10 percent of each licensee's machines during each inspection:

(a) Bed and breakfast facilities must be inspected once per year;

(b) Travelers' accommodations and hostels must be inspected on a schedule in accordance with local public health priorities and with consideration of the following criteria:

(A) Complaints received from a guest at a particular facility;

(B) A history of rule violations;

(C) A request for inspection or consultation from a licensee;

(D) Reports of illness or accidents associated with the facility;

(E) Change of owner or operator;

(F) The facility's method of sewage disposal, source of water and availability of local fire protection services;

(G) Length of time since the last inspection of the facility;

(H) A minimum of one inspection every two years is recommended.

(c)(A) Single-event, seasonal and intermittent temporary restaurants must receive a minimum of one inspection during operation for each license issued;

(B) Notwithstanding paragraph (1)(c)(A) of this rule benevolent single-event temporary restaurants may receive an inspection or a consultation in lieu of an inspection, as determined by the Local Public Health Authority.

(2) The Local Public Health Authority may substitute an alternative inspection procedure or intervention once per year in place of an inspection using alternative criteria approved by the Authority.

(3) The Local Public Health Authority must:

(a) Implement an increased inspection schedule for restaurants as described in OAR 333-157-0027. Up to two of the quarterly inspections may be based upon a menu review consultation, an announced inspection, a risk control plan or other method approved by the Authority;

(b) Conduct a pre-operational or construction inspection after plan review and prior to operation of a new, remodeled, converted, renovated or altered establishment or facility. The pre-operational inspection is in addition to the requirement for a complete inspection in section (1) of this rule;

(c) Conduct a complete inspection to assign a public notice of sanitation within 45 days after opening for a restaurant or bed and breakfast facility. This inspection counts toward one of the inspections required in section (1) of this rule;

(d) Completely fill out inspection reports and include at least the following information:

(A) Specific problem and correction statements for all violations, including Oregon Administrative Rule references;

(B) Except in the food service programs, specify time limits for all corrections stated;

(C) Food Service — Document inspections as specified in OAR chapter 333, division 157, Inspection and Licensing Procedures. In addition, the Local Public Health Authority must indicate on the inspection report how a priority and priority foundation item violation has been corrected during complete and recheck inspections; and

(D) Public Swimming Pools — Document pH, free residual chlorine, total chlorine, total alkalinity, total hardness, cyanuric acid (if used), water clarity (recorded as acceptable or unacceptable),

water temperature, pressure and vacuum gauge readings and flow rate as measured by flow meter.

(e) Conduct recheck inspections of establishments and facilities to determine if timely corrective action has been taken on noted priority or priority foundation item violations or public health hazards;

(f) At a minimum, furnish each environmental health specialist with the following equipment or materials to conduct inspections:

(A) Temperature measuring devices, flashlight, inspection forms and computer inspection equipment, identification and business cards, rules, stickers and forms;

(B) Food Service — Sanitizing swabs, test strips for chlorine and quaternary ammonium;

(C) Public Swimming Pools — Current state-approved pool test kit and a 25-foot tape measure or equivalent device with the ability to accurately measure distance and depth; and

(D) Food and waterborne illness investigation materials, specified in guidelines provided by the Authority, and a light meter for staff to share.

(g) Maintain and update the Food Program Policy Manual as well as other information required by the Authority; and

(h) Upon request, provide technical information and consultation to the public and those holding permits and licenses.

Stat. Auth.: ORS 446.425, 448.100 & 624.510
Stats. Implemented: ORS 446.425, 448.100 & 624.510
Hist.: HD 105, f. & ef. 2-5-76; HD 1-1979, f. & ef. 1-18-79; HD 9-1994, f. & cert. ef. 4-1-94; HD 14-1995, f. 12-28-95, cert. ef. 1-1-96; PH 13-2004, f. & cert. ef. 4-9-04; PH 3-2012, f. 2-29-12, cert. ef. 3-1-12; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12;

333-012-0057
Consultation Services Remittance

(1) Food Service — On behalf of the Authority, the Local Public Health Authority must collect fees from food service establishments and remit to the Authority the monies necessary to maintain the Foodborne Illness Prevention Program. The Local Public Health Authority must keep the remainder to cover administration and enforcement costs.

(a) The Authority must consult with representatives of local health officials in determining the amount to be remitted by each Local Public Health Authority to support the state Foodborne Illness Prevention Program;

(b) The consultation must occur no later than April of each legislative year in order to determine the amount required to be remitted to the Authority in the following biennium;

(c) The consultation must consider program expenditures, the program workplan and other activities, and current food service establishment inventories to determine the amount of the remittance;

(d) For the purposes of this rule, food service establishments are considered to be full and limited service restaurants, bed and breakfast facilities, mobile food units, commissaries and warehouses;

(e) The remittance amount must be determined by first projecting statewide food service license revenue for the biennium using state marker fees. Then, the biennial budget of the Foodborne Illness Prevention Program is divided by the revenue projection to yield a percentage factor. Each Local Public Health Authority's revenue projection for food service facilities, using state marker fees, is then multiplied by that factor to yield the remittance amount;

(f) The Foodborne Illness Prevention Program budget must be developed after consultation with groups representing local health officials pursuant to ORS 624.510. The cost to the Local Public Health Authority of the Foodborne Illness Prevention Program shall be represented in the annual Intergovernmental Agreement.

(g) The Local Public Health Authority must provide to the Authority a quarterly remittance based on the total biennial assessment. Fifty percent of the assessment is payable each year unless otherwise negotiated with the Authority. The annual amount remitted by the Local Public Health Authority in the first year of the biennium may not be less than 35 percent of the total biennial amount. Each Local Public Health Authority must provide a statement identifying the proposed timetable and schedule for remittance;

(h) In April of even-numbered years, the Authority must recalculate the assigned assessment for the second year of the biennium, based on updated facility counts and program expenditures and provide the Local Public Health Authority with a revised assessment for the second year of the biennium;

(i) All assessments may not be represented as a surcharge or added charge.

(2) Public Swimming Pools — The Authority must consult with representatives of local health officials and industry in determining the amount to be remitted by each Local Public Health Authority that has accepted delegation for the Public Swimming, Spa and Wading Pool Programs for the purposes of supporting the statewide consultation and program services costs:

(a) The consultation must occur no later than April of each legislative year in order to determine the amount required to be remitted to the Authority in the following biennium;

(b) The consultation must consider program expenditures and current public swimming pool, public spa pool and public wading pool facility inventories while determining the amount of the remittance;

(c) The county shall remit, on a quarterly basis, a portion of the fee for each license issued in that quarter;

(d) All assessments may not be represented as a surcharge or added charge.

(3) Tourist Facilities — Each quarter, the Local Public Health Authority must remit 15 percent of the state licensing fee or 15 percent of the Local Public Health Authority license fee, whichever is less, to the Authority for consultation services and maintenance of the statewide program for facilities licensed under ORS 446.425. All assessments may not be represented as a surcharge or added charge

Stat. Auth.: ORS 446.425, 448.100 & 624.510
Stats. Implemented: ORS 446.425, 448.100 & 624.510
Hist.: HD 12-1995, f. 12-28-95, cert. ef. 1-1-96; PH 13-2004, f. & cert. ef. 4-9-04; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-012-0060
Staffing and Training

(1) The Local Public Health Authority must provide the staff, facilities, materials and equipment necessary to comply with these rules.

(2) Inspections must be conducted by staff that are registered as required by ORS Chapter 700.

(3) Each Local Public Health Authority must:

(a) Require at least one environmental health specialist engaged in the food, tourist facility and public swimming pool programs to attend annual Authority sponsored or approved training in all three program areas;

(b) Within one year of hiring, send all environmental health specialists to an orientation provided by the Authority. This requirement does not apply to staff that have previously attended the training while employed in another jurisdiction;

(c) Maintain at least one environmental health specialist on staff or through contract that has a current certification from the Authority as a food service standardization officer.

(A) New employees must be certified within 18 months of employment or within 18 months after becoming registered as an environmental health specialist as required in section (2) of this rule;

(B) Notwithstanding the time limits specified in paragraph (3)(c)(A) of this rule, the Local Public Health Authority may develop a training plan approved by the Authority that allows for a longer time limit to comply with the certification requirement in subsection (c) of this section.

(d) Maintain at least one environmental health specialist on staff or through contract that has successfully completed a NSPF Certified Pool Operator course or equivalent approved by the Authority within 24 months of employment. The Authority may waive this requirement upon request.

Stat. Auth.: ORS 446.425, 448.100 & 624.510
Stats. Implemented: ORS 446.425, 448.100 & 624.510
Hist.: HD 105, f. & ef. 2-5-76; HD 1-1979, f. & ef. 1-18-79; HD 15-1980(Temp), f. & ef. 12-29-80; HD 5-1985, f. & ef. 4-25-85; HD 9-1994, f. & cert. ef. 4-1-94; PH 13-2004, f. & cert. ef. 4-9-04; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-012-0061
Food Handler Training

The Local Public Health Authority must ensure the provision of a food handler training program using minimum criteria developed by the Authority. The Local Public Health Authority must secure Authority approval before deviating from the criteria of the training program for food handlers, and must document in a manner satisfactory to the Authority the training methods used for food handler training.

Stat. Auth.: ORS 446.425, 448.100 & 624.510
Stats. Implemented: ORS 446.425, 448.100 & 624.510
Hist.: PH 13-2004, f. & cert. ef. 4-9-04; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-012-0063
Record Keeping and Reporting

The Local Public Health Authority must:

(1) Maintain records of all administrative matters delegated under ORS 446.425, 448.100 or 624.510, including a record of the hearing, the time, date, place and copies of the complaint, all intended actions, orders, and final disposition of the proceedings and retained for at least three years.

(2) At a minimum, maintain records according to the Secretary of State, Archives Division rules, OAR chapter 166, of the following:

(a) Inspection reports;

(b) Complaints and their disposition;

(c) Communicable disease or suspected foodborne illness investigations;

(d) Public swimming pool accidents;

(e) License applications and licenses issued;

(f) Food service inspection scores;

(g) Changes in public notice placards;

(h) Food handler training materials;

(i) Plan review records;

(j) Records of all license denials, revocations, suspensions or other temporary closures; and

(k) Failed to Comply notices posted or any other enforcement actions taken.

(3) Provide to the Authority program information such as inspections conducted, workload indicators, fee schedules and violation summaries on request.

(4) Respond to surveys conducted by the Authority. Program information and surveys must be submitted on forms or in a format as required by the Authority.

Stat. Auth.: ORS 446.425, 448.100 & 624.510
Stats. Implemented: ORS 446.425, 448.100 & 624.510
Hist.: PH 13-2004, f. & cert. ef. 4-9-04; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-012-0065
Epidemiology and Accident Investigation and Reporting

The Local Public Health Authority must:

(1) Investigate all suspected illnesses connected with food service facilities, public swimming pools and tourist facilities;

(2) Submit reports of all investigations of confirmed illnesses to the Authority as required by OAR chapter 333, division 018;

(3) Notify the Authority of investigations expected to result in confirmed foodborne illness; and

(4) Investigate all reportable accidents and report the results of investigations in writing, including copies of accident reports, to the Authority.

Stat. Auth.: ORS 446.425, 448.100 & 624.510
Stats. Implemented: ORS 446.425, 448.100 & 624.510
Hist.: HD 105, f. & ef. 2-5-76; HD 1-1979, f. & ef. 1-18-79; HD 9-1994, f. & cert. ef. 4-1-94; PH 13-2004, f. & cert. ef. 4-9-04; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-012-0067
Enforcement Procedures

The Local Public Health Authority must:

(1) Adopt and comply with rules for conducting administrative hearings for permit and license denial, suspension or revocation in accordance with the requirements of ORS Chapter 183.

(2) Utilize all administrative and legal means necessary to enforce the applicable statutes and rules and implement policies relating to the programs and to eliminate conditions endangering public health or safety.

Stat. Auth.: ORS 446.425, 448.100 & 624.510
Stats. Implemented: ORS 446.425, 448.100 & 624.510
Hist.: PH 13-2004, f. & cert. ef. 4-9-04; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-012-0070
Minimum Standards, Program Review and Penalties

(1)(a) The Local Public Health Authority may request approval from the Authority to implement alternative inspection or enforcement procedures by submitting a plan that includes expected performance measures and outcomes. If approved, the alternative inspection or enforcement procedures must be included in the annual Intergovernmental Agreement.

(b) The Local Public Health Authority may adopt ordinances on applicable matters provided they are not less stringent than the Oregon Administrative Rules adopted pursuant to ORS Chapters 183, 446, 448 and 624. Any ordinance proposed for adoption on matters applicable to food service operators more stringent than those set forth in ORS Chapter 624 and rules adopted thereunder must be approved by the Authority and the cost of implementing any ordinance so adopted may not be charged to license fees adopted pursuant to ORS 624.510(2). Notwithstanding the provisions of this subsection, when an emergency exists and delay may result in an immediate danger to public health, Local Public Health Authorities may adopt ordinances without prior Authority approval. This subsection does not affect ordinances that are required to be adopted as specified in these rules.

(2) The Local Public Health Authority is subject to a performance review by the Authority of both office and field activities to determine compliance with these rules. A review of each Local Public Health Authority shall be conducted at least once every three years by the Authority. The Authority shall submit the results of the review to the Local Public Health Authority. The field review may be conducted using an inspection protocol approved by the Authority. The Authority may waive the requirement for a field review.

(3) The Authority shall conduct a triennial fiscal audit of the Local Public Health Authority and the Authority may conduct additional fiscal audits of the Local Public Health Authority if deemed necessary.

(4) The Local Public Health Authority shall be surveyed by the Authority at least annually to determine accomplishments and needs. The survey results shall guide the Authority in providing assistance, guidance, training, consultation and support as needed.

(5) If a performance review reveals that the Local Public Health Authority is not complying with the provisions of these rules or the Intergovernmental Agreement, the Local Public Health Authority shall be notified by the Authority of the areas of noncompliance. The Local Public Health Authority must correct the deficiencies within the time frames required and report the corrections to the Authority.

(a) If the Authority determines that the deficiencies result in a serious human health hazard, compliance shall be required immediately. If the Authority determines that the deficiencies do not result in a serious human health hazard, a longer period of time may be allowed for compliance. However, the maximum time allowed for compliance, after notice is issued by the Authority, is as follows:

(A) Up to 90 days to correct administrative deficiencies such as, but not limited to, accounting reports and records;

(B) Up to 180 days to correct program deficiencies such as, but not limited to, inadequate frequency of inspections, scoring, staffing and lack of enforcement action.

(b) Notwithstanding subsection (5)(a) of this rule, the Authority may allow a longer time frame for compliance if deemed necessary;

(c) If the Authority determines that the Local Public Health Authority did not use the proper cost elements in determining the fee or that the amount of the fee is not justified, the Authority may order the Local Public Health Authority to adjust any fee, as soon as is possible, to a level supported by the Authority's analysis of the fee.

(6) When a Local Public Health Authority has been notified of an emergency health hazard and is either unwilling or unable to administer or enforce delegated standards, the Authority may, pursuant to ORS 431.170, immediately take responsibility of the functions and collect the monies necessary to protect public health. When the health hazard has been resolved or is no longer an emergency, the Authority may return authority to the Local Public Health Authority and may initiate a review to determine if delegation is to be continued.

(7) The Authority may deny or revoke the delegation of a program if the Local Public Health Authority:

(a) Does not have sufficient qualified personnel to conduct the program;

(b) Has failed to perform its delegated duties satisfactorily;

(c) Has engaged in deceit or fraud in the conduct of the program or maintenance of its associated records.

(8) Suspension or rescission of a delegation must be in accordance with ORS Chapter 183 relating to contested cases.

(9) The Authority shall immediately respond to a request by the Local Public Health Authority for personnel or equipment during an emergency. If the Authority is unable to assist as requested, the Authority shall immediately notify the Local Public Health Authority and provide any possible assistance.

Stat. Auth.: ORS 446.425, 448.100 & 624.510
Stats. Implemented: ORS 446.425, 448.100 & 624.510
Hist.: HD 105, f. & ef. 2-5-76; HD 1-1979, f. & ef. 1-18-79; HD 9-1994, f. & cert. ef. 4-1-94; PH 13-2004, f. & cert. ef. 4-9-04; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-012-0500 [Renumbered to **830-040-0090**]

DIVISION 13

CHEMICAL ANALYSIS FOR ALCOHOLIC CONTENT OF BLOOD

Laboratory Methods

333-013-0004
Definitions

The term "Blood" as used in ORS 813.010 and 813.160 means any of the following:

(1) "Plasma" means the liquid portion of blood including the clotting factors, prepared by mechanical separation of the liquid from cellular components after the inhibition of the clotting process.

(2) "Serum" means the liquid portion of blood minus the clotting factors, prepared by separation of the liquid from the clot upon completion of the clotting process.

(3) "Whole Blood" means the fluid that circulates through the heart, arteries and veins; composed of cellular and liquid components.

Stat. Auth.: ORS 813.160
Stats. Implemented: ORS 813.010 & 813.160
Hist.: HD 27-1988, f. & cert. ef. 12-7-88; HD 8-1989, f. & cert. ef. 9-21-89; PH 9-2012, f. & cert. ef. 6-11-12

DIVISION 14

CONFERENCE OF LOCAL HEALTH OFFICIALS

Standards for County and District Health Departments

333-014-0040
Purpose

The purpose of these rules is to establish minimum standards and administrative rules to:

(1) Define the organization, operation, and extent of activities required or expected of county and district health departments to carry out their responsibilities in implementing the public health laws of this state, and the rules and regulations of the State Public Health Division.

(2) Assist in the development, improvement, and support of local health departments in their efforts to promote and protect the health of Oregon citizens.

(3) Govern the process if a county or health district makes a decision to relinquish local public health authority and the actions that the Public Health Division must take following a relinquishment of local public health authority.

Stat. Auth.: ORS 431.350
Stats. Implemented: ORS 431.345 & 431.375
Hist.: HB 269, f. 4-19-71, ef. 5-11-71; HD 5-1990, f. & cert. ef. 1-24-90; PH 19-2014(Temp), f. & cert. ef. 6-20-14 thru 12-17-14; PH 31-2014, f. & cert. ef. 12-17-14

333-014-0042
Definitions

As used in OAR chapter 333, division 14:

(1) "Enforcement" means an action taken to compel the requirements of the law.

(2) "Local public health administrator" has the meaning given that term in ORS 431.260.

(3) "Local public health authority" has the meaning given that term in ORS 431.260.

(4) "Public Health Division" means the public health division within the Oregon Health Authority.

(5) "Public health law" has the meaning given that term in ORS 431.260.

Stat. Auth.: ORS 413.042, 431.350
Stats. Implemented: ORS 431.345, 431.380, 431.385
Hist.: Hist.: PH 19-2014(Temp), f. & cert. ef. 6-20-14 thru 12-17-14; PH 31-2014, f. & cert. ef. 12-17-14

333-014-0050
Health Department Services

(1) Each county and district health department shall perform (or cause to be performed) all of the duties and functions imposed upon it by Oregon Revised Statutes, and by official administrative rules adopted by the Public Health Division and filed with the Secretary of State. These duties and functions shall be performed in a manner consistent with Minimum Standards for Local Health Departments, adopted by the Conference of Local Health Officials (CLHO).

(2) The following program areas shall be considered essential, and be specifically included in the overall annual plan of each county and district health department who shall assure programs are available:

(a) Control of reportable communicable disease which includes providing epidemiologic investigations which report, monitor, and control communicable disease and other health hazards; providing diagnostic and consultative communicable disease services; assuring early detection, education, and prevention activities which reduce the morbidity and mortality of reportable communicable disease; assuring the availability of immunizations for human and animal target populations; and collecting and analyzing of communicable disease and other health hazard data for program planning and management to assure the health of the public;

(b) Parent and child health which includes education, screening and follow up, counseling, referral, or health services for family planning, perinatal care, infants, and children;

(c) Health statistics which includes birth and death reporting, recording, and registration; analysis of health indicators related to morbidity and mortality; and analysis of services provided with technical assistance from the Public Health Division;

(d) Information and referral services to the public regarding local health and human services;

(e) Environmental health services which includes inspection, licensure, consultation and complaint investigation of food services, tourist facilities, institutions, public swimming and spa pools, and regulation of water supplies, solid waste and on site sewage disposal systems.

(3) In addition, each county and district health department should include or provide for programs in the following areas (according to the community's health needs):

(a) Dental health, including preventive education, promotion of fluoride use and procedures for early detection and treatment of dental problems;

(b) Emergency preparedness including participation in the development of the county's emergency response plans and internal procedures necessary to carry out the health department's role in the plans;

(c) Health education/health promotion including activities and programs to promote health and assist individuals and groups to achieve and maintain healthy behaviors;

(d) Laboratory services including providing diagnostic and screening tests to support public health services which are in compliance with quality assurance guidelines established by the Public Health Division;

(e) Medical examiner services to coordinate the epidemiological investigation of deaths of public health significance with the county medical examiner;

(f) Nutrition services including identification and intervention with clients at nutritional risk, and education and consultation for the promotion of good dietary habits;

(g) Older adult health including services to reduce morbidity and premature death; detect conditions which impair functioning; strengthen the ability to remain independent; and to promote physical, social and emotional well-being;

(h) Primary health care services including participation in community efforts to promote necessary services and/or provide health services;

(i) Shellfish Sanitation (in coastal counties) to monitor harvesting and provide public information to harvesters of shellfish.

(4) Each county and district health department, given the specific needs of their local communities, may decide to implement additional programs.

Stat. Auth.: ORS 431.350
Stats. Implemented: ORS 431.345, 431.385 & 431.416
Hist.: HB 205, f. 3-26-68; HD 5, 1990, f. & cert. ef. 1-24-90

333-014-0060
Program Plans

(1) Each county and district health department shall submit an annual plan by May 1 of each year to the Public Health Division.

(2) The Public Health Division shall develop the format of the plan in consultation with the Conference of Local Health officials.

(3) The plan should address all program areas identified in section (2) of this rule and any that are applicable in OAR 333-014-0050(3) including:

(a) Program indicators as defined by CLHO standards and agreed upon by the local health department and the Public Health Division; and/or

(b) A statement describing why services defined in OAR 333-014-0050(2) are not being provided.

(4) The annual plan shall become a key element of the county review done by the Public Health Division.

(5) The Public Health Division shall provide technical assistance on request to local health departments in developing the annual plan.

Stat. Auth.: ORS 431.350
Stats. Implemented: ORS 431.385
Hist.: HB 269, f. 4-19-71, ef. 5-11-71; HD 5-1990, f. & cert. ef. 1-24-90

333-014-0070
Organization

Each county and district health department shall:

(1) Employ a qualified administrator who is responsible for the operation of the health department;

(2) Employ registered nurses licensed by the Board of Nursing, sanitarians registered by the Sanitarians Registration Board, and such other administrative professional, technical, and clerical staff sufficient to carry out the responsibilities of the department;

(3) Employ or contract with a physician licensed by the Oregon Medical Board as health officer;

(4) Use as guidelines for employment the minimum personnel qualifications as defined in the CLHO standards;

(5) Adhere to state or county civil service, merit system, or personnel rule requirements in the selection, promotion, or termination of all health department staff;

(6) Maintain an office open to the public during the normal work week of the local government.

Stat. Auth.: ORS 431.350
Stats. Implemented: ORS 431.345
Hist.: HB 269, f. 4-19-71, ef. 5-11-71; HD 5-1990, f. & cert. ef. 1-24-90

333-014-0080
Relinquishment of Local Public Health Authority

(1) If a county or health district chooses to relinquish its local public health authority under ORS 431.375(2) it must submit a written notice to the Public Health Division that it intends to relinquish its local public health authority, at least 365 days prior to the date of relinquishment. The notice must include an explanation of why the county or health district intends to relinquish public health authority and must include the date of relinquishment. The date of relinquishment must not be less than 365 days from the date of the notice.

(2) Within 30 days of receipt of the notice described in section (1) of this rule the Public Health Division will schedule a public hearing in the affected county or health district to inform the public on the process of relinquishment and solicit input from the community. The Public Health Division shall conduct as many public meetings in the affected county or health district as it deems necessary to obtain public input.

(3) Within 45 days of receipt of the notice described in section (1) of this rule the Public Health Division must attempt to schedule a meeting with the governing body of the county, county board of health or district board of health, as applicable to determine what steps might be taken to reverse or mitigate the county's or health district's proposed action to relinquish public health authority.

(4) A county or health district that has relinquished its public health authority:

(a) Is not eligible for funds under ORS 431.380 or funds that are customarily distributed through an agreement delegating state public health authority to the county or health district; and

(b) May not be delegated any authority under ORS 433.855, 446.425, 448.100, 448.170, and 624.510 because in relinquishing its public health authority it has refused to provide environmental health services under 431.416(2)(d), or is no longer the local public health authority.

(5) On the date of relinquishment the county or health district must return any unexpended funds that were distributed under ORS 431.380, or through any other agreement through which state public health authority was delegated to a county or health district.

(6) A county or health district must continue to comply with any contract or agreement with the Public Health Division that concerns any of the services or activities required by a local public health authority under OAR 333-014-0050(2), including but not limited to the financial assistance agreement for local public health services, until the date of relinquishment. The county or health district must provide notice to the Public Health Division, in accordance with the termination provisions of the contract or agreement, that the contract or agreement is terminated as of the date of relinquishment.

(7) The Public Health Division will reasonably act to take actions necessary to ensure that basic public health services are provided in the affected county or health district in accordance with OAR 333-014-0090. Such actions by the Public Health Division do not:

(a) Relieve the county or health district of its obligations arising during the period of its authority;

(b) Constitute a release or waiver by the Public Health Division with respect to such obligations; or

(c) Relieve the county or health district of obligations it may have under state law notwithstanding the relinquishment of its local public health authority.

(8) A county or health district that relinquishes its local public health authority remains responsible for fulfilling the responsibilities of the county or health district, local public health administrator or local public health department as follows:

(a) Enforce public health laws under ORS 431.150.

(b) Appoint a local public health administrator and health officer under ORS 431.418.

(c) Receive reports of reportable diseases under ORS 433.004.

(d) Investigate reports of reportable diseases, in coordination with the Public Health Division, under ORS 433.006.

(e) Disease control in schools, including but not limited to review of administrative records for required vaccinations and related school exclusions under ORS 433.235 to 433.284 and OAR chapter 333, division 50.

(f) Receive reports of animal bites under ORS 433.345.

(g) Permit mass gatherings under ORS 433.745.

(9) A county or health district that has relinquished its public health authority may, at any time, request that its authority be restored. Such a request must be made to the State Public Health Director in writing and shall include an annual plan, a detailed explanation about how the issues that led to relinquishment have been addressed, and a plan to transition authority from the Public Health Division to the county or health district. The State Public Health Director shall consider the request and respond, in writing, either granting or denying the request within 90 days of the receipt of the request.

(a) If the request is approved, the Public Health Division shall identify the date that authority shall be transferred back to the county or health district.

(b) If the request is denied the State Public Health Director shall explain the basis for rejecting the request and shall include information about how the county or health district can address its deficiencies.

Stat. Auth.: ORS 413.042 & 431.375
Stats. Implemented: ORS 431.375
Hist.: PH 19-2014(Temp), f. & cert. ef. 6-20-14 thru 12-17-14; PH 31-2014, f. & cert. ef. 12-17-14

333-014-0090
Public Health Division as Local Public Health Authority

(1) If the local public health authority has relinquished its public health authority the Public Health Division shall perform the services or activities necessary to provide basic local public health services under ORS 431.380 to the extent funds are available, and may contract with a private person or entity; an agency; or another county or health district to perform all or part of the necessary public health services or activities. The services that are considered basic local public health services are those required to fulfill statutory obligations as follows:

(a) Investigation of reportable diseases, disease outbreaks, or epidemics under ORS 433.004;

(b) Isolation and quarantine under ORS 433.121 to 433.142;

(c) Investigation and control of tuberculosis (TB) under ORS 433.332;

(d) Order the destruction of animals with rabies under ORS 433.350;

(e) Indoor Clean Air Act enforcement under ORS 433.875;

(f) Family planning and birth control services under ORS 435.205;

(g) Initiate and conduct discussions of family planning under ORS 435.205;

(h) Women, Infants and Children (WIC) services under ORS 413.500;

(i) Licensure of tourist accommodations, including hostels, picnic parks, recreation parks and organizational camps under ORS 446.310 to 446.350;

(j) Licensure of pools and spas under ORS 448.005 to 448.100;

(k) Restaurant licensure, including commissaries, mobile units, vending machines and bed and breakfasts under ORS 624.310 to 624.430; and

(l) Regulation of public water systems under ORS 448.115 to 448.285

(2) A county or health district shall be financially responsible for the costs incurred by the Public Health Division or its contractor in taking enforcement actions as a result of a county or health district's relinquishment of local public health authority. Enforcement actions include but are not limited to:

(a) Any action taken by the Public Health Division necessary to fulfill a county, health district, local public health administrator or local public health department obligation described in OAR 333-014-0080(8);

(b) Any action taken by the Public Health Division under ORS 431.170;

(c) Isolation or quarantine under ORS 433.121 to 433.142;

(d) Inspections, investigations, and legally required activities under:

(A) ORS 433.004 and 433.006 (control of communicable disease);

(B) ORS 433.267 (immunization of school children); or

(C) ORS 433.235 to 433.284 (disease control in schools).

(e) Court actions to ensure compliance with state public health laws; and

(f) The defense of any Public Health Division action in court.

(3) Notwithstanding section (2) of this rule, a county or health district shall not be financially responsible for an enforcement action as described in section (2) of this rule if the action was commenced by the Public Health Division under its own authority and not as a result of the relinquishment of local authority.

(e) The defense of any agency action in court.

Stat. Author: ORS 413.042, 431.262 & 431.375
Stats. Implemented: ORS 431.170 & 431.375
Hist.: PH 19-2014(Temp), f. & cert. ef. 6-20-14 thru 12-17-14; PH 31-2014, f. & cert. ef. 12-17-14

333-014-0100
Applicability

(1) OAR 333-014-0080 and 333-014-0090 apply to any county or health district that provides notice of its intent to relinquish its local public health authority or has relinquished its public health authority on or after June 20, 2014.

(2) For purposes of these rules the date of relinquishment is the date the county or health district identifies in its notice as the date it will no longer be the local public health authority.

Stat. Author: ORS 413.042 & 431.375
Stats. Implemented: ORS 431.375
Hist.: PH 19-2014(Temp), f. & cert. ef. 6-20-14 thru 12-17-14; PH 31-2014, f. & cert. ef. 12-17-14

DIVISION 15

IMPLEMENTATION OF REQUIREMENTS FOR OREGON'S INDOOR CLEAN AIR ACT, NUTRITIONAL INFORMATION AT CHAIN RESTAURANTS AND

STANDARDS FOR REDUCING THE SALE OF TOBACCO AND INHALANT DELIVERY SYSTEMS TO MINORS

Oregon Indoor Clean Air Act

333-015-0025
Authority and Purpose

(1) These rules are adopted pursuant to the authority granted to Oregon Health Authority, Public Health Division, in ORS 433.835 through 433.875 and 433.990(5) concerning smokefree places of employment and public places.

(2) The purpose of the Oregon Indoor Clean Air Act is to reduce the health hazard caused to persons by inhaling smoke from tobacco products.

Stat. Auth.: ORS 433.855
Stats. Implemented: ORS 433.835 -433.875, 433.990(5)
Hist.: HD 10-1983, f. & ef. 7-1-83; OHD 8-2002(Temp), f. & cert. ef. 5-28-02 thru 11-22-02; OHD 12-2002, f. & cert. ef. 8-27-02; PH 18-2004(Temp), f. & cert. ef. 5-7-04 thru 10-27-04; PH 27-2004, f. & cert. ef. 8-19-04; PH 12-2008, f. 8-15-08, cert. ef. 1-1-09; PH 2-2012, f. & cert. ef. 2-1-12

333-015-0030
Definitions

For purposes of OAR chapter 333, division 15, the following definitions shall apply:

(1) "Accessibility ramp" means a ramp intended to provide access for people with disabilities to and from an entrance or exit.

(2) "Act" means the Oregon Indoor Clean Air Act as it appears in ORS 433.835 through 433.875 and 433.990(5).

(3) "Authority" means the Oregon Health Authority.

(4) "Certificate holder" means the individual or entity on record with the Oregon Health Authority as the owner of a certified cigar bar or smoke shop.

(5) "Cigar bar" means a business that:

(a) Has on-site sales of cigars as defined in ORS 323.500;

(b) Has a humidor on the premises;

(c) Allows the smoking of cigars on the premises but prohibits the smoking, aerosolizing or vaporizing of other inhalants on the premises;

(d) Has been issued and operates under a full on-premises sales license issued under ORS 471.175;

(e) Prohibits persons under 21 years of age from entering the premises and posts notice of the prohibition;

(f) Does not offer video lottery games as authorized under ORS 461.217;

(g) Has a maximum seating capacity of 40 persons;

(h) Has a ventilation system that exhausts smoke from the business, and is designed and terminated in accordance with the state building code standards for the occupancy classification in use; and

(i) Requires all employees to read and sign a form approved and published by the Public Health Division that explains the dangers of exposure to secondhand smoke.

(6) "Cigarillos" means a smoking device wrapped in tobacco leaf, rather than paper, that contains less than three grams of tobacco and measures less than 100 mm in length.

(7) "Employer" means any entity or individual who engages an individual to perform work or services in an area where smoking is prohibited under the employer's control.

(8) "Enclosed area" means all space between a floor and a ceiling that is enclosed on two or more sides by permanent or temporary walls or windows, exclusive of doors, passageways or gaps. If no ceiling is present, "enclosed area" means all space that is included by three or more sides by permanent or temporary walls or windows, exclusive of doors, passageways or gaps.

(9) "Entity in charge of a public place" means any person or organization that has responsibility because of ownership, proprietorship, management, or oversight over a place that is open to the public. Entity in charge of a public place is used to refer only to a person or organization in charge that is not also an employer.

(10) "Entrance" means any point of ingress, including an accessibility ramp, to an enclosed area from a non-enclosed area.

(11) "Exit" means any point of egress, including an accessibility ramp, from an enclosed area to a non-enclosed area.

(12) "Extended period of time" means more than 365 consecutive days.

(13) "Gross revenue" means all receipts from the sale of product(s) less the amount of any rebates, refunds, or credits.

(14) "Humidor" means a storage container designed to allow controlled airflow and equipped with a device that maintains the internal humidity in the range of 68 percent to 75 percent and an internal temperature in the range of 68 degrees to 70 degrees Fahrenheit.

(15) "Inhalant" means nicotine, a cannabinoid or any other substance that:

(a) Is in a form that allows the nicotine, cannabinoid or substance to be delivered into a person's respiratory system;

(b) Is inhaled for the purpose of delivering the nicotine, cannabinoid or other substance into a person's respiratory system; and

(c)(A) Is not approved by, or emitted by a device approved by, the United States Food and Drug Administration for a therapeutic purpose; or

(B) If approved by, or emitted by a device approved by, the United States Food and Drug Administration for a therapeutic purpose, is not marketed and sold solely for that purpose.

(16)(a) "Inhalant delivery system" means:

(A) A device that can be used to deliver nicotine or cannabinoids in the form of a vapor or aerosol to a person inhaling from the device; or

(B) A component of a device described in this subsection or a substance in any form sold for the purpose of being vaporized or aerosolized by a device described in this subsection, whether the component or substance is sold separately or is not sold separately.

(b) Inhalant delivery system does not include:

(A) Any product that has been approved by the United States Food and Drug Administration for sale as a tobacco cessation product or for any other therapeutic purpose, if the product is marketed and sold solely for the approved purpose; and

(B) Tobacco products.

(17) "Local Public Health Authority" or "LPHA" means the county government, unless a health district has been formed under ORS 431.414, the county has contracted with a person or agency to act as the public health authority, or the county has relinquished its authority to the state.

(18) "Maximum seating capacity" means the total number of seats available to patrons, including, but not limited to, bar stools, seating at cocktail tables, seats at buddy-bar tables, banquette seating, dining seating, couch space, and floor pillows intended as seating; as well as the total number of patrons a business permits inside the business at the same time.

(19) "Noncommercial tobacco products" means unprocessed tobacco plants or tobacco by-products used for ceremonial or spiritual purposes by American Indians.

(20) "Place of employment" means an enclosed area under the control of a public or private employer, including work areas, employee lounges, vehicles that are operated in the course of an employer's business and that are not operated exclusively by one employee, rest rooms, conference rooms, classrooms, cafeterias, hallways, meeting rooms, elevators and stairways. Place of employment does not include a private residence unless it is used as a child care facility as defined in ORS 657A.250 or a facility providing adult day care as defined in 410.490.

(21) "Private residence" means a residence or part of a residence that is not operated as a place of business where clients or customers use the premises. A residence that is considered a place of employment or public place is subject to ORS 433.835 through 433.875 during its hours of operation. Only that part of a residence used as a place of business is subject to ORS 433.835 through 433.875.

(22) "Public Health Director" means the director of the Public Health Division of the Oregon Health Authority.

(23) "Public Health Division" means the Public Health Division of the Oregon Health Authority.

(24) "Public place" means an enclosed area open to the public.

(25) "Rooms designated by the owner or entity in charge of a hotel or motel as rooms in which smoking is permitted" means sleeping rooms or suites in that hotel or motel.

(26) "Smoking instrument" means any cigar, cigarette, pipe, or other instrument used to smoke tobacco, marijuana or any other inhalant.

(27) "Smoke shop" means a business that is certified with the Oregon Health Authority as a smoke shop under OAR 333-015-0068.

(28) "Stand-alone business" means a business that is not attached to, does not use or occupy the same space as, is not located within, and does not share a common entryway or area with another business, another place of employment, or residential property.

(29) "Tobacco Prevention and Education Program" means the Tobacco Prevention and Education Program in the Public Health Division of the Oregon Health Authority.

(30) "Wall" means any architectural partition, permanent or temporary, with a height and length greater than its thickness, used to divide or enclose an area or to support another structure. Walls include, but are not limited to, partitions constructed of plastic, mesh or other screening materials, slats, louvered blinds, fabric, or blankets, and partitions with latticing or other open frameworks.

(31) "10 feet" means 10 linear feet, measured in a straight line between the points in question.

Stat. Auth.: ORS 433.855
Stats. Implemented: ORS 433.835
Hist.: HD 10-1983, f. & ef. 7-1-83; OHD 8-2002(Temp), f. & cert. ef. 5-28-02 thru 11-22-02; OHD 12-2002, f. & cert. ef. 8-27-02; PH 18-2004(Temp), f. & cert. ef. 5-7-04 thru 10-27-04; PH 27-2004, f. & cert. ef. 8-19-04; PH 12-2008, f. 8-15-08, cert. ef. 1-1-09; PH 18-2008, f. 11-14-08, cert. ef. 1-1-09; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 11-2011, f. & cert. ef. 10-27-11; PH 2-2012, f. & cert. ef. 2-1-12; PH 26-2014, f. & cert. ef. 10-8-14; PH 30-2015, f. 12-29-15, cert. ef. 1-1-16

333-015-0035
General Provision

(1) No person shall smoke, aerosolize or vaporize an inhalant or carry a lighted smoking instrument in a public place except in those areas that are not required to be smoke, aerosol or vapor free under ORS 433.850(2) and OAR 333-015-0035(5) and (6).

(2) Employers shall provide for employees a place of employment that is free of all smoke, aerosols and vapors containing inhalants; and may not allow employees to smoke, aerosolize or vaporize inhalants at the place of employment, except in those areas listed in ORS 433.850(2) and in OAR 333-015-0035(4) through (7). In providing a smoke, aerosol, or vapor free place of employment, an employer is responsible for taking steps to ensure that no person smokes, aerosolizes or vaporizes an inhalant within 10 feet of the following parts of a place of employment:

(a) Entrances;

(b) Exits;

(c) Windows that open;

(d) Ventilation intakes that serve an enclosed area; and

(e) Accessibility ramps.

(3) No person shall smoke, aerosolize or vaporize an inhalant or carry a lighted smoking instrument within 10 feet of the following parts of public places or places of employment:

(a) Entrances;

(b) Exits;

(c) Windows that open;

(d) Ventilation intakes that serve an enclosed area; and

(e) Accessibility ramps.

(4) The owner or entity in charge of a hotel or motel may designate up to 25 percent of the sleeping rooms of the hotel or motel as rooms in which smoking, aerosolizing or vaporizing is permitted.

(a) If the owner or entity in charge of a hotel or motel chooses to designate up to 25 percent of sleeping rooms as smoking, aerosolizing or vaporizing permitted, all smoking, aerosolizing or vaporizing rooms on the same floor must be contiguous. The status of the rooms may not be changed, except to add more non-smoking, non-aerosolizing or non-vaporizing rooms.

(b) The owner or entity in charge of a hotel or motel shall provide written notice to patrons upon check-in as to the smoking, aerosolizing or vaporizing status of the sleeping rooms.

(c) The owner or entity in charge of a hotel or motel shall post signs at each entrance and exit in accordance with OAR 333-015-0040, with the exception of sleeping room entrances and exits. Signs shall notify all patrons that smoking, aerosolizing or vaporizing is limited to certain sleeping rooms.

(d) The owner or entity in charge of a hotel or motel shall provide written information to patrons upon check-in, describing how patrons may notify management of smoking, aerosolizing or vaporizing occurring in non-smoking, non-aerosolizing or non-vaporizing areas or rooms.

(e) Nothing in these rules shall prevent the owner or entity in charge of a hotel or motel from prohibiting smoking, aerosolizing or vaporizing on the entire premises.

(5) Smoking of noncommercial tobacco products for ceremonial purposes is permitted in spaces designated for traditional ceremonies in accordance with the American Indian Religious Freedom Act, 42 U.S.C. 1996.

(6) The following areas are not required to be smokefree:

(a) Smoke shops that are certified by the Authority under OAR 333-015-0068;

(b) Cigar bars if:

(A) The cigar bar generated on-site retail sales of cigars of at least $5,000 for the calendar year ending December 31, 2006; and

(B) The cigar bar has provided the Public Health Division with proper documentation as required by OAR 333-015-0066.

(c) Up to 25 percent of the sleeping rooms of a hotel or motel, as designated by the owner or entity in charge. The hotel or motel must be in compliance with the rules set forth in OAR 333-015-0035(4).

(7) The medical use of marijuana is permitted in the place of employment of a licensee of a professional licensing board as described in ORS 475.328.

(8) Nothing in these rules shall prevent an employer in charge of a place of employment or an entity in charge of a public place from designating the entire place of employment or public place as smoke, aerosol or vapor free.

Stat. Auth.: ORS 433.855
Stats. Implemented: ORS 433.835 - 433.870
Hist.: HD 10-1983, f. & ef. 7-1-83; OHD 8-2002(Temp), f. & cert. ef. 5-28-02 thru 11-22-02; OHD 12-2002, f. & cert. ef. 8-27-02; PH 18-2004(Temp), f. & cert. ef. 5-7-04 thru 10-27-04; PH 27-2004, f. & cert. ef. 8-19-04; PH 12-2008, f. 8-15-08, cert. ef. 1-1-09; PH 2-2010, f. & cert. ef. 1-14-10; PH 2-2012, f. & cert. ef. 2-1-12; PH 26-2014, f. & cert. ef. 10-8-14; PH 30-2015, f. 12-29-15, cert. ef. 1-1-16

333-015-0040
Signs

(1) An employer or entity in charge, except in those places described in OAR 333-015-0035(5) and (6), shall post signs prohibiting smoking, aerosolizing or vaporizing of inhalants. Nothing in these rules shall prevent an employer from increasing the amount of property where smoking, aerosolizing or vaporizing of inhalants is prohibited beyond the 10-foot requirement or from designating the entire premises as smoke, aerosol or vapor free. Signs may be used without specifically including the words "within 10 feet" if the signs specify a restriction greater than 10 feet or designate the entire premises as smoke, aerosol or vapor free. Signs shall be posted prominently at each entrance and exit to the place of employment or public place.

(2) In addition to requirements under this rule, an owner or entity in charge of a hotel or motel shall comply with signage requirements as described in OAR 333-015-0035(4).

(3) An owner or entity in charge of tables or outdoor seating or dining areas within 10 feet of entrances, exits, windows that open, ventilation intakes that serve an enclosed area of a public place or place of employment, or any portion of an accessibility

ramp shall clearly mark the tables or outdoor seating or dining areas as non-smoking, non-vaporizing and non-aerosolizing.

(4) In a cigar bar where smoking is allowed under OAR 333-015-0035(6), the employer or entity in charge shall post signs at each entrance and exit clearly stating that:

(a) Smoking is allowed on all or part of the premises;

(b) Smoking, aerosolizing or vaporizing of inhalants that are not cigars is prohibited; and

(c) Anyone under the age of 21 is prohibited from entering the premises.

(5) In a smoke shop where smoking is allowed under OAR 333-015-0035(6), the employer or entity in charge shall post signs at each entrance and exit clearly stating that:

(a) Smoking is allowed on all or part of the premises;

(b) Anyone under the age of 18 is prohibited from entering the premises; and

(c) Cigarette smoking is prohibited on the premises, in smoke shops where cigarette smoking is not allowed under OAR 333-015-0068(7)(e).

(d) Smoking, aerosolizing or vaporizing of inhalants that are not tobacco products is prohibited. (6) All signs used to describe whether smoking is prohibited or allowed in a place of employment or public place shall be placed at a height and location easily seen by a person entering the establishment and shall not be obscured in any way.

Stat. Auth.: ORS 433.855
Stats. Implemented: ORS 433.835 - 433.870
Hist.: HD 10-1983, f. & ef. 7-1-83; OHD 8-2002(Temp), f. & cert. ef. 5-28-02 thru 11-22-02; OHD 12-2002, f. & cert. ef. 8-27-02; PH 18-2004(Temp), f. & cert. ef. 5-7-04 thru 10-27-04; PH 27-2004, f. & cert. ef. 8-19-04; PH 12-2008, f. 8-15-08, cert. ef. 1-1-09; PH 18-2008, f. 11-14-08, cert. ef. 1-1-09; PH 2-2010, f. & cert. ef. 1-14-10; PH 2-2012, f. & cert. ef. 2-1-12; PH 26-2014, f. & cert. ef. 10-8-14; PH 30-2015, f. 12-29-15, cert. ef. 1-1-16

333-015-0045
Ashtrays

(1) Ashtrays and any receptacles to be used for smoking, aerosolizing or vaporizing or depositing cigarette or inhalant delivery system debris are prohibited within 10 feet of entrances, exits, windows that open, ventilation intakes that serve an enclosed area of a public place or place of employment, and any portion of an accessibility ramp.

(2) Except for those areas described in OAR 333-015-0035(6), ashtrays and any receptacles to be used for smoking or depositing cigarette or inhalant delivery system debris are prohibited inside public places and places of employment.

Stat. Auth.: ORS 433.855
Stats. Implemented: ORS 433.835 - 433.870
Hist.: HD 10-1983, f. & ef. 7-1-83; OHD 8-2002(Temp), f. & cert. ef. 5-28-02 thru 11-22-02; OHD 12-2002, f. & cert. ef. 8-27-02; PH 18-2004(Temp), f. & cert. ef. 5-7-04 thru 10-27-04; PH 27-2004, f. & cert. ef. 8-19-04; PH 12-2008, f. 8-15-08, cert. ef. 1-1-09; PH 2-2012, f. & cert. ef. 2-1-12; PH 26-2014, f. & cert. ef. 10-8-14; PH 30-2015, f. 12-29-15, cert. ef. 1-1-16

333-015-0062
Vehicles

(1) An employer may allow smoking in vehicles only when the vehicle is permanently assigned to a single employee and no other employees, clients, or members of the public are required or compelled to operate or otherwise occupy the vehicle.

(2) Nothing in these rules shall prevent an employer from designating all vehicles as smokefree.

Stat. Auth.: ORS 433.855
Stats. Implemented: ORS 433.835 - 433.870
Hist.: PH 12-2008, f. 8-15-08, cert. ef. 1-1-09

333-015-0064
Outdoor Smoking Areas

(1) The owner or entity in charge of a place of business may establish an outdoor smoking, aerosolizing or vaporizing of inhalants area if that area is:

(a) Not within 10 feet of entrances, exits, windows that open, ventilation intakes that serve an enclosed area of any public place or place of employment, or any portion of an accessibility ramp;

(b) Not, at any time, an enclosed area as defined in OAR 333-015-0030(8); and

(c) In compliance with all other state, city, and county codes.

(2) Nothing in these rules shall prevent an employer from increasing the amount of property where smoking, aerosolizing or vaporizing is prohibited beyond the 10-foot requirement or from designating the entire premises as smokefree.

Stat. Auth.: ORS 433.855
Stats. Implemented: ORS 433.835 - 433.870
Hist.: PH 12-2008, f. 8-15-08, cert. ef. 1-1-09; PH 2-2012, f. & cert. ef. 2-1-12; PH 26-2014, f. & cert. ef. 10-8-14; PH 30-2015, f. 12-29-15, cert. ef. 1-1-16

333-015-0066
Cigar Bars

(1) A business must apply to the Authority for certification before allowing cigar smoking on its premises.

(2) A business must apply for certification on a form prescribed by the Authority and include the following information or documentation:

(a) A copy of the business's full on-premises liquor sales license issued by the Oregon Liquor Control Commission under ORS 471.175;

(b) A site map of the premises that denotes maximum seating capacity and includes a detailed seating chart;

(c) A copy of the business's certificate of occupancy and official documentation from the building authority with jurisdiction that the business was approved as a smoking lounge;

(d) Using the official form provided by the Public Health Division, Tobacco Prevention and Education Program, proof that all employees have read and signed a document explaining the dangers of exposure to secondhand smoke (this form is available at www.healthoregon.org/smokefree or by calling the Tobacco Prevention and Education Program); and

(e) Documentation demonstrating to the satisfaction of the Public Health Director that the cigar bar generated on-site retail sales of cigars of at least $5,000 in the calendar year 2006.

(3) Application Review:

(a) The Authority shall review application materials within 30 days of receipt and determine whether the application is complete.

(b) Within 10 days of declaring an application complete, the Authority shall deny or grant the application. The Authority shall grant a business certification if, upon review of the application materials, the Authority finds that sufficient documentation has been provided to demonstrate compliance with section (2) of this rule. In lieu of denying an application, the Authority may request additional information from the applicant to determine compliance with section (2) of this rule.

(c) The Authority may deny an application for cigar bar certification if the Authority issued a civil penalty against an applicant for any violation of the Act or these rules within 12 months prior to application.

(d) The Authority may deny an application for cigar bar certification and prohibit an applicant from reapplying for up to two years if the applicant provides information that is false or deliberately misleading.

(4) Ongoing Requirements for Certification:

(a) If a cigar bar was certified before February 1, 2012, and has not provided the information or documentation required under section (2) of this rule, the cigar bar must furnish the missing information or documentation upon request by the Authority to remain certified.

(b) A certified cigar bar must meet the definition of a cigar bar, as defined in ORS 433.835(1) and OAR 333-015-0030(5), at all times. The Authority may revoke certification if the business no longer meets the definition of a cigar bar.

(c) A cigar bar must submit a completed form, as described in subsection (2)(d) of this rule, to the Authority by December 31 of each calendar year for every new employee hired during that year.

(5) Cigar bar certification is only valid for the business location authorized by the Authority.

(6) Certification may be revoked if a cigar bar ceases operation because it has gone out of business. The certificate

holder must notify the Authority that the cigar bar is no longer in operation within 30 days of closing the business.

Stat. Auth.: ORS 433.855
Stats. Implemented: ORS 433.835 - 433.870
Hist.: PH 12-2008, f. 8-15-08, cert. ef. 1-1-09; PH 2-2012, f. & cert. ef. 2-1-12

333-015-0068
Smoke Shops

(1) A business must apply to the Authority for certification prior to allowing smoking on the premises.

(2) A business must apply for smoke shop certification on a form prescribed by the Authority (this form is available at www.healthoregon.org/smokefree or by calling the Tobacco Prevention and Education Program at 971-673-0984).

(3) To obtain certification as a smoke shop under any part of this rule, a business must agree to allow the Authority or LPHA to make unannounced inspections of the business to determine compliance with the Act.

(4) Smoke shop certification is only valid for the business location authorized by the Authority.

(5) Certification Criteria:

(a) A business may apply for smoke shop certification by submitting the following documentation to the Authority, along with a completed application form:

(A) A notarized, sworn statement attesting that the business:

(i) Is primarily engaged in the sale of tobacco products and smoking instruments intended for off-premises consumption or use, and derives at least 75 percent of its gross revenue from such sales;

(ii) Prohibits persons under 18 years of age from entering the premises;

(iii) Does not offer video lottery games as authorized under ORS 461.217, social gaming, or betting on the premises;

(iv) Does not sell or offer food, beverages or alcoholic beverages. On-premises consumption of food or beverages, excluding alcoholic beverages is permitted;

(v) Has a maximum seating capacity of no more than four persons;

(vi) Allows the smoking of tobacco product samples only for the purpose of making retail purchase decisions, in a manner that complies with ORS 180.486 and 431.840; and

(vii) Does not allow the smoking, aerosolizing or vaporizing of inhalants that are not tobacco products.

(B) Documentation of the business's sales, broken down by category of product;

(C) Evidence, such as photographs, of signs prohibiting:

(i) Persons under 18 years of age from entering the premises, and

(ii) On premises consumption of alcohol.

(D) A building map and photographs of the premises demonstrating that the business is a stand-alone business;

(E) A site map of the premises that denotes maximum seating capacity and includes a detailed seating chart; and

(F) Any other documentation, as specified in the application form, necessary to demonstrate compliance with the Act or these rules.

(b) A business existing on December 31, 2008, may apply for certification as a smoke shop by submitting the following documentation to the Authority, along with a completed application form:

(A) Proof of registration with the Oregon Secretary of State, Corporation Division, since 2008 or, if not required to be registered, tax documentation proving that the business has been in operation since 2008;

(B) A notarized, sworn statement attesting that:

(i) On December 31, 2008, the business:

(I) Was primarily engaged in the sale of tobacco products and smoking instruments intended for off-premises consumption or use, and derived at least 75 percent of its gross revenue from such sales;

(II) Prohibited persons under 18 years of age from entering the premises;

(III) Did not offer video lottery games as authorized under ORS 461.217, social gaming, or betting on the premises; and

(IV) Did not sell or offer food or beverages, including alcoholic beverages. On premises consumption of food and beverages, excluding alcohol, is permitted.

(ii) Presently, the business meets the criteria listed under subparagraph (5)(b)(B)(i) of this rule;

(C) Documentation of the business's sales, broken down by category of product;

(D) Either of the following:

(i) Documentation, such as a building map or photographs, demonstrating that on December 31, 2008, the business was a stand-alone business with no other businesses or residential property attached; or

(ii) Documentation demonstrating that on December 31, 2008, it had a ventilation system that exhausted smoke from the business and was designed and terminated in accordance with the state building code standards for the occupancy classification in use. Such documentation must include either:

(I) A certificate of occupancy that was current on December 31, 2008, and official documentation from the building authority with jurisdiction of the occupancy classification for which the business was approved; or

(II) If the documentation described in (5)(b)(D)(ii)(I) of this rule is unavailable, a current certificate of occupancy, proof that the business's ventilation system was installed in 2008 or earlier, and official documentation from the building authority with jurisdiction that the business was approved as a smoking lounge;

(E) Either of the following:

(i) Documentation, such as a building map or photographs, demonstrating that the business presently is a stand-alone business with no other businesses or residential property attached; or

(ii) A current certificate of occupancy and official documentation from the building authority with jurisdiction that the business was approved as a smoking lounge;

(F) Evidence, such as photographs, of signs prohibiting persons under 18 years of age from entering the premises; and

(G) Any other documentation, as specified in the application form, necessary to demonstrate compliance with the Act or these rules.

(c) A business that filed an application with the Authority for certification as a smoke shop prior to June 30, 2011, may be certified by the Authority on or before December 31, 2012, according to the requirements of the Act as it was in effect on June 29, 2011. To achieve certification under these criteria, the business must submit the following documentation to the Authority:

(A) A notarized, sworn statement attesting that:

(i) At the time of application, the business:

(I) Was primarily engaged in the sale of tobacco products and smoking instruments, and derived at least 75 percent of its gross revenue from such sales;

(II) Prohibited persons under 18 years of age from entering the premises;

(III) Did not offer video lottery games as authorized under ORS 461.217, social gaming, or betting on the premises;

(IV) Did not sell or offer on-premises consumption of alcoholic beverages; and

(V) Was a stand-alone business with no other businesses or residential property attached to the premises; and

(ii) Presently, the business meets the criteria listed under subparagraph (5)(c)(A)(i) of this rule;

(B) Documentation of the business's sales, broken down by category of product, including cigarette sales; and

(C) Any other documentation, as specified in the application form, necessary to demonstrate compliance with the Act or these rules.

(6) Application Review:

(a) The Authority shall review application materials within 45 days of receipt and determine whether the application is complete.

(b) Within 15 days of declaring an application complete, the Authority shall deny or grant the application. The Authority shall

grant a business certification if, upon review of the application materials, the Authority finds that sufficient documentation has been provided to demonstrate the business's compliance with this rule. In lieu of denying an application, the Authority may request additional information from the business for the purpose of assessing compliance with this rule.

(c) The Authority may deny an application for smoke shop certification if the Authority issued a civil penalty against an applicant for any violation of the Act or these rules within 12 months prior to application.

(d) The Authority may deny an application for smoke shop certification and prohibit an applicant from reapplying for up to two years if the applicant provides information that is false or deliberately misleading.

(7) Ongoing Requirements for Certification:

(a) A smoke shop certified under this rule must continue to meet the criteria for certification once certified. The Authority may revoke certification if the smoke shop ceases to meet the criteria for certification.

(b) Every year, within 30 days of the calendar date on which certification was originally granted, a smoke shop must provide the Authority with documentation demonstrating that at least 75 percent of the smoke shop's gross revenue is derived from the sale of tobacco products or smoking instruments. Such documentation must include:

(A) A notarized, sworn statement attesting that at least 75 percent of the smoke shop's gross revenue is derived from the sale of tobacco products or smoking instruments; and

(B) Documentation of the smoke shop's sales broken down by category of product, including cigarette sales if the business is certified under subsection (5)(b) or (5)(c) of this rule and permits cigarette smoking on the premises.

(c) The Authority may inspect a business's financial records to determine compliance with the Act and these rules. The Authority shall attempt to contact the business and provide at least 48 hours' notice prior to conducting such an inspection.

(d) A smoke shop must maintain up-to-date contact information with the Authority. If the Authority is unable, despite a good-faith effort, to contact the smoke shop because the smoke shop's mailing address, phone number, and other contact information are out of date, then the Authority may suspend the smoke shop's certification until up-to-date contact information is provided.

(e) A smoke shop certified under subsection (5)(b) or (5)(c) of this rule may not allow the smoking of cigarettes unless at least 75 percent of its gross revenue, as reflected in the documentation described in paragraph (7)(b)(B) of this rule, is derived from the sale of cigarettes.

(f) A smoke shop that is closed for an extended period of time or otherwise ceases to operate at the location that is certified is considered by the Authority to not meet certification requirements.

(8) Renewal of Certification:

(a) A smoke shop certified under subsection (5)(b) or (5)(c) of this rule must renew its certification every five years within 30 days of the calendar date on which certification was originally granted.

(b) To renew certification, a smoke shop certified under subsection (5)(b) or (5)(c) of this rule must submit:

(A) Updated versions of the documentation required for initial certification under subsection (5)(b) or (5)(c) of this rule, respectively; and

(B) If the smoke shop allows the smoking of cigarettes, documentation demonstrating that the smoke shop derives at least 75 percent of its gross revenue from the sale of cigarettes.

(9) Transfer of Certification with Ownership:

(a) Smoking is not permitted on the premises of a smoke shop operating under new ownership until certification is effectively transferred from the certificate holder to the new owner in accordance with this section.

(b) If a smoke shop certified under subsection (5)(a) of this rule changes ownership, the following steps must be completed before the Authority shall transfer certification to the new owner:

(A) The certificate holder must notify the Authority of the intent to transfer ownership and certification;

(B) The new owner must submit a notarized, sworn statement to the Authority attesting that the smoke shop will continue to meet the certification requirements under the new ownership; and

(C) The certificate holder or the new owner must update the business's certification documentation with the Authority.

(c) If a smoke shop certified under subsection (5)(b) or (5)(c) of this rule changes ownership, the certificate holder or new owner of the smoke shop must submit the following documentation to the Authority to transfer certification to the new owner:

(A) Proof of transfer of ownership of the smoke shop, including, where applicable, updated registration with the Oregon Secretary of State, Corporation Division;

(B) A notarized, sworn statement attesting that the business will continue to meet the requirements for certification under the new ownership; and

(C) A completed application for transfer of certification (available on the Internet at www.healthoregon.org/smokefree or by calling the Tobacco Prevention and Education Program at 971-673-0984).

(d) After certification is transferred, the new certificate holder must submit financial documentation, including, but not limited to, sales receipts, demonstrating that at least 75 percent of the smoke shop's gross revenue during the first 90 days of operation under new ownership was derived from the sale of tobacco products or smoking instruments.

(10) Change of Location:

(a) A smoke shop certified under subsection (5)(a) of this rule that seeks to operate the business at a different location must reapply for certification in the new location.

(b) A smoke shop certified under subsection (5)(b) or (5)(c) of this rule that seeks to operate the business at a different location must submit the following documentation to the Authority, along with a completed application for transfer of certification, at least 30 days prior to permitting smoking at the new location:

(A) A copy of the deed or rental lease for the new location, indicating that the business does not occupy more than 3,500 square feet unless the original location exceeded 3,500 square feet;

(B) If the new location occupies more than 3,500 square feet, documentation demonstrating that the square footage of the new location is no more than 110 percent of the square footage of the location at which the smoke shop was originally certified;

(C) A notarized, sworn statement attesting that the smoke shop will cease to operate in the old location; and

(D) Documentation demonstrating that the smoke shop, as operated in the new location:

(i) Meets the original requirements for certification set forth in subsection (5)(b) or (5)(c), respectively;

(ii) Does not allow the smoking of cigarettes unless at least 75 percent of the gross revenue of the business is derived from the sale of cigarettes.

(c) Smoking is not permitted on the premises of the new location until the Authority certifies the new location pursuant to subsection (10)(a) or (10)(b) of this rule.

(11) Certification may be revoked if a smoke shop is closed for an extended period of time or ceases operating at the location that is certified. The certificate holder must notify the Authority immediately if the smoke shop is closing for an extended period of time or will no longer be operating.

(12) Certification may be revoked if a smoke shop fails to meet certification requirements or fails to submit required documentation in accordance with subsection (7)(b) of this rule.

Stat. Auth.: ORS 433.855

Stats. Implemented: ORS 433.835 - 433.870

Hist.: PH 12-2008, f. 8-15-08, cert. ef. 1-1-09; PH 2-2012, f. & cert. ef. 2-1-12; PH 26-2014, f. & cert. ef. 10-8-14; PH 30-2015, f. 12-29-15, cert. ef. 1-1-16

333-015-0069
Revocation of Cigar Bar and Smoke Shop Certification

The Authority may revoke the certification of a cigar bar or smoke shop and prohibit the business from reapplying for up to two years if the business violates the Act or these rules.

Stat. Auth.: ORS 433.855
Stats. Implemented: ORS 433.835 - 433.870
Hist.: PH 12-2008, f. 8-15-08, cert. ef. 1-1-09; PH 2-2012, f. & cert. ef. 2-1-12

333-015-0070
Oregon Health Authority Responsibilities

(1) The Authority shall maintain a system for receiving complaints, providing educational materials, conducting site visits, and issuing notices of violation.

(2) The Authority shall:

(a) Upon request and satisfactory review, provide certification to cigar bars and smoke shops verifying that they have met the definitions and standards for allowing smoking as set forth in ORS 433.835(1) and 433.850(2)(d) and these rules;

(b) Provide education and assistance to employers and entities in charge of public places to help them comply with the Act;

(c) Receive, respond to, and investigate complaints of non-compliance with the Act and these rules;

(d) Prepare and follow up on remediation plans with sites found to be out of compliance with the Act or these rules; and

(e) Issue citations to violators of the Act or these rules, and conduct contested cases under ORS Chapter 183 as necessary.

(3) Upon request of the LPHA that assumes authority for any or all of the responsibilities pursuant to ORS 433.855(4), provide consultation and technical assistance to the LPHA.

Stat. Auth.: ORS 433.855
Stats. Implemented: ORS 433.835 - 433.870
Hist.: OHD 8-2002(Temp), f. & cert. ef. 5-28-02 thru 11-22-02; OHD 12-2002, f. & cert. ef. 8-27-02; OHD 12-2002, f. & cert. ef. 8-27-02; PH 18-2004(Temp), f. & cert. ef. 5-7-04 thru 10-27-04; PH 27-2004, f. & cert. ef. 8-19-04; PH 12-2008, f. 8-15-08, cert. ef. 1-1-09; PH 2-2012, f. & cert. ef. 2-1-12; PH 26-2014, f. & cert. ef. 10-8-14; PH 30-2015, f. 12-29-15, cert. ef. 1-1-16

333-015-0075
Complaint Response

The Authority or the LPHA shall respond to complaints as follows:

(1) Initial Complaint:

(a) The Authority or the LPHA shall assess whether the site in question is required to be smoke, aerosol or vapor free under the provisions of ORS 433.835 through 433.850.

(b) If the Authority or the LPHA determines that the place of employment, or public place (or any portion thereof), is required to be smoke, aerosol or vapor free, the Authority or the LPHA shall send a letter ("initial response letter") to the place of employment, or public place named in the complaint within 10 business days after receipt of the complaint of violation. The letter shall contain notification that the employer, or public place was reported as being in violation of the Act or these rules, and information on whom to contact for further information and assistance with compliance.

(c) The Authority or the LPHA shall send a form letter to the complainant, if the complainant has supplied his or her name and contact information, notifying the complainant that the complaint has been received and is being investigated or that the place of employment is not required to be smokefree under ORS 433.835 through 433.850.

(2) Second or Subsequent Complaint:

(a) If the Authority or the LPHA receives additional complaint(s) about the site within five business days after the "initial response letter" was sent, the Authority or the LPHA shall send a form letter to the complainant if the complainant has supplied his or her name and contact information, notifying the complainant that the complaint has been received and the investigation process begun.

(b) If the Authority or the LPHA receives a second or subsequent complaint about the site more than five business days after the "initial response letter" was sent, a representative of the Authority or the LPHA shall make an unannounced site visit within 30 days of complaint receipt to determine whether the employer or public place is in violation of the Act or these rules.

(c) An employer, entity in charge of a public place, smoke shop or cigar bar must permit the Authority or the LPHA access to the place of employment, public place (or any portion thereof), or smoke shop or cigar bar, in order to determine compliance with the ICAA. Failure to permit the Authority or LPHA access is a violation and may result in the imposition of civil penalties under OAR 333-015-0085(1).

(3) Remediation Plan:

(a) If, after a site visit, the Authority or LPHA finds violations of the ICAA an employer or entity in charge of a public place, certified smoke shop or cigar bar, or his or her designee, must cooperate with the Authority or LPHA to develop a remediation plan. All remediation plans must be completed within 15 days of the site visit.

(b) In special circumstances, an employer or entity in charge may request in writing an extension of time in which to complete the remediation plan. An extension may be granted only by the Public Health Director or designee.

(4) Post-remediation plan follow-up site visit:

(a) The Authority or the LPHA shall make a follow-up visit within 30 days of the remediation plan completion date to confirm completion.

(b) If a violation of the ICAA is found during the follow-up site visit the Authority may impose civil penalties.

(5) Post-remediation plan complaints:

(a) If an additional complaint is received within three years of the date the remediation plan was entered into, the Authority or the LPHA shall make an unannounced site visit within 21 days of complaint receipt. If a violation is found the Authority may impose a civil penalty.

(b) If an additional complaint is received more than three years of the date the remediation plan was entered into and there is no evidence of other violations in that three-year period, the Authority or the LPHA shall make an unannounced site visit and must follow the procedures in sections (3) and (4) of this rule.

Stat. Auth.: ORS 433.855
Stats. Implemented: ORS 433.835 - 433.870
Hist.: OHD 8-2002(Temp), f. & cert. ef. 5-28-02 thru 11-22-02; OHD 12-2002, f. & cert. ef. 8-27-02; PH 18-2004(Temp), f. & cert. ef. 5-7-04 thru 10-27-04; PH 27-2004, f. & cert. ef. 8-19-04; PH 12-2008, f. 8-15-08, cert. ef. 1-1-09; PH 2-2010, f. & cert. ef. 1-14-10; PH 2-2012, f. & cert. ef. 2-1-12; PH 26-2014, f. & cert. ef. 10-8-14; PH 30-2015, f. 12-29-15, cert. ef. 1-1-16

333-015-0078
Violations

(1) The following are violations of the ICAA:

(a) Smoking, aerosolizing, vaporizing or carrying a lighted smoking instrument or inhalant delivery systems in an area where smoking, aerosolizing, or vaporizing of inhalants is prohibited.

(b) Cigar or cigarette butts in an area where smoking is prohibited.

(c) Ashtrays intended for use in an area where smoking is prohibited.

(d) Absence or insufficiency of signs that are required under these rules.

(e) Operating a cigar bar without proper certification from the Authority.

(f) Operating as a smoke shop without proper certification from the Authority.

(g) Smoking of non-cigar tobacco products in a cigar bar.

(h) Smoking, aerosolizing or vaporizing instruments intended for use in an area where smoking, aerosolizing or vaporizing of inhalants is prohibited.

(i) Non-compliance with any of the cigar bar or smoke shop certification requirements set forth in the Act or these rules.

(j) Smoking, aerosolizing or vaporizing of inhalants or carrying a lighted smoking instrument or inhalant delivery system within 10 feet of entrances, exits, windows that open, ventilation

intakes that serve an enclosed area of any public place or place of employment, or any portion of an accessibility ramp.

(k) Ashtrays intended to be used for smoking within 10 feet of entrances, exits, windows that open, ventilation intakes that serve an enclosed area of any public place or place of employment, or any portion of an accessibility ramp.

(l) Tables or outdoor seating or dining areas not clearly marked as non-smoking, non-aerosolizing or non-vaporizing, within 10 feet of entrances, exits, windows that open, ventilation intakes that serve an enclosed area of any public place or place of employment, or any portion of an accessibility ramp.

(m) Failure of an employer or entity in charge to cooperate in developing a remediation plan.

(n) Failure of an employer or entity in charge of a public place, a cigar bar or smoke shop to permit the Authority or the LPHA to inspect all or any part of the premises.

(o) Failure of an employer to provide a smoke, aerosol, or vapor free place of employment by permitting smoking, aerosolizing or vaporizing of inhalants within 10 feet of the entrances, exits, windows that open, ventilation intakes that serve an enclosed area, and accessibility ramps.

(2) Notice of Violation:

(a) If the Authority has evidence of violations of the ICAA or these rules the Authority may impose civil penalties against an individual, an employer, an entity in charge of a public place, a cigar bar or smoke shop, in accordance with OAR 333-015-0085.

(b) A Notice of Violation must be issued in compliance with the notice and civil penalty provision in ORS Chapter 183 and OAR 333-015-0085.

(c) Payment of civil penalties shall be made by mail to the Public Health Director and credited to the Tobacco Use Reduction Account, as required by ORS 433.855(1)(c).

(3) Failure to Cooperate: In addition to imposing civil penalties under OAR 333-015-0085 the Authority may initiate further legal action against an employer or entity in charge of a public place, a cigar bar or smoke shop including, but not limited to, requesting a court to enjoin operation of the business or public place if the employer or entity in charge of a public for violations of the ICAA or these rules.

(4) Revocations: The Authority may revoke a smoke shop certification for a substantial violation of any of the prohibitions of OAR 333-015-0078.

Stat. Auth.: ORS 433.855
Stats. Implemented: ORS 433.835 - 433.870
Hist.: PH 26-2014, f. & cert. ef. 10-8-14; PH 30-2015, f. 12-29-15, cert. ef. 1-1-16

333-015-0080
Public Places which Oregon Health Authority, Public Health Authority Regularly Inspects

If, in public places that the Authority regularly inspects and that are required to be smokefree under these rules, the Authority's inspector, during a regular inspection, notes a possible violation of ORS 433.835 through 433.875 or these rules, the inspector shall report the violation to the Authority.

Stat. Auth.: ORS 433.855
Stats. Implemented: ORS 433.835 - 433.870
Hist.: OHD 8-2002(Temp), f. & cert. ef. 5-28-02 thru 11-22-02; OHD 12-2002, f. & cert. ef. 8-27-02; PH 18-2004(Temp), f. & cert. ef. 5-7-04 thru 10-27-04; PH 27-2004, f. & cert. ef. 8-19-04; PH 12-2008, f. 8-15-08, cert. ef. 1-1-09; PH 2-2012, f. & cert. ef. 2-1-12

333-015-0082
Public Places Regulated by Other State Agencies or Local Governments

If, during the course of an inspection of a public place that is regulated by the State of Oregon or a local government, an inspector notes a possible violation of ORS 433.835 through 433.875 or these rules, the inspector may report the possible violation to the Authority.

Stat. Auth.: ORS 433.855
Stats. Implemented: ORS 433.835 - 433.870
Hist.: PH 12-2008, f. 8-15-08, cert. ef. 1-1-09; PH 2-2012, f. & cert. ef. 2-1-12

333-015-0085
Penalties

The Authority may impose a civil penalty of up to $500 per day for each violation according to the following schedule:

(1) $500 for violations of OAR 333-015-0078(1)(a) (c), (e), (f), (g), (i) and (n).

(2) $300 for the first violation of OAR 333-015-0078(1)(b), (d), (h), (j), (k), (l), (m) and (o).

(3) $500 for the second violation of OAR 333-015-0078(1)(a), (c), (e), (f), (g), (i) and (n).

(4) $400 for the second violation of OAR 333-015-0078(1)(b), (d), (h), (j), (k), (l), (m) and (o).

(5) $500 for the third and any subsequent violations of OAR 333-015-0078(1)(a) through (o).

Stat. Auth.: ORS 433.855
Stats. Implemented: ORS 433.835 - 433.870
Hist.: OHD 8-2002(Temp), f. & cert. ef. 5-28-02 thru 11-22-02; OHD 12-2002, f. & cert. ef. 8-27-02; PH 18-2004(Temp), f. & cert. ef. 5-7-04 thru 10-27-04; PH 27-2004, f. & cert. ef. 8-19-04; PH 12-2008, f. 8-15-08, cert. ef. 1-1-09; PH 2-2010, f. & cert. ef. 1-14-10; PH 2-2012, f. & cert. ef. 2-1-12; PH 26-2014, f. & cert. ef. 10-8-14; PH 30-2015, f. 12-29-15, cert. ef. 1-1-16

Oregon Menu Labeling Act

333-015-0100
Authority and Purpose

(1) These rules are adopted pursuant to the authority granted Oregon Health Authority, Public Health Division in ORS 616.575.

(2) The purpose of the Oregon Menu Labeling Act is to provide consumers with basic nutrition information about prepared food sold at chain restaurants.

Stat. Auth.: ORS 616.575
Stats. Implemented: ORS 616.555 – 616.570
Hist.: PH 17-2009, f. 12-29-09, cert. ef. 1-1-10; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 11-2011, f. & cert. ef. 10-27-11

333-015-0105
Definitions

For purposes of OAR 333-015-0100 through 333-015-0165, the following definitions shall apply:

(1) "Act" means the Oregon Menu Labeling Act as it appears in 2009 Oregon Laws, chapter 314 (House Bill 2726).

(2) "Alcoholic beverage" means any liquid or solid containing more than one-half of one percent alcohol by volume and capable of being consumed by a human being.

(3) "Calorie and nutrient database" means a commercial computer application or a raw nutrient database that is based on United States Department of Agriculture's (USDA) National Nutrient Database for Standard Reference.

(4)(a) "Chain restaurant" means a restaurant that is located in Oregon that:

(A) Is a part of an affiliation of 15 or more restaurants within the United States;

(B) Sells standardized menu items that constitute 80 percent or more of the menu items served in the restaurant and at least 14 of the other affiliated restaurants; and

(C) Operates under a trade name or service mark, both as defined in ORS 647.005, which is identical or substantially similar to the trade names or service marks of the affiliated restaurants.

(b) "Chain restaurant" does not mean:

(A) A restaurant located inside a facility that is subject to Oregon Department of Agriculture inspection under an interagency agreement described in ORS 624.530, unless the trade name or service mark for the restaurant differs from the trade name or service mark of the facility containing the restaurant;

(B) A cafeteria of a public or private educational institution;

(C) A health care facility as defined in ORS 422.015; or

(D) A motion picture theater.

(5) "Combination meal menu item" means a group of two or more food products or menu items that is offered on a menu, menu board or food tag as a distinct item for sale and that is offered for sale for more than 90 days during a calendar year and which may or may not give the consumer a choice of food items to be included in the meal.

(6) "Condiment" means a sauce, seasoning or dressing including but not limited to butter, jellies or jams, ketchup, mustard, hot sauce, tartar sauce, and similar items offered for general use without charge and not a part of a standard recipe.

(7) "Food product" means a discrete unit serving of a ready-to-eat food or beverage.

(8)(a) "Food tag" means an informational label placed near a menu item, combination meal menu item, or food product that is identified or indicated by the label.

(b) "Food tag" does not mean a menu or menu board.

(9) "Government standards" means nutrient values defined by the USDA National Nutrient Database for Standard Reference.

(10) "Laboratory testing" means the chemical analysis of food products to determine nutrient content.

(11) "Menu" means a pictorial display or written description of menu items, combination meal menu items, or food products that does not have a fixed location and is not intended for joint viewing by multiple patrons.

(12)(a) "Menu board" means a pictorial or written description of menu items, combination meal menu items, or food products that:

(A) Is located where the customer places an order for a menu item; and

(B) Is not a menu or a food tag.

(b) "Menu board" does not mean a pictorial display used solely for the purpose of marketing.

(13)(a) "Menu item" means a prepared food product that is offered on a menu, menu board or food tag as a distinct article for sale.

(b) "Menu item" does not mean the following:

(A) Condiments that are made available on tables or counters for general use without charge;

(B) Food products that are offered for sale for less than 90 days during a calendar year;

(C) Alcoholic beverages, except as provided for under OAR 333-015-0160; or

(D) Food products in sealed manufacturer packaging.

(14) "Restaurant" means any establishment where food or drink is prepared for consumption by the public or any establishment where the public obtains food or drink so prepared in form or quantity consumable then and there, whether or not it is consumed within the confines of the premises where prepared, and also includes establishments that prepare food or drink in consumable form for service outside the premises where prepared, but does not include railroad dining cars, bed and breakfast facilities or temporary restaurants.

(15) "Self-service item" means any menu item that restaurant customers are permitted to obtain without assistance of a restaurant employee or agent.

(16) "Sealed manufacture packaging" means any food product sold in a sealed package subject to the nutrition labeling requirements for the Federal Nutrition Labeling and Education Act of 1990 (21USC 301) (21CFR101) (PL101-535) (NLEA).

(17) "Serving" means the discrete amount or portion of food as determined by the chain restaurant. Serving does not have the same definition given by the USDA and cited in the NLEA.

(18) "Standardized menu item" means any food product that is prepared with a standard recipe or formula within a chain restaurant, regardless of its name as a menu item.

(19) "Variable menu item" means a menu item that is available in different flavors and varieties at the same price point.

(20) "Verifiable reference values" means nutrient values based on the USDA National Nutrient Database for Standard Reference.

Stat. Auth.: 2009 OL Ch. 314
Stats. Implemented: 2009 OL Ch. 314
Hist.: PH 17-2009, f. 12-29-09, cert. ef. 1-1-10

333-015-0110
General Provisions

(1) Each chain restaurant shall accurately ascertain and make available on site, and in written format, the typical nutrient values for each menu item and combination meal menu item, as the item is usually prepared and offered for sale on menus, menu boards and food tags, including condiments routinely added to a menu item as part of a standard recipe:

(a) Total calories;

(b) Total grams of saturated fat;

(c) Total grams of trans fat;

(d) Total grams of carbohydrates; and

(e) Total milligrams of sodium.

(2) OAR 333-015-0110(1) does not apply to:

(a) Food products that are offered for sale for less than 90 days in a calendar year;

(b) Condiments;

(c) Alcoholic beverages not listed as menu items; or

(d) Unopened food products sold in sealed manufacturer packaging that are not intended to be part of the menu item or combination meal menu item.

Stat. Auth.: 2009 OL Ch. 314
Stats. Implemented: 2009 OL Ch. 314
Hist.: PH 17-2009, f. 12-29-09, cert. ef. 1-1-10

333-015-0115
Written Formats for Nutrition Information

(1) Chain restaurants must provide nutrition information in one or more of the following formats:

(a) A printed menu;

(b) A printed menu insert; or

(c) A brochure or printed handout.

(2) A copy of nutrition information shall be made available to each customer who requests it. Customers must not be required to return copies of nutrition information to the chain restaurant.

(3) Nutrition information for menu items must be labeled and organized in a manner that is readable, consistent with the organization and naming conventions of menu items on menus, menu boards or food tags and must be in a font size of not less than nine point.

(4) Nutrition information for menu items and food products in a combination meal menu item must be clearly labeled in a manner that is consistent with the name of the item as it is sold in the combination meal menu item.

(5) Nutrition information for menu items that are also sold as a part of a combination meal menu item under a different name must be listed under both names.

Stat. Auth.: 2009 OL Ch. 314
Stats. Implemented: 2009 OL Ch. 314
Hist.: PH 17-2009, f. 12-29-09, cert. ef. 1-1-10

333-015-0120
Nutrition Labeling of Variable Menu Items

For variable menu items, the chain restaurant shall provide required nutrition information as follows:

(1) If both the highest and lowest value of the variable menu item is within 0 to 10 percent of the median value, the median value alone of the required nutrition information may be listed.

(2) If both the highest and lowest value of the variable menu item is within 11 to 20 percent of the median value, the range of values of the required nutrition information must be listed.

(3) If neither section (1) or (2) of this rule applies, each flavor or variety of the menu item must be listed as a separate menu item and accompanied by required nutrition information.

(4) In lieu of sections (1) through (3) of this rule, each flavor or variety of a menu item may be listed as a separate menu item and accompanied by required nutrition information.

Stat. Auth.: 2009 OL Ch. 314
Stats. Implemented: 2009 OL Ch. 314
Hist.: PH 17-2009, f. 12-29-09, cert. ef. 1-1-10

333-015-0125
Nutrition Labeling of Combination Meal Menu Items

Labeling of combination meal menu items is not required as long as typical nutrient values are provided for the individual food products or menu items that comprise the combination meal menu item.

Stat. Auth.: 2009 OL Ch. 314
Stats. Implemented: 2009 OL Ch. 314

Hist.: PH 17-2009, f. 12-29-09, cert. ef. 1-1-10

333-015-0130
Nutrition Information for Shared Menu Items or Shared Combination Meal Menu Items

Nutrition information for menu items or combination meal menu items intended to serve multiple individuals must state the number of individuals intended to be served by the menu items or combination meal menu items and the total typical nutrient values per individual serving.

Stat. Auth.: 2009 OL Ch. 314
Stats. Implemented: 2009 OL Ch. 314
Hist.: PH 17-2009, f. 12-29-09, cert. ef. 1-1-10

333-015-0135
Acceptable Methods for Determining Typical Nutrient Values for Required Nutrition Information

A chain restaurant must utilize one of the following methods for determining typical nutrient values for menu items and combination meal menu items:

(1) Calorie and nutrient databases as that term is defined in OAR 333-015-0105;

(2) Verifiable reference values as that term is defined in OAR 333-015-0105;

(3) Laboratory testing as that term is defined in OAR 333-015-0105; and

(4) Government standards as that term is defined in OAR 333-015-0105.

Stat. Auth.: 2009 OL Ch. 314
Stats. Implemented: 2009 OL Ch. 314
Hist.: PH 17-2009, f. 12-29-09, cert. ef. 1-1-10

333-015-0140
Verifiable and Accurate Information

(1) A chain restaurant may not make available to customers any typical nutrient values that are substantially inaccurate or that the restaurant knows or should know to be false or misleading.

(2) A chain restaurant may be found by the Oregon Public Health Division to have substantially inaccurate nutrient values if the chain restaurant failed to use one (or more) of the acceptable methods for determining nutrient values described in these rules.

Stat. Auth.: 2009 OL Ch. 314
Stats. Implemented: 2009 OL Ch. 314
Hist.: PH 17-2009, f. 12-29-09, cert. ef. 1-1-10

333-015-0145
Nutrition Information for Self-Service Items

For menu items offered in a buffet, salad bar or other self-service area, nutrition information within a chain restaurant must specify — The typical nutrient values for an individual serving including:

(1) The size of an individual serving expressed in standard weights and measures; and

(2) The size of an individual serving expressed in relation to the utensil provided by the chain restaurant for serving that item or the individual servings as prepared or displayed by the chain restaurant.

Stat. Auth.: 2009 OL Ch. 314
Stats. Implemented: 2009 OL Ch. 314
Hist.: PH 17-2009, f. 12-29-09, cert. ef. 1-1-10

333-015-0150
Trans Fat

A restaurant shall follow U.S. Food and Drug Administration (FDA) guidelines for labeling trans fat. This means that trans fat does not have be listed if the total trans fat in the food is less than 0.5 grams per labeled serving, and the chain restaurant makes no claims regarding fat, fatty acids or cholesterol content.

Stat. Auth.: 2009 OL Ch. 314
Stats. Implemented: 2009 OL Ch. 314
Hist.: PH 17-2009, f. 12-29-09, cert. ef. 1-1-10

333-015-0155
Rounding Rules

Chain restaurants may round numerical values as follows, except for typical nutrient values for alcoholic beverages:

(1) Total calories values:

(a) For values above 50 calories, the disclosed value shall be rounded to the nearest value evenly divisible by 10.

(b) For values equal to or less than 50 calories, the disclosed value shall be rounded to the nearest value evenly divisible by five.

(2) Total grams of saturated fat values:

(a) For values above five grams of saturated fat, the disclosed value shall be rounded to the nearest gram.

(b) For values equal to or less than five grams of saturated fat, the disclosed value shall be rounded to the nearest 0.5 gram.

(c) For values below 0.5 grams of saturated fat, the disclosed value shall be rounded down to zero.

(3) Total grams of carbohydrates values:

(a) For values equal to or greater than one gram of carbohydrate, the disclosed value shall be rounded to the nearest gram.

(b) For values less than one gram of carbohydrate, the disclosed value shall be expressed as "contains less than one gram" or "less than one gram."

(c) For values below 0.5 grams of carbohydrate, the disclosed value shall be rounded down to zero.

(4) Total milligrams of sodium values:

(a) For values above 140 milligrams of sodium, the disclosed value shall be rounded to the nearest value evenly divisible by 10.

(b) For values between 5 and 140 milligrams of sodium, the disclosed value shall be rounded to the nearest value evenly divisible by five.

(c) For values below five milligrams of sodium, the disclosed value shall be rounded down to zero.

Stat. Auth.: 2009 OL Ch. 314
Stats. Implemented: 2009 OL Ch. 314
Hist.: PH 17-2009, f. 12-29-09, cert. ef. 1-1-10

333-015-0160
Alcoholic Beverages

(1) Chain restaurants must provide nutrition information for alcoholic beverages offered on a menu, menu board or food tag for more than 90 days. Nutrition information for alcoholic beverages must be based on the following typical nutrient values for alcohol:

(a) For wine, 122 calories, 4 grams of carbohydrate and 7 milligrams of sodium per 5-ounces;

(b) For beer, other than light beer, 153 calories, 13 grams of carbohydrates and 14 milligrams of sodium per 12-ounces;

(c) For light beer, 103 calories, 6 grams of carbohydrates and 14 milligrams of sodium per 12-ounces;

(d) For distilled spirits, 96 calories per 1.5 ounces; and

(e) For mixed drinks or drinks that are a combination of wine, beer, or distilled spirits and one or more additional ingredients, chain restaurants must provide the total typical nutrient value for the mixed drink using the values for alcohol in OAR 333-015-0160(1), combined with the typical nutrient values for other ingredients based on acceptable methods for determining typical nutrient values under 333-015-0135(1).

Stat. Auth.: 2009 OL Ch. 314
Stats. Implemented: 2009 OL Ch. 314
Hist.: PH 17-2009, f. 12-29-09, cert. ef. 1-1-10

333-015-0165
Disclaimers and Additional Nutrition Information

(1) Chain restaurants may publish truthful disclaimers, notifying customers that there may be variations in nutrient content across servings, due to differences in preparation, inconsistent service sizes, ingredients, or custom orders.

(2) Chain restaurants may publish truthful additional nutrition information for menu items including but not limited to cholesterol, fiber, sugar, protein, calcium, iron, vitamin C, vitamin A, and allergens.

(3)(a) Chain restaurants may publish a statement providing information about the recommended daily intake amounts for calories, saturated fat and sodium as follows:

(b) "Recommended limits for a 2,000 calorie daily diet are 20 grams of saturated fat and 1,700 milligrams of sodium."

Stat. Auth.: 2009 OL Ch. 314
Stats. Implemented: 2009 OL Ch. 314
Hist.: PH 17-2009, f. 12-29-09, cert. ef. 1-1-10

Tobacco and Inhalant Delivery Systems Sales to Minors

333-015-0200
Definitions

(1) "Authority" means the Oregon Health Authority.

(2) "Block grant" means the Substance Abuse Prevention and Treatment Block Grant pursuant to 42 USC 300x21e et seq.

(3)(a) "Inhalant delivery system" means:

(A) A device that can be used to deliver nicotine or cannabinoids in the form of a vapor or aerosol to a person inhaling from the device; or

(B) A component of a device described in this subsection or a substance in any form sold for the purpose of being vaporized or aerosolized by a device described in this subsection, whether the component or substance is sold separately or is not sold separately.

(b) Inhalant delivery system does not include:

(A) Any product that has been approved by the United States Food and Drug Administration for sale as a tobacco cessation product or for any other therapeutic purpose, if the product is marketed and sold solely for the approved purpose; and

(B) Tobacco products.

(4) "Minor" means an individual under 18 years of age.

(5) "Outlet" means any location which sells at retail or otherwise distributes tobacco products or inhalant delivery systems to consumers including, but not limited to, locations that sell such products over the counter or through vending machines.

(6) "Secretary" means the Secretary of the United States Department of Health and Human Services.

(7) "Smoking instrument" means any cigar, cigarette, pipe or other instrument used to smoke tobacco, marijuana, cocaine or other inhalant as defined in ORS 433.835 and ORS 163.575.

(8) "Tobacco product" means bidis, cigars, cheroots, stogies, periques, granulated, plug cut, crimp cut, ready rubbed and other smoking tobacco, snuff, snuff flour, cavendish, shisha, hookah tobacco, plug and twist tobacco, fine-cut and other chewing tobaccos, shorts, refuse scraps, clippings, cutting and sweepings of tobacco prepared in such a manner as to be suitable for chewing or smoking in a pipe or otherwise, or both for chewing and smoking, and cigarettes as defined in ORS 431A.175.

(9) "Vending machine" means a mechanical, electronic or similar device that, upon the insertion of tokens, money or another form of payment, dispense tobacco products or inhalant delivery systems as defined in ORS 167.402.

Stat. Auth.: ORS 431.853
Stats. Implemented: ORS 431.853
Hist.: PH 32-2015(Temp), f. 12-29-15, cert. ef. 1-1-16 thru 6-28-16; PH 19-2016, f. & cert. ef. 6-24-16

333-015-0205
Notice Posting Requirement

(1) An outlet must post a notice substantially similar to the notice described in section (2) of this rule in a location that is clearly visible to the seller and the purchaser.

(2) Content of the Notice: NOTICE: The sale of tobacco products, smoking instruments and inhalant delivery systems to persons under 18 years of age is prohibited by law. Any person who sells, or allows to be sold, a tobacco product, smoking instrument or inhalant delivery system to a person under 18 years of age is in violation of Oregon law.

(3) The Authority may impose a civil penalty for each violation of this rule that is not less than $250 or more than $1,000.

Stat. Auth.: ORS 431.840, 431.845
Stats. Implemented: 431.840, 431.845
Hist.: PH 32-2015(Temp), f. 12-29-15, cert. ef. 1-1-16 thru 6-28-16; PH 19-2016, f. & cert. ef. 6-24-16

333-015-0210
Location of Tobacco Products Within a Retail Store

(1) A person having authority over the location of tobacco products or inhalant delivery systems in a retail store may not locate the tobacco products or inhalant delivery systems in a location where the tobacco products or inhalant delivery systems are accessible by store customers without assistance by a store employee.

(2) This rule does not apply to a person if the location at which the tobacco products or inhalant delivery systems are sold is a store or other establishment at which persons under 18 years of age are prohibited.

Stat. Auth.: ORS 163.575, 167.400, 167.402, 167.407, 431.840, 431.853
Stats. Implemented: ORS 431.853
Hist.: PH 32-2015(Temp), f. 12-29-15, cert. ef. 1-1-16 thru 6-28-16; PH 19-2016, f. & cert. ef. 6-24-16

333-015-0215
Enforcement

(1) The Authority shall coordinate with law enforcement agencies to conduct random, unannounced inspections of wholesalers and retailers of tobacco products, smoking instruments or inhalant delivery systems to ensure compliance with, and to enforce, the laws of this state designed to discourage the sale of tobacco products, smoking instruments and inhalant delivery systems to minors. Nothing in these rules shall preempt local jurisdictions from passing ordinances to conduct unannounced inspections.

(2) Random Sample Procedures: Random, unannounced inspections will be based on the following methodological procedures

(a) Cover a range of outlets, not to be preselected on the basis of prior violations, to measure overall levels of compliance as well as to identify violations;

(b) Be conducted in such a way as to provide a probability sample of outlets in order to estimate the success of enforcement actions being taken throughout the state;

(c) Use reliable methodological design and adequate sample design to reflect:

(A) Distribution of the population of those under 18 throughout the state; and

(B) Distribution of outlets throughout the state that are accessible to minors; and

(d) Be conducted at times when minors are likely to purchase tobacco products, smoking instruments or inhalant delivery systems.

(3) Targeted Inspections: The Authority may conduct targeted inspections of outlets where a compliance problem exists or is suspected. Information gained in targeted inspection will not be included in data used to determine rate of offense in random inspections.

(4) Conducting Inspections: Inspections may take place:

(a) Only in areas open to the public;

(b) Only during the hours that tobacco products, smoking instruments or inhalant delivery systems are sold; and

(c) No more frequently than once a month in any single outlet unless a compliance problem exists or is suspected. For purposes of this rule, a "single outlet" refers to a specific address location of an outlet, regardless of ownership.

(5) The Authority may use minors to complete inspections to determine compliance with these rules.

Stat. Auth.: ORS 431.853
Stats. Implemented: ORS 431.853
Hist.: PH 32-2015(Temp), f. 12-29-15, cert. ef. 1-1-16 thru 6-28-16; PH 19-2016, f. & cert. ef. 6-24-16

333-015-0220
Annual Report

(1) Contents of Report: The Authority shall annually submit a report to the Oregon Legislature and to the Secretary, along with the state's application for block grant funding. The report shall include:

(a) A description of the state's activities to enforce the laws described in OAR 333-015-0200 through OAR 333-015-0215 during the fiscal year preceding the fiscal year for which the state is seeking the grant;

(b) A description outlining the overall success the state has achieved during the previous fiscal year in reducing the availability of tobacco products, smoking instruments and inhalant delivery systems to individuals under the age of 18, showing:

(A) Results of the random and targeted unannounced inspections;

(B) Results of over-the-counter and vending machine outlet inspections reported separately;

(c) A description of how the unannounced inspections were conducted and the methods used to identify outlets; and

(d) Strategies to be utilized by the state for enforcing such laws during the fiscal year for which the grant is sought.

(2) Public Comment Required: The annual report shall be made public and public comment shall be obtained and considered before submitting the report to the Secretary.

Stat. Auth.: ORS 431.853
Stats. Implemented: ORS 431.853
Hist.: PH 32-2015(Temp), f. 12-29-15, cert. ef. 1-1-16 thru 6-28-16; PH 19-2016, f. & cert. ef. 6-24-16

Packaging and Labeling

333-015-0300
Purpose, Scope and Effective Date

(1) The purpose of OAR 333-015-0305 to 333-015-0375 is to set the minimum standards for the labeling and packaging of inhalant delivery systems that are sold to a consumer.

(2) These minimum standards are applicable on and after July 1, 2016.

(3) These rules do not apply to an inhalant delivery system or prefilled inhalant delivery system that contains cannabinoids if that inhalant delivery system or prefilled inhalant delivery system complies with the packaging requirements in OAR 845-025-7000 to 845-025-7060 and the labeling requirements in OAR 333-007-0010 to 333-007-0100.

Stat. Auth.: ORS 431A.175
Stats. Implemented: ORS 431A.175
Hist.: PH 20-2016, f. & cert. ef. 6-24-16

333-015-0305
Definitions

For the purposes of OAR 333-015-0300 to 333-015-0375:

(1) "Authority" means the Oregon Health Authority.

(2) "Cannabinoid" means any of the chemical compounds that are the active constituents of marijuana.

(3) "Cartoon" means any drawing or other depiction of an object, person, animal or creature or any similar caricature that satisfies any of the following criteria:

(a) The use of exaggerated features;

(b) The attribution of human characteristics to animals, plants or other objects, or the similar use of anthropomorphic technique; or

(c) The attribution of unnatural or extra-human abilities, such as imperviousness to pain or injury, X-ray vision, tunneling at very high speeds or transformation.

(4) "Child-resistant" means packaging that is:

(a) Intended to protect children from nicotine exposure in the household environment or other environment where the product is used;

(b) Designed or constructed to be significantly difficult for children under five years of age to open and not difficult for adults to use properly, as defined by 16 CFR 1700.20 (1995); and

(c) Re-sealable for any product intended for more than a single use, such as a fillable inhalant delivery system.

(5) "Consumer product" means any article, or component part thereof, produced or distributed for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise.

(6) "Distributor" means a person or company that supplies stores or businesses with goods.

(7) "Fillable inhalant delivery system" means a product that is sold without nicotine or non-nicotine inhalants, not permanently sealed and can be opened and filled with any inhalant.

(8) "Inhalant" means nicotine, or any other substance that:

(a) Is in a form that allows the nicotine, cannabinoid or substance to be delivered into a person's respiratory system;

(b) Is inhaled for the purpose of delivering the nicotine, cannabinoid or other substance into a person's respiratory system; and

(c)(A) Is not approved by, or emitted by a device approved by, the United States Food and Drug Administration (FDA) for a therapeutic purpose; or

(B) If approved by, or emitted by a device approved by, the United States Food and Drug Administration for a therapeutic purpose, is not marketed and sold solely for that purpose.

(9)(a) "Inhalant delivery system" means:

(A) A device that can be used to deliver nicotine or cannabinoids in the form of a vapor or aerosol to a person inhaling from the device; or

(B) A component of a device described in this section or a substance in any form sold for the purpose of being vaporized or aerosolized by a device described in this section, whether the component or substance is sold separately or is not sold separately.

(b)(A) Inhalant delivery system does not include any product that has been approved by the United States Food and Drug Administration for sale as a tobacco cessation product or for any other therapeutic purpose, if the product is marketed and sold solely for the approved purpose; and

(B) Tobacco products.

(10) "Inner package" means the package that must be opened by a consumer in order to have access to the product and that may also be but is not required to be the outer package.

(11) "Liquid nicotine container" means a consumer product that consists of a container that:

(a) Has an opening from which nicotine in a solution or other form is accessible and can flow freely through normal and foreseeable use by a consumer; and

(b) Is used to hold soluble nicotine in any concentration.

(12) "Manufacturer or distributor contact information" means the name, city, state and country of the manufacturer who made the inhalant delivery system.

(13) "Minor" means an individual under 18 years of age.

(14) "Nicotine" means any form of the chemical nicotine, including any salt or complex, regardless of whether the chemical is naturally or synthetically derived.

(15) "Non-nicotine liquid container" means a container that:

(a) Has an opening from which liquid non-nicotine or liquid non-cannabinoid substances can flow freely through normal and foreseeable use by a consumer; and

(b) Is not used to hold liquid nicotine or cannabinoids.

(16) "Outer package" means the external package visible to a consumer in the retail setting such as, but not limited to, a box or container.

(17) "Outlet" means any location in Oregon which sells at retail or otherwise distributes tobacco products or inhalant delivery systems to consumers including, but not limited to, locations that sell such products over the counter or through vending machines.

(18) "Packaged in a manner attractive to minors" means an inhalant delivery system product where any package, including the outer package or label on the outer package, or the inner package or label on the inner package:

(a) Depicts cartoons;

(b) Depicts celebrities or fictitious characters played by people;

(c) Depicts people using the product;

(d) Depicts food or beverage;

(e) Resembles any product of the type that is typically marketed to minors; or

(f) Resembles the shape of any animal, commercially recognizable toy or candy.

(19) "Prefilled inhalant delivery system" means an inhalant delivery system that is permanently sealed, prefilled, disposable and not intended to be disassembled by the consumer.

(20) "Retail setting" means a place of business in which merchandise is primarily sold directly to an ultimate consumer.

(21) "These rules" means OAR 333-015-0300 to 333-015-0375.

Stat. Auth.: ORS 431A.175
Stats. Implemented: ORS 431A.175
Hist.: PH 20-2016, f. & cert. ef. 6-24-16

333-015-0310
Labeling Requirements for Liquid Nicotine Containers

A label on a liquid nicotine container must conform to the labeling standards set forth in 21 CFR Parts 1100, 1140 and 1143.

Stat. Auth.: ORS 431A.175
Stats. Implemented: ORS 431A.175
Hist.: PH 20-2016, f. & cert. ef. 6-24-16

333-015-0320
Labeling Requirements for Prefilled Inhalant Delivery Systems

A label on a prefilled inhalant delivery system must conform to the labeling standards set forth in 21 CFR Parts 1100, 1140 and 1143.

Stat. Auth.: ORS 431A.175
Stats. Implemented: ORS 431A.175
Hist.: PH 20-2016, f. & cert. ef. 6-24-16

333-015-0325
Labeling Requirements for Fillable Inhalant Delivery Systems

A label on a fillable inhalant delivery system must conform to the labeling standards set forth in 21 CFR Parts 1100, 1140 and 1143.

Stat. Auth.: ORS 431A.175
Stats. Implemented: ORS 431A.175
Hist.: PH 20-2016, f. & cert. ef. 6-24-16

Packaging

333-015-0340
Packaging Requirements for Liquid Nicotine Containers

A liquid nicotine container for sale to a consumer:

(1) Must be:

(a) In child-resistant safety packaging; and

(b) Labeled in accordance with these rules.

(2) May not be placed in an inner or outer package that is attractive to minors.

Stat. Auth.: ORS 431A.175
Stats. Implemented: ORS 431A.175
Hist.: PH 20-2016, f. & cert. ef. 6-24-16

333-015-0345
Packaging Requirements for Non-nicotine Liquid Containers

A non-nicotine liquid container for sale to a consumer:

(1) Must be:

(a) In child-resistant safety packaging; and

(2) May not be placed in an inner or outer package that is attractive to minors.

Stat. Auth.: ORS 431A.175
Stats. Implemented: ORS 431A.175
Hist.: PH 20-2016, f. & cert. ef. 6-24-16

333-015-0350
Packaging Requirements for Prefilled Inhalant Delivery Systems

A prefilled inhalant delivery system for sale to a consumer:

(1) Must be labeled in accordance with these rules.

(2) May not be placed in an inner or outer package that is attractive to minors.

Stat. Auth.: ORS 431A.175
Stats. Implemented: ORS 431A.175
Hist.: PH 20-2016, f. & cert. ef. 6-24-16

333-015-0355
Packaging Requirements for Fillable Inhalant Delivery Systems

(1) A fillable inhalant delivery system that is not packaged with a liquid nicotine container for sale to a consumer:

(a) Must be labeled in accordance with these rules.

(b) May not be packaged in any packaging, including an inner or outer package, that is attractive to minors.

(2) A fillable inhalant delivery system that is packaged with a liquid nicotine container for sale to a consumer must comply with OAR 333-015-0340.

Stat. Auth.: ORS 431A.175
Stats. Implemented: ORS 431A.175
Hist.: PH 20-2016, f. & cert. ef. 6-24-16

333-015-0360
Verification of Child-Resistant Packaging

Oregon-based outlets must provide verification of a manufacturer's written laboratory testing report describing child-resistant packaging results based on using the protocol set forth in 16 CFR 1700.20 (1995) to the Authority upon the Authority's request.

Stat. Auth.: ORS 431A.175
Stats. Implemented: ORS 431A.175
Hist.: PH 20-2016, f. & cert. ef. 6-24-16

Enforcement

333-015-0365
Inspections

The Authority shall coordinate random, unannounced inspections of Oregon-based outlets of inhalant delivery systems to ensure compliance with these rules.

Stat. Auth.: ORS 431A.183
Stats. Implemented: ORS 431A.183
Hist.: PH 20-2016, f. & cert. ef. 6-24-16

Violations

333-015-0370
Violations

It is a violation for a manufacturer, retailer or distributor to:

(1) Distribute, sell or allow to be sold an inhalant delivery device that does not comply with a labeling requirement in OAR 333-015-0310 to 333-015-0030.

(2) Distribute, sell or allow to be sold an inhalant delivery device that does not comply with a packaging requirement in OAR 333-015-0340 to 333-015-0360.

Stat. Auth.: ORS 431A.175, 431A.178
Stats. Implemented: ORS 431A.175, 431A.178
Hist.: PH 20-2016, f. & cert. ef. 6-24-16

Penalties

333-015-0375
Civil Penalties

(1) The Authority may impose a civil penalty for each violation of 333-015-0340 to 333-015-0360 against a manufacturer, retailer or distributor according to the following schedule:

(a) $0 together with the issuance of a warning letter to the retailer for the first violation

(b) Minimum of $500 for the second violation within a 24-month period of the first violation.

(c) Minimum of $800 for the third violation within a 24-month period of the second violation.

(d) Minimum of $2000 for the fourth violation within a 24-month period of the third violation.

(e) Minimum of $8000 for the fifth violation within a 36-month period of the fourth violation.

(f) Minimum of $15,000 for the sixth or subsequent violation within a 48-month period of the fifth violation.

(2) A civil penalty may not to exceed $15,000 for each violation or $1,050,000 for all violations found in a single inspection.

(3) Each product that does not comply with these rules or that is distributed, sold, or allowed to be sold in violation of these rules

is a separate violation. For example, if 10 liquid nicotine containers are distributed, sold, or allowed to be sold without child-resistant packaging the civil penalty could be $5000 (10 x $500).

Stat. Auth.: ORS 431A.178
Stats. Implemented: ORS 431A.178
Hist.: PH 20-2016, f. & cert. ef. 6-24-16

DIVISION 16

HAZARDOUS SUBSTANCES

Definitions and Interpretations

333-016-0005
Definitions

(1) "Act" as used in these rules means ORS 453.005 to 453.135 relating to hazardous substances.

(2) "Administrator" means the Administrator of the Public Health Division of Oregon Health Authority.

(3) "Hazardous Substances Intended or Packaged in a Form Suitable for Use in the Household" or "Hazardous Household Substances" means any hazardous substances as defined in the Act, whether or not packaged, that under any customary or reasonably forseeable condition of purchase, storage, or use may be brought into or around a house, apartment, or other place where people dwell, or in or around any related building or shed, including, but not limited to, a garage, carport, barn, or storage shed. The term includes such articles as polishes or cleaners designed primarily for professional use but that are available in retail stores such as hobby shops for nonprofessional use. Also included are such items as antifreeze and radiator cleaners that although principally for car use may be stored in or around dwelling places. The term does not include industrial supplies that might be taken into a home by a serviceman. An article labeled and marketed solely for industrial use does not become subject to this Act because of the possibility that an industrial worker may misappropriate a supply for his own use. Size of unit or container is not the only index of whether the article is suitable for use in or around the household. The test shall be whether under any reasonably foreseeable condition of purchase, storage, or use, the article may be likely to be found in or around a dwelling.

(4) "Prominently" and "Conspicuously" means that under customary conditions of purchase, storage, and use, the required information shall be visible, noticeable, and in clear and legible English. Some factors affecting a warning's prominence or conspicuousness are: location, size of type, and contrast of printing against background. Also bearing on the effectiveness of a warning might be the effect of the package contents if spilled on the label. Unless impracticable because of the nature of the substance, the label shall be of such construction and finish as to withstand reasonably foreseeable spillage through foreseeable use.

(5) "Highly Toxic Substance" is any substance falling within any of the following categories:

(a) Any substance that produces death within 14 days in half or more than half of a group of ten or more laboratory white rats each weighing between 200 grams and 300 grams, at a single dose of 50 milligrams or less per kilogram of body weight, when orally administered;

(b) Any substance that produces death within 14 days in half or more than half of a group of ten or more laboratory white rats each weighing between 200 grams and 300 grams when inhaled continuously for a period of one hour or less in an atmospheric concentration of 200 parts per million by volume or less of gas or vapor or two milligrams per liter by volume or less of mist or dust, provided that such concentration is likely to be encountered by humans when the substance is used in any reasonably foreseeable manner;

(c) Any substance that produces death within 14 days in half or more than half of a group of ten or more rabbits weighing between 2.3 kilograms and 3.0 kilograms each, tested in a dosage of 200 milligrams or less per kilogram of body weight when administered by continuous contact with the bare skin for 24 hours or less by the method described in OAR 333-016-0020. The number of animals tested shall be sufficient to give a statistically significant result and be in conformity with good pharmacological practices;

(d) Any substance determined by the Administrator to be "highly toxic" on the basis of human experience.

(6) "Toxic Substance" means any substance other than radioactive substance falling within any of the following categories:

(a) Any substance that produces death within 14 days in one-half or a group of ten or more white rats each weighing between 200 grams and 300 grams, at a single dose of more than 50 milligrams per kilogram but not more that five grams per kilogram of body weight, when orally administered. Substances falling in the toxicity range between 500 milligrams and five grams per kilogram of body weight will be considered for exemption from some or all of the labeling requirements of ORS 453.035 upon showing that, because of the physical form of the substances (solid, a thick plastic, emulsion, etc.) the size or closure of the container, human experience with the article, or any other relevant factors, such labeling is not needed;

(b) Any substance that produces death within 14 days in one-half of a group of ten or more white rats each weighing between 200 grams and 300 grams, when inhaled continuously for a period of one hour or less at an atmospheric concentration of more than 200 parts per million, but not more than 20,000 parts per million by volume of gas or vapor or more than two milligrams but not more than 200 milligrams per liter by volume of mist or dust, provided such concentration is likely to be encountered by man when the substance is used in any reasonably foreseeable manner;

(c) Any substance that produces death within 14 days in one-half of a group of ten or more rabbits weighing between 2.3 kilograms and 3.0 kilograms each tested at a dosage of more than 200 milligrams per kilogram of body weight but not more than 2 grams per kilogram of body weight when administered by continuous contact with the bare skin for 24 hours in the method described in rule 333-016-0020. The number of animals tested shall be sufficient to give statistically significant results and be in conformity with good pharmacological practice;

(d) Any substance that is "toxic" (but not "highly toxic") on the basis of human experience.

(7) "Irritant" includes primary irritant to the skin as well as substances irritant to the eye or mucous membranes:

(a) The term "primary irritant" means a substance that is not corrosive and that the available data of human experience indicate is a primary irritant; or which results in an empirical score of five or more when tested by the method described in OAR 333-016-0025;

(b) "Eye irritants" means a substance is an irritant to the eye if the available data or human experience indicate it is an irritant to the eye, or if a positive test result is obtained when the substance is tested by the method described in OAR 333-016-0030.

(8) "Corrosive substance" is one that causes visible destruction or irreversible alterations in the tissue at the site of contact. A test for a corrosive substance is whether, by human experience, such tissue destruction occurs at the site of application. A substance would be considered corrosive to the skin if, when tested on the intact skin of the albino rabbit by the technique described in OAR 333-016-0025, the structure of the tissue at the site of contact is destroyed or changed irreversibly in 24 hours or less. Other appropriate tests should be applied when contact of the substance with other than skin tissue is being considered.

(9) A "Strong Allergic Sensitizer" is a substance that produces an allergenic sensitization in a substantial number of persons who come into contact with it. An allergic sensitization develops by means of an "antibody mechanism" in contradistinction to a primary irritant reaction which does not arise because of the participation of an "antibody mechanism." An allergic reaction ordinarily does not develop on first contact because of necessity of prior exposure to the substance in question. The sensitized tissue exhibits a greatly increased capacity to react to subsequent exposures of the offending agent. Thus, subsequent exposures may

produce severe reactions with little correlation to the amounts of excitant involved. A "photodynamic sensitizer" is a substance that causes an alteration in the skin or mucous membranes, in general, or to the skin or mucous membrane at the site to which it has been applied, so that when these areas are subsequently exposed to ordinary sunlight or equivalent radiant energy an inflammatory reaction will develop.

(10) "Extremely Flammable" or "Flammable" substances:

(a) "Extremely flammable" means any substance that has a flashpoint at or below 20°F, as determined by the method described in OAR 333-016-0035;

(b) "Flammable" means any substance that has a flashpoint of above 20°F, to and including 80°F, as determined by the method described in OAR 333-016-0035.

(11) "Extremely Flammable" and "Flammable" solids:

(a) A solid substance is "extremely flammable" if it ignites and burns at an ambient temperature of 80°F or less when subjected to friction, or to percussion or to an electrical spark;

(b) A solid substance is "flammable" if, when tested by the method described in OAR 333-016-0040, it ignites and burns with a self-sustained flame at a rate greater than one-tenth of an inch per second along its major axis.

(12) "Extremely Flammable" and "Flammable" contents of self-pressurized containers:

(a) Contents of self-pressurized containers are "extremely flammable" if, when tested by the method described in OAR 333-016-0045, flashback (a flame extending back to the dispenser) is obtained at any degree of valve opening and the flashpoint, when tested by the method described in OAR 333-016-0050, is less than 20°F;

(b) Contents of self-pressurized containers are "flammable" if, when tested by the method described in rule 333-016-0045, a flame projection exceeding 18 inches is obtained a full valve opening or a flashback (a flame extending back to the dispenser) is obtained at any degree of valve opening.

(13) "Substances that generate pressure." A substance is hazardous because it generates pressure through decomposition, heat, or other means:

(a) If it explodes when subjected to an electrical spark, or to percussion, or to the flame of a burning paraffin candle for five seconds or less;

(b) If it expels the closure of its container or bursts its container when held at or below 130°F for two days or less;

(c) If it erupts from its opened container at a temperature of 130°F or less after having been held in the closed container at 130°F for two days;

(d) If it comprises the contents of a self-pressurized container.

(14) "Radioactive Substance" means a substance which, because of nuclear instability, emits electromagnetic and/or particulate radiation that is capable of producing ions in its passage through matter. Source materials, special nuclear material, and by-product materials described in ORS 453.605 et seq. are exempt.

(15) As used in ORS 453.005(11) "accompanying literature" means any placard, pamphlet, booklet, book, sign, or other written, printed, or graphic matter or visual device that provides directions for use, written or otherwise, and is used in connection with the display, sale, demonstration, or merchandising of a hazardous substance intended for or packaged in a form suitable for use in the household or by children.

(16) A "Substantial Personal Injury" or "Substantial Illness" means any illness or injury sufficiently significant to cause one or more days of restricted activity. A day of restricted activity is one on which a person cuts down on his usual activities for the whole of that day because of an illness or an injury. The term "usual activities" for any day means the things that the person would ordinarily do on that day. For children under school age, usual activities depend on whatever the usual pattern is for the child's day, which will in turn be affected by the age of the child, weather conditions, and so forth. For retired or elderly persons, usual activities might consist of almost no activity, but cutting down on even a small amount for as much as a day would constitute restricted activity. On Sundays or holidays "usual activities" are taken to be the things the person usually does on such days — going to church, playing golf, visiting friends or relatives, or staying at home and listening to the radio, reading, looking at television, and so forth. Restricted activity does not imply complete inactivity, but it does imply only the minimum of usual activities. A special nap for an hour after lunch does not constitute cutting down on usual activities, nor does the elimination of a heavy chore as cleaning ashes out of the furnace or hanging out the wash. If a farmer or housewife carries on only the minimum of the day's chores, however, this is a day of restricted activity. A day spent in bed or a day home from work or school because of illness or injury is, of course, a restricted activity day.

(17) A "Proximate Result" is one that follows in the course of events without an unforeseeable, intervening, independent cause.

(18) "Reasonably Foreseeable Handling or Use" includes the reasonably foreseeable accidental handling or use, not only by the purchaser or intended user of the product, but by all others in a household, especially children.

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.005 & 453.035
Hist.: HD 40, f. 8-2-73, ef. 8-15-73; HD 89, f. 7-31-75, ef. 8-25-75

333-016-0010
Human Experience with Hazardous Substances

Reliable data on human experience with any substance shall be taken into account in determining whether an article is a "hazardous substance" within the meaning of the Act, and when such data give reliable results different from results with animal data, the human experience takes precedence. Experience may show that an article is more or less toxic, irritant, or corrosive to man than to test animals. Experience may also show other factors that are important in determining the degree of hazard to humans represented by the substance; for example, that radiator antifreeze is likely to be stored in the household or garage and likely to be ingested in significant quantities by some persons. Experience also indicates that a particular substance in liquid form is more likely to be ingested than is the same substance in a paste or solid, and that an aerosol is more likely to get into the eyes and the nasal passages than is a liquid.

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.005 & 453.055
Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0015
Hazardous Mixtures

For a mixture of substances, the determination of whether such mixture is "hazardous" as defined in ORS 453.005(7) should be based on the physical, chemical, and pharmacological characteristics of the mixture. A mixture of substances may therefore be less hazardous or more hazardous than its components because of synergistic or antagonistic reactions. It may not be possible to reach a fully satisfactory decision concerning the toxic, irritant, corrosive, flammable, sensitizing, or pressure-generating properties of a substance from what is known about its components or ingredients. It is prudent to test the mixture itself.

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.005 & 453.055
Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0020
Testing Procedures for Hazardous Substances

Method of testing toxic substances. The method of testing the toxic substances defined in OAR 333-016-0005(5)(c) and (6)(c) is as follows:

(1) Acute dermal toxicity (single exposure). In the acute exposures the agent is held in contact with the skin by means of a sleeve for periods varying up to 24 hours. The sleeve, made of rubber dam or other impervious material, is so constructed that the ends are reinforced with additional strips and should fit snugly around the trunk of the animal. The ends of the sleeve are tucked, permitting the central portion to "balloon" and furnish a reservoir for the dose. The reservoir must have sufficient capacity to contain the dose

without pressure. In the following table are given the dimensions of sleeves and the approximate body surface exposed to the test substance. The sleeves may vary in size to accommodate smaller or larger subjects. In the testing of unctuous materials that adhere readily to the skin, mesh wire screen may be employed instead of the sleeve. The screen is padded and raised approximately two centimeters from the exposed skin. In the case of dry powder preparations, the skin and substance are moistened with physiological saline prior to exposure. The sleeve is then slipped over the gauze which holds the dose applied to the skin. In the case of finely divided powders, the measured dose is evenly distributed on cotton gauze, which is then secured to the area of exposure. (See **Table 1**.)

(2) Preparation of test animals. The animals are prepared by clipping the skin of the trunk free of hair. Approximately one-half of the animals are further prepared by making epidermal abrasions every 2 centimeters or 3 centimeters longitudinally over the area of exposure. The abrasions are sufficiently deep to penetrate the stratum corneum (horny layer of the epidermis), but not to disturb the derma — that is, not to obtain bleeding.

(3) Procedures for testing. The sleeve is slipped onto the animal which is then placed in a comfortable but immobilized position in a multiple animal holder. Selected doses of liquids and solutions are introduced under the sleeve. If there is slight leakage from the sleeve which may occur during the first few hours of exposure, it is collected and reapplied. Dosage levels are adjusted in subsequent exposures (if necessary) to enable a calculation of a dose that would be fatal to 50 percent of the animals. This can be determined from mortality ratios obtained at various doses employed. At the end of 24 hours the sleeves or screens are removed, the volume of unabsorbed material, if any, is measured, and the skin reactions are noted. The subjects are cleaned by thorough wiping, observed for gross symptoms of poisoning, and then observed for two weeks.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 453.095

Stats. Implemented: ORS 453.005 & 453.055

Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0025

Method of Testing Primary Irritant Substances

(1) Primary irritation to the skin is measured by a patch test technique on the abraded and intact skin of the albino rabbit, clipped free of hair. A minimum of six subjects are used in abraded and intact skin tests. Introduce under a square patch such as surgical gauze measuring 1" X 1" two single layers thick, 0.5 milliliter (in the case of liquids) or 0.5 gram (in the case of solids and semi-solids) of the test substance. Dissolve solids in an appropriate solvent and apply the solution as for liquids. The animals are immobilized with patches secured in place by adhesive tape. The entire trunk of the animal is then wrapped with an impervious material such as rubberized cloth, for the 24-hour period of exposure. This material aids in maintaining the test patches in position and retards the evaporation of volatile substances. After 24 hours of exposure, the patches are removed and the resulting reactions are evaluated on the basis of the designated values in the following evaluation of skin reactions:

(a) Erythema and eschar formation:

(A) No erythema — Value of 0;

(B) Very slight erythema (barely perceptible) — Value of 1;

(C) Well-defined erythema — Value of 2;

(D) Moderate to severe erythema — Value of 3;

(E) Severe erythema (beet redness) to slight eschar (injuries in depth) — Value of 4.

(b) Edema formation:

(A) No edema — Value of 0;

(B) Very slight edema (barely perceptible) — Value of 1;

(C) Slight edema (edges of area well defined by definite raising) — Value of 2;

(D) Moderate edema (raised approximately 1 millimeter) — Value of 3;

(E) Severe edema (raised more than 1 millimeter and extending beyond the area of exposure) — Value of 4.

NOTE: The "value" recorded for each reading is the average value of the six or more animals subject to the test.

(2) Readings are again made at the end of a total of 72 hours (48 hours after the first reading). An equal number of exposures are made on areas of skin that have been previously abraded. The abrasions are minor incisions through the stratum corneum, but not sufficiently deep to disturb the derma or to produce bleeding. Evaluate the reactions of the abraded skin at 24 hours and 72 hours, as described in this paragraph. Add the values for erythema and eschar formation at 24 hours and at 72 hours for intact skin to the values on abraded skin at 24 hours and at 72 hours (four values). Similarly, add the values for edema formation at 24 hours and at 72 hours for intact and abraded skin (four values). The total of the eight values is divided by four to give the primary irritation score. Exposure times and units:

(a) Erythema and eschar formation:

(A) Intact skin:

(i) 24 hours — Value of 2;

(ii) 72 hours — Value of 1.

(B) Abraded skin:

(i) 24 hours — Value of 3;

(ii) 72 hours — Value of 2.

(C) Subtotal of exposure unit values = 8.

(b) Edema formation:

(A) Intact skin:

(i) 24 hours — Value of 0;

(ii) 12 hours — Value of 1.

(B) Abraded skin:

(i) 24 hours — Value of 1;

(ii) 72 hours — Value of 2.

(C) Subtotal of exposure unit values = 8.

(c) Total exposure unit values = 12.

NOTE: Primary irritation score is 12 divided by 4 = 3.

Stat. Auth.: ORS 453.095

Stats. Implemented: ORS 453.005 & 453.055

Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0030

Test for Eye Irritants

(1)(a) Six albino rabbits are used for each test substance. Animal facilities for such procedures shall be so designed and maintained as to exclude sawdust, wood chips, or other extraneous material that might produce eye irritation. Both eyes of each animal in the test group shall be examined before testing, and only those animals without eye defect or irritation shall be used. The animal is held firmly but gently until quiet. The test material is placed on one eye of each animal by gently pulling the lower lid away from the eyeball to form a cup into which the test substance is dropped. The lids are then gently held together for one second and the animal is released. The other eye, remaining untreated, serves as a control. For testing liquids, 0.1 milliliter is used. For solids or pastes, 100 milligrams of the test substance is used, except that for substances in flake, granule, powder, or other particulate form the amount that has a volume of 0.1 milliliter (after compacting as much as possible without crushing or altering the individual particles, such as by tapping the measuring container) shall be used whenever this volume weighs less than 100 milligrams. In such a case, the weight of the 0.1 milliliter test dose should be recorded. The eyes are not washed following instillation of test material except as noted below;

(b) The eyes are examined and the grade of ocular reaction is recorded at 24, 48, and 72 hours. Reading of reactions is facilitated by use of a binocular loupe, hand slit-lamp, or other expert means. After the recording of observations at 24 hours, any or all eyes may be further examined after applying fluorescein. For this optional test, one drop of fluorescein sodium ophthalmic solution, U.S.P., or equivalent is dropped directly on the cornea. After flushing out the excess fluorescein with sodium chloride solution, U.S.P., or equivalent, injured areas of the cornea appear yellow; this best visualized in a darkened room under ultraviolet illumination. Any or all eyes may be washed with sodium chloride solution, U.S.P., or equivalent after the 24-hour reading.

(2)(a) An animal shall be considered as exhibiting a positive reaction if the test substance produces at any of the readings ulceration of the cornea (other than a fine stipplin), or opacity of the cornea (other than a slight dulling of the normal luster), or inflammation of the iris (other than a slight deepening of the folds (or rugae) or a slight circumcorneal injection of the blood vessels), or if such substance produces in the conjunctive (excluding the cornea and iris) an obvious swelling with partial eversion of the lids or a diffuse crimson-red with individual vessels not easily discernible;

(b) The test shall be considered positive if four or more of the animals in the test group exhibit a positive reaction. If only one animal exhibits a positive reaction, the test shall be regarded as negative. If two or three animals exhibit a positive reaction, the test is repeated using a different group of six animals. The second test shall be considered positive if three or more of the animals exhibit a positive reaction. If only one or two animals in the second test exhibit a positive reaction, the test shall be repeated with a different group of six animals. Should a third test be needed, the substance will be regarded as an irritant if any animal exhibits a positive response.

(3) To assist testing laboratories and other interested persons in interpreting the results obtained when a substance is tested in accordance with the method described in section (1) of this rule, an "**Illustrated Guide for Grading Eye Irritation by Hazardous Substances**" will be sold by the Superintendent of Documents, Government Printing Office, Washington, D.C. The guide will contain color plates depicting responses of varying intensity to specific test solutions. The grade of response and the substance used to produce the response will be indicated.

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.005 & 453.055
Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0035
Tentative Method of Test for Flashpoint of Volatile Flammable Materials by Tagliabue Open-Cup Apparatus

(1) Scope:

(a) This method describes a test procedure for the determination of open-cup flashpoints of volatile flammable materials having flashpoints below 175°F;

(b) This method, when applied to paints and resin solutions which tend to skin over or which are very viscous, gives less reproducible results than when applied to solvents.

***NOTE:** The Public Health Division has obtained permission from the American Society for Testing Materials, Philadelphia, Pennsylvania, to reprint this method in their regulations. The test has been slightly modified for practical reasons.

****NOTE:** ASTM Designation: D 1310-59T, issued 1954, revised 1955, 1956, and 1959. This tentative method has been approved by the sponsoring committee and accepted by the American Society for Testing Materials in accordance with established procedures for use pending adoption as standard. Suggestions for revisions should be addressed to the Society at 1916 Race Street, Philadelphia, Pennsylvania.

(2) Outline of Method. The sample is placed in the cup of a Tag Open Tester, and heated at a slow but constant rate. A small test flame is passed at a uniform rate across the cup at specified intervals. The flashpoint is taken as the lowest temperature at which application of the test flame causes the vapor at the surface of the liquid to flash; that is, ignite but not continue to burn.

(3) Apparatus. The Tag Open-Cup Tester is illustrated in **Figure 1**. It consists of the following parts which must conform to the dimensions shown and have the additional characteristics as noted:

(a) Copper bath, preferably equipped with a constant level overflow so placed as to maintain the bath liquid level one-eighth inch below the rim of the glass cup;

(b) Thermometer holder. Support firmly with ringstand and clamp;

(c) Thermometer. For flashpoints above 40 °F, use the ASTM Tag Closed Tester Thermometer, range of plus 20 to plus 230 °F, in one degree Fahrenheit divisions and conforming to thermometer 9F of ASTM Standard E1. For flashpoints from 20°F to 40°F, use ASTM Tag Closed Tester, Low Range Thermometer 57F. For flashpoints below 20°F, use ASTM Thermometer 33F.;

(d) Glass test cup. Glass test cup (**Figure 2**) of molded clear glass, annealed, heat-resistant, and free from surface defects;

(e) Leveling device. Leveling device or guide, for proper adjustment of the liquid level in the cup (**Figure 3**). This shall be made of No. 18-gauge polished aluminum with a projection for adjusting the liquid level when the sample is added to exactly one-eighth inch below the level of the edge or rim of the cup;

(f) "Micro" or small gas burner of suitable dimensions for heating the bath. A screw clamp may be used to help regulate the gas. A small electric heater may be used;

(g) Ignition taper, which is a small, straight, blow-pipe type gas burner. The test flame torch prescribed in the method of test for flash and fire points by Cleveland Open Cup (ASTM designation: D 92) is satisfactory;

(h) Alternative methods for maintaining the ignition taper in a fixed horizontal plane above the liquid may be used, as follows:

(A) Guide wire, 3/32 inch in diameter and 3-1/2 inches in length, with a right-angle bend one-half inch from each end. This wire is placed snugly in holes drilled in the rim of the bath, so that the guide wire is 5/8 inch from the center of the cup and resting on the rim of the cup;

(B)(i) Swivel-type taper holder, such as is used in ASTM Method D 92. The height and position of the taper are fixed by adjusting the holder on a suitable ringstand support adjacent to the flash cup.

(ii) Draft shield, consisting of two rectangular sheets of noncombustible material, 24 inches x 28 inches, are fastened together along the 28 inch side, preferably by hinges. A triangular sheet, 24 inches x 24 inches x 34 inches is fastened by hinges to one of the lateral sheets (to form a top when shield is open). The interior of the draft shield shall be painted a flat black.

(4) Procedure:

(a) Place the tester on a solid table free of vibration, in a location free of perceptible draft, and in a dim light;

(b) Run water, brine, or water-glycol solution into the bath to a predetermined level, which will fill the bath to one-eighth inch below the top when the cup is in place. An overflow is permissible for water level control;

(c) Firmly support the thermometer vertically halfway between the center and the edge of the cup on a diameter at right angles to the guide wire, or on a diameter passing through the center of the cup and the pivot of the taper. Place so that the bottom of the bulb is one-fourth inch from the inner bottom surface of the cup. If the old Tagliabue thermometer is used, immerse to well cover the mercury bulb, but not the wide body of the thermometer;

(d) Fill the glass cup with the sample liquid to a depth just one-eighth inch below the edge, as determined by the leveling device;

(e) Place the guide wire or swivel device in position, and set the draft shield around the tester so that the sides form right angles with each other and the tester is well toward the back of the shield;

(f) If a guide wire is used, the taper, when passed, should rest lightly on the wire, with the end of the jet burner just clear of the edge of the guide wire. If the swivel-type holder is used, the horizontal and vertical positions of the jet are so adjusted that the jet passes on the circumference of a circle, having a radius of at least six inches across the center of the cup at right angles to the diameter passing through the thermometer, and in a plane one-eighth inch above the upper edge of the cup. The taper should be kept in the "off" position, at one end or the other of the swing, except when the flame is applied;

(g) Light the ignition flame and adjust it to form a flame of spherical form matching in size the 5/32-inch sphere on the apparatus;

(h) Adjust heater source under bath so that the temperature of the sample increases at a rate of two plus or minus 0.5°F per minute. With viscous materials, this rate of heating cannot always be obtained.

(5) Initial Test. Determine an approximate flashpoint by passing the taper flame across the sample at intervals of 2°F. Each pass must be in one direction only. The time required to pass the ignition flame across the surface of the sample should be one second. Remove bubbles from the surface of the sample liquid

before starting a determination. Meticulous attention to all details relating to the taper, size of taper flame, and rate of passing the taper is necessary for good results. When determining the flashpoint of viscous liquids and those liquids that tend to form a film of polymer, etc., on the surface, the surface film should be disturbed mechanically each time before the taper flame is passed.

(6) Recorded Tests. Repeat the procedure by cooling a fresh portion of the sample, the glass cup, the bath solution, and the thermometer at least 20°F below the approximate flashpoint. Resume heating and pass the taper flame across the sample at two intervals of 5°F, and then at intervals of 2°F until the flashpoint occurs.

(7) Reporting Data. The average of not less than three recorded tests, other than the initial test, shall be used in determining the flashpoint and flammability of the substance.

(8) Standardization:

(a) Make determinations in triplicate on the flashpoint of standard paraxylene and of standard isopropyl alcohol which meet the following specifications:

(A) Specifications of p-xylene, flashpoint check grade. P-xylene shall conform to the following requirements:

(i) Specific Gravity: 15.56°C/15.56°C, 0.860 minimum, 0.866 maximum;

(ii) Boiling Range: 2°C maximum from start to dry point when tested in accordance with the method of test for distillation of industrial aromatic hydrocarbons (ASTM designation: D 850), or the method of test for distillation range of lacquer solvents and effluents (ASTM designation: D 1078). The range shall include the boiling point of pur-xylene, which is 138.35°C (281.03°F);

(iii) Purity: 95 percent minimum, calculated in accordance with the method of test for determination of purity from freezing points of high-purity compounds (ASTM designation: D 1016), from the experimentally determined freezing point, measured by the method of test for measurement of freezing points of high purity compounds for evaluation of purity (ASTM designation: D 1015).

(B) Specifications for isopropanol, flashpoint check grade. Isopropanol shall conform to the following requirements:

(i) Specific Gravity: 0.8175 to 0.8185 at 20°C/20°C, as determined by means of a calibrated pycnometer;

(ii) Distillation Range: Shall entirely distill within a 1.0 degree Centigrade range which shall include the temperature 80.4°C as determined by ASTM method D 1078. Average these values for each compound. If the difference between the values for these two compounds is less than 15°F (8.5°C) or more than 27°F (16°C), repeat the determinations or obtain fresh standards.

(b) Calculate a correction factor as follows:

X = 92 - A

Y = 71 - B

Correction:

$$\frac{X + Y}{Z}$$

Where:

A = Observed flash of p-xylene

B = Observed flash of isopropyl alcohol

Apply this correction to all determinations. Half units in correction shall be discarded.

(9) Precision:

(a) For hydrocarbon solvents having flashpoints between 60°F and 110°F, repeatability is plus or minus 2°F and the reproducibility is plus or minus 5°F;

(b) If results from two tests differ by more than 10°F, they shall be considered uncertain and should be checked. The calibration procedure provided in this method will cancel out the effect of barometric pressure if calibration and tests are run at the same pressure. (Data supporting the precision are given in Appendix III of the **1956 Report of Committee D-1 on Paint, Varnish, Lacquers, and Related Products**, **Proceedings**, **American Soc. Testing Mats., Volume 56 (1956)**.)

[ED. NOTE: Figures referenced are available from the agency.]

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.095

Stats. Implemented: ORS 453.005 & 453.055

Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0040

Method for Determining Extremely Flammable and Flammable Solids

(1) Preparation of sample:

(a) Granules, powders, and pastes. Pack the sample into a flat, rectangular metal boat with inner dimensions of 6 inches long x 1 inch wide x 1/4 inch deep;

(b) Rigid and pliable solids. Measure the dimensions of the sample and support it by means of metal ringstands, clamps, rings, or other suitable devices as needed, so that the major axis is oriented horizontally and the maximum surface is freely exposed to the atmosphere.

(2) Procedure. Place the prepared sample in a draft-free area that can be ventilated and cleaned after each test. The temperature of the sample at the time of testing shall be between 68°F and 86°F. Hold a burning paraffin candle whose diameter is at least one inch so that the flame is in contact with the surface of the sample at the end of the major axis for five seconds or until the sample ignites, whichever is less. Remove the candle. By means of a stopwatch, determine the time of combustion with self-sustained flame. Do not exceed 60 seconds. Extinguish flame with a CO_2 or similar nondestructive type extinguisher. Measure the dimensions of the burnt area and calculate the rate of burning along the major axis of the sample.

Stat. Auth.: ORS 453.095

Stats. Implemented: ORS 453.005 & 453.055

Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0045

Method for Determining Extremely Flammable and Flammable Contents of Self-Pressurized Containers

(1) Equipment required. The test equipment consists of a base eight inches wide, two feet long, marked in six-inch intervals. A rule two feet long and marked in inches is supported horizontally on the side of the base and about six inches above it. A paraffin candle one inch or more in diameter and of such height that the top third of the flame is at the height of the horizontal rule, is placed at the zero point in the base.

(2) Procedure. The test is conducted in a draft-free area that can be ventilated and cleared after each test. Place the self-pressurized container at a distance of six inches from the flame source. Spray for periods of 15 seconds to 20 seconds (one observer noting the extension of the flame and the other operating the container) through the top third of the flame and at a right angle to the flame. The height of the flame should be approximately two inches. Take three readings for each test, and average. As a precaution, do not spray large quantities in a small, confined space. Free space of previously discharged material.

Stat. Auth.: ORS 453.095

Stats. Implemented: ORS 453.005 & 453.055

Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0050

Method for Determining Flashpoint of Extremely Flammable Contents of Self-Pressurized Containers

The apparatus used in the Tagliabue Open-Cup Flashpoint Apparatus as described in OAR 333-016-0035. Some means such as dry ice in an open container is used to chill the pressurized container. The container, the flash cup, and the bath solution of the apparatus (brine or glycol may be used) are chilled to a temperature of about 25°F below zero. The chilled container is punctured to exhaust the propellant. The chilled formulation is transferred to the test apparatus and tested in accordance with the method described in OAR 333-016-0035.

Stat. Auth.: ORS 453.095

Stats. Implemented: ORS 453.005 & 453.055

Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0055

Method for Determining the Sound Pressure Level Produced by Toy Caps

(1) Equipment required. The equipment for the test includes a microphone, a preamplifier (if required), and an oscilloscope:

(a) The microphone-preamplifier system shall have a free-field response uniform to within plus or minus two decibels from 50 hertz to 70 kilohertz or beyond, and a dynamic range covering the interval 70 to 160 decibels relative to 20 micronewtons per square meter. Depending on the model, the microphone shall be used at normal or grazing incidence, whichever gives the most uniform free-field response. The microphone shall be calibrated both before and after the test of a model of cap. The calibration shall be accurate to within plus or minus one decibel. If the calibration is of the pressure type or of the piston-phone plus electro-static actuator type, it shall be corrected to free-field conditions in accordance with the manufacturer's instructions;

(b) The oscilloscope shall be the storage type or one equipped with a camera. It shall have a response uniform to within plus or minus one decibel from 50 hertz to 250 kilohertz or higher. It shall be calibrated to within plus or minus one decibel against an external voltage source periodically during the tests.

(2) Procedure:

(a) Place the sound source and testing equipment so that neither the sound source nor the microphone is closer than one meter from any wall, floor, ceiling, or other large obstruction. Locate the sound source and the microphone in the same horizontal plane with a distance of 25 centimeters between the diaphragm of the microphone and the position of the sound producing component of the sound source, e.g., explosive or diaphragm. Measure the peak sound pressure level at each of the six designated orientations of the sound source with respect to the measuring microphone. When caps are tested use the type of pistol that would ordinarily be used with the caps being tested. The zero degree orientation corresponds to an unobstructed and direct line from the sound source to the microphone, e.g., the muzzle of a pistol pointing at the microphone. The 90, 180 , and 270 degree orientations are measured in a clockwise direction when looking down on the sound source and correspond to looking down on a pistol with its barrel horizontal as illustrated by the following figure:

0°
270° 90°
180°

(b) Testing Caps With a Pistol and Testing Gun. The hammer and trigger orientations are obtained by rotating the pistol about the axis of the barrel, when the pistol is in the 90-degree of 270-degree orientation, so that the hammer and the trigger are each respectively closest to and in the same horizontal plane with the microphone. Fire ten shots at each of the six orientations, obtaining readings on the oscilloscope of the maximum peak voltage for each shot. Average the results of the ten firings for each of the six orientations;

(c) Sound Sources Other Than Caps and Guns. Rotate the sound source about its axis to the four degrees of orientation. Produce ten sound emissions at each of the orientations obtaining readings on the oscilloscope of the maximum peak voltage for each emission. Average the results of the ten firings for each of the four orientations;

(d) Computation. Using the orientation that yields the highest average value, convert the value to sound pressure levels in decibels relative to 20 micronewtons per square meter using the response to the calibrated measuring microphone.

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.005 & 453.055
Hist.: HD 40, f. 8-2-73, ef. 8-15-73; HD 89, f. 7-31-75, ef. 8-25-75

333-016-0056
Test Methods for Simulating Use and Abuse, Toys, Games, and Other Articles Intended for Use by Children

(1) Objective. This rule and OAR 333-016-0057, 333-016-0058, and 333-016-0059 describe specific test methods for simulating normal use of toys and other articles intended for children as well as the reasonably foreseeable damage or abuse to which the articles may be subjected. The test methods are for use in exposing potential hazards that would result from the normal use or the reasonably foreseeable damage or abuse of such articles intended for children.

(2) Application:

(a) Toys intended for children 96 months of age or less must satisfy all tests in this section and shall also satisfy tests which have been established for articles intended for the specified age groups of children: 18 months of age and less, over 18 months but not over 36 months of age, and over 36 months but not over 96 months of age, which are set forth in OAR 333-016-0057, 333-016-0058, and 333-016-0059. If an article is marked, labeled, advertised, or otherwise intended for children of an age spanning more than one of such age groups, the article will be subjected to those tests providing the most stringent requirements. If an article is not age-labeled or is unreasonably age-labeled and is intended for children 96 months of age or less, it will also be subjected to the most stringent test requirements;

(b) Each of the test methods described in this rule and in OAR 333-016-0057, 333-016-0058, and 333-016-0059 shall be applied to a previously untested sample, except the tension test which shall be conducted with the test sample used in the torque test if no failure occurred during that test;

(c) Normal use testing:

(A) (Known herein as Requirement No. 1) These tests are intended to simulate normal use conditions so as to assure that hazards are not generated through normal wear and deterioration. The object of these tests shall be to simulate the normal play mode of the toy, and the tests in Requirement No. 2, are therefore unrelated. The tests are intended to uncover hazards, rather than to demonstrate the reliability of the toy. The fact that a mechanism or material of a toy fails during testing is only relevant if the failure creates a potential hazard. Toys shall be subjected to appropriate tests to repeatedly simulate the normal use of the particular toy. For example, levers, wheels, catches, triggers, strings, wires, chains, and so on, that are intended to be actuated by a child shall be repeatedly operated. Spring or power-operated devices shall be similarly tested. The tests shall be carried out in a normal use environment. For example, toys intended for use in the bathtub shall be tested in soapy water, and toys intended for use in the sandbox shall be exposed to sand during testing. The toy should be inspected after such tests, and hazards such as points, sharp edges, and release of small parts shall be evaluated according to the relevant requirements under OAR 333-016-0080;

(B) Abuse testing and impact testing. Tests in (A,i) through (A,iii); (B,i) through (B,v); (E,i) through (E,v); (F,i) through (F,v); and (G,i) through (G,v); (known herein as Requirement No. 2) are to simulate the exposure of a toy to mechanical damage through dropping, throwing, and other actions likely to be performed by a child, and to simulate situations in which possible damage can occur to a toy by reason of it falling from a crib, a table or counter top, or other impact situation which may occur as a result of reasonably foreseeable abuse. After testing, the toy shall be examined for mechanical hazards, such as hazardous sharp edges and points, and ingesting hazards, such as small liberate components, chips, or fragments according to the particular age grading requirement for each hazard, as described in OAR 333-016-0080.

(d) Special impact tests for certain classes of toys exempted from drop tests:

(A) Tip over test for large floor-standing toys. Toys intended for use on the floor, such as refrigerators and ovens, that have a volume of greater than 3 cubic feet, calculated without regard to minor appendages, or a projected base area of 400 square inches or more, shall be tipped over onto an impact area of the construction described in Test (E,i). The impact area shall be sufficiently large to accommodate the toy in whatever attitude it falls. The toy shall be placed on the floor in intended use position and tipped over 3 times by pushing on the floor in intended use position and tipped over 3 times by pushing it slowly past its center of balance, and allowed to fall without restraint. For toys with legs, projected base area is determined by calculation area enclosed by straight lines connecting outermost edge of each leg of the perimeter (Known herein as Test (A,i));

(B) Impact test for projectiles. Projectiles shall be propelled by their discharge mechanism three times into a concrete block wall (or equivalent surface) located at a distance twice the length of

the projectile from the front end of the launcher. The discharge mechanism shall be aimed perpendicular to the wall. (Known herein as Test (A,ii)) The discharge mechanisms shall be drop tested according to another test, (F,i);

(C) Tumble test for wheeled toys. Wheeled toys weighing more than 3.0 pounds shall be tumbled down a flight of six steps with risers not less than seven inches high (see **Figure 4**). The treads may be wood, cement, or metal. The toy shall be caused to fall down the steps two times in each of four attitudes: Tumbling forwardly, tumbling rearwardly end-over-end, and tumbling from each side. The toy shall be pushed slowly over the edge of the top step in the appropriate attitude, and released as soon as it begins to fall of its own weight. The test shall be considered complete for an attitude even if the toy does not reach the bottom of the flight of steps (Known herein as Test (A,iii));

(D) Exemptions from impact tests. The following categories are exempted from test (A,i) through test (A,iii):

(i) Toys or assembled toys having nonwheeled bases, such as gas stations and farm sets in which the base has an area greater than 175 square inches and which do not tip over when placed on a 45 degree incline in any direction. If the toy tips, then it shall be tested according to test (A,i). However, accessories, or components of these toys that are not affixed to the base structure shall conform to test (E,i) or test (F,i) or test (G,i);

(ii) Toys weighing more than ten pounds; and

(iii) Paints, chalks, and crayons. However, the containers provided for these articles shall conform to test (E,i), test (F,i), or test (G,i).

(E) Impact test for toys that cover the face. The toy shall be held firmly in a suitable clamp with that portion covering the eyes in a horizontal plane. Drop a 5/8-inch diameter steel ball weighing 0.56 ounce (tolerance plus 0.03 ounce, minus zero ounce) from a height of 50 inches upon the horizontal upper surface of the toy in the area that would cover the eyes in normal use. The ball may be guided, but not restricted, in its fall by being dropped through a perforated tube extending to within approximately 4-inches of the toy. The toy will be considered to have failed if the material cracks through its entire thickness or if any material visible to the naked eye becomes detached. (Known herein as Test (A,iv).)

(e) Special tests for certain classes of toys exempted from drop and impact tests. These tests relate to the requirements of OAR 333-016-0080:

(A) Tires, wheels, axles:

(i) The toy shall be clamped so that the wheel axle is vertical. A wire hook shaped as shown in **Figure 5** shall be positioned on the lower tire and attached to a dead weight of ten pounds if the tire is on a toy intended for children aged up to 18 months, or to a dead weight of 15 pounds if the tire is on a toy intended for children aged from 18 months to 36 months and if the tire falls within the limits of ingestion hazards as defined in OAR 333-016-0080. The load shall be applied gradually and maintained for ten seconds. Test (E,iii) and (E,iv) shall also be applied (Known as Test (B,i).);

(ii) Pull test for wheels on hubs free to rotate. The toy shall be supported or clamped with the axle in a vertical position. If the lower wheel is accessible so that all of the claws of a three-pronged claw hook can be engaged around the wheel hub or tire, then a load of 10, 15, or 20 pounds shall be applied. The load shall be 10 pounds in the case of wheels 3/4-inch or less in diameter on toys intended for children aged less than 18 months, 15 pounds in the case of wheels 3/4-inch or less in diameter on toys intended for children from 18 months but not over 96 months, and 20 pounds in the case of wheels greater than 3/4-inch in diameter. The three-pronged claw hook shall be equivalent in type to that shown in **Figure 6** and described in **British Standard No. 3443**, **Code of Safety Requirements for Children's Toys and Playthings**, **1968**, **p. 12**. The load shall be applied gradually over a five-second period and shall be maintained for ten seconds. If the wheel hub or tire is inaccessible to the three-pronged claw, then a suitable test hook shall be substituted for the three-pronged device. The hook shall be applied to the periphery, and the test shall be carried out as described above. Tests (E,iii) and E,iv) shall also be applied (Known herein as Test (B,ii));

(iii) Pull test for wheels fixed onto axles. A schematic diagram of a device for applying torque is shown in **Figure 7**. A load of 20 pounds is applied. The procedure is that used in Test (B,ii) (Known herein as Test (B,iii));

(iv) Toys assembled with "snap-in" axles. A 15 pound dead weight shall be applied to the axle, adjacent to a bearing, for ten seconds, using a hook and string for attachment to the toy. The toy shall be held horizontally in a test-convenient fixture, and the load shall be applied gradually over a five second period and then shall be maintained for ten seconds. If the axle cannot be hooked as described above, the toys shall be held horizontally, and a ten pound dead weight shall be attached to one wheel by means of a hook or clamp. The load shall be applied gradually over a five-second period and then shall be maintained for ten seconds (Known herein as Test (B,iv));

(v) Compression test for "snap-on" wheel and axle assemblies. This test is for compliance with OAR 333-016-0080(3)(b)(A)(iii) if the axle and wheel are removed by the procedure described in test (B,iv). The wheel and axle assembly shall be positioned with the axle vertical over a hole in a rigid plate as shown in **Figure 8**. The hole shall be large enough in diameter to permit the axle to pass through. A load of 20 pounds is applied to the upper wheel, using a suitable adaptor to prevent interference with the axle. The load shall be applied gradually over a five-second period and then shall be maintained for ten seconds. When applying the load, the upper wheel shall be guided, if necessary, in order to maintain the axle vertical, but shall not be restrained from moving downward. In those cases where the axle is forced through either wheel, the axle shall not form a hazardous point or projection. (Known herein as Test (B,v))

(B) Bending test for wires and rods. Any toy that is intended to be bent or formed and that is equipped with metal wire(s) or other metal material(s) for retention of form shall be subject to this test. The toy shall be suitably secured in a vise equipped with vise shields of 3/8-inch inside diameter as shown in **Figure 9**. The component containing the wire or rod shall be held not less than three inches from the clamping point. The component shall then be bent through a 60 degree arc. The component shall then be bent in the reverse direction through a 120 degree arc. A back and forth bending through the 120 degree arc shall be repeated for 30 cycles. One back and forth bending (two 120 degree arc bends) shall constitute one cycle. The test shall be conducted at the rate of one-half cycle or 120 degrees per second with a 60 second rest period occurring after each ten cycles. Apply a maximum force of 10 pounds plus or minus 0.5 pound when testing toys covered by OAR 333-016-0057 and 15 pounds plus or minus 0.5 pound when testing toys covered by OAR 333-016-0058 or 333-016-0059. Apply the force perpendicularly to the major axis of the component at a point two inches (5 centimeters) from the intersection of the component with the main body of the toy or at the end of the component if the component is less than 2 inches plus or minus 0.05 inch (5 centimeters) long (Known herein as Test C,i));

(C) Test for removal of components from toys. The toy shall be restrained in a test-convenient clamp, and the component connected to an extensometer by a 3-pronged claw hook or other suitable means of attachment. Care shall be taken to ensure that the hook or attachment device does not compress the protective components of OAR 333-016-0080(3)(a)(C)(i) and (3)(b)(A)(iii) so that it hinders possible removal. The extensometer shall be pulled perpendicular to the joint between the component and the body of the toy. The load shall be applied gradually over a five second period and then shall be maintained for ten seconds. With regard to the push force requirement in OAR 333-016-0080, the projection, or the toy, shall be held in a test-convenient clamp. A push force of ten pounds shall be applied using an extensometer or dead weight gradually over a period of five seconds and then shall be maintained for ten seconds (Known herein as Test (D,i));

(D) Test for mouth-actuated toys. A piston pump, such as bicycle pump, capable of discharging and taking in more than 18

cubic inches of air in less than three seconds shall be connected to the mouthpiece of the toy, and to the air outlet if applicable. The toy shall be subjected to ten alternation blowing and sucking cycles of 18 cubic inches of air. Any objects released as a result of this test shall be inspected for conformance with OAR 333-016-0080(4)(a) (Known herein as Test D,ii));

(E) Tests for thermal and fire features:

(i) Electrical toy. When tested under the conditions described in test (T,i) an electrical toy shall not attain a temperature at any point sufficiently high to constitute a fire hazard or to adversely affect any materials employed and shall not show a maximum temperature higher than those established by subparagraphs (2)(e)(E)(v) and (vi) of this rule. These maximum surface temperature requirements are not applicable to educational or hobby-type products such as lead-casting sets and wood-burning tools which are appropriately labeled on the shelf pack or package as being intended only for children over twelve years provided that the maximum surface temperature of any such toy does not exceed that reasonably required to accomplish the intended technical effect. Such toys shall be provided with specific instructions and the warning statements required by and in accordance with 333-016-0080, and shall be appropriately labeled as educational or hobby-type products;

(ii) Test conditions (Known herein as Test (T,i)):

(I) General. Tests shall be conducted while the toy is connected to a circuit of 60-cycle-per-second (60 Hertz) current using the materials supplied with the toy or using materials otherwise intended to be used with the toy. Following such tests, the toy shall be energized for a 6-hour period to determine that no hazardous conditions would result from unattended use of the toy;

(II) Voltage. The toy shall be tested at the voltage indicated in the manufacturer's rating or at 120 volts, whichever is greater.

(iii) Temperature measurements:

(I) General. (Known herein as Test (T,ii)) Temperatures shall be measured by means of instruments utilizing thermocouples of No. 30 AWG (American Wire Gage) wire (either copper and constantan or iron and constantan) and potentiometer-type instruments that are accurate and are calibrated in accordance with current good laboratory practices. The thermocouple wire shall conform with the requirements for "special" thermocouples as listed in the table of limits of error of thermocouples **(Table VIII)** in "**American Standard for Temperature Measurement Thermocouples, C96.1-1964**," approved June 9, 1964, by American National Standards Institute, Inc. The Standard was sponsored and published by the Instrument Society of America;

(II) Test procedures. The thermocouple junction and adjacent thermocouple lead wire shall be securely held in good thermal contact with the surface of the material whose temperature thermal contact will result from securely taping or cementing the thermocouple in place. If a metal surface is involved, brazing or soldering the thermocouple to the metal may be necessary. The surface temperatures of a toy shall be measured with the toy operating in any unattended condition (e.g., with and without opening and closing doors or covers) for a sufficient period of time to allow temperatures to become constant, or, in the case of a toy with a thermostatically controlled heating element, for a sufficient period of time to determine the maximum surface temperature attained. A temperature shall be considered to be constant when three successive readings taken at 15 minute intervals indicate no change.

(iv) Heating devices. Toy ovens, casting toys, popcorn, and candy makers, and other toys requiring the insertion of any materials or substances shall be additionally tested by feeding crumpled strips of newspaper and tissue paper into or onto the toy in place of the intended materials or substances. The test strips shall be conditioned for at least 48 hours in air at a temperature of 25 °C plus or minus 4°C. (77°F plus or minus 7°F) and a relative humidity of 50 percent plus or minus five percent. The test strips shall be two inches wide by eight inches long before crumpling. The crumpled paper shall occupy not more than 25 percent of the accessible volume. The performance of the toy shall be considered unacceptable if flaming occurs within a 60 minute period following the attainment of normal operating temperatures. If a light bulb is used for heating purposes, the test shall be conducted using the largest wattage bulb that can be easily inserted into the socket;

(v) Maximum acceptable surface temperatures. The maximum acceptable surface temperatures for electrically operated toys is set out in **Table 1**;

(vi) Maximum acceptable material temperatures. The maximum acceptable material temperatures for electrically operated toys is set out in **Table 2**. (Classes 105, 130, A and B are from "**Motors and Generators**," Standard MG-1-1967 published by the National Electrical Manufacturer's Association.)

(3) Definitions. As used in this rule and in OAR 333-016-0057, 333-016-0058, and 333-016-0059:

(a) "Accessible" — Accessible refers to any portion of a toy that can be contacted by a probe of the approximate shape and size of a child's finger. The insertion length and diameter of the probe shall be as specified below: Dimensions of probes for defining accessibility:

(A) Age 0–24 months (inclusive): Insertion length of probe — 2 inches; Diameter of probe — 1/4 inch;

(B) Age 25–60 months (inclusive): Insertion length of probe — 2-1/2 inches; Diameter of probe — 1/4 inch;

(C) Age 61–168 months (inclusive): Insertion length of probe — 3 inches; Diameter of probe — 1/4 inch.

NOTE: Age — Refers to the whole time of a beings existence since birth and may be expressed in either months or in years. When years are indicated, it means that the attained age in months is at least 12 times the numerical value indicated.

(b) "Curled Edge" — A curled edge is one in which the portion of the sheet adjacent to the edge is bent into an arc and forms an angle of less than 90 degrees with the base sheet as shown in **Figure 10**;

(c) "Discharge Mechanism" — A discharge mechanism is a system for releasing and propelling a projectile in a direction determined by the operator of the toy;

(d) "Edge, Hazardous" — A hazardous edge is defined as an edge that can cut a child's skin during normal use or reasonably foreseeable abuse of a toy. Such an edge is subjectively judged as hazardous if it appears sharp to the casual observer;

(e) "Elastic" — An elastic material is defined as one which will not break and will, essentially, instantaneously recover its former size and shape after being elongated at least ten percent at a testing speed of not less than 20 inches per minute;

(f) "Fabric" — Any material, woven, knitted, fitted, or otherwise produced from or in combination with any natural or synthetic fiber;

(g) "Feathering" — Feathering is a beveling of an edge (or decrease in thickness moving toward the edge) caused during shearing or cutting of sheet metal;

(h) "Flash" — Flash is excess material which escapes between the mating parts of a mold assembly;

(i) "Folding Mechanisms" — Folding mechanisms are those have an assembly of hinged, pivoted, or sliding members that can produce a scissor or shear action during the operation of the mechanisms;

(j) "Hazard" — A hazard is defined as any characteristic of a toy that presents an unreasonable risk of injury or illness during normal use or as a result of reasonably foreseeable abuse;

(k) "Hemmed Edge" — A hemmed edge is one in which the portion of the sheet adjacent to the edge is folded back on the sheet itself through an angle of approximately parallel to the main sheet, as shown in **Figure 11**;

(l) "Hinge Line Clearance" — The hinge line clearance is the clearance between the stationary portion of the toy and the movable portion along, or adjacent to, a line projected through the axis of rotation. **Figure 12** illustrates the hinge line clearance, using a box with a lid as an example;

(m) "Impulsive Noise" — An impulsive noise is one in which the variations in noise level involve maxima at intervals of greater than one second;

(n) "Lap Joint" — A lap joint is one in which an edge overlaps a parallel surface but is not necessarily mechanically attached to it

at all points along the length. Typical lap joints are shown in **Figure 13**;

(o) "Normal Use" — Normal use of a toy is defined as those play modes which conform to the instructions that accompany the toy, or which have been established by tradition or custom;

(p) "Point, Hazardous" — A hazardous point is one that can puncture or lacerate a child's skin during normal use or reasonably foreseeable abuse. Such a point is subjectively judged as hazardous if it appears sharp to the casual observer;

(q) "Projectile" — A projectile is an unrestrained object propelled by means of a discharge mechanism that is capable of storing and releasing energy under the control of the operator;

(r) "Projection, Hazardous" — A hazardous projection is one that, because of its material and configuration, appears to the casual observer to present a puncture hazard if a child should fall onto it;

(s) "Protective Cap or Cover" — A protective cap or cover is a component that is attached to a potentially hazardous edge or projection to reduce the possibility of injury;

(t) "Protective Tip" — A protective tip is a component that is attached to the impacting end of a projectile to minimize injury if it should impact on the body. A protective tip may perform other functions such as the prevention of damage to the projectile on striking a target, providing a means of attaching the projectile to the target as in the case of suction cups, or the prevention of damage to inanimate objects;

(u) "Reasonably Foreseeable Abuse" — Reasonably foreseeable abuse is defined as conditions to which a child may subject a toy that is not normal use conditions. Examples of abuse would result from:

(A) Curiosity, such as deliberate disassembly;

(B) Lack of physical coordination or manual dexterity, such as dropping; and

(C) Use for a purpose for which the toy is not intended, such as use of a toy football helmet as if it were a real protective device.

(v) "Rigid" — Rigid refers to any material that has a Young's modulus in tension of greater than 100,000 psi;

(w) "Rolled Edge" — Rolled edge is one in which the portion of the sheet adjacent to the edge is bent into an arc and forms an angle between 90 degrees and 120 degrees with the main sheet, as shown in **Figure 14**;

(x) "Toy":

(A) "Toy" means any toy, game, pacifier, or other article designed, labeled, advertised, or otherwise intended for use by children;

(B) "Mouth toy" means any toy reasonably intended to be placed into or in contact with a child's mouth.

(4) Prior to testing, each sample shall be subjected to a temperature of 73°F plus or minus 3°F (23°C plus or minus 2°C.) at a relative humidity of 20–70 percent for a period of at least four hours. The toy testing shall commence within five minutes after the toy has been removed from the preconditioning atmosphere.

(5) Toys reasonably intended to be assembled by an adult and not intended to be taken apart by a child shall be tested only in the assembled state if the shelf package and the assembly instruction prominently indicate that the article is to be assembled only by an adult.

(6) Toys intended to be repeatedly assembled and taken apart shall have the individual pieces as well as the completed article subjected to these test procedures.

(7) In situations where a test procedure may be applied in more than one way to a toy test component, the point (or direction) of force (or torque) application which results in the most severe conditions shall be used.

[ED. NOTE: Tables and Figures referenced are available from the agency.]

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.095

Stats. Implemented: ORS 453.005 & 453.055

Hist.: HD 40, f. 8-2-73, ef. 8-15-73; HD 89, f. 7-31-75, ef. 8-25-75

333-016-0057

Test Methods for Simulating Use and Abuse of Toys and Other Articles Intended for Children 18 Months of Age or Less

(1) Application. The test methods described in this section shall be used in determining compliance, in addition to other requirements of toys intended for use by children 18 months of age or less.

(2) Impact test. (Drop Test) Known as Test (E,i). Toys subject to special impact test in OAR 333-016-0056(2)(d) excepted.

(a) Application. Toys having a weight of less than three pounds shall be subjected to this test;

(b) Impact medium. The impact medium shall consist of a 0.125-inch nominal thickness of Type IV vinyl-asbestos tile, as specified in Federal specification SS-T-31-2A, over at least 2.5-inch thickness of concrete. The impact area shall be at least three square feet;

(c) Testing procedure. The toy shall be dropped ten times from a height of 4.5 feet plus or minus 0.5-inch. The toy shall be dropped in random orientation. After each drop the test sample shall be allowed to come to rest and examined and evaluated before continuing.

(3) Bite test. Known as Test (E,ii).

(a) Application. A toy (or component or any accessible portion thereof) that has an external dimension of 1-1/4 inches plus or minus .05-inch or less and a design configuration that would permit a child to insert a portion into the mouth in any orientation up to a biting thickness of 1-1/4 inches plus or minus .05-inch, for a penetration of at least one-fourth inch, shall be subject to this test;

(b) Test equipment:

(A) Contact mechanism. The contact mechanism shall be two metal strips, each one thirty-second inch thick. The strips shall be circular or semicircular in shape with a 1-1/2 inch diameter and a one-half inch height. The edges thereof shall be rounded to a radius of one sixty-fourth inch measuring 0.25-inch plus or minus 0.002-inch (0.635 centimeter), high and each having a contact edge radius of 0.020-inch plus or minus 0.002-inch (0.05 centimeter), for at least a 150-degree cross-sectional arc. A suggested contact mechanism appears in **Figure 15**;

(B) Loading device. The loading device shall be a scale or force gauge having an accuracy of plus or minus .05 pound;

(C) Testing procedure. The toy shall be placed in the loading device in any reasonable position for a restriction of 0.25-inch to 0.5-inch utilizing not more than 180 degrees of the arc and a test load increasing to 25 pounds plus or minus .05 pound over five seconds shall be evenly applied. This load shall be maintained for an additional ten seconds.

(4) Torque test. Known herein as Test (E,iii):

(a) Application:

(A) General. A toy with a projection, part, or assembly that the child can grasp by at least the thumb and forefinger or the teeth shall be subject to this test;

(B) Toys with rotating components. Projections, parts, or assemblies that are rigidly mounted on a rod or shaft designed to rotate shall be tested with the rod or shaft clamped to prevent rotation.

(b) Test equipment:

(A) Loading device. The loading device shall be a torque gauge, torque wrench, or other appropriate device having an accuracy of -2 inch-pound (-0.23 kilogram-centimeter);

(B) Clamp. The clamp shall be capable of holding the test component firmly and transmitting a torsional force (see **Figure 16**);

(C) Test procedure. With the sample rigidly fastened in any reasonable test position, the clamp is fastened to the test object or component. A torque of two inch-pounds plus or minus 0.2 pound shall be applied clockwise over a period of five seconds or until a rotation of 180 degrees from the original position has been attained, or two inch-pounds exceeded. The torque or maximum rotation shall be maintained for an additional ten seconds. The torque shall then be removed and the test component permitted to

return to relaxed condition. This procedure shall then be repeated in a counter-clockwise direction.

(5) Tension test. Known herein as Test (E,iv):

(a) Application:

(A) General. With the exception of tires, wheels, and axles, which are tested by 333-016-0065(2)(e)(A) and test (E,iii) and test (E,iv). Any projection of a toy that the child can grasp by at least the thumb and forefinger or the teeth shall be subject to this test. This test is to be conducted on the toy after it has been subjected to test (E,iii);

(B) Mouth toy. A mouth toy shall be tested immediately after being subjected to the procedure described in paragraph (4)(b)(C) of this rule;

(C) Stuffed toys and beanbags. A stuffed toy or beanbag constructed of pliable materials having seams (such as fabrics) shall have the seams subjected to 10 pounds plus or minus 0.5 pound (4.55 kilograms) of force applied in any direction.

(b) Test equipment:

(A) Clamps. One clamp capable of applying a tension load to the test component is required. A second clamp suitable for applying a tension load perpendicularly to the major axis of the test component is also required;

(B) Loading device. The loading device is a self-indicating gauge or other appropriate means having an accuracy of -0.5 pound (-225 grams);

(c) Test procedure. With the test sample fastened in a convenient position, an appropriate clamp shall be attached to the test object or component. A 10 pound plus or minus 0.5 pound direct force shall be evenly applied parallel to the major axis of the test component over a period of five seconds and then maintained for an additional ten seconds. The tension clamp shall then be removed and a second clamp appropriate for pulling at 90 degrees shall be attached to the test object or component. A ten pound plus or minus 0.5 pound tensile force shall be evenly applied perpendicular to the major axis of the test component over a period of five seconds and then maintained for an additional ten seconds.

(6) Compression test. Known herein as Test (E,v):

(a) Application. This test is required in addition to any other test which may be required in these rules. Any area on the surface of a toy that is accessible to a child and inaccessible to flat-surface contact during the impact test shall be subject to this test;

(b) Test apparatus. The loading device shall be a rigid metal disk of 1-1/2 inches plus or minus 0.15-inch in diameter and three-eighths inch in thickness. The perimeter of the disk shall be rounded to a radius of one thirty-second inch to eliminate irregular edges. The disk shall be attached to a self-indicating gauge scale having an accuracy of plus or minus 0.5 pound;

(c) Test procedure. The shaft shall be positioned so that it is generally perpendicular to the surface under test. A direct force increasing to 20 pounds plus or minus 0.5 pound over a period of five seconds shall be applied through the disk. This load shall be maintained for an additional ten seconds. During the test the toy is to rest on a flat, hard surface in any convenient position.

[ED. NOTE: Figures referenced are available from the agency.]

Stat. Auth.: ORS 453.095

Stats. Implemented: ORS 453.005 & 453.055

Hist.: HD 40, f. 8-2-73, ef. 8-15-73; HD 89, f. 7-31-75, ef. 8-25-75

333-016-0058

Test Methods for Simulating Use and Abuse of Toys and Other Articles Intended for Children Over 18 But not Over 36 Months of Age

(1) Application. The test methods described in this section shall be used in addition to other requirements in determining compliance of toys intended for use by children over 18 but not over 36 months of age.

(2) Impact test. (Drop test.) Known herein as Test (F,i):

(a) Application. Toys subject to special impact tests in OAR 333-016-0056(2)(d) excepted. Toys having a weight of less than four pounds plus or minus .01 pound shall be subject to this test;

(b) Impact medium. The impact medium shall consist of a 0.125-inch nominal thickness of Type IV vinyl-asbestos tile, as specified in federal specification SS-T-312A, over at least a 2.5-inch thickness of concrete. The impact area shall be at least three square feet;

(c) Testing procedure. The toy shall be dropped four times from a height of three feet plus or minus 0.5-inch. The toy shall be dropped in random orientation. After each drop the test sample shall be allowed to come to rest and examined and evaluated before continuing.

(3) Bite test. Known herein as Test (F,ii):

(a) Application. A toy (or component or any accessible portion thereof) that has an external dimension of 1-1/4 inches plus or minus 0.05-inch or less and a design configuration that would permit a child to insert a portion into the mouth in any orientation up to a biting thickness of 1-1/4 inches plus or minus 0.05 inch for a penetration of at least one-fourth inch, shall be subject to this test;

(b) Test equipment:

(A) Contact mechanism. The contact mechanism shall be two metal strips each measuring 0.25 inch plus or minus 0.002 inch (0.635 centimeter) high and each having a contact edge radius of 0.020 inch plus or minus 0.002 inch (0.05 centimeter) for at least a 150 degree cross-sectional arc. A suggested contact mechanism appears in **Figure 15**.

(B) Loading device. The loading device shall be a seal or force gauge having an accuracy of -0.5 pound.

(C) Testing procedure. The toy shall be placed in a loading device in any reasonable position for a penetration of 0.25 inch to 0.5 inch utilizing not more than 180 degrees of the arc and a test load increasing to 50 pound plus or minus 0.5 pound over five seconds shall be evenly applied. This load shall be maintained for an additional ten seconds.

(4) Torque test. Known herein as Test (F,iii):

(a) Application:

(A) General. A toy with a projection, part, or assembly that the child can grasp by at least the thumb and forefinger or the teeth shall be subject to this test;

(B) Toys with rotating components. Projections, parts, or assemblies that are rigidly mounted on a rod or shaft designed to rotate shall be tested with the rod or shaft clamped to prevent rotation.

(b) Test equipment:

(A) Loading device. The loading device shall be a torque gauge, torque wrench, or other appropriate device having an accuracy of -0.2 inch-pound (-0.23 kilogram-centimeter);

(B) Clamp. The clamp shall be capable of holding the test component firmly and transmitting a torsional force (see **Figure 16**);

(C) Test procedure. With the sample rigidly fastened in any reasonable test position, the clamp is fastened to the test object or component. A torque of three inch-pounds plus or minus 0.2 inch-pounds shall be evenly applied clockwise over a period of five seconds or until a rotation of 180 degrees from the original position has been attained, or 3 inch-pounds plus or minus 0.2 inch-pounds exceeded. The torque or maximum rotation shall be maintained for an additional ten seconds. The torque shall then be removed and the test component permitted to return to relaxed condition. This procedure shall then be repeated in a counterclockwise direction.

(5) Tension test. Known herein as Test (F,iv):

(a) Application:

(A) General. With the exception of tires, wheels, and axles which are tested by 333-016-0056(2)(e)(A) and test (E,iii) and test (E,iv). Any projection of a toy that the child can grasp by at least the thumb and forefinger, or the teeth, shall be subject to this test. This test is to be conducted on the toy after it has been subjected to test (E,iii);

(B) Stuffed toys and beanbags. A stuffed toy or beanbag constructed of pliable materials having seams (such as fabrics) shall have the seams subjected to 15 pounds plus or minus 0.5 pound (6.80 kilograms) of force applied in any direction.

(b) Test equipment:

(A) Clamps. One clamp capable of applying a tension load to the test component is required. A second clamp suitable for

applying a tension load perpendicularly to the major axis of the test component is also required.

(B) Loading device. The loading device is to be a self-indicating gauge or other appropriate means having an accuracy of plus or minus 0.5 pound (255 grams).

(c) Test procedure. With the test sample fastened in a convenient position, an appropriate clamp shall be attached to the test object or component. A 15 pound plus or minus 0.5 pound direct force shall be evenly applied parallel to the major axis of the test component over a period of five seconds and then maintained for an additional ten seconds. The tension clamp shall then be removed and a second clamp appropriate for pulling at 90 degrees shall be attached to the test object or component. A 15 pound plus or minus 0.5 pound tensile force shall be evenly applied perpendicular to the major axis of the test component over a period of five seconds and then maintained for an additional ten seconds.

(6) Compression test:

(a) Application. This test is required in addition to any other test which may be required in these rules. Any area on the surface of a toy that is accessible to a child and inaccessible to flat-surface contact during the impact test shall be subject to this test;

(b) Test apparatus. The loading device shall be a rigid metal disk 1-1/8 inches plus or minus 0.015-inch in diameter and three-eighths inch in thickness. The perimeter of the disk shall be rounded to a radius of one 30-second inch to eliminate irregular edges. The disk shall be attached to a self-indicating gauge scale having an accuracy of plus or minus .05 pound;

(c) Test procedure. The shaft shall be positioned so that it is generally perpendicular to the surface under test. A direct force increasing to 25 pounds plus or minus .05 pound over a period of five seconds shall be evenly applied through the disk. This load shall be maintained for an additional ten seconds. During the test the toy is to rest on a flat, hard surface in any convenient position.

[ED. NOTE: Figures referenced are available from the agency.]

Stat. Auth.: ORS 453.095

Stats. Implemented: ORS 453.005 & 453.055

Hist.: HD 40, f. 8-2-73, ef. 8-15-73; HD 89, f. 7-31-75, ef. 8-25-75

333-016-0059

Test Methods for Simulating Use and Abuse of Toys and Other Articles Intended for Children Over 36 But Not Over 96 Months of Age

(1) Application. The test methods described in this section shall be used in addition to other requirements in determining compliance of toys intended for use by children over 36 but not over 96 months of age.

(2) Impact test. Known herein as Test (G,i):

(a) Application. Toys subject to special impact tests in 333-016-0056(2)(d) are exempted. Toys having a weight of less than ten pounds plus or minus 0.1 pound shall be subject to this test;

(b) Impact medium. The impact medium shall consist of a 0.125-inch nominal thickness of Type IV vinyl-asbestos tile, as specified in federal specification SS-T-312A, over at least a 2.5-inch thickness of concrete. The impact area shall be at least three square feet;

(c) Testing procedure. The toy shall be dropped four times from a height of three feet plus or minus 0.5-inch. The toy shall be dropped in random orientation. After each drop the test sample shall be allowed to come to rest and examined and evaluated before continuing.

(3) Bite test. Known herein as Test (G,ii):

(a) Application. A toy (or component) that is a mouth toy shall be subject to this test;

(b) Test equipment:

(A) Contact mechanism. The contact mechanism shall be two metal strips each measuring 0.25-inch plus or minus 0.002-inch (0.635 centimeter) high and each having a contact edge radius of 0.020-inch plus or minus 0.002-inch (0.5 centimeter) for at least a 150 degree cross-sectional arc. A suggested contact mechanism appears in **Figure 15**;

(B) Loading device; The loading device shall be a scale or force gauge having an accuracy of plus or minus 0.5 pound.

(c) Testing procedure. The toy shall be placed in the loading device in any reasonable position for a penetration of 0.25 to 0.5-inch utilizing not more than 180 degrees of the arc and a test load increasing to 100 pounds plus or minus 0.5 pound over five seconds shall be evenly applied. This load shall be maintained for an additional ten seconds.

(4) Torque test. Known herein as Test (G,iii):

(a) Application:

(A) General. A toy with a projection, part, or assembly that the child can grasp by at least the thumb and forefinger or the teeth shall be subject to this test;

(B) Toys with rotating components. Projections, parts, or assemblies that are rigidly mounted on a rod or shaft designed to rotate shall be tested with the rod or shaft clamped to prevent rotation.

(b) Test equipment:

(A) Loading device. The loading device shall be a torque gauge, torque wrench, or other appropriate device having an accuracy of plus or minus 0.2 inch-pound;

(B) Clamp. The clamp shall be capable of holding the test component firmly and transmitting a torsional force (see **Figure 16**);

(C) Test procedure. With the sample rigidly fastened in any reasonable test position, the clamp is fastened to the test object or component. A torque of four inch-pounds plus or minus 0.2 inch-pound shall be evenly applied clockwise over a period of five seconds or until a rotation of 180 degrees from the original position has been attained, or four inch-pounds plus or minus 0.2 inch-pound exceeded. The torque or maximum rotation shall be maintained for an additional ten seconds. The torque shall then be removed and the test component permitted to return to a relaxed condition. This procedure shall then be repeated in a counterclockwise direction.

(5) Tension test. Known herein as Test (G,iv):

(a) Application:

(A) General. Any projection of a toy that the child can grasp by at least the thumb and forefinger or the teeth shall be subject to this test. The test is to be conducted on the toy after it has been subjected to test (E, iii);

(B) Stuffed toys and beanbags. A stuffed toy or beanbag constructed of pliable materials having seams (such as fabrics) shall have the seams subjected to 15 pound plus or minus 0.5 pound (6.80 kilograms) of force applied in any direction.

(b) Test equipment:

(A) Clamps. One clamp capable of applying a tension load to the test component is required. A second clamp suitable for applying a tension load perpendicularly to the major axis of the test component is also required;

(B) Loading device. The loading device is to be a self-indicating gauge or other appropriate means having an accuracy of plus or minus 0.5 pound (plus or minus 225 grams).

(c) Test procedure. With the test sample fastened in a convenient position, an appropriate clamp shall be attached to the test object or component. A 15 pound plus or minus 0.5 pound direct force shall be evenly applied parallel to the major axis of the test component over a period of five seconds and then maintained for an additional ten seconds. The tension clamp shall then be removed and a second clamp appropriate for pulling at 90 degrees shall be attached to the test object or component. A 15 pound plus or minus 0.5 pound tensile force shall be evenly applied perpendicular to the major axis of the test component over a period of five seconds and then maintained for an additional ten seconds.

(6) Compression test. Known herein as Test (G,v):

(a) Application. This test is required in addition to any other test which may be required in these rules. Any area on the surface of a toy that is accessible to a child and inaccessible to flat-surface contact during the impact test shall be subject to this test;

(b) Test apparatus. The loading device shall be a rigid metal disk 1-1/8 inches plus or minus 0.15-inch in diameter and three-eighths of an inch in thickness. The perimeter of the disk shall be rounded to a radius of one thirty-second of an inch to eliminate

irregular edges. This disk shall be attached to the self-indicating gauge scale having an accuracy of plus or minus 0.5 pound;

(c) Test procedure. The shaft shall be positioned so that it is generally perpendicular to the surface under test. A direct force increasing to 30 pounds plus or minus 0.5 pound over a period of five seconds shall be evenly applied through the disk. This load shall be maintained for an additional ten seconds. During the test the toy is to rest on a flat, hard surface in any convenient position.

[ED. NOTE: Figures referenced are available from the agency.]

Stat. Auth.: ORS 453.095

Stats. Implemented: ORS 453.005 & 453.055

Hist.: HD 40, f. 8-2-73, ef. 8-15-73; HD 89, f. 7-31-75, ef. 8-25-75

333-016-0060

Products Declared to be Hazardous Substances Under ORS 453.055(1)

The Administrator finds that the following articles are hazardous substances within the meaning of ORS 453.055(1) and 453.005 because they are capable of causing substantial person injury or illness during or as approximate result of any customary or reasonably foreseeable handling or use:

(1) Charcoal Briquettes and other forms of charcoal in containers for retail sale that may be used for cooking or heating indoors with inadequate ventilation.

(2) Paraphenylenediamine and products containing it.

(3) Powdered orris root and products containing it.

(4) Epoxy resins systems containing in any concentration ethylenediamine, diethylenetriamine, and diglycidyl ethers of molecular weight of less than 200.

(5) Formaldehyde and products containing one percent or more of formaldehyde.

(6) Oil of bergamot products containing two percent or more of oil of bergamot.

(7) Fluorocarbons when used as propellants for self-pressurized products.

Stat. Auth.: ORS 453.095

Stats. Implemented: ORS 453.005 & 453.055

Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0065

Products Requiring Special Labeling Under ORS 453.055(2)

(1) Based on human experience as reported in the scientific literature or to the Poison Control Centers or the National Clearing House for Poison Control Centers, together with opinions of informed medical experts, the Administrator finds that the following substances are hazardous:

(a) Diethylene glycol including mixtures containing ten percent or more by weight of diethylene glycol;

(b) Ethylene glycol, including mixtures containing ten percent or more by weight of ethylene glycol;

(c) Products containing five percent or more, by weight, of benzene (also known as benzol) and products containing ten percent or more, by weight, of toluene (also known as toluol), exylene (also known as xylol), or petroleum distillates such as kerosene, mineral seal oil, naptha, gasoline, mineral spirits, stoddard solvent, and related petroleum distillates;

(d) Methyl alcohol including mixtures containing four percent or more by weight of methyl alcohol;

(e) Turpentine, including gum turpentine, gum spirits of turpentine, steam-distilled wood turpentine, sulfate wood turpentine, and destructively distilled wood turpentine and mixtures containing ten percent or more by weight of such turpentine.

(2) The Administrator also finds that these substances present special hazards and that the labeling required by ORS 453.035 is not adequate for the protection of the public health. The following specific label statements are deemed necessary to supplement the labeling required by ORS 453.035:

(a) Methyl alcohol. Because death and blindness might result from the ingestion of methyl alcohol, the label for this substance (including mixtures) within the percentages specified in subsection (1)(d) of this rule shall include the word "**danger**," and the additional word "**poison**," and the skull and crossbones symbol. The statement of hazard shall include "**vapor harmful**" and "**May be fatal or cause blindness if swallowed**." The label shall also bear the statement "**Cannot be made nonpoisonous**";

(b) Benzene, toluene, xylene, petroleum distillates:

(A) Because inhalation of the vapors of products containing five percent or more by weight, of benzene may cause blood dyscrasias, such products shall be labeled with the signal word "**danger**," the statement of hazard "**vapor harmful**," and the word "**poison**," and the skull and crossbones symbol. If the product contains ten percent or more, by weight, of benzene, it shall bear the additional statement of hazard "**Harmful or fatal if swallowed**" and the additional statements, "**If swallowed, do not induce vomiting. Call physician immediately**";

(B) Because products containing ten percent or more, by weight, of toluene, xylene, or any of the other substances listed in subsection (1)(c) of this rule may be aspirated into the lungs, with resulting chemical pneumonitis, pneumonia, and pulmonary edema, such products shall be labeled with the signal word "**danger**," the statement of hazard "**Harmful or fatal if swallowed**," and the statements, "**If swallowed, do not induce vomiting. Call physician immediately**";

(C) Because inhalation of the vapor of products containing ten percent or more, by weight, of toluene or xylene may cause systemic injury, such products shall bear the statement of hazard "**vapor harmful**" in addition to the statements prescribed in paragraph (B) of this subsection.

(c) Ethylene glycol and diethylene glycol. Because these substances (including mixtures) within the percentages specified above are commonly marketed, stored, and used in a manner increasing the possibility of accidental ingestion, the signal word "**warning**" is specified. In addition, for ethylene glycol the statement "**Harmful or fatal if swallowed**" and for diethylene glycol the statement "**Harmful if swallowed**" are required;

(d) Turpentine. Because products containing ten percent or more, by weight, of turpentine, in addition to oral toxicity resulting in systemic poisoning, may be aspirated into the lungs, with resulting chemical pneumonitis, pneumonia, and pulmonary edema, such products shall be labeled with the signal word "**danger**" and the statement of hazard "**Harmful or fatal if swallowed**";

(e) Charcoal briquettes and other forms of charcoal in containers for retail sale and intended for cooking or heating:

(A) Because inhalation of the carbon monoxide produced by burning charcoal indoors or in confined areas may cause serious injury or death, containers of such products shall bear the following borderlined statement: **WARNING: Do Not Use for Indoor Heating or Cooking Unless Ventilation is Provided for Exhausting Fumes to Outside. Toxic Fumes May Accumulate and Cause Death**;

(B) For bags of charcoal the statement specified in paragraph (A) of this subsection shall appear within a heavy borderline in a color sharply contrasting to that of the background, on both front and back panels in the upper 25 percent of the panels of the bag at least two inches below the seam, and at least one inch above any reading material or design elements in type size as follows: The signal word "**WARNING**" shall appear in capital letters at least three-eights inch in height; the remaining text of the aforementioned warning statement shall be printed in letters at least 3/16-inch in height.

(f) Fluorocarbon propellants. Because sudden death may follow deliberate misuse by inhalation of self-pressurized products containing fluorocarbon propellants, containers of such products shall bear the statement: "**WARNING — USE ONLY AS DIRECTED; intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal**." This statement shall be in addition to any other required under the Act or these rules.

Stat. Auth.: ORS 453.095

Stats. Implemented: ORS 453.005 & 453.055

Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0070
Labeling of Fire Extinguishers

(1) When a substance or mixture of substances labeled for use in or as a fire extinguisher produces substances that are toxic within the meaning of OAR 333-016-0005(5) and (6) when used according to label directions to extinguish a fire, the containers for such substances shall bear the following labeling:

(a) When substances are produced which meet the definition of highly toxic within the meaning of OAR 333-016-0005(5), the signal word "**danger**" and the statement of hazard "**Poisonous gases formed when used to extinguish flame or on contact with heat**" are specified;

(b) When substances are produced which meet the definition of toxic within the meaning of OAR 333-016-0005(6), the signal word "**caution**" or "**warning**," and the statement of hazard "**Dangerous gas formed when used to extinguish flame or on contact with heat**" are specified;

(c) Regardless of whether subsection (a) or (b) of this section apply, any substance or mixture of substances labeled for use as a fire extinguisher that if applied to an electrical fire would subject the user to the likelihood of electrical shock shall be conspicuously labeled, "**Caution: Do not use on electrical fires**."

(2) These statements shall be in addition to any other that may be required under the Act or this section. All such substances or mixture of substances shall also bear the additional statements: "**Use in an enclosed place may be fatal**," and "**Do not enter area until well ventilated and all odor of chemical has disappeared**."

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.005 & 453.055
Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0075
Banned Hazardous Substances

Under the authority of ORS 453.055(4), the Administrator declares as banned hazardous substances the following articles because they possess such a degree of hazard that adequate cautionary labeling cannot be written and the public health and safety can be served only by keeping such articles out of commerce:

(1) Mixtures that are intended primarily for application to interior masonry walls, floors, etc., as a water repellent treatment and that are "extremely flammable" within the meaning of ORS 453.005(5).

(2) Carbon tetrachloride and mixtures containing it (including carbon tetrachloride and mixtures containing it used in fire extinguishers), excluding unavoidable manufacturing residues carbon tetrachloride in other chemicals that under reasonably foreseeable conditions of use do not result in an atmospheric concentration of carbon tetrachloride greater than ten parts per million.

(3) Liquid drain cleaners containing ten percent or more by weight of sodium and/or potassium hydroxide; except that this subparagraph shall not apply to such liquid drain cleaners if packed in accordance with a standard for special packaging of such articles promulgated under the Federal Poison Prevention Packaging Act of 1970 (Public Law 91-601).

(4) Any full-size baby crib that is not designed and constructed in accordance with paragraphs (4)(a)(A) through (E) of this rule:

(a) The rules in this section set forth the conditions, requirements, and specifications whereby full-size baby cribs are not banned articles intended for use by children under OAR 333-016-0080:

(A) Dimensions. Full-size cribs shall have dimensions as follows:

(i) Interior. The interior dimensions shall be 28-3/8 inches wide as measured between the innermost surfaces of the crib sides and 52-3/8 inches long as measured between the innermost surfaces of the crib end panels, slats, rods, or spindles. Both measurements are to be made at the level of the mattress support spring in each of its adjustable positions and no more than two inches from the crib corner posts;

(ii) Rail height. The rail height dimensions shall be as follows:

(I) The height of the rail or end panel as measured from the top of the dropside rail or panel in its lowest position to the top of the mattress support in its highest position shall be at least nine inches;

(II) The height of the dropside rail or end panel as measured from the top of the dropside rail or end panel in its highest position to the top of the mattress support in its lowest position shall be at least 26 inches.

(B) Spacing of full-size crib components:

(i) The distance between components (such as slats, spindles, crib rods, and corner posts), except those which are more than 20 inches above the mattress support in its lowest position shall not be greater than 2-3/8 inches at any point. Measurement of distance between contoured or irregular slats or spindles shall be done by a 2-3/8 inch wide x 4 inch high x 4 inch long rectangular block which shall not pass through the space;

(ii) The distance between such components shall not exceed 2-1/2 inches when a 20 pound direct force is applied in accordance with the test method in paragraph (C) below. For contoured or irregular slats or spindles the spacing shall not permit passage of a 2-1/2 inch wide x 2-3/4 inch high x 2-3/4 inch long rectangular block above and below the loading wedge when a 20 pound direct force is applied in accordance with said test method.

(C) Component spacing test method:

(i) Construct a right triangular prism (2-1/2 inches high x 5 inches wide x 1-1/2 inches deep) from a rigid material (steel, wood, aluminum, or equivalent). Drill a one-fourth inch diameter hole from the center of the apex to the center of the base and secure a 4 inch eyebolt in the hole;

(ii) Place the wedge midway between two vertical components. Attach a dial push-pull gauge (Chatillon Model DPP-50 or equivalent spring scale) to the eyebolt and exert a 20 pound direct pull on the wedge. The test may be performed by suspending a 20 pound weight from the eyebolt with the crib component placed in a horizontal position.

(D) Hardware:

(i) The full-size crib shall be designed and constructed in a manner that eliminates from any hardware accessible to a child the possibility of the hardware's presenting a mechanical hazard through pinching, bruising, lacerating, crushing, breaking, amputating, or otherwise injuring portions of the human body when the crib is in normal use or when subjected to reasonably foreseeable damage or abuse;

(ii) Locking or latching devices used to secure dropside rails shall not be accessible to a child from inside the crib. Such devices shall require a minimum force of ten pounds to activate the release mechanism or shall consist of a double-action device requiring two distinct actions to release;

(iii) Wood screws shall not be used in the assembly of stationary sides, dropside rails, or stabilizing bars to crib ends or other components that must be removed in the normal assembly or disassembly of a crib.

(E) Construction and finishing:

(i) All wood surfaces shall be smooth and free from splinters;

(ii) All wood parts shall be free from splits or cracks;

(iii) Crib ends and sides shall have no horizontal bar or other surface accessible to the child inside the crib capable of being used as a toehold located less than 20 inches above the mattress support in its lowest position when the side rail is in its highest position, except the lower horizontal bar of the crib rail may have a vertical dimension that extends no higher than three inches above the mattress support in its lowest position. (A toehold is defined as any ledge projection accessible to the child inside the crib with a dimension greater than three-eighths of an inch.) Spacing between components above the 20 inch level in the crib end panels and crib sides shall not allow the passage of a 4 inch square block;

(iv) Attachments accessible to the child while in the crib, including but not limited to, "built-in" toys, decorations, teething rails, or design components, must be tested in accordance with the test methods of OAR 333-016-0057 and 333-016-0058 of this chapter specifying test methods for simulating use and abuse for toys, games, and other articles intended for use by children. The test methods shall include those for pull, torque, impact, and bite,

which would result in a potential for causing laceration, puncture wound, aspiration, ingestion, or other injury. For determining if any small parts present choking, aspiration, and/or ingestion hazards, see OAR 333-016-0057;

(v) The crib's design shall not incorporate any features accessible to the child inside the crib, such as cutout shapes, scroll designs, wedge configurations, etc., which could trap fingers, hands, or clothing, or that present a potential for laceration or puncture or other injury.

(F) Assembly instructions:

(i) Full-size cribs, when shipped other than completely assembled, shall be accompanied by detailed instructions that include an assembly drawing, a list, and description of all parts and tools required for assembly, and a full-size diagram of the required bolts and other fasteners;

(ii) The instructions:

(I) Shall be so written that an unskilled layman can correctly assemble the crib without making errors that would result in improper and unsafe assembly;

(II) Shall include cautionary statements concerning the secure tightening of bolts and other fasteners;

(III) Shall contain a cautionary statement that when child's height reaches 35 inches, the child should be placed in a youth or regular bed.

(iii) The warning relative to mattress size for full-size cribs in subparagraph (4)(a)(G)(ii) of this rule may be included in the instructions as an optional measure.

(G) Identifying marks and warning statement. All cribs and retail cartons thereof shall be suitably marked or labeled in accordance with this section:

(i) The crib shall be clearly marked to indicate:

(I) The name and place of business (city and state) of the manufacturer, importer, distributor, and/or seller; and

(II) A model number, stock number, catalogue number, item number, or other symbol expressed numerically, in code, or otherwise, such that only cribs of identical construction, composition, and dimensions shall bear identical markings.

(ii) In the case of full-size cribs, the following warning shall appear on the inside of the head end in a type size of at least one-fourth inch: "Any mattress used in this crib must be at least 27-1/4 inches x 51-5/8 inches with a thickness not exceeding 6 inches." The marking shall appear in block letters, shall contrast sharply with the background (by color, projection, and/or indentation), and shall be clearly visible and legible;

(iii) Markings on the crib shall be of a permanent nature whether paint-stenciled, die-stamped, molded, or indelibly stamped directly thereon or permanently affixed, fastened, or attached thereto by means of a tag, token, or other suitable medium. The markings shall not be readily removable or subject to obliteration during normal use of the article or when the article is subjected to reasonably foreseeable damage or abuse;

(iv) The retail carton of a crib, under customary conditions of display, shall clearly indicate: The name and place of business (mailing address, including ZIP code) of the manufacturer, importer, distributor, and/or seller; and the model number, stock number, catalogue number, item number, or other symbol described in paragraph (4)(a)(G)(i)(II) of this rule. The information required by this paragraph need not be placed on the retail carton if it appears on the crib in such a manner as to be visible under customary conditions of retail display.

(H) Recordkeeping. The manufacturer or importer shall keep and maintain for three years after production or importation of each lot of full-size cribs records of sale, distribution, and results of all inspections and tests conducted in accordance with this section. These records shall be made available upon request at reasonable times to any officer or employee acting on behalf of the Public Health Division. The manufacturer or importer shall permit such officer or employee to inspect and copy such records, to make such inventories of stock as he deems necessary, and to otherwise verify the accuracy of such records;

(I) Compliance with the foregoing paragraphs (4)(a)(A) through (H) of this rule is required by December 31, 1974.

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.005 & 453.055
Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0077
Pointed Objects in Food Items of Particular Appeal to Children

(1) Under the authority of ORS 453.005(7)(c) and pursuant to provisions of ORS 453.055(3), the Administrator has determined that the following types of articles intended for use by children present a mechanical hazard within the meaning of ORS 453.005(12) because in normal use or when subjected to reasonably foreseeable abuse, they present an unreasonable risk of personal injury by their design and such articles are therefore banned and shall be removed from commerce:

(a) Pointed objects used or intended to be used as handles when contained in food items having particular appeal to children;

(b) A pointed object shall mean an object made of wood, plastic, metal, or other rigid material, any end of which has been sharpened, molded, or otherwise shaped in such a way that:

(A) If the longitudinal axis of the object is round and the tip is flat, the cross section of the tip or the end surface is less than 0.0123 square inches in area (approximately 1/8 of an inch in diameter), or if the tip is rounded, the radius of the arc of the rounded sphere at the tip is less than 1/16 of an inch; or

(B) If the longitude axis is flat, or shaped other than round, the thickness of the cross section at the end is less than 1/16 of an inch and if the dimensions of the end are such that the surface area of the tip is less than 0.0123 square inches, or if such tip is rounded, the arc of this roundness is less than 1/16 inch in radius.

(2) The pointed objects defined in paragraphs (1)(b)(A) and (B) of this rule are illustrated in **Figure 17**.

[ED. NOTE: Figures referenced are available from the agency.]
Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.005 & 453.055
Hist.: HD 60, f. 5-16-74, ef. 6-11-74; HD 89, f. 7-31-75, ef. 8-25-75

333-016-0080
Toys and Other Articles Intended for Use by Children

Under the authority of ORS 453.005 and pursuant to provisions of ORS 453.055 the Administrator has determined that the following types of toys, including their packaging, and pacifiers and other articles intended for use by children, are banned hazardous substances:

(1) Any toy or material intended for use by children which the customer must assemble, and which after assembly presents a hazardous edge. Hazardous edges shall not be produced when the toy is tested in accordance with Requirements No. 1 and No. 2 (see **Appendix 2**).

(2) Any toy or article intended for use by children not constructed of new material or reprocessed material that has been so refined that the level of contamination from foreign matter does not exceed that found in new material:

(a) Reprocessed plastic, foam scrap, textile producers fibrous scrap, and fabric trimmings from garment manufacture are acceptable, provided that they are clean and have been sanitized;

(b) Loose fillers for toys shall be free of objectionable matter originating from insect, bird, rodent, man, or other animal infestation and of contaminants such as splinters and metal chips to the extend possible in good manufacturing practice.

(3) Any toy or article intended for use by children which does not comply with the following provisions and the labeling provisions of OAR 333-016-0110:

(a) General:

(A) Sharp edges. Known herein as Requirement No. 4:

(i) Toys in which a potentially hazardous sharp edge is a necessary part of the function of the toy shall carry cautionary labeling as specified in OAR 333-016-0110, if the toy is intended for use by children from 48 months to 120 months. Toys intended for children aged less than 48 months shall not have accessible hazardous functional sharp edges;

(ii) Protection of sheet metal edges. Accessible edges of sheet metal less than 0.020 inch thick except those covered by subparagraph (3)(a)(A)(iii) of this rule, shall be protected by hemming, rolling, curling, or shall be covered with a protective cap or sleeve. If caps or sleeves are used, they shall withstand a pull force of ten pounds, applied in accordance with Test (D,i). Hemmed edges shall be closed to a gap of 0.030 inch or less and the cut edge shall not present hazards from feathering. Gaps of rolled or curled edges shall not exceed 0.060 inch between the bare edge and the base sheet. The gap restriction shall not apply to curled edges if the curled portion of the sheet describes an arc of greater than 360 degrees, as shown in **Figure 18**. However, the gap at the point at which the curled edge has established a 360 degree arc shall not admit a 1/4 inch diameter probe. If accessible holes or slots in sheet metal of less than 0.020 inch thickness admit a rod of 1/2 inch diameter, to a depth of greater than 0.030 inch, then the edges shall be protected in accordance with this requirement (Additional size requirements for holes are given in Requirement No. 11.);

(iii) Exemptions for sharp metal edges. The edges at the ends of tubes, or the edges at the ends of formed sheet metal profiles, such as those at the ends of a curled edge as shown in **Figure 19(a)**, shall be exempt if the aperture will not admit a 1/4 inch diameter rod and is free of burrs and feathering. Also exempted are unprotected edges less than 3/8 inch in length at the end of a formed profile similar to that shown in **Figure 19(b)**, provided that the unprotected edge is free of burrs and feathering.

(B) Lap joints. Known herein as Requirement No. 5. If the gap between the sheet metal edge and the underlying surface in a lap joint exceeds 0.030 inch, the exposed sheet metal edge shall be protected as described in subparagraph (3)(a)(A)(i) of this rule. The accessible surfaces shall be free of burrs and feathering;

(C) Sharp points. Known herein as Requirement No. 6:

(i) If the ends of bolts or threaded rods are accessible, then the thread shall be finished or covered at the end by cap nuts so as to avoid hazardous sharp edges and burrs. The cap nut shall resist a pull of ten pounds for toys intended for children aged up to 18 months, or 15 pounds for toys intended for children aged from 18 months to and including 168 months of age, applied parallel to the axis of the bolt or threaded rod when tested according to Test (D,i);

(ii) Hazardous points. These requirements are intended to eliminate unexpected hazards from sharp points that may occur because of assembly devices and fasteners such as wires, pins, nails, and staples that are improperly fastened; poorly sheared sheet metal; burrs on screws; splintery wood, etc. Hazardous sharp points may be produced or revealed in use or reasonably foreseeable abuse by the exposure of parts which were designed to be structurally protected. Examples would include the exposure of wire ends and pins or of fasteners through fracture of plastics or deterioration of wood;

(iii) Nails and fasteners. Nails and fasteners that could present a point, edge, ingestion, or projection hazard, except for those used as axles (in which case, see Requirement No. 9) shall not pull out under a force of 20 pounds, applied perpendicular to the joint between the two components, when tested in accordance with Test (D,i). The points of nails or fasteners shall not protrude so as to be accessible. Hazardous points shall not be developed or become accessible after the toy has been tested in accordance with Requirements No. 1 and 2;

(iv) Toys in which an accessible potentially hazardous point is a necessary part of the function of the toy, such as a needle in a sewing kit, or phonograph needle, or darts, shall carry cautionary labeling as specified in OAR 333-016-0110 if the toy is intended for children from 48 to 120 months old. Toys intended for children less than 48 months old shall not have accessible hazardous functional points;

(v) Darts and similar sharp-pointed articles marketed solely for adults shall not be sold by toy stores or in store departments dealing predominately in toys or childrens' articles. Labels shall bear the following statement on the front of the panel of the carton and on any accompanying literature: **WARNING: Not a toy for use by children**. **May cause serious or fatal injury**. **Read instructions carefully**. **Keep out of the reach of children**. Such statement shall be printed in sharply contrasting color within a borderline and in letters at least one-quarter inch high on the main panel of the container and at least one-eighth inch high on all accompany literature. Labels shall include in the instructions and rules clear and adequate directions and warning for safe use, including a warning against use when any person or animal is in the vicinity of the intended play or target area;

(vi) Toy bow and arrow sets providing arrow tips shall be protected with rubber or similarly soft, blunt coverings that are firmly glued or affixed in such a manner that they cannot be removed by Test (D,i).

(D) Wires or rods. Known herein as Requirement No. 7. Wires or rods used in the interior of dolls or stuffed toys shall have their ends turned back or covered with protective caps or covers as described in subparagraph (3)(a)(E)(ii) of this rule, if they can become accessible after use or reasonably foreseeable abuse. Wires or rods used as stiffeners or skeletons in toys intended to be bent or formed shall not fracture to produce an accessible point, edge, or projection hazard when tested according to Test (C,i);

(E) Projections. Known herein as Requirement No. 8. This requirement is intended to minimize possible puncture hazards that might be caused by rigid projections such as unprotected ends of axles, actuating levers, and decorative features. This requirement relates to potentially hazardous projections in toys intended for use by children aged 60 months or less. Hazardous projections shall not be exposed after the toy has been tested according to Requirements No. 1 and 2:

(i) Protection of rigid projections. The toy shall be examined in all natural (unsupported) angles of repose. If the toy has a flat, unwheeled base greater than 175 square inches in area, it shall be examined in the normal play position; if however, the toy tips when placed on an incline of 45 degrees in any direction, it shall also be examined in the position that it assumes when it comes to rest. If a projection appears to constitute a potential puncture hazard, then the projection shall be protected by suitable means, such as by turning back the end of a wire, or by affixing a protective cap or cover as described in Protective caps and covers, subparagraph (3)(a)(E)(ii) of this rule, which effectively increases the surface area for potential contact with the body;

(ii) Protective caps or covers. Protective caps or covers shall be smoothly finished, and shall support the weight of the toy when the toy is suspended from the cap or cover, or shall resist a pull of ten pounds parallel to the axis of the projection when tested according to Test (D,i), whichever is greater. Caps or covers shall also resist a push load of ten pounds when tested according to Test (D,i), so as to prevent the cap or cover from being punctured or split during use or abuse.

(b) Wheels, tires, and axles. Known herein as Requirement No. 9. These requirements are intended to eliminate the possibility of ingestion hazards that might be caused by small wheels or tires that separate during normal use or reasonably foreseeable abuse, and puncture hazards from projecting axles, either on the toy or on wheel assemblies that may be removed from the toy during abuse. The requirements in subparagraphs (3)(b)(A)(i), (ii), and (iii) of this rule, apply to transportation wheels on both preassembled and knocked-down toys intended for children aged 96 months or less. In the case of knocked-down toys, the toy shall be tested in the form that it would be assembled by the purchaser, using simple household tools and/or special tools provided by the manufacturer, if any. The requirements do not apply to toys that are designed to be repeatedly assembled and taken apart and are so described on the package, so that the purchaser expects to find removable wheel systems as part of the function of the toy (however, in no case shall the size requirements of Requirements No. 21 and 22 be disregarded). The tests shall be carried out in accordance with methods described in Test (B,i) and the performance levels shall be maintained after testing as described in Requirements No. 1 and 2:

(A) Tire Removal. Tires which are not an ingestion hazard as defined in Requirement 21, shall be tested in accordance with Test (B,i), tires affixed to toys shall withstand a pull force of not less

than 10 pounds, if intended for children aged up to 18 months, or 15 pounds, if intended for children aged from 18 months to 36 months. If tires which are not an ingestion hazard pull off under the above conditions, then the remaining hub shall be tested according to subparagraphs (3)(b)(A)(i) and (ii) of this rule:

(i) Wheels 3/4 inch or less in diameter. Wheels 3/4 inch or less in diameter shall withstand a pull force of ten pounds in the case of toys intended for children aged less than 18 months, and 15 pounds for toys intended for children from 18 months but not over 96 months, applied in line with, or parallel to, the axle for 19 seconds if the wheel or axle constitutes an ingestion hazard, as described in Requirements No. 21 and 22, or if the axle presents a laceration or puncture hazard, as described in OAR 333-016-0056(3). The pull test described in Test (B,ii) shall be applied to the wheels while they are on the toy;

(ii) Wheels greater than 3/4 inch diameter. Wheels with a diameter greater than 3/4 inch that are free to rotate on their axles shall withstand a pull force of 20 pounds applied in line with or parallel to the axle, for a period of ten seconds, if when the wheel is removed or displaced, the wheel or axle presents a laceration, puncture, or ingestion hazard, as defined in OAR 333-016-0056(3), Requirements No. 21 and 22, respectively. The parallel pulling force shall be applied to the wheels while they are on the toy, in accordance with Test (B,ii). Wheels with a diameter greater than 3/4 inch that are not free to rotate on their axles shall, in addition, be subjected to a torsional force of four inch-pounds at the same time that the parallel pulling force is applied, in accordance with Test (B,iii);

(iii) "Snap-in" assemblies. If the axle and wheel assembly of a toy is of the "snap-in" type and if there is a clearance between the axle and the body of the toy of 1/2 inch or greater so that fingers can be hooked behind the axle, then a 15 pound pull shall be applied perpendicular to the axle, as described in Test (B,iv). If the wheel assembly is removed by either of these tests, then the wheel assembly shall be examined for possible puncture hazards, as described in Requirement No. 8 that might be caused by the axle if a wheel slides along the axle. A compressive load of 20 pounds shall be applied according to the test specified in Test (B,v).

(c) Folding mechanisms and hinges. Known herein as Requirement No. 10. These requirements are intended to eliminate possible crushing or laceration hazards that might occur in folding mechanisms and hinges. Examples are the sudden collapse or unexpected motion of a folding mechanism or hinge that produces a scissor action; and the changing clearances at the hinge line between two hinged portions, such that the gap will admit fingers at one position of the hinge but not at all positions. These requirements do not relate to the recognized and familiar hazards associated with the changing clearances around the edges of doors or pivoted or hinged sections in toy truck bodies, toy earth moving machinery, and similar toys. The requirements specified in paragraphs (3)(c)(A) and (B) of this rule shall be maintained after testing according to Requirements No. 1 and 2:

(A) Folding mechanisms. Toy furniture and other toys in which a folding mechanism, arm, or bracing is intended to support a weight of greater than five; pounds in normal use or reasonably foreseeable abuse shall have a safety stop, locking device, or adequate clearance to give protection for the fingers, hands, and toes against crushing or laceration by preventing unexpected or sudden movement or collapse of the article;

(B) Hinge line clearances. Toys having a gap or clearance along the hinge line between a stationary portion and a moveable portion that weighs more than 1/2 pound, shall be so constructed that, if the accessible gap at the hinge line will admit a 3/16 inch diameter rod, it will also admit a 1/2 inch diameter rod at all positions of the hinge.

(d) Slots, holes, clearances, and protection of mechanisms. Known herein as Requirement No. 11. These requirements are intended to eliminate possible hazards that may be caused by changing clearances. These requirements shall be maintained after testing according to Requirements No. 1 and 2. The different pinch clearance requirements in paragraphs (3)(d)(A) through (H) of this rule reflect the different modes of entrapment or pinching that may be encountered:

(A) Wheel clearances. This requirement concerns clearance between wheels and rigid wheel wells or fenders of ride-on toys, or the driven wheel(s) of toys powered by electrical, spring, or inertial energy. If such clearances admit a 3/16 inch diameter rod, they shall also admit a 1/2 inch diameter rod in order to prevent the trapping of fingers;

(B) Holes and slots in rigid materials. This requirement is intended to avoid finger entrapment (which may cut off blood circulation). Inaccessible holes and slots in sheet metal and other rigid materials in toys intended for children aged 60 months or less. If an accessible circular hole in any rigid material less than 0.062 inch in thickness can admit a 1/4 inch diameter rod to a depth of 3/8 inch or greater, it shall also admit a 1/2 inch diameter rod;

(C) Chains and belts. These requirements are to prevent finger crushing through entrapment between links of supporting chains or between chains and sprockets, or pulleys and belts;

(D) Supporting chains. Chains that support the weight of a child in toys, such as hanging seats or similar devices, intended for children up to 36 months old shall be shielded if the chain is accessible and if a 3/16 inch diameter rod can be inserted between two links, as in **Figure 20**, with the chain in slack configuration;

(E) Chains or belts for ride-on toys. Power transmission chains and belts in ride-on toys intended for children through the age of 120 months shall be shielded;

(F) Shielding of mechanisms. Clockwork, battery operated, inertial, or other power driven mechanisms in toys intended for children through the age of 60 months shall be enclosed or shielded so that a 1/4 inch diameter rod three inches long cannot contact parts that could present pinch or laceration hazards;

(G) Winding keys. This requirement is to avoid pinching or laceration of fingers by entrapment between the key and the body of the toy. It applies to toys intended for children aged 24 months or less that use winding keys which rotate as the mechanism unwinds. This requirement applies to keys with flat plates attached to the stem, as distinct from those that have circular knobs to which to apply the torque, and which protrude from a rigid surface. If the clearance between the flukes of the key and the body of the toy will admit a 1/4 inch diameter rod, it shall also admit a 1/2 inch diameter rod at all positions of the key. For keys covered by this requirement, there shall be no opening in the key which can admit a 3/16 inch diameter rod;

(H) Coil springs. This requirement applies to toys containing springs so as to avoid pinching of fingers or toes:

(i) Coil extension springs. Coil extension springs that form part of a component that carries the weight of a child shall be shielded so as to prevent access during use or reasonably foreseeable abuse if a 1/8 inch diameter rod cannot be freely inserted between coils when the spring is at rest, and if a weight of between 3 and 50 pounds can separate adjacent coils so as to admit a 1/8 inch diameter rod;

(ii) Coil compression springs. Accessible coil compression springs that are subjected to a compressive load of 3 to 50 pounds during normal use or reasonably foreseeable abuse of the toy shall be shielded if a 1/4 inch diameter rod can be inserted between the adjacent coils at any point in the action cycle, or when the spring is at rest.

(e) Strings and elastics. Known herein as Requirement No. 12. These requirements are intended to minimize hazards that might be caused by flexible strings and elastics. The term "string" shall include monofilaments, plastic and textile tapes, and chains, as well as those fibrous materials commonly called string:

(A) Crib and playpen toys. Flexible strings attached at one end to a toy intended for use in cribs or playpens shall be less than 12 inches in length. If a string is attached to form a loop, then the perimeter of the loop shall be less than 14 inches;

(B) Pull toys. Flexible strings greater than 12 inches long for pull toys intended for children less than 36 months old shall not be provided with loops or beads or other attachments that could tangle to form a loop;

(C) Self-retracting pull strings. Strings used in string-actuated mechanisms for toys intended for use by children under age 18 months, except monofilament-type strings 1/16 inch or less in diameter, shall not retract when a weight of two pounds is attached to the fully extended string, with the string vertical and the toy held firmly in the most favorable position for retraction. Monofilament-type strings 1/16 inch or less in diameter shall not retract under a load of one pound, when tested in the manner described above;

(D) Elastics. The unaffixed portion of elastic in toys intended for children less than 36 months old shall not extend to more than 12 inches under a load of 5 pounds;

(E) Strings and lines for flying devices. Kite strings and hand-held lines over six feet long attached to flying devices intended for use as playthings shall have an electric resistance of more than 108 ohm/cm when tested at a relative humidity of 50 plus or minus five percent and a temperature of 70 plus or minus 5°F when measured by a high voltage, resistance breakdown meter.

(f) Projectiles. Known herein as Requirement No. 13. These requirements relate to certain, but not all, potential unexpected hazards that might be caused by projectiles and by the firing of improvised projectiles. Certain well-recognized hazards, inherent in such traditional toys as slingshots and darts, are not covered by this requirement. The requirements in paragraphs (3)(f)(A) and (B) of this rule shall apply to toys that discharge projectiles intended for use by children under age of 120 months:

(A) The integrity of protective tips. Protective tips of projectiles shall withstand a pulling force of 15 pounds, when tested according to the procedure of Test (D,i), and shall not produce or reveal hazardous points or edges when fired into a solid object, according to the test procedures described in Test (A,ii);

(B) Discharge mechanisms. Discharge mechanisms shall be unable to discharge hazardous improvised projectiles such as pencils or rocks without modification by the user.

(g) Protection devices. Known herein as Requirement No. 14. Toy protection devices and simulated protective devices such as football helmet and pads which are not the real protective device but which may be worn as a real protective device:

(A) Simulated protective devices, such as helmets, hats, and goggles. This requirement is intended to minimize hazards that might be caused, for example, by goggles or space helmets if the material from which they are constructed readily shatters; or by toys that simulate protective devices, such as football helmets and pads, if the wearer uses the article as a real protective device rather than as a toy. The toy shall conform to the following requirements after testing according to Requirements No. 1 and 2:

(i) Eye protection. Toys that cover the face, such as goggles, space helmets, or face shields, shall be constructed of impact resistant material that will not fail under normal use or reasonably foreseeable abuse so as to generate sharp edges, points, or small pieces that could enter the eye. Toys shall be tested for compliance according to Test (A,iv). Toys that enclose the head are discussed in subsection (3)(m) of this rule;

(ii) Interior finish. The interiors of toys that cover the face shall be smoothly finished so as to be free of hazardous edges, points, and projections.

(B)(i) Simulated protective devices. Toys that simulate safety protective devices, such as football helmets and pads and baseball caps, shall be clearly marked warning the purchaser that they are not safety protective devices. Also, the packages in which these toys come shall be marked in accordance with OAR 333-016-0110;

(ii) The marking on the toy shall withstand normal use, and reasonably foreseeable abuse, and shall be of the same size as required for the package.

(h) Flotation devices. Known herein as Requirement No. 15. This term means toys designed for recreational use but does not include toys used in bathtubs or boats designed for children to ride in. A hazard that needs to be considered is the possible erroneous assumption that flotation toys are life saving devices. This requirement applies to toys designed for water recreational use, as distinct from flotation toys used in the bathtub, but excludes boats designed for children to ride in. Flotation toys designed for recreational use and their packages shall be clearly labeled in accordance with OAR 333-016-0110 so that the purchaser is informed that they are not life saving devices and that they should be used in water only under parental supervision. (The labeling or marking on the toy shall resist normal use and reasonably forseeable abuse, and shall conform to the same size requirements as that for the package.) No advertising copy or graphics shall imply that the child will be safe with such a toy if left unsupervised;

(i) Toxicology. Known herein as Requirement No. 16:

(A) Food and cosmetics. Toys which are intended to be used in conjunction with food or in the preparation of food, or are intended to simulate cosmetics, shall conform to the Federal Food, Drug, and Cosmetic Act;

(B) Handling and packaging of food. All food products supplied with toys shall be handled and packaged incompliance with **Title 21**, **CFR Section 128**, which is concerned with sanitation practices in the manufacture, processing, packaging, or holding of human foods;

(C) Crayons, paints, chalks, and other similar material. All crayons, paints, chalks, and other similar material shall conform to the safety requirements of the Act. (These are the same as appear in the Federal Hazardous Substances Act.);

(D) Paint or other similar surface coating material. Surface coatings shall not contain compounds and impurities of antimony, arsenic, cadmium, mercury, lead, or selenium of which the metal content individually or in total (calculated as Sb, As, Cd, Hg, Pb, Se, respectively) is in excess of 0.06 percent by dry weight of the contained solids (including pigments, film solids, and driers). In preparing the coating sample for testing the above metals other than lead, the paint film shall be ground into a fine powder and extracted with five percent hydrochloric acid for one hour at a temperature of 45° to 50°C. also, the surface coatings shall not contain barium compounds or impurities of which the water soluble barium (calculated as Ba) is in excess of 1 percent of the total barium in such coatings. For the purpose of these rules, "paint" includes lacquer, varnish, and similar substances;

(E) Liquids. Liquids contained in toys shall conform to the requirement of the Federal Hazardous Substances Act and Shall conform to State of Oregon requirements for potable water. Liquids shall be tested for coliform bacteria and total plate count according to the rules of the Oregon Public Health Division. (These are "**Standard Methods for Examination of Water and Wastewater**" **published by the American Public Health Association, 13th edition**, **1971**, **Part 405**, **pages 657**, **658**, **659**, and **660**.)

(j) Flammability. Known herein as Requirement No. 17. Fabric used in toys or as components of toys shall comply with the requirements of the Flammable Fabrics Act. Materials other than textile materials shall comply with OAR 333-016-0005(11)(b) and 333-016-0040. These are the same as **Title 16**, **Section 1500.3(c)(6)(iv)** and **Section 1500.44**, **CFR**;

(k) Plastic, wood, and other components used to make the toy or article. Known herein as Requirement No. 18:

(A) Plastic toys or components made from plastics having a Young's modulus in tension of greater than 100,000 psi shall be free of accessible hazardous flash, points, and burrs. Accessible portions of plastic toys shall be deburred or deflashed so that their edges are not hazardous. Sections should be designed so as to avoid generation of sharp edges during reasonably foreseeable use or misuse;

(B) Wood. The accessible surfaces and edges of wood used in toys shall be smoothly finished to avoid splinters and sharp edges and free from splinters;

(C)(i) Metal toys. The accessible edges, corner, or mold parting areas of metal parts of 0.020 inch or greater in thickness shall be free of burrs and flash, or covered by durable coatings such as baked enamel. Baked enamel coating or equivalent shall be not less than 0.001 inch thick on the edge, and hazardous edges shall not be exposed after testing according to Requirements No. 1 and 2;

(ii) Sheet metal toys. Sheet metal parts less than 0.020 inch thick shall have the edges protected as described in subparagraph (3)(a)(A)(i) of this rule, if the edges are accessible in use or become accessible as a result of reasonably foreseeable abuse. If a sheet metal edge of less than 0.020 inch in thickness is unprotected on a toy designed for consumer assembly, the outside of the package shall carry a label cautioning the purchaser to exercise care in unpackaging and assembly, according to the requirements of OAR 333-016-0110.

(D) Cellulose Nitrate. A toy shall not, whether wholly or in part, be made of or impregnated with cellulose nitrate. This rule shall not apply to a ball of the kind used for ping-pong or table tennis;

(E) Glass mirrors, vanity sets, or china sets that are either:

(i) Made of shatter resistant, tempered, or laminated glass, plastic, or other material which would not, under normal conditions of use or reasonably foreseeable abuse, break, forming sharp or piercing edges; or

(ii) Labeled as intended for children age six and older.

(l) Stability. Known herein as Requirement No. 19:

(A) Stability of ride-on toys and seats. Any toy intended for use by children age 60 months or less: i.e., ride-on toys with three or more load bearing wheels, such as tricycles and wagon; ride-on action type toys such as hobby horses, stationary toys with seats, such as play furniture and ride-on toys of spherical, cylindrical, or other shapes which do not normally have a stable base shall satisfy subparagraphs (3)(l)(A)(i) through (3)(l)(C) of this rule:

(i) Sideways stability requirement. These requirements recognize two types of possible stability hazards: Those associated with ride-on toys or seats where the feet can provide stabilization, and those situations where the feet are restricted by an enclosing structure. There shall be no sideways stability requirement for ride-on toys if a child at the lowest age of the age range for which the toy is intended can touch the ground flat-footed when sitting on, or straddling, the seat;

(ii) Sideways stability, feet available for stabilization. If a child at the lowest age of the age range for which the ride-on toy or seat is intended cannot place both feet on the ground when seated on or when straddling the seat of a ride-on toy or seat, and his legs are unrestricted in their sideways motion and are thus available for stabilizing, then the toy shall not tip when placed across the slope of a smooth surface inclined ten degrees to the horizontal. A load simulating a child's weight such as a bag of sand or shot, shall be applied to the seat, and the steering mechanism, if any, shall be in the position where the toy is most likely to tip. The load shall be equal to the upper 97 percentile weight of a child at the highest age of the age range for which the toy is intended, according to the anthropometric charts given in **Appendix 1**. The load shall be applied so that its center of gravity lies in the true vertical six inches above the center of the seat. In the case of wagons, the load is to be applied on the rearmost one third of the wagon bed. Wheels shall be chocked during the test to restrict rolling, but castors shall be allowed to assume their natural position before chocks are applied;

(iii) Sideways stability, feet unavoidable for stabilization. If the sideways motion of the feet and/or legs is restricted, such as by the enclosed sides of a toy automobile, then the ride-on toy or seat shall not tip when placed across the slope of a smooth surface inclined 15 degrees to the horizontal. Requirements for steering, loading, chocks, and castors, shall be as for sideways stability, feet available subparagraph (3)(l)(A)(ii) of this rule;

(iv) Fore and aft stability. This requirement relates to the stability of the ride-on toy or seat in the front and back direction with respect to the rider, so that the rider cannot easily use the legs for stabilization. All ride-on toys or seats falling within the scope of paragraph (3)(l)(A) of this rule shall not tip forward or backward when the toy, which shall be loaded with a simulated child's weight, is placed both facing down and up the slope of a smooth surface inclined 15 degrees to the horizontal. Requirements for steering, loading, chocks, and castors shall be as for subparagraph (3)(l)(A)(ii) of this rule. The load shall be applied in the least favorable position on the seat for each direction;

(B) Tipping of stationary floor toys. This requirement is intended to minimize hazards that might be caused by a toy that tips when a door, drawer, or other movable portion is extended to its fullest travel. Stationary floor toys of greater than 30 inches in height and weighing more than ten pounds shall not tip when placed on a ten degree incline in any direction;

(C) Overload requirement for ride-on toys and seats. This requirement is intended to minimize unexpected hazards that could be caused by a toy that is not capable of accepting an overload. All ride-on toys, toys intended for use as seats, or toys designed to support all or part of the weight of a child shall support an overload applied to the seat, or other load-bearing component, without collapsing to produce a hazardous condition. This overload shall be three times the upper 97 percentile weight of a child at the highest age of the age range for which the toy is intended, according to the anthropometric charts given in **Appendix 1**.

(m) Confined spaces. Known herein as Requirement No. 20. Toys that form enclosures, such as toy storage chests or toy refrigerators, and head-enclosing toys such as space helmets. Paragraphs (3)(m)(A), (B), and (C) of this rule shall be maintained after testing according to Requirements No. 1 and 2:

(A) Ventilation. Any toy having a door or lid, which encloses a continuous volume greater that 1.1 cubic feet, and in which all internal dimensions are greater than six inches, shall provide an unobstructed ventilation area of greater than a total of two square inches when placed on the floor in any configuration and adjacent to two vertical plane surfaces meeting at a 90 degree angle, so as to simulate the corner of a room. If a permanent partition or bars (two or more) which effectively limit the continuous space by making the smallest internal dimension six inches, or less, are used to subdivide a continuous space, the ventilation area shall not be required;

(B) Doors. Doors to enclosures falling within the scope of paragraph (3)(m)(A) of this rule shall be fitted with closures that cannot mechanically latch (examples of acceptable closures are magnetic or friction types);

(C) Toys that enclose the head. Toys that enclose the head, wholly or partially, such as space helmets, which are made of impermeable materials shall provide means for breathing by the incorporation of four ventilation holes, each of which is at least 1/2 square inch, situated at least six inches apart. The requirements of OAR 333-016-0056(2)(d)(E) shall be maintained. Simulated protection toys are in paragraph (3)(g)(B) of this rule.

(4) Any toy or article or packaging intended for use by children which contains the following type of hazard and does not comply with the following provisions, and the provisions of OAR 333-016-0110:

(a) Small toys and small parts of toys. Known herein as Requirement No. 21:

(A)(i) Any toy intended for children under three years of age and such toy or other article or any of its components which are accessible, or parts of the toy or other article which become accessible under conditions of normal use or reasonably foreseeable damage or abuse, will not completely fit, in a noncompressed state, into the truncated right cylinder shown in **Figure 21** is banned. Chalk, crayons, and books made entirely of paper are excluded;

(ii) For determining whether or not parts of such toy or other article may become accessible under conditions of normal use or reasonably foreseeable damage or abuse, the applicable tests prescribed in 333-016-0057 shall be utilized in conjunction with Tests (B,i) through (B,v), (C,i), (D,i) and (D,ii). Performance levels after testing in Requirements No. 1 and 2 and of Tests (A,i), (A,ii), and (A,iii) shall be satisfied. Highly porous materials, such as cheesecloth, string, and pom-poms, and any toy or other children's article that is not generally recognized as being suitable for use only by children three years of age or older will be subject to the provisions of subsection (4)(a) of this rule unless it meets the requirements of subparagraphs (4)(a)(A)(i)and (ii) of this rule:

(I) The shelf package of the article is prominently and clearly marked in the upper right-hand quarter of the principal display panel with the statement: "**Contains Small Pieces — Easily Swallowed — Therefore Intended for Children Over 3 Years of Age**";

(II) If the article is unpackaged, the required statement shall appear on the article itself or on a tag securely attached to the article, and the applicable labeling requirement in OAR 333-016-0110 and 333-016-0155.

(B) Known herein as Requirement No. 22. Any mouth-actuated toy or other mouth-actuated article intended for use by children under eight years of age is banned, if such toy or other such article or any of its components which are accessible, or parts of such toy or other such article which becomes accessible under conditions of normal use or reasonably foreseeable damage or abuse, will not completely fit, in a noncompressed state, into the truncated right cylinder shown in **Figure 21**. For determining whether or not parts of such toy or other such article may become accessible under conditions of normal use or reasonably foreseeable damage or abuse, the applicable tests in OAR 333-016-0058 shall be utilized in conjunction with Test (D,ii) and applicable tests in OAR 333-016-0059. If the air outlet is capable of being inserted into or covered by mouth, then the procedure of Test (D,ii) shall also be applied to the outlet;

(C)(i) Any mouth-actuated toy or other mouth-actuated children's article that is not generally recognized as being suitable for use only by children eight years of age or older will be subject to the provisions of paragraph (4)(a)(B) of this rule unless it meets the following requirements;

(ii) The shelf package of the article is prominently and clearly marked in the upper right-hand quarter of the principal display panel with the statement: "**Contains Small Pieces — Easily Swallowed — Therefore Intended for Children Over 8 Years of Age**." If the article is unpackaged, the required statement shall appear on the article itself or on a tag securely attached to the article and the applicable labeling requirements of OAR 333-016-0110(5) and 333-016-0115.

(b) Toys which induce sound levels:

(A) Impulse sound. Known herein as Requirement No. 23:

(i) Articles which produce impulse sound shall not produce peak sound pressure levels greater than 158 decibels when tested in accordance with OAR 333-016-0055;

(ii) Any article producing peak sound pressure levels greater than 138 decibels but not greater than 158 decibels when tested in accordance with OAR 333-016-0055 shall bear the following statement on the carton and in the accompanying literature in accordance with OAR 333-016-0115: "**Warning: Do not fire closer than one foot to the ear**. **Do not use indoors**." Labeling requirements of OAR 333-016-0110 shall also be satisfied;

(iii) Caps (paper or plastic) intended for use with toy guns and toy guns not intended for use with caps if such caps when so used or such toy guns produce impulse-type sound at a peak pressure level at or above 138 decibels, referred to 0.0002 dyne per square centimeter when measured in an anechoic chamber at a distance of 24 centimeters (or the distance at which the sound source would ordinarily be from the ear of the child using it if such distance is less than 25 centimeters) in any direction from the source of the sound.

(B) Continuous sound levels. Known herein as Requirement No. 24. Continuous sound levels which exceed the following intensity and duration limits when measured on the scale of a standard sound level meter at a slow response. When noise levels are determined by octave band analysis, the equivalent A-weighted sound level may be determined by octave band analysis, the equivalent A-weighted sound level may be determined as follows: Equivalent sound level contours. Octave band sound pressure levels may be converted to the equivalent A-weighted sound level by plotting them on the graph as set out in **Exhibit 1** and noting the A-weighted sound level corresponding to the point of highest penetration into the sound level contours. This equivalent A-weighted sound level, which may differ from the actual A-weighted sound level of the noise, is used to determine exposure limits from the table in **Exhibit 1**.

*If the variations in noise levels involve maxima at intervals of 1 second or less, it is to be considered continuous.

(c) An electrical toy. This term means any electrically operated toy or other electrically operated article intended for use by children which is intended to be operated by electrical current from nominal 120 volt (110–120 v.) branch circuits. If the package (including packaging materials) of the toy is intended to be used with the product, it is considered to be part of the toy:

(A) General labeling requirements. Known herein as Requirement No. 25:

(i) Any electrical toy shall conform to the general labeling requirements of this section, i.e., paragraphs (4)(c)(A) and (B) of this rule and to the specific requirements relating to hot surfaces, i.e., paragraph (4)(c)(B) of this rule;

(ii) The markings required on an electrical toy by this section shall be of a permanent nature, such as paint-stenciled, die-stamped, molded, or indelibly stamped. The markings shall not be permanently obliterable by spillage of any material intended for use with the toy and shall not be readily removable by cleaning substances. All markings on the toy and labeling of the shelf pack or package required by this section shall contrast sharply with the background (whether by color, projection, or indentation) and shall be readily visible and legible. Such markings and labeling shall appear in lettering of a height not less than that specified in OAR 333-016-0110(2), except that those words shown in capital letters in this section shall appear in capital lettering of a height not less than twice that specified in OAR 333-016-0110(2). Electrically operated toys shall bear the statement: "**CAUTION — ELECTRIC TOY**." The shelf pack or package and the instructions of such toys shall bear the statement in the upper right-hand quarter of the principal display panel: "**CAUTION — ELECTRIC TOY: Not Recommended For Children _____Years of Age**. **As with all electric products, precautions should be observed during handling and use to prevent electric shock**." The blank in the preceding statement shall be filled in by the manufacturer, but in no instance shall the manufacturer indicate that the article is recommended for children under eight years of age if it contains a heating element. In the case of other electrically operated products which may not be considered to be "toys" but are intended for use by children, the term "**ELECTRICALLY OPERATED PRODUCT**" may be substituted for the term "**ELECTRIC TOY**."

(B) Hot surfaces. Known herein as Requirement No. 26:

(i) Labeling. Electrical toys having Type "C" or "D" surfaces described in this paragraph as Type "C" or "B" which reach temperatures greater than those shown in Table 3 shall be defined as hot and shall be marked where readily noticeable when the hot surface is in view with the statement: "**HOT — Do Not Touch**." When the marking is on other than the hot surface, the word "**HOT**" shall be followed by appropriate descriptive words such as "**Molten Material**," "**Sole Plate**," or "**Heating Element**," and the statement "**Do Not Touch**." An alternative statement for a surface intended to be handheld as a functional part of the toy shall be "**HOT — Handle Carefully**," the blank being filled in by the manufacturer with a description of the potential hazard such as "**Curier**" or "**Cooking Surface**." Surfaces requiring precautionary statements of thermal hazards are those exceeding the following temperatures when measured by the test described in Test (T,i) and (T,ii);

(ii) Surface types:

(I) Type A. A part or surface of a toy (such as a handle) likely to be grasped by the hand or fingers for the purpose of carrying the toy or lifting a separable lid;

(II) Type B. A part or surface of a toy that part of a handle, knob, or similar component, but which is not normally grasped or contacted by the hand or fingers for carrying (including parts of a handle within seven-sixteenths of an inch of the surface to which the handle is attached and parts of a knob within 1/4 inch of the surface to which the knob is attached, if the remainder of the knob is large enough to be grasped), or a handle, knob, or part that may

be touched but which need not be grasped for carrying the toy or lifting a lid, door, or cover (e.g., support part of a handle or knob);

(III) Type C. A part or surface that can be touched by casual contact or that can be touched without employing the aid of a common household tool (screwdriver, pliers, or other similar household tool) and that is either a surface that performs an intended heating function (e.g., the sole plate of a flatiron, a cooking surface, or a heating element surface), or a material heated by the element and intended to be used as the product of the toy, excluding pans, dishes, or other containers used to hold the material to be cooked or baked if a common utensil or other device is supplied with the toy and specific instruction are established for using such a device to remove the container from the heated area;

(IV) Type C Marked. A Type C surface which has been marked with a precautionary statement of thermal hazards in accordance with subparagraph (4)(c)(B)(i) of this rule;

(V) Type D. An accessible part or surface of a toy other than Types A, B, C, or E, of this paragraph;

(VI) Type D Marked. A Type D surface which has been marked with a precautionary statement of thermal hazards in accordance with subparagraph (4)(c)(B)(i) of this rule;

(VII) Type E. A heated surface in an oven or other article that is inaccessible or protected by an electrical-thermal safety interlock.

(d) Any article known as a "baby-bouncer," "walker-jumper," or "baby-walker" and any other similar article which is intended to be used by very young children (usually from about four months to 18 months old) while sitting, walking, bouncing, jumping, and/or reclining for napping shall comply with the following provisions:

(A) Frames are designed and constructed in such a manner as to prevent injury from any scissoring or pinching which may occur when the members of the frame or other components rotate about a common axis or fastening point;

(B) Coil springs which expand sufficiently to allow space for insertion of a finger, toe, or another part of a child's anatomy are covered or otherwise designed to prevent injuries;

(C) Holes, slots, cracks, or hinged components in any portion of the article through which a child could insert a finger, toe, or another part of the anatomy are guarded or otherwise designed to prevent injuries;

(D) The articles are designed and constructed so as to eliminate from any portion of the article the possibility of presenting a mechanical hazard through pinching, bruising, lacerating, crushing, breaking, amputating, or otherwise injuring normal use or when subjected to reasonably foreseeable damage or abuse;

(E) The article is labeled:

(i) With a conspicuous statement of the name and address of the manufacturer, packer, distributor, or seller; and

(ii) To bear on the article itself and/or the package containing the article and/or shipping container in addition to the invoice(s) and shipping document(s), a code or mark in a form or manner that will permit future identification of any given batch, lot, or shipment by the manufacturer; and

(F) A company manufacturing the article shall make, keep, and maintain for three years records of sale, distribution, and the results of the inspections and tests conducted in accordance with these rules and shall make such records available upon request at all reasonable hours of any officer or employee of the Public Health Division, or any other employee acting on behalf of the Administrator, and shall permit such officer or employee to inspect and copy such records and to make such inventories of stock as he deems necessary and otherwise to check the correctness of such records.

(e) "Clacker balls." Toys usually known as "clacker balls" and consisting of two balls of plastic or other material connected by a length of line or cord or similar connector intended to be operated in a rhythmic manner by a upward and downward motion of the hand so that the balls will meet forcefully at the top and bottom of two semicircles, thus causing a "clacking" sound shall comply with the following conditions: "Clacker balls" shall have been designed, manufactured, assembled, labeled, and tested in accordance with the following requirements, and when tested at the point of production or while in interstate commerce or while held for sale after shipment in interstate commerce do not exceed the failure rate requirements as set out in **Table 4**:

(A) The toy shall be so designed and fabricated that:

(i) Each ball weighs less than 50 grams; will not shatter, crack, or chip; is free of cracks, flash (ridges due to imperfect moldings), totally enclosed internal voids (holes, cavities, or air bubbles), and crazing (tiny surface cracks); and is free of rough or sharp edges around any hole where the cord enters or over any surface with which the cord may make contact;

(ii) The cord is of high tensile strength, synthetic fibers that are braided or woven, having a breaking strength in excess of 100 pounds; is free of fraying or any other defect that might tend to reduce its strength in use; is not molded in balls made of casting resins which tend to wick or run up into the cord; and is affixed to a ball at the center of the horizontal plane of the ball when it is suspended by the cord;

(iii) When the cord is attached to the ball by means of a knot, the end beneath the knot is chemically fused or otherwise treated to prevent the knot from slipping out or untying in use.

(B) The toy shall be tested at the time of production:

(i) By using a sampling procedure described in Table 4 to determine the number of units to be tested;

(ii) By subjecting each ball tested to ten drops of a five-pound steel impact rod or weight (2-1/2 inches in diameter with a flat head) dropped 48 inches in a vented steel or aluminum tube (2-3/8 inches in diameter) when the ball is placed on a steel or cast iron mount. Any ball showing any chipping, cracking, or shattering shall be counted as a failure within the meaning of the third column in **Table 4**;

(iii) By inspecting each ball tested for smoothness of finish in any holes, on outer surfaces, and on any other portion with which the cord is intended to come into contact. A cotton swab shall be rubbed vigorously over each such surface or area; if any cotton fibers are removed, the ball shall be counted as a failure within the meaning of the fourth column of **Table 4**;

(iv) By fully assembling the toy and testing the cord in such a manner as to test both the strength of the cord and the adequacy with which the cord is attached to the ball and any holding device such as a tab or ring included in the assembly. The fully assembled article shall be vertically suspended by one ball and a 100-pound test applied to the bottom ball. Any breaking, fraying, or unraveling of the cord or any sign of slipping, loosening, or unfastening shall be counted as a failure within the meaning of the fourth column in **Table 4**;

(v) By additionally subjecting any ring or other holding device to a 50-pound test load applied to both cords. The holding device is to be securely fixed horizontally in a suitable clamp in such a manner as to support 50 percent of the area of such holding device and the balls are suspended freely. Any breaking, cracking, or crazing of the ring or other holding device shall be counted as a failure within the meaning of the fourth column in **Table 4**;

(vi) By cutting each ball tested in half and then cutting each half perpendicularly to the first cut into three or more pieces of approximately equal thickness. Each portion is to be inspected before and after cutting, and any ball showing any flash, crack, crazing, or internal voids on such inspection is to be counted as a failure within the meaning of the fourth column in **Table 4**. A transparent ball shall be subjected to the same requirements except that it may be visually inspected without cutting.

(C) The toy shall be fully assembled for use at the time of sale, including the proper attachments of balls, cords, knots, loops, or other holding devices;

(D) The toy shall be labeled:

(i) With a conspicuous statement of the name and address of the manufacturer, packer, distributor, or seller;

(ii) To bear on the toy itself and/or the package containing the toy and/or the shipping container, in addition to the invoice(s) and shipping document(s), a code or mark in a form and manner that

will permit future identification of any given batch, lot, or shipment by the manufacturer;

(iii) To bear a conspicuous warning statement on the front panel of the retail and display carton and on any accompanying literature: That if cracks develop in a ball or if the cord becomes frayed or loose or unfastened, use of the toy should be discontinued; and if a ring or loop or other holding device is present, the statement, "**In use, the ring or loop must be placed around the middle finger and the two cords positioned over the forefinger and held securely between the thumb and forefinger**" or words to that effect which will provide adequate instructions and warnings to prevent the holding device from accidentally slipping out of the hand. Such statements shall be printed in sharply contrasting color within a borderline and in letters at least one-quarter inch high on the main panel of the container and at least 1-1/8 inch high on all accompanying literature.

(E) The manufacturer of the toy shall make, keep, and maintain for three years records of sale, distribution, and results of inspections and tests conducted in accordance with this subparagraph and shall make such records available upon request at all reasonable hours by any officer or employee of the Public Health Division, or any other employee acting on behalf of the Administrator; and shall permit such officer or employee to inspect and copy such records, and to make such inventories of stock as he deems necessary and otherwise to check the correctness of such records;

(F) The lot size, sample size, and failure rate for testing clacker balls are set out in **Table 4**;

(G) Applicability of the exemption provided by this subparagraph shall be determined through use of Table 4. A random sample of the number of articles as specified in the second column of the table shall be selected according to the number of articles in a particular batch, shipment, deliver, lot, or retail stock per the first column. A failure rate as shown in either the third or fourth column shall indicate that the entire batch, shipment, delivery, lot, or retail stock has failed and thus is not exempted under this subparagraph from classification as a banned hazardous substance.

(f) Packaging. Known herein as Requirement No. 27. This requirement is intended to minimize the possibility of asphyxiation hazards that might be caused by thin packaging plastic. Flexible plastic sheets used as packaging materials for shelf packages or used with toys shall be at least 0.00150 inch in nominal thickness but the actual thickness shall ever be less than 0.00125 inch, except for flexible film bags having a combined length and fully extended opening perimeter of less than 23 inches, or bags having an opening perimeter of less than 14 inches, measured after the perimeter has been stretched to its fullest extent. Shrink plastic of less than 0.00150 inch nominal thickness shall be exempt from this requirement, if it is in the form of an overwrap that would normally be destroyed when the package is opened by a consumer. Thickness shall be determined in accordance with **Method C of American Society for Testing and Materials (ASTM) D 374-68, Standard Methods of Test for Thickness of Solid Electrical Insulation**.

(5) Any toy or article intended for use by children which, even though labeled in accordance with these rules, reliable data on human experience shows the toy or article to be hazardous within the meaning of the Act.

(6) Any toy or article intended for use by children which does not satisfy any applicable requirement or test of these rules. All applicable requirements and tests shall be satisfied.

[ED. NOTE: Exhibits, Appendices, Tables referenced are available from the agency.]

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.095

Stats. Implemented: ORS 453.005, 453.035 & 453.055

Hist.: HD 40, f. 8-2-73, ef. 8-15-73; HD 89, f. 7-31-75, ef. 8-25-75

333-016-0082

Repurchase of Banned Hazardous Substances

Banned hazardous toys and other banned hazardous substances shall be repurchased in accordance with ORS 453.075.

Stat. Auth.: ORS 453.095

Stats. Implemented: ORS 453.055 & 453.075

Hist.: HD 40, f. 8-2-73. ef. 8-15-73

333-016-0085

Exemptions for Foods, Drugs, Cosmetics, and Fuels

(1) Foods and drugs otherwise regulated by this state are exempted by ORS 453.015(5); but where a food, drug, or cosmetic offers a substantial risk of injury or illness from any handling or use that is customary or usual, it may be regarded as misbranded under the laws of this state because its label fails to reveal material facts with respect to consequences that may result from use of the article when its label fails to bear information to alert the householder to this hazard.

(2) Fuels. A substance intended to be used as a fuel is exempt from the requirements of the Act when in containers that are intended to be or are installed as part of the heating, cooking, or refrigeration system of a house. A portable container used for delivery or temporary or additional storage, and containing a substance that is a hazardous substance as defined in ORS 453.005(7)(a), is not exempt from the labeling prescribed in ORS 453.015(2) even though it contains a fuel to be used in the heating, cooking, or refrigeration system of a house.

Stat. Auth.: ORS 453.095

Stats. Implemented: ORS 453.015

Hist.: HD 40, f. 8-2-73. ef. 8-15-73

333-016-0090

Exemption from Full Labeling and Other Requirements

(1) Any person who believes a particular hazardous substance intended or packaged in a form suitable for use in the household or by children should be exempted from full label compliance otherwise applicable under the Act, because of the size of the package or because of the minor hazard presented by the substance, or for other good and sufficient reason, may submit to the Administrator a request for exemption under ORS 453.035(4), presenting facts in support of the view that full compliance is impracticable or is not necessary for the protection of the public health. The Administrator shall determine on the basis of the facts submitted and all other available information whether the requested exemption is consistent with the adequate protection of the public health and safety. If he so finds, he shall detail the exemption granted and the reasons therefore by an appropriate means.

(2) The Administrator may on his own initiative determine on the basis of facts available to him that a particular hazardous substance intended or packaged in a form suitable for use in the household or by children should be exempted from full labeling compliance otherwise applicable under the Act because of the size of the package or because of minor hazard presented by the substance or for other good and sufficient reason. If he so finds, he shall detail the exemption granted and the reasons therefore by an appropriate means.

(3) Any person who believes a particular article should be exempted from being classified as a "banned hazardous substance" as provided by ORS 453.055 because it falls within the provisions of ORS 453.035(4) may submit to the Administrator a request for exemption presenting facts in support of his contention. The Administrator shall determine on the basis of the facts submitted, and all other available information, whether the requested exemption is consistent with the purposes of the Act. If he so finds, he shall detail the exemption granted and the reasons therefore by an appropriate means.

(4) On his own initiative the Administrator may determine on the basis of available facts that a particular banned hazardous substance should be exempted from ORS 453.055, because it falls within the provisions of ORS 453.035(4). If he so finds, he shall detail the exemption granted and the reasons therefore by an appropriate means.

(5) Any person who believes that a particular toy should be temporarily exempted from the labeling provisions of these rules promulgated in 1975 because of the minor hazard presented by the toy or for other good and sufficient reason may submit to the Administrator a request for such temporary exemption from the 1975 labeling requirements until March 30, 1976, provided that the labeling requirements of the rules in effect between August 15,

1973, and the 1975 rules will apply during the temporary exemption.

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.035 & 453.055
Hist.: HD 40, f. 8-2-73, ef. 8-15-73; HD 89, f. 7-31-75, ef. 8-25-75

333-016-0095
Exemptions for Small Packages, Minor Hazards, and Special Circumstances

The following exemptions are granted for the labeling of hazardous substances under the provisions of OAR 333-016-0090:

(1) When the sole hazard from a substance in a self-pressurized container is that it generates pressure or when the sole hazard from a substance is that it is flammable or extremely flammable, the name of the component which contributes the hazard need not be stated.

(2) Common matches, including book matches, wooden matches, and so-called "safety" matches are exempted from the labeling requirements of ORS 453.035(2) insofar as they apply to the product being considered hazardous because of being "flammable" or "extremely flammable" as defined in OAR 333-016-0005.

(3) Paper items such as newspapers, wrapping papers, toilet and cleansing tissues, and paper writing supplies are exempted from the labeling requirements of ORS 453.005 to 453.135 insofar as they apply to the products being considered hazardous because of being "flammable" or "extremely flammable" as defined in OAR 333-016-0005.

(4) Thread, string, twine, rope, cord, and similar materials are exempted from the labeling requirements of ORS 453.035(2) insofar as they apply to the products being considered hazardous because of being "flammable" or "extremely flammable" as defined in OAR 333-016-0005.

(5) Laboratory chemicals intended only for research or investigational and other laboratory uses (except those in home chemistry sets) shall be exempt from the requirements of placement provided in OAR 333-016-0115 if all information required by this section and the Act are placed with the required prominence on the label panel adjacent to the main panel.

(6) Small-arms ammunition packaged in retail containers is exempted from the labeling requirements of ORS 453.035(2), provided that such containers bear the following label statements:

(a) The common or usual name of the ammunition in the container;

(b) The statement: "**Warning — Keep out of the reach of children**" or its practical equivalent;

(c) The name and place of business of the manufacturer, packer, seller, or distributor;

(d) The term "ammunition" as used in this paragraph includes small-arms ammunition and loads for powder-actuated tools in a form ready for use in a pistol, revolver, rifle, shotgun, or powder-actuated tool, including blank cartridges and shells.

(7) Rigid or semi-rigid ball-point ink cartridges are exempt from the labeling requirements of ORS 453.035(2) insofar as such requirements would be necessary because the ink contained therein is a "toxic" substance as defined in OAR 333-016-0005, provided that:

(a) The ball-point ink cartridge is of such construction that the ink will, under any reasonably foreseeable conditions of manipulation or use, emerge only from the ball-point end;

(b) When tested by the method described in OAR 333-016-0005, the ink does not have an LD 50 single oral dose of less than 500 milligrams per kilogram of body weight of the test animal;

(c) The cartridge does not have a capacity of more than two grams of ink.

(8) Containers of paste shoe waxes, paste auto waxes, and paste furniture and floor waxes containing toluene (also known as toluol), xylene (also known as xylol), petroleum distillates, and/or turpentine in the concentrations described in OAR 333-016-0065 are exempt from the labeling requirements of OAR 333-016-0065 if the viscosity of such products is sufficiently high that they will not flow from their opened containers when inverted for five minutes at a temperature of 80°F and are exempt from bearing a flammability warning statement if the flammability of such waxes is due solely to the presence of solvents which have flashpoints above 80°F when tested by the method described in OAR 333-016-0035.

(9) Porous-tip ink marking devices are exempt from the labeling requirements of ORS 453.035(2) and OAR 333-016-0065 insofar as such requirements would be necessary because the ink contained therein is a toxic substance as defined in OAR 333-016-0005 and/or because the ink contains ten percent or more by weight of toluene (also known as toluol), xylene (also known as xylol), or petroleum distillates as defined in 333-016-0065 and/or because the ink contains ten percent or more by weight of ethylene glycol, provided that:

(a) The porous-tip ink marking devices are of such construction that the ink is held within the device by an absorbent material so that there is no free liquid within the device, and under any reasonably foreseeable conditions of manipulation and use including reasonably foreseeable abuse by children, the ink will emerge only through the porous writing nib of the device; and

(b)(A) The device has a capacity of not more than 10 grams of ink, and the ink, when tested by methods described in OAR 333-016-0005 has an LD 50 single oral dose of not less than 2.5 grams per kilogram of body weight of the test animal; or

(B) The device has a capacity of not more than 12 grams of ink, and the ink, when tested by methods described in OAR 333-016-0005 has an LD 50 single oral dose of not less than 3.0 grams per kilogram of body weight of the test animal.

(10) Viscous nitrocellulose-base adhesives containing more than four percent methyl alcohol by weight are exempted from the label statement: "**Cannot be made nonpoisonous**" required by OAR 333-016-0065, provided that:

(a) The total amount of methyl alcohol by weight in the product does not exceed 15 percent; and

(b) The contents of any container does not exceed two fluid ounces.

(11) Packages containing polishing or cleaning products which consist of a carrier of solid particulate or fibrous composition and which contain toluene (also known as toluol), xylene (also known as xylol), petroleum distillates in the concentrations described in OAR 333-016-0065 are exempt from the labeling requirements of OAR 333-016-0065 provided that such toluene, xylene, or petroleum distillates are fully absorbed by the solid, semi-solid, or fibrous carrier and cannot be expressed therefrom with any reasonably foreseeable conditions of manipulation.

(12) Containers of dry ink intended to be used as a liquid ink after the addition of water are exempt from the labeling requirements of ORS 453.035(2) and OAR 333-016-0065, insofar as such requirements would be necessary because the dried ink contained therein is a toxic substance as defined in OAR 333-016-0005 and/or because the ink contains ten percent or more by weight of ethylene glycol as defined in OAR 333-016-0065, provided that:

(a) When tested by the method described in OAR 333-016-0005, the dry ink concentrate does not have an LD 50 single oral dose of less than one gram per kilogram of body weight of the test animal;

(b) The dry ink concentrate enclosed in a single container does not weigh more than 75 milligrams;

(c) The dry ink concentrate does not contain over 15 percent by weight of ethylene glycol.

(13) Containers of liquid and semi-solid substances such as viscous-type paints, varnishes, lacquers, roof coating, rubber-vulcanizing preparations, floorcovering adhesives, glazing compounds, and other viscous products containing toluene (also known as toluol), xylene (also known as xylol), or petroleum distillates in concentrations described in OAR 333-016-0065 are exempt from the labeling requirements of OAR 333-016-0065 insofar as that paragraph applies to such toluene, xylene, or petroleum distillates, provided that the viscosity of the substances, or any liquid that may separate or be present in the container, is not less than 150 Saybolt Universal seconds at 100°F.

(14) Customer-owned portable containers that are filled by retail vendors with gasoline, kerosene (kerosene), or other petroleum distillates are exempt from the provision of ORS 453.035(2)(i) which requires that the name and place of business of the manufacturer, distributor, packer, or seller appear on the label of such containers, provided that all the other label statements required by ORS 453.035(2) and OAR 333-016-0065 appear on the labels of containers of the substances named in this paragraph.

(15) Cellulose sponges are exempt from the labeling requirements of ORS 453.035(2) and OAR 333-016-0065 insofar as such requirements would be necessary because they contain ten percent or more of diethylene glycol as defined in OAR 333-016-0065, provided that:

(a) The cellulose sponge does not contain over 15 percent by weight of diethylene glycol;

(b) The diethylene glycol content is completely held by the absorbent cellulose material so that there is no free liquid within the sponge as marketed.

(16) Containers of substances which include salt (sodium chloride) as a component are exempt from the labeling requirements of ORS 453.035(2) insofar as such requirements would be necessary because the salt contained therein is present in a quantity sufficient to render the article "toxic" as defined in OAR 333-016-0005, provided that the labels of such containers bear a conspicuous statement that the product contains salt.

(17) The labeling of substances containing ten percent or more of ferrous oxalite is exempt from the requirement of OAR 333-016-0145 provided that it bears the word "poison" which would otherwise be required for such concentration of a salt of oxalic acid.

(18) Packages containing articles intended as single-use spot removers, and which consist of a cotton pad or other absorbent material saturated with a mixture of dry-cleaning solvents, are exempt from the labeling requirements of ORS 453.035(2) insofar as they apply to the "flammable" hazard as defined in OAR 333-016-0005, provided that:

(a) The article is packaged in a sealed foil envelope;

(b) The total amount of solvent in each package does not exceed 4.5 milliliters;

(c) The article will ignite only when in contact with an open flame, and when so ignited, the article burns with a sooty flame.

(19) Packages containing article intended as single-use spot removers and which consist of a cotton pad or other absorbent material containing methyl alcohol, are exempted from the labeling requirements of OAR 333-016-0065, provided that:

(a) The total amount of cleaning solvent in each package does not exceed 4.5 milliliters, of which not more than 25 percent is methyl alcohol;

(b) The liquid is completely held by the absorbent materials so that there is no free liquid within the packages marketed.

(20) Cigarette lighters containing petroleum distillate fuel are exempt from the labeling requirements of ORS 453.035(2) and OAR 333-016-0065, insofar as such requirements would be necessary because the petroleum distillate contained therein is "flammable" and because the substance is named in 333-016-0065 of the rules as requiring special labeling, provided:

(a) That such lighters contain not more than ten cubic centimeters of fuel at the time of sale; and

(b) That such fuel is contained in a sealed compartment that cannot be opened without the deliberate removal of the flush-set, screw-type refill plug of the lighter.

(21) Containers of dry granular fertilizers and dry granular plant foods are exempt from the labeling requirements of ORS 453.035(2) insofar as such requirements would be necessary because the fertilizer or plant food contained therein is a toxic substance as defined in OAR 333-016-0005, provided that:

(a) When tested by the method described in 333-016-0005, the product has an LD 50 single dose of not less than 3.0 grams per kilogram of body weight of the test animal;

(b) The label of any such exempt dry granular fertilizers discloses the identity of each of the hazardous ingredients;

(c) The label bears the name and address of the manufacturer, packer, distributor, or seller; and

(d) The label bears the statement "**Keep out of the reach of children**" or its practical equivalent.

(22) Small, plastic capsules containing a paste composed of powdered metal solder mixed with a liquid flux are exempt from the requirements of ORS 453.035(2), provided that:

(a) The capsule holds not more than one-half milliliter of the solder mixture;

(b) The capsule is sold only as a component of a kit; and

(c) Adequate caution statements appear on the carton of the kit and on any accompanying labeling which bears directions for use.

(23) Chemistry sets and other science education sets intended primarily for use by juveniles, and replacement containers of chemicals for such sets, are exempt from the requirements of ORS 453.035(2), provided that:

(a) The immediate container of each chemical that is hazardous as defined in the Act and rules bears on its main panel the name of such chemicals, the appropriate signal word for that chemical, and the additional statement, "**Read back panel before using**" (or "**Read side panel before using**" if appropriate) and bears on the back (or side) panel of the immediate container the remainder of the appropriate cautionary statement for the specific chemical in the container;

(b) The experiment manual or other instruction booklet accompanying such set bears on the front page of the leaflet as a preface to any written matter in the leaflet (or on the cover, if there is any) the following caution statement within the borders of a rectangle and in the type size specified in OAR 333-016-0115: **WARNING: This set contains chemicals that may be harmful if misused. Read cautions on individual containers carefully**. **Not to be used by children except under adult supervision**.

(c) The outer carton of such set bears on the main display panel within the borders of a rectangle and in the type size specified in OAR 333-016-0115 the caution statement specified in subsection (b) of this subparagraph.

(24) Fire extinguishers containing fire extinguishing agents which are stored under pressure or which develop pressure under normal conditions of use are exempt from the labeling requirements of ORS 453.035(2) insofar as such requirements apply to the pressure hazard as defined in OAR 333-016-0005(13), provided that:

(a) If the container is under pressure both during storage and under conditions of use, it shall be designed to withstand a pressure of at least six times the charging pressure at 70°F, except that carbon dioxide extinguishers shall be constructed and tested in accordance with applicable Interstate Commerce Commission specifications; or

(b) If the container is under pressure only during conditions of use, it shall be designed to withstand a pressure of not less than five times the maximum pressure developed under closed-nozzle conditions at 70°F or one and one-half times the maximum pressure developed under closed-nozzle conditions at 120°F, whichever is greater.

(25) Cleaning and spot removing kits intended for use in cleaning carpets, furniture, and other household objects; kits intended for use in coating, painting, antiquing, and similarly processing furniture, furnishings, equipment, sidings, and various other surfaces; and kits intended for use in photographic color processing are exempt from the requirements of ORS 453.035(2) and OAR 333-016-0065, provided that:

(a) The immediate container of each hazardous substance in the kit is fully labeled and in conformance with the requirements of the Act and rules issued thereunder;

(b) The carton of the kit bears on the main display panel (or panels) within a borderline, and in the type size specified in OAR 333-016-0115, the following caution statement: "**(Insert proper signal word as specified in subsection (c) of this rule). This kit contains the following chemicals that may be harmful if misused: (List hazardous chemical components by name).**

Read cautions on individual containers carefully. Keep out of the reach of children"; and

(c) If either the word "**POISON**" or "**DANGER**" is required in the labeling of any component or components in the kit, the word "**POISON**" shall be used. In all other cases, the word "**WARNING**" or "**CAUTION**" shall be used.

(26) Packages containing articles intended as single use spot removers and containing methyl alcohol are exempt from the labeling specified in OAR 333-016-0065, provided that:

(a) The total amount of cleaning solvent in each unit does not exceed one milliliter, of which not more than 40 percent is methyl alcohol;

(b) The liquid is contained in a sealed glass ampoule enclosed in a plastic container with a firmly attached absorbent wick at one end through which the liquid from the crushed ampoule must pass, under the contemplated conditions of use;

(c) The labeling of each package of the cleaner bears the statement, "**Warning: Keep out of the reach of children**." **or its practical equivalent, and the name and place of business of the manufacturer**, **packer**, **distributor**, **or seller**.

(27) Packaged fireworks assortments intended for retail distribution are exempt from ORS 453.035(2), provided that:

(a) The package contains only fireworks devices exempted under ORS 480.110 to 480.165;

(b) Each individual article in the assortment is fully labeled and in conformance with the requirements of the Act and rules issued thereunder; and

(c) The outer package bears on the main display panel (or panels) within the borders of a rectangle and in the type size specified in 333-016-0115 the following caution statement: "**Warning: This assortment contains items that may be hazardous if misused and should be used only under adult supervision. Important: Read cautions on individual items carefully**."

(28) Packages containing felt pads impregnated with ethylene glycol are exempt from the labeling requirements of 333-016-0065, provided that:

(a) The total amount of ethylene glycol in each pad does not exceed one gram; and

(b) The liquid is held by the felt pad so that there is no free ethylene glycol within the package.

(29) Cigarette lighters containing butane and/or isobutane fuel are exempt from the labeling requirements of ORS 453.035(2) insofar as such requirements would otherwise be necessary because the fuel therein is extremely flammable under pressure, provided that:

(a) The lighters contain not more than 12 grams of fuel at the time of sale;

(b) The fuel reservoir is designed to withstand a pressure of at least one and one-half times the maximum pressure which will be developed in the container at 120°F.

(30) The outer retail containers of solder kits each consisting of a small tube of flux partially surrounded by a winding of wire-type cadmium-free silver solder are exempt from the labeling requirements of ORS 453.035(2), provided that:

(a) The metal solder contains no cadmium and is not otherwise hazardous under the provisions of the Act;

(b) The tube of flux in the kit is fully labeled and in conformance with the Act and rules thereunder, and any accompanying literature which bears directions for use also bears all the information required by ORS 453.035(2);

(c) The main panel of the outer container bears in type size specified in OAR 333-016-0115 the following: The signal word, the statement of principal hazard or hazards, the statement, "**Keep out of the reach of children**" or its practical equivalent, and instructions to read other cautionary instructions on the tube of flux within.

(31) Visual novelty devices consisting of sealed units, each of which unit is a steel or glass cell containing perchloroethylene, among other things, are exempted from the requirements of OAR 333-016-0115 that would otherwise require a portion of the warning statement to appear on the glass face of the device, provided that:

(a) The device contains not more than 105 milliliters of perchloroethylene and contains no other component that contributes substantially to the hazard;

(b) The following cautionary statement appears on the device (other than on the bottom) in the type size specified in OAR 333-016-0115: "**Caution: If broken, resultant vapors may be harmful. Contains perchloroethylene. Do not expose to extreme heat. If broken indoors, open windows and doors until all odor of chemical is gone. Keep out of the reach of children.**" **A practical equivalent may be substituted for the statement** "**Keep out of the reach of children**."

(32) Hollow plastic toys containing mineral oil are exempt from the labeling specified in OAR 333-016-0065 under the following conditions:

(a) The article contains no other ingredient that would cause it to possess the aspiration hazard specified in OAR 333-016-0065;

(b) The article contains not more than six fluid ounces of mineral oil;

(c) The mineral oil has a viscosity of at least 70 S.U.S. at 100°F;

(d) The mineral oil meets the specifications in the N.F. for light liquid petrolatum;

(e) The container bears the statement "**Caution: Contains light liquid petrolatum N.F. Discard if broken or leak develops**."

(33) Containers of mineral oil having a capacity of not more than one fluid ounce and intended for use in producing a smoke effect for toy trains are exempt from the labeling specified in 333-016-0065 under the following conditions:

(a) The mineral oil meets the specifications in the N.F. for light liquid petrolatum;

(b) The mineral oil has a viscosity of at least 130 S.U.S. at 100°F;

(c) The article contains no other ingredient that contributes to the hazard;

(d) The label declares the presence of light liquid petrolatum and the name and place of business of the manufacturer, packer, distributor, or seller.

(34) Viscous products containing more than four percent by weight of methyl alcohol, such as adhesives, asphalt-base roof and tank coatings, and similar products are exempt from bearing the special labeling that would otherwise be required by OAR 333-016-0065, provided that:

(a) The product contains not more than 15 percent by weight of methyl alcohol;

(b) The methyl alcohol does not separate from the other ingredients upon standing or through any foreseeable use or manipulation;

(c) The viscosity of the product is not less than 7,000 centipoises at 77°F, unless the product is packaged in a pressurized container and is dispensed as a liquid unsuitable for drinking;

(d) Labeling bears the statement, "**Contains methyl alcohol — Use only in well-ventilated area — Keep out of the reach of children**."

(35) Individual blasting caps are exempt from bearing the statement, "**Keep out of the reach of children**" or its practical equivalent, provided that:

(a) Each cap bears conspicuously in the largest type size practicable the statement, "**DANGEROUS — BLASTING CAPS — EXPLOSIVE**";

(b) The outer carton and any accompanying printed matter bear appropriate complete cautionary labeling.

(36) Individual toy rocket propellant devices and separate delay train and/or recovery system activation devices intended for use with premanufactured model rocket engines are exempted from bearing the full labeling required by ORS 453.035(2) insofar as such requirements would otherwise be necessary because the articles are flammable or generate pressure, provided that:

(a) The devices are designed and constructed in accordance with the specifications in OAR 333-016-0105(6);

(b) Each individual device or retail package of devices bears the following:

(A) The statement, "**Warning — Flammable. Read instructions before use**";

(B) The common or usual name of the article;

(C) A statement of the type of engine and use classification;

(D) Instructions for safe disposal;

(E) Name and place of business of manufacturer or distributor.

(c) Each individual rocket engine or retail package of rocket engines distributed to users is accompanied by an instruction sheet bearing complete cautionary labeling and instructions for safe use and handling of the individual rocket engines.

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.005 & 453.035
Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0100
Exemption for Unlabeled Containers

(1) Except as provided by sections (2) and (3) of this rule, a shipment or other delivery of a hazardous substance that, in accordance with the practice of the trade is to be labeled in substantial quantity at an establishment other than that where originally manufactured or packed, shall be exempt during the time of introduction into the movement in commerce within this state during the time of holding in that establishment from compliance with the labeling requirement of ORS 453.035(2) if:

(a) The person who introduced the shipment or delivery into commerce within this state is the operator of the establishment where the hazardous substance is to be received and labeled; or

(b) The person who introduced the shipment or delivery is not the operator, and the shipment or delivery is made to the establishment under a written agreement, signed by and containing the post office address of the person and the operator, and containing whatever specifications for the labeling of the hazardous substance that are necessary to insure, if such specifications are followed, that the hazardous substance will not be misbranded within the meaning of the Act upon completion of the labeling. The person and the operator shall each keep a copy of the agreement until two years after the final shipment or delivery under the agreement has been completed and shall make copies of the agreement available for inspection upon request of any properly authorized officer or employee of the Public Health Division.

(2) An exemption of a shipment or delivery of a hazardous substance under subsection (1)(a) of this rule shall, at the beginning of the act of removing the shipment or delivery or any part thereof from the establishment, become void ab initio if the hazardous substance comprising the shipment, delivery, or part is misbranded within the meaning of the Act when so removed.

(3) An exemption of a shipment or delivery of a hazardous substance under subsection (1)(b) of this rule shall become void ab initio with respect to the person who introduced the shipment or delivery into commerce within this state upon refusal by that person to make available for inspection a copy of the agreement as required by subsection (1)(b) of this rule.

(4) An exemption of a shipment or other delivery of a hazardous substance under subsection (1)(b) of this rule shall expire:

(a) At the beginning of the act of removing the shipment or delivery, or any part thereof, from the establishment if the hazardous substance comprising the shipment, delivery, or part is misbranded within the meaning of the Act when so removed; or

(b) Upon refusal by the operator of the establishment where the hazardous substance is to be labeled, to make available for inspection a copy of the agreement required by subsection (1)(b) of this rule.

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.035
Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0105
Exemptions from Classification as Banned Hazardous Substances

The term "banned hazardous substances" as used in ORS 453.055 shall not apply to the following articles, provided that these articles bear labeling giving adequate directions and warnings for safe use:

(1) Chemistry sets and other science education sets intended primarily for juveniles, and replacement components for such sets when labeled in accordance with ORS 453.015 and 453.035 and OAR 333-016-0095(23).

(2) Educational materials such as art materials, preserved biological specimens, laboratory chemicals, and other articles intended and used for educational purposes.

(3) Liquid fuels containing more than four percent by weight of methyl alcohol that are intended and used for operation of miniature engines for model airplanes, boats, cars, etc.

(4) Novelties consisting of a mixture of polyvinyl acetate, U.S. certified colors, and not more than 25 percent by weight of acetone, and intended for blowing plastic balloons.

(5) Games containing, as the sole hazardous component, a self-pressurized container of soap solution or similar foam-generating mixture, provided that the foam-generating component has no hazards other than being in a self-pressurized container.

(6) Model rocket propellant devices designed for use in lightweight, recoverable, and reflyable model rockets, provided such devices:

(a) Are designed to be ignited by electrical means;

(b) Contain no more than 62.5 grams (2.2 ounces) of propellant material and produce less than 80 newton-seconds (17.92 pound-seconds) of total impulse with thrust duration not less than 0.050 second;

(c) Are constructed such that all chemical ingredients are preloaded into a cylindrical paper or similarly constructed nonmetallic tube that will not fragment into sharp, hard pieces;

(d) Are designed so that they will not burst under normal conditions of use, are incapable of spontaneous ignition, and do not contain any type of explosive or pyrotechnic warhead other than a small parachute or recovery-system activation charge.

(7) Separate delay train and/or recovery system activation devices intended for use with premanufactured model rocket engines wherein all of the chemical ingredients are preloaded so the user does not handle any chemical ingredient and are so designed that the main casing or container does not rupture during operation.

(8) Self-pressurized products containing fluorocarbon propellants, provided that the product has no hazards other than being self-pressurized and containing a fluorocarbon propellant and is labeled in accordance with OAR 333-016-0150.

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.015, 453.035 & 453.055
Hist.: HD 40, f. 8-2-73, ef. 8-15-73; HD 89, f. 7-31-75, ef. 8-25-75

333-016-0110
Labeling of Toys, Including Games

(1)(a) Labeling, literature, and marking. Known herein as Requirement No. 28. References in these rules to OAR 333-016-0110 shall include all subparagraphs of OAR 333-016-0110. Labeling requirements of OAR 333-016-0115 which are applicable to the product and which are in addition to or more demanding of the manufacturers shall apply in addition to the requirements of this section.

(b) General labeling requirements:

(A) Age grading. Toy packages shall be labeled to indicate the minimum recommended age (by months or by years) of children for whom the toy is intended;

(B) Instructional literature. Information and instructions provided with the toy, whether on the package or in leaflet form, shall be easy to read and understand;

(C) Producers markings. The principal components of toys or containers shall be marked with the name and address of the producer or distributor. This marking shall be legible and so posi-

tioned as to be easily seen by the customer and shall resist normal use conditions. Toys shall carry a code which will enable the producer to identify model changes, except for toys comprising many loose components, in which case, the code shall be placed on the permanent storage container.

(2) Protective labeling. Known herein as Requirement No. 29:

(a) Certain toys or packages are required to carry protective labeling in order to comply with OAR 333-016-0080(3)(a)(A)(i) (sharp edges); 333-016-0080(3)(a)(C)(iv); 333-016-0080(3)(g)(A) and (B); 333-016-0080(3)(h); and 333-016-0080(4)(b)(A), (B), and (C). They shall be labeled with the word "**CAUTION**" and a statement of the hazard on the principal display panel. In addition, the toys falling under the requirements of OAR 333-016-0080(3)(g)(A) and 333-016-0080(3)(h) shall themselves be labeled with the word "**CAUTION**" and a statement of the hazard. The principal display panel is defined as that part of a package which is most likely to be displayed, presented, shown, or examined under normal and customary conditions of display for retail sale;

(b) Additional and special cautionary labeling requirements are provided in OAR 333-016-0080(3)(a)(C)(v); 333-016-0080(4)(a)(A), (B), and (C); 333-016-0080(4)(b)(A)(i); 333-016-0080(4)(c)(A)(i), (ii), and (iii); 333-016-0080(4)(d)(E); and 333-016-0080(4)(e)(D).

(3) Printing size. Known herein as Requirement No. 30. All markings required by rules OAR 333-016-0080 and 333-016-0110 shall be of a permanent nature, whether paint-stenciled, die-stamped, molded, or indelibly stamped. All required markings shall appear in block lettering. Markings shall contrast sharply with their background (whether by color, projection, or indentation), and shall be readily visible and legible. Minimum lettering heights shall be as follows: Surface Area Displayed Marking (square inches) — Minimum Height of Lettering (inches):

(a) Under 5 — 1/16;

(b) 5 or more and under 25 — 1/8;

(c) 25 or more and under 100 — 3/16;

(d) 100 or more and under 400 — 1/4;

(e) 400 or more — 1/2.

(4) The term "toy" as used in this rule includes games.

Stat. Auth.: ORS 453.095

Stats. Implemented ORS 453.035

Hist.: HD 40, f. 8-2-73, ef. 8-15-75; HD 89, f. 7-31-75, ef. 8-25-75

333-016-0115

Labeling Requirements, Placement, Conspicuousness, Contrast

(1) The signal word, the statement of the principal hazard or hazards, and instructions to read carefully any cautionary information that may be placed elsewhere on the label shall appear together on the main panel of the label. Such information shall be placed together and distinctively apart from other wording or designs. The necessary prominence shall be achieved by placement within the borders of a square or rectangle with or without a borderline, and by the use of suitable contrasts with the background achieved by distinctive typography or color, and by both color and typography when needed. For hazardous substances that contain toxic or highly toxic chemicals, the label shall include in addition to all other requirements of these rules the generic name of the chemical or chemicals which present the most significant hazards.

(2) If the product is "highly toxic" as defined in OAR 333-016-0005 and ORS 453.005(a), (B), or (C), the labeling shall also include in conjunction with the word "poison," the skull and crossbones symbol. The word "poison" is not considered a signal word as that term is used in section (1) of this rule.

(3) The signal word and statement of hazard shall be in capital letters. The size of the signal word (and the word "poison" if required) shall be of a size bearing a reasonable relationship to the other type on the main panel, but shall not be less than 18 point type, and the size of the statement of hazard shall not be less than 12 point type, unless the label space on the container is too small to accommodate such type size. When the size of the label space requires a reduction in type size, the reduction shall be made to a size no smaller than is necessary and in no event to a size smaller than six point type.

(4) All the items of label information required by ORS 453.035(2)(a) through (i) may appear on the main panel; but if they do not, all such items not required by section (1) of this rule to appear on the main panel shall be placed together in a distinctive place elsewhere on the label with adequate contrast, achieved by typography, color, or layout except that the name and place of business of the manufacturer, packer, distributor, or seller may appear separately on the same or on a different panel. The type size used shall bear a reasonable relationship to the printing on the panel involved and shall be no smaller than ten point unless the available label space requires reduction, in which event it shall be reduced no smaller than 6 point type unless because of small label space an exception has been granted under ORS 453.035(4) and 333-016-0095.

(5) Collapsible metal tubes containing hazardous substances shall be labeled so that all items of label information required by ORS 453.035(2)(a) through (i) shall appear as close to the dispensing end of the container as possible. The size, placement, and conspicuousness of these statements shall conform with sections (1), (3), and (4) of this rule.

(6) Unpackaged hazardous substances intended or in a form suitable for use in or around a household or by children shall be labeled so that all items of information required by the Act or by rules in this part shall appear upon the article itself. In instances where such labeling is impracticable because of the size or nature of the article, the required cautionary labeling must be displayed by means of a tag or other suitable material that is securely affixed to the article so that the labeling will remain attached throughout conditions of merchandising and distribution to the ultimate consumer. The size, placement, and conspicuousness of these statements shall conform with sections (1), (3), and (4) of this rule.

Stat. Auth.: ORS 453.095

Stats. Implemented: ORS 453.005 & 453.035

Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0120

Deceptive Use of Disclaimers

A hazardous substance shall not be deemed to have met the requirements of ORS 453.035(2)(a) through (i) if there appears in or on the label or in accompanying literature, words, statements, designs, or other graphic material that in any manner negates or disclaims any of the label statements required by the Act; for example, a statement on a toxic or irritant substance, such as "harmless" or "safe around pets."

Stat. Auth.: ORS 453.095

Stats. Implemented: ORS 453.035

Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0125

Condensation of Label Information

Whenever the statement of the principal hazard or hazards itself provides the precautionary measures to be followed or avoided, a clear statement of the principal hazard will satisfy both the provisions of ORS 453.035(2)(c) and (d). When the statement of precautionary measures in effect provides instruction for first-aid treatment the statement of the precautionary measures will satisfy both ORS 453.035(2)(d) and (e).

Stat. Auth.: ORS 453.095

Stats. Implemented: ORS 453.035

Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0130

Labeling Requirements for Accompanying Literature

When any accompanying literature includes or bears any directions for use (by printed word, picture, design, or combination of such methods), such placard, pamphlet, booklet, book, sign, or other graphic or visual device shall bear all the information required by ORS 453.035(2).

Stat. Auth.: ORS 453.095

Stats. Implemented: ORS 453.035

Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0135
Substances Determined to be "Special Hazards" (e.g., to children)

Whenever the Administrator determines that for a particular hazardous substance intended or packaged in a form suitable for use in the household or by children, the requirements of ORS 453.035(2) are not adequate for the protection of the public health and safety because of some special hazard, he shall issue an order by an appropriate means, which specifies such reasonable variations or additional label requirements that he finds are necessary for the protection of the public health and safety. Such order shall specify a date that is not less than 90 days after the order is published (unless emergency conditions stated in the order specify an earlier date) after which any such hazardous substance intended, or packaged in a form suitable for use in the household or by children, that fails to bear a label in accordance with such order shall be deemed as a misbranded hazardous substance.

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.035
Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0140
Substances with Multiple Hazards or Other Special Hazards

(1) Any article that presents more than one type of hazard (for example, if the article is both "toxic" and "flammable") must be labeled with an affirmative statement of each such hazard; precautionary measures describing the action to be followed or avoided for each such hazard; instructions, when necessary or appropriate, for first-aid treatment of persons suffering from the ill effects that may result from each such hazard; instructions for handling and storage of articles that require special care in handling and storage because of more than one type of hazard presented by the article, or for any other reason, as well as the common or usual name (or the chemical name if there is no common or usual name) for each hazardous component present in the article.

(2) Label information referring to the possibility of one hazard may be combined with parallel information concerning any additional hazards presented by the article, provided that the resulting condensed label statement shall contain all of the information needed for dealing with each type of hazard presented by the article.

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.035
Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0145
For the Following Substances and at the Following Concentrations, the Word "Poison" Is Necessary Instead of Any Signal Word

(1) Hydrochloric acid and any preparation containing free or chemicallyunneutralized hydrochloric acid ($HC_{1)}$ in a concentration of ten percent or more.

(2) Sulfuric acid and any preparation containing free or chemically unneutralized sulfuric acid (HSO_4) in a concentration of ten percent or more.

(3) Nitric acid or any preparation containing free or chemically unneutralized nitric acid (HNO_3) in a concentration of five percent or more.

(4) Carbolic acid (C_6H_5OH), also known as phenol, and any preparation containing carbolic acid in a concentration of five percent or more.

(5) Oxalic acid and any preparation containing free or chemically unneutralized oxalic acid ($COOH_22H_2O$) in a concentration of ten percent or more.

(6) Any salt of oxalic acid and any preparation containing any such salt in a concentration of ten percent or more.

(7) Acetic acid or any preparation containing free or chemically unneutralized acetic acid (CH_3COOH) in a concentration of 20 percent or more.

(8) Hypochlorous acid, either free or combined and any preparation containing the same in a concentration that will yield ten percent or more by weight of available chlorine.

(9) Potassium hydroxide and any preparation containing free or chemically unneutralized potassium hydroxide (KOH) including caustic potash and vienna paste (vienna caustic) in a concentration of ten percent or more.

(10) Sodium hydroxide and any preparation containing free or chemically unneutralized sodium hydroxide (NaOH) including caustic soda and lye in a concentration of ten percent or more.

(11) Silver nitrate, sometimes known as lunar caustic and any preparation containing silver nitrate ($AgNO_3$) in a concentration of five percent or more.

(12) Ammonia water and any preparation containing free or chemically uncombined ammonia (NH_3) including ammonium hydroxide and "hartshorn" in a concentration of five percent or more.

(13) Arsenic and its preparations, in concentrations that fall within the definition of toxic substance described in OAR 333-016-0005(6)(a).

(14) Corrosive sublimate (mercuric-chloride), in concentrations that fall within the definition of toxic substance described in OAR 333-016-0005(6)(a).

(15) Cyanides and preparations of cyanides, including hydrocyanic acid, in concentrations that fall within the definition toxic substance described in OAR 333-016-0005(6)(a).

(16) Strychnine ($C_2H_22N_2O_2$) in concentrations that fall within the definition of toxic substance described in OAR 333-016-0005(6)(a).

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.005 & 453.035
Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0150
Self-Pressurized Containers; Labeling

(1) Self-pressurized containers that fail to bear a warning statement adequate for the protection of the public health and safety may be misbranded under the Act, except as otherwise provided pursuant to ORS 453.035.

(2) The following warning statement will be considered as meeting the requirements of ORS 453.035 if the only hazard associated with an article is that the contents are under pressure:

"WARNING — CONTENTS UNDER PRESSURE. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120 degrees Fahrenheit. Keep out of the reach of children."

The word "**CAUTION**" may be substituted for the word "**WARNING**." A practical equivalent may be substituted for the statement "Keep out of the reach of children."

(3) That portion of the warning statement set forth in section (2) of this rule in capital letters should be printed on the main (front) panel of the container in capital letters of the type size specified in OAR 333-016-0115. The balance of the cautionary statements may appear together on another panel, provided that the front panel also bears a statement such as, "**Read carefully other cautions on _____ panel**."

(4) If an article has additional hazards, such as skin or eye irritancy, toxicity, or flammability, appropriate additional front and rear panel precautionary labeling is required.

(5) If the article contains a fluorocarbon propellant, it shall bear on its label the additional statement,

"WARNING — Use only as directed; intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal," and "contains fluorocarbons."

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.035
Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0155
Methyl Alcohol-Base Radiator Antifreeze; Labeling

(1) Methyl alcohol-base (methanol-base) radiator antifreeze distributed in containers intended or suitable for household use may be misbranded under the Act if the containers fail to bear a warning statement adequate to the protection of the public health and safety, except as otherwise provided pursuant to ORS 453.025.

(2) The following warning statement will be considered as meeting the requirements of ORS 453.005 to 453.135 with respect to methyl alcohol-base radiator antifreeze when the only hazard

foreseeable is that caused by the methyl alcohol content and when the article has a flashpoint in the "flammable" range as that term is defined in ORS 453.005:

"DANGER — POISON (Skull and Crossbones Symbol) MAY BE FATAL OR CAUSE BLINDNESS IF SWALLOWED FLAMMABLE — VAPOR HARMFUL

Contains methyl alcohol (methanol). Cannot be made nonpoisonous. Avoid contact with eyes. Use only in a well-ventilated area. Keep away from heat and open flame. Do not store in open or unlabeled containers. First-aid: In case of contact with eyes, flush thoroughly with water. If swallowed, induce vomiting (give a tablespoonful of salt in a glass of warm water). Repeat until vomit fluid is clear. Call a physician immediately. Keep out of reach of children."

(3) The words that are in capital letters in the warning statement set forth in section (2) of this rule shall be printed on the main (front) panel or panels of the container in capital letters of the type size specified in OAR 333-016-0115, except that the word "**POISON**" and the skull and crossbones symbol may appear on another panel with the balance of the cautionary information. The balance of the cautionary statements may appear together on another panel, provided the front panel bears a statement such as, "**Read carefully other cautions on _____ panel**."

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.005, 453.015, 453.025, 453.035, 453.045, 453.055, 453.065, 453.075, 453.085, 453.095, 453.105, 453.115, 453.125 & 453.135
Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0160
Ethylene Glycol-Base Radiator Antifreeze; Labeling

(1) Ethylene glycol-base radiator antifreeze distributed in containers intended or suitable for household use may be misbranded under the Act if the containers fail to bear the following warning statements which the Administrator considers necessary for the protection of the public health and safety, and which will be considered as meeting the requirements of ORS 453.005 to 453.135 with respect to ethylene glycol-base radiator antifreeze, with and without added sodium arsenite of over 0.01 percent by weight, when the only hazard foreseeable is by the ethylene glycol and (if present) the added sodium arsenite:

(a) Ethylene glycol antifreeze containing less than 0.01 percent by weight of sodium arsenite:

"WARNING — HARMFUL OR FATAL IF SWALLOWED

Do not drink antifreeze or solution. If swallowed, induce vomiting immediately. Call a physician. Ethylene glycol base. Do not store in open or unlabeled containers. Keep out of reach of children."

(b) Ethylene glycol antifreeze containing 0.01 percent but no more than one percent by weight of sodium arsenite:

"WARNING — HARMFUL OR FATAL IF SWALLOWED

"Do not drink antifreeze or solution. If swallowed, induce vomiting immediately. Call a physician. Ethylene glycol base containing sodium arsenite (less than one percent).
Antidote for sodium arsenite: Dimercaprol (BAL) to be administered only by a physician.
Do not store in open or unlabeled containers. Keep out of reach of children."

(2) The words that are in capital letters in the warning statements set forth in subsection (b) of this section shall be printed on the main (front) panel or panels of the container in capital letters of the type size specified in OAR 333-016-0115. The balance of the cautionary statements may appear together on another panel, provided the front panel bears a statement such as, "**Read carefully other cautions on _____ panel**."

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.005, 453.015, 453.025, 453.035, 453.045, 453.055, 453.065, 453.075, 453.085, 453.095, 453.105, 453.115, 453.125 & 453.135
Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0165
Extremely Flammable Contact Adhesives; Labeling

(1) Extremely flammable contact adhesives, also known as contact bonding cements, when distributed in containers intended or suitable for household use may be misbranded under the Act if the containers fail to bear a warning statement adequate for the protection of the public health and safety.

(2) The following warning statement is considered as a minimum cautionary labeling adequate to meet the requirements of ORS 453.005 to 453.135 of the Act with respect to containers of more than one-half pint of contact adhesive and similar liquid or semiliquid articles having a flashpoint at or below 20°F as determined by the method in 333-016-0035 when the only hazard foreseeable is that caused by the extreme flammability of the mixture:

"DANGER EXTREMELY FLAMMABLE VAPORS MAY CAUSE FLASH FIRE

Vapors may ignite explosively. Prevent build-up of vapors — open all windows and doors — use only with cross ventilation. Keep away from heat, sparks, and open flame. Do not smoke, extinguish all flames and pilot lights, and turn off stoves, heaters, electric motors, and other sources of ignition during use and until all vapors are gone. Close container after use.
Keep out of the reach of children."

(3) The words that are in capital letters in the warning statement set forth in section (2) of this rule shall be printed on the main (front) panel or panels of the container in capital letters of the type size specified in OAR 333-016-0115. The balance of the cautionary information may appear together on another panel, provided the front panel bears a statement such as, "**Read carefully other cautions on _____ panel**," the blank being filled in with the identification of the specific label panel bearing the balance of the cautionary labeling. It is recommended that a borderline be used in conjunction with the cautionary labeling.

(4) If an article has additional hazards, or contains ingredients listed in OAR 333-016-0065 as requiring special labeling, appropriate additional front and rear panel precautionary labeling is required.

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.005, 453.015, 453.025, 453.035, 453.045, 453.055, 453.065, 453.075, 453.085, 453.095, 453.105, 453.115, 453.125 & 453.135
Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0170
Procedural Rules

Procedure for the issuance, amendment, or repeal of rules declaring particular substances to be hazardous substances or banned hazardous substances shall be as specified in ORS Chapter 183 and the Attorney General's Model Rules of Procedure thereunder.

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.095
Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0175
Prohibited Acts and Penalties

The provisions of these rules with respect to the doing of any act shall be applicable also to the causing of such act to be done.

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.085 & 453.095
Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0180
Guaranty

In case of the giving of a guaranty or undertaking referred to in ORS 453.085(5), each person signing such guaranty or undertaking or causing it to be signed, shall be considered to have given it. Each person causing a guaranty or undertaking to be false is chargeable with violation of ORS 453.085(5).

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.085
Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0185
Examinations and Investigations; Samples

When any officer or employee of the Public Health Division collects a sample of a hazardous substance for analysis under the Act, the sample shall be designated as an official sample if records

or other evidence is obtained by him or any other officer or employee of the Public Health Division, indicating that the shipment or other lot of the article from which such sample was collected was introduced or delivered for introduction into this state or was in or was received in this state. Only samples so designated by an employee of the Public Health Division shall be considered to be official samples. All employees shall pay or offer to pay the owner, operator, or agent in charge, their cost for any such sample and give a receipt describing the sample obtained. For the purpose of determining whether or not a sample is collected for analysis, the term "analysis" includes examinations and tests. The owner of a hazardous substance of which an official sample is collected is the person who owns the shipment or other lot of the article from which the sample is collected.

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 453.105
Hist.: HD 40, f. 8-2-73, ef. 8-15-73

333-016-0190
"Administrator" Intended to Include "State Public Health Officer"

Wherever in the foregoing rules OAR 333-016-0005 through 333-016-0185 the term "Administrator" is used, it is intended to also include and shall be deemed to additionally refer to the "State Public Health Officer" as defined in ORS 431.045.

Stat. Auth.: ORS 453.095
Stats. Implemented: ORS 431.045
Hist.: HD 40, f. 8-2-73, ef. 8-15-73

List of High Priority Chemicals of Concern for Children's Health When Used In Children's Products

333-016-2000
Purpose, Scope, and Effective Date

(1) These rules establish the initial list of high priority chemicals of concern for children's health when used in children's products. The presence of a high priority chemical of concern in a children's product does not necessarily mean that the product is harmful to human health or that there is any violation of existing safety standards or laws. The information required to be reported in these rules will help fill a data gap that exists for both consumers and agencies.

(2) A manufacturer of children's products sold or offered for sale in this state must provide biennial notice to the Oregon Health Authority, of all children's products that contain a high priority chemical listed in OAR 333-016-2020.

(3) A manufacturer's first report is due no later than January 1, 2018.

Stat. Auth.: OL 2015, ch. 786, sec. 3
Stats. Implemented: OL 2015, ch. 786, sec. 3
Hist.: PH 29-2015, f. 12-29-15, cert, ef. 1-1-16

333-016-2010
Definitions

(1) "Chemical" means:

(a) A substance with a distinct molecular composition and the breakdown products of the substance that form through decomposition, degradation or metabolism.

(b) A group of structurally related substances and the breakdown products of the substances that form through decomposition, degradation or metabolism.

(2) "Children's cosmetics" means products that are intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, moisturizing, beautifying, promoting attractiveness or altering the appearance. "Children's cosmetics" does not mean soap, dietary supplements or food and drugs approved by the United States Food and Drug Administration.

(3)(a) "Children's product" means:

(A) Any of the following products that are made for, marketed for use by or marketed to children under 12 years of age:

(i) A product designed or intended by the manufacturer to facilitate sucking, teething, sleep, relaxation, feeding or drinking.

(ii) Children's clothing and footwear.

(iii) Car seats.

(iv) Children's cosmetics.

(v) Children's jewelry.

(vi) Toys.

(B) Any component part of a product specified in paragraph (A) of this subsection.

(b) "Children's product" does not mean:

(A) Athletic shoes with cleats or spikes.

(B) Batteries.

(C) BB guns, pellet guns and air rifles.

(D) Bicycles and tricycles.

(E) Chemistry sets.

(F) Consumer electronic products, including personal computers, audio and video equipment, calculators, wireless telephones and game consoles, handheld devices that incorporate a video screen and are used to access interactive software, and the associated peripherals.

(G) Interactive software intended for leisure and entertainment, such as computer games, and their storage media, such as compact discs.

(H) Model rockets.

(I) Pocketknives and multitools.

(J) Roller skates.

(K) Scooters.

(L) Sets of darts with metallic points.

(M) Slings and catapults.

(N) Snow sporting equipment, including skis, poles, boots, snowboards, sleds and bindings.

(O) Sporting equipment and accessories, including but not limited to bats, balls, gloves, sticks, pucks, pads, helmets and other protective equipment, weight training and exercise aids, protective eyewear, backpacks and tents, raingear, sport bags and luggage, and golf equipment.

(P) Video toys that can be connected to a video screen and are operated at a nominal voltage exceeding 24 volts.

(Q) Food and beverages and food and beverage packaging regulated by the United States Food and Drug Administration or the United States Department of Agriculture.

(4) "These rules" mean OAR 333-016-2000 through 333-016-2030.

Stat. Auth.: OL 2015, ch. 786, sec. 3
Stats. Implemented: OL 2015, ch. 786, sec. 3
Hist.: PH 29-2015, f. 12-29-15, cert, ef. 1-1-16

333-016-2020
Chemicals of High Concern to Children

The following chemicals are designated as high priority chemicals of concern for children's health when used in children's products:

(1) Formaldehyde (50-00-0).
(2) Aniline (62-53-3).
(3) N-Nitrosodimethylamine (62-75-9).
(4) Benzene (71-43-2).
(5) Vinyl chloride (75-01-4).
(6) Acetaldehyde (75-07-0).
(7) Methylene chloride (75-09-2).
(8) Carbon disulfide (75-15-0).
(9) Methyl ethyl ketone (78-93-3).
(10) 1,1,2,2-Tetrachloroethane (79-34-5).
(11) Tetrabromobisphenol A (79-94-7).
(12) Bisphenol A (80-05-7).
(13) Diethyl phthalate (84-66-2).
(14) Dibutyl phthalate (84-74-2).
(15) Di-n-hexyl phthalate (84-75-3).
(16) Phthalic anhydride (85-44-9).
(17) Butyl benzyl phthalate (BBP) (85-68-7).
(18) N-Nitrosodiphenylamine (86-30-6).
(19) Hexachlorobutadiene (87-68-3).
(20) Propyl paraben (94-13-3).
(21) Butyl paraben (94-26-8).
(22) 2-Aminotoluene (95-53-4).

(23) 2,4-Diaminotoluene (95-80-7).
(24) Methyl paraben (99-76-3).
(25) p-Hydroxybenzoic acid (99-96-7).
(26) Ethylbenzene (100-41-4).
(27) Styrene (100-42-5).
(28) 4-Nonylphenol (104-40-5); 4-NP and its isomer mixtures including CAS 84852-15-3 and CAS 25154-52-3.
(29) para-Chloroaniline (106-47-8).
(30) Acrylonitrile (107-13-1).
(31) Ethylene glycol (107-21-1).
(32) Toluene (108-88-3).
(33) Phenol (108-95-2).
(34) 2-Methoxyethanol (109-86-4).
(35) Ethylene glycol monoethyl ester (110-80-5).
(36) Tris(2-chloroethyl) phosphate (115-96-8).
(37) Di-2-ethylhexyl phthalate (117-81-7).
(38) Di-n-octyl phthalate (DnOP) (117-84-0).
(39) Hexachlorobenzene (118-74-1).
(40) 3,3'-Dimethylbenzidine and Dyes Metabolized to 3,3'-Dimethylbenzidine (119-93-7).
(41) Ethyl paraben (120-47-8).
(42) 1,4-Dioxane (123-91-1).
(43) Perchloroethylene (127-18-4).
(44) Benzophenone-2 (Bp-2); 2,2',4,4'-Tetrahydroxybenzophenone (131-55-5).
(45) 4-tert-Octylphenol; 4(1,1,3,3-Tetramethylbutyl) phenol (140-66-9).
(46) Estragole (140-67-0).
(47) 2-Ethylhexanoic acid (149-57-5).
(48) Octamethylcyclotetrasiloxane (556-67-2).
(49) Benzene, Pentachloro (608-93-5).
(50) C.I. Solvent yellow 14 (842-07-9).
(51) N-Methylpyrrolidone (872-50-4).
(52) 2,2',3,3',4,4',5,5',6,6'-Decabromodiphenyl ether; BDE-209 (1163-19-5).
(53) Perfluorooctanyl sulphonic acid and its salts; PFOS (1763-23-1).
(54) Phenol, 4-octyl (1806-26-4).
(55) 2-Ethyl-hexyl-4-methoxycinnamate (5466-77-3).
(56) Mercury (7439-97-6) and mercury compounds including methyl mercury (22967-92-6).
(57) Molybdenum and molybdenum compounds (7439-98-7).
(58) Antimony and Antimony compounds (7440-36-0).
(59) Arsenic and Arsenic compounds (7440-38-2), including arsenic trioxide (1327-53-3) and dimethyl arsenic (75-60-5).
(60) Cadmium and cadmium compounds (7440-43-9).
(61) Cobalt and cobalt compounds (7440-48-4).
(62) Tris(1,3-dichloro-2-propyl)phosphate (13674-87-8).
(63) Butylated hydroxyanisole; BHA (25013-16-5).
(64) Hexabromocyclododecane (25637-99-4).
(65) Diisodecyl phthalate (DIDP) (26761-40-0).
(66) Diisononyl phthalate (DINP) (28553-12-0).
Stat. Auth.: OL 2015, ch. 786, sec. 3
Stats. Implemented: OL 2015, ch. 786, sec. 3
Hist.: PH 29-2015, f. 12-29-15, cert, ef. 1-1-16

333-016-2030
Modifications to the List of High Priority Chemicals of Concern for Children's Health

(1) The Oregon Health Authority shall consider adding a chemical to the list of high priority chemicals of concern for children's health in OAR 333-016-2020 if that the chemical, on or after the effective date of these rules:
(a) Has been added to any of the following:
(A) Washington's list of Chemicals of High Concern to Children (WAC 173-334-130);
(B) Maine's list of Chemicals of High Concern (Maine law 38 § 1693-A(2));
(C) Minnesota's list of Chemicals of High Concern (Minn. Stat. 2010 116.9401 – 116.9407);
(D) Vermont's list of Chemicals of high concern to children (18 V.S.A. chapter 38A § 1773);
(b) Is currently or subsequently identified by the United States Environmental Protection Agency (USEPA) as being "carcinogenic to humans", or "likely to be carcinogenic to humans" through USEPA's Integrated Risk Information System;
(c) Has been or is subsequently found to have a reference dose or reference concentration based on neurotoxicity through USEPA's Integrated Risk Information System;
(d) Is currently or subsequently identified in monographs on the Potential Human Reproductive and Developmental Effects, United States Office of Health and Human Services National Toxicology Program, Office of Health Assessment and Translation as a reproductive or developmental toxicant; or
(e) Is currently or subsequently identified by the Centers for Disease Control and Prevention in its National Report on Human Exposure to Environmental Chemicals.
(2) The Authority shall also consider adding a chemical to the list of high priority chemicals of concern for children's health in OAR 333-016-2020 if that the chemical, on or after the effective date of these rules:
(a) Is found to have the potential, as demonstrated by credible, peer-reviewed scientific evidence to:
(A) Harm the normal development of a fetus or child or cause other developmental toxicity;
(B) Act as a carcinogen;
(C) Cause genetic damage or reproductive harm;
(D) Disrupt the endocrine system;
(E) Damage the nervous system, immune system or organs;
(F) Cause other systemic toxicity;
(G) Be a very persistent toxic substance by having a half-life greater than or equal to one of the following:
(i) A half-life in soil or sediment of greater than one hundred eighty days.
(ii) A half-life greater than or equal to sixty days in water or evidence of long-range transport; or
(H) Be a very bioaccumulative toxic substance by having a bioconcentration factor or bioaccumulation factor greater than or equal to five thousand, or if neither are available, having a log Kow greater than 5.0; and
(b) Has been found through:
(A) Biomonitoring to be present in human blood, umbilical cord blood, breast milk, urine or other bodily tissues or fluids;
(B) Sampling and analysis to be present in household dust, indoor air, drinking water or elsewhere in the home environment; or
(C) Monitoring to be present in fish, wildlife or the natural environment.
(3) The Oregon Health Authority may remove a chemical from the list if the Authority determines that:
(a) The chemical is no longer being used in children's products; or
(b) The chemical has been removed from any of the lists identified in subsection (1)(a) through (e) of this rule.
(4) The list of high priority chemicals of concern for children's health in OAR 333-016-2020 may only be modified by following the Administrative Procedures Act rulemaking process.
Stat. Auth.: OL 2015, ch. 786, sec. 3
Stats. Implemented: OL 2015, ch. 786, sec. 3
Hist.: PH 29-2015, f. 12-29-15, cert, ef. 1-1-16

DIVISION 17

DISEASE CONTROL (DEFINITIONS AND REFERENCES)

333-017-0000
Definitions

For purposes of OAR chapter 333, divisions 17, 18 and 19, unless the context requires otherwise or a rule contains a more specific definition, the following definitions shall apply.
(1) "AIDS": AIDS is an acronym for acquired immunodeficiency syndrome. An individual is considered to have AIDS when their illness meets criteria published in Morbidity and Mortality

Weekly Report, Volume 41, Number RR-17, pages 1–4, December 18, 1992.

(2) "Animal Suspected of Having Rabies": An animal is suspected of having rabies when:

(a) It is a dog, cat, or ferret not known to be satisfactorily vaccinated against rabies (as defined in OAR 333-019-0017), or it is any other mammal; and

(b) It exhibits one or more of the following aberrant behaviors or clinical signs: unprovoked biting of persons or other animals, paralysis or partial paralysis of limbs, marked excitation, muscle spasms, difficulty swallowing, apprehensiveness, delirium, or convulsions; and it has no other diagnosed illness that could explain the neurological signs.

(3) "Approved Fecal Specimen" means a specimen of feces from a person who has not taken any antibiotic orally or parenterally for at least 48 hours prior to the collection of the specimen. Improper storage or transportation of a specimen, or inadequate growth of the culture suggestive of recent antibiotic usage can, at the discretion of public health microbiologists, result in specimen rejection.

(4) "Authority" means the Oregon Health Authority.

(5) "Bite, Biting, Bitten": The words bite, biting, and bitten refer to breaking of the skin by the teeth of an animal, or mouthing a fresh abrasion of the skin by an animal.

(6) "Case" means a person who has been diagnosed by a health care provider as having a particular disease, infection, or condition, or whose illness meets defining criteria published in the Authority's Investigative Guidelines.

(7) "Children's facility" means:

(a) A certified child care facility as described in ORS 329A.030 and 329A.250 to 329A.450, except an "exempted children's facility" as defined in OAR 333-050-0010;

(b) A program operated by, or sharing the premises with, a certified child care facility, school or post-secondary institution where care is provided to children, six weeks of age to kindergarten entry, except an "exempted children's facility" as defined in OAR 333-050-0010; or

(c) A program providing child care or educational services to children, six weeks of age to kindergarten entry, in a residential or nonresidential setting, except an "exempted children's facility" as defined in OAR 333-050-0010.

(8) "Control" has the meaning given that term in ORS 433.001.

(9) "Disease outbreak" has the meaning given that term in ORS 431A.005.

(10) "Enterobacteriaceae family" means the family of bacteria that includes but is not limited to the following genera and taxonomic groups:

(a) Budvicia;
(b) Buttiauxella;
(c) Cedecea;
(d) Citrobacter;
(e) Edwardsiella;
(f) Enteric Group 58;
(g) Enteric Group 59;
(h) Enteric Group 60;
(i) Enteric Group 63;
(j) Enteric Group 64;
(k) Enteric Group 68;
(l) Enteric Group 69;
(m) Enteric Group 137;
(n) Enterobacter;
(o) Escherichia;
(p) Ewingella;
(q) Hafnia;
(r) Klebsiella;
(s) Kluyvera;
(t) Leclercia;
(u) Leminorella;
(v) Moellerella;
(w) Morganella;
(x) Obesumbacterium;
(y) Pantoea;
(z) Photorhabdus;
(aa) Plesiomonas;
(bb) Pragia;
(cc) Proteus;
(dd) Providencia;
(ee) Rahnella;
(ff) Salmonella;
(gg) Serratia;
(hh) Shigella;
(ii) Tatumella;
(jj) Trabulsiella;
(kk) Xenorhabdus;
(ll) Yersinia;
(mm) Yokenella.

(11) "Food Handler" means any business owner or employee who handles food utensils or who prepares, processes, handles or serves food for people other than members of their immediate household, for example restaurant, delicatessen, and cafeteria workers, caterers, and concession stand operators.

(12) "Food Service Facility" means an establishment that processes or serves food for sale.

(13) "Health Care Facility" has the meaning given that term in ORS 442.015.

(14) "Health Care Provider" has the meaning given that term in ORS 433.443.

(15) "HIV" means the human immunodeficiency virus, the causative agent of AIDS.

(16) "HIV Test" means a Food and Drug Administration (FDA)-approved test for the presence of HIV (including RNA testing), or for antibodies or antigens that result from HIV infection, or for any other substance specifically associated with HIV infection and not with other diseases or conditions.

(17) "HIV Positive Test" means a positive result on the most definitive HIV test procedure used to test a particular individual. In the absence of the recommended confirmation tests, this means the results of the initial test done.

(18) "Lead Poisoning" means:

(a) A confirmed blood lead level of at least 5 micrograms per deciliter for children under 18 years of age; or

(b) A confirmed blood lead level of at least 10 micrograms per deciliter for people 18 years of age and older.

(19) "Licensed Laboratory" means a medical diagnostic laboratory that is inspected and licensed by the Authority or otherwise licensed according to the provisions of the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. § 263a). Any laboratory operated by the U.S. Centers for Disease Control and Prevention shall also be considered a Licensed Laboratory.

(20) "Licensed Physician" means any physician who is licensed by the Oregon Medical Board or the Board of Naturopathic Medicine.

(21) "Licensed Veterinarian" means a veterinarian licensed by the Oregon Veterinary Medical Examining Board.

(22) "Local Public Health Administrator" has the meaning given that term in ORS 431.260.

(23) "Local Public Health Authority" has the meaning given that term in ORS 431.260.

(24) "Non-Susceptible to any Carbapenem Antibiotic" means the finding of any of the following:

(a) Gene sequence specific for carbapenemase;

(b) Phenotypic test (for example, Carba NP) positive for production of carbapenemase; or

(c) Resistance to any carbapenem antibiotic with elevated minimum inhibitory concentration (MIC):

(A) MIC for imipenem greater than or equal to 4 mcg/ml; or

(B) MIC for meropenem greater than or equal to 4 mcg/ml; or

(C) MIC for ertapenem greater than or equal to 2 mcg/ml.

(25) "Novel Influenza" means influenza A virus that cannot be subtyped by commercially distributed assays.

(26) "Onset": Unless otherwise qualified, onset refers to the earliest time of appearance of signs or symptoms of an illness.

(27) "Pesticide Poisoning" means illness in a human that is caused by acute or chronic exposure to:

(a) Any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest; or

(b) Any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant as defined in ORS 634.006.

(28) "Public Health Division (Division)" means the Public Health Division within the Oregon Health Authority.

(29) "School" means a public, private, parochial, charter or alternative educational program offering kindergarten through grade 12 or any part thereof.

(30) "School Administrator" means the principal or other person having general control and supervision of a school or children's facility and has the same meaning as "administrator" in ORS 433.235.

(31) "Specimen Source Site" means the source from which the specimen was obtained.

(a) For environmental samples, "specimen source site" means the location of the source of the specimen.

(b) For biological samples, "specimen source site" means the anatomical site from which the specimen was collected.

(32) "Specimen Type" means the description of the source material of the specimen.

(33) "Suspected Case" means a person whose illness is thought by a health care provider to have a significant likelihood of being due to a reportable disease, infection, or condition, based on facts such as but not limited to the patient's signs and symptoms, possible exposure to a reportable disease, laboratory findings, or the presence or absence of an alternate explanation for the illness.

(34) "Uncommon Illness of Potential Public Health Significance": These illnesses include:

(a) Any infectious disease with potentially life-threatening consequences that is exotic to or uncommon in Oregon, for example, variola (smallpox) or viral hemorrhagic disease;

(b) Any illness related to a contaminated medical device or product; or

(c) Any acute illness suspected to be related to environmental exposure to any infectious or toxic agent or to any household product.

(35) "Veterinary Laboratory" means a laboratory whose primary function is handling and testing diagnostic specimens of animal origin.

[Publications: Publications referenced are available from the Agency.]
Stat. Auth.: ORS 413.042, 433.004, 437.010, 616.745 & 624.080
Stats. Implemented: ORS 433.004, 433.360, 437.030, 616.745 & 624.380
Hist.: HD 15-1981, f. 8-13-81, ef. 8-15-81; HD 12-1983, f. & ef. 8-1-83; HD 4-1987, f. 6-12-87, ef. 6-19-87; HD 13-1990(Temp), f. 3-25-90, cert. ef. 8-1-90; HD 5-1991, f. 5-29-91, cert. ef. 4-1-91; HD 10-1991, f. & cert. ef. 7-23-91; HD 9-1992, f. & cert. ef. 8-14-92; HD 29-1994, f. & cert. ef. 12-2-94; OHD 2-2002, f. & cert. ef. 3-4-02; PH 11-2005, f. 6-30-05, cert. ef. 7-5-05; PH 5-2010, f. & cert. ef. 3-11-10; PH 7-2011, f. & cert. ef. 8-19-11; PH 16-2013, f. 12-26-13, cert. ef. 1-1-14; PH 10-2015, f. 7-2-15, cert. ef. 7-3-15; PH 24-2016, f. 8-8-16, cert. ef. 8-16-16

333-017-0005
Reference Documents

The following publication, which is available for inspection at the Public Health Division, is incorporated by reference in whole or in part in OAR chapter 333, divisions 12, 17, 18, and 19: "*Investigative Guidelines*": Investigative Guidelines for Reportable Diseases, published on an ongoing basis by the Division's Center for Public Health Practice.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 413.042, 433.004, 437.010, 616.745 & 624.080
Stats. Implemented: ORS 413.042, 433.004, 437.010, 616.745 & 624.080
Hist.: HD 15-1981, f. 8-13-81, ef. 8-15-81; HD 4-1987, f. 6-12-87, ef. 6-19-87; HD 9-1992, f. & cert. ef. 8-14-92; HD 29-1994, f. & cert. ef. 12-2-94; OHD 2-2002, f. & cert. ef. 3-4-02; PH 5-2010, f. & cert. ef. 3-11-10; PH 7-2011, f. & cert. ef. 8-19-11

DIVISION 18

DISEASE REPORTING

333-018-0000
Who Is Responsible for Reporting

(1) Each health care provider knowing of or attending a human case or suspected human case of any of the diseases, infections, or conditions listed in OAR 333-018-0015 shall report such cases as specified. Where no health care provider is in attendance, any individual knowing of such a case shall report in a similar manner. An individual required to report reportable diseases who is unsure whether a case meets the definition of a suspect case as that is defined in OAR 333-017-0000 should err on the side of reporting if the suspected disease, infection, or condition is one that:

(a) Is required to be reported immediately or within 24 hours under OAR 333-018-0015;

(b) Is highly transmissible; or

(c) Results in serious or severe health consequences.

(2) Each health care facility, where more than one health care provider may know or attend a human case or suspected human case, may establish administrative procedures to ensure that every case is reported.

(3) Each licensed laboratory shall report human test results as specified in OAR 333-018-0015(5). When more than one licensed laboratory is involved in testing a specimen, the laboratory that is responsible for reporting the test result directly to the health care provider that ordered the test shall be responsible for reporting.

(4) Each veterinary laboratory or licensed laboratory shall report animal test results as specified in OAR 333-018-0017. When more than one laboratory is involved in testing a specimen, the laboratory that is responsible for reporting the test result directly to the licensed veterinarian or client of record caring for the animal shall be responsible for reporting.

Stat. Auth.: ORS 413.042, 433.004 & 437.010
Stats. Implemented: ORS 433.004 & 437.030
Hist.: HD 15-1981, f. 8-13-81, ef. 8-15-81; HD 4-1987, f. 6-12-87, ef. 6-19-87; HD 29-1994, f. & cert. ef. 12-2-94; OHD 3-2002, f. & cert. ef. 3-4-02; PH 5-2010, f. & cert. ef. 3-11-10; PH 7-2011, f. & cert. ef. 8-19-11

333-018-0005
To Whom Reports Shall Be Made

(1) In general, if the patient is an Oregon resident, reports shall be made to the local public health administrator for the patient's place of residence.

(2) In lieu of reporting to the local public health administrator, with the consent of the local public health administrator and the Authority, reports may be made directly to the Authority (for example, via electronic reporting).

(3) In urgent situations when local public health staff are unavailable, case reports shall be made directly to the Authority.

(4) Where the case is not an Oregon resident, reports shall be made either to the patient's local public health authority (if the patient resides in the United States) or directly to the Authority.

(5) In lieu of reporting to the local public health administrator, with the consent of the local public health administrator, licensed laboratories shall report directly to the Authority's HIV Program:

(a) All tests indicative of and specific for HIV infection as required by OAR 333-018-0015;

(b) All CD4+ T-lymphocyte counts; and

(c) All HIV viral load tests.

Stat. Auth.: ORS 431.110, 433.001, 433.004, 433.006
Stats. Implemented: ORS 431.110, 433.001, 433.004, 433.006, 433.106
Hist.: HD 15-1981, f. 8-13-81, ef. 8-15-81; HD 20-1985(Temp), f. & ef. 9-30-85; HD 4-1987, f. 6-12-87, ef. 6-19-87; HD 15-1988, f. 7-11-88, cert. ef. 9-1-88; HD 13-1990(Temp), f. 5-25-90, cert. ef. 8-1-90; HD 5-1991, f. 3-29-91, cert. ef. 4-1-91; HD 10-1991, f. & cert. ef. 7-23-91; HD 29-1994, f. & cert. ef. 12-2-94; OHD 22-2001, f. & cert. ef. 10-19-01; OHD 3-2002, f. & cert. ef. 3-4-02; PH 11-2005, f. 6-30-05, cert. ef. 7-5-05; PH 1-2007, f. & cert. ef. 1-16-07; PH 7-2011, f. & cert. ef. 8-19-11; PH 16-2013, f. 12-26-13, cert. ef. 1-1-14

333-018-0010
Form of the Report

(1) A health care provider required to report reportable diseases under ORS 433.004 and these rules shall submit to the local public health administrator a report that includes but is not limited to:

(a) The identity, address, and telephone number of the person reporting;

(b) The identity, address, and telephone number of the attending health care provider, or other treating health care provider if any;

(c) The name of the person affected or ill, that person's current address, telephone number, and date of birth;

(d) The diagnosed or suspected disease, infection, or condition; and

(e) The date of illness onset.

(2) A licensed laboratory required to report reportable diseases under ORS 433.004 and these rules shall submit to the local public health administrator a report that includes but is not limited to:

(a) The name and telephone number of the reporting laboratory;

(b) The name, gender, age or date of birth, the address and county of residence of the person from whom the laboratory specimen was obtained, if known;

(c) The date the specimen was obtained;

(d) The specimen source site and the specimen type; for example, the specimen source site | specimen type pairings could be (knee | fluid, synovial) (cervix | tissue), (venous | blood).

(e) The name, address and telephone number of the health care provider of the person from whom the laboratory specimen was obtained;

(f) The name or description of the test;

(g) The test result; and

(h) Information required by the Authority's Manual for Mandatory Electronic Laboratory Reporting, if electronic reporting is required under OAR 333-018-0013.

(3) Reportable disease reports shall be made in the following manner:

(a) Reports for diseases or suspected diseases that are immediately reportable under OAR 333-018-0015 shall be submitted orally, by telephone, with a follow-up written report via facsimile.

(b) Reports for diseases or suspected diseases that are required to be reported within one to seven days under OAR 333-018-0013 shall be submitted in writing via facsimile or by other means approved by the local public health administrator, consistent with the need for timely reporting as provided in OAR 333-018-0015.

(c) Electronically, if required by OAR 333-018-0013.

(4) If requested by a local public health administrator or the Oregon Public Health Division, health care providers and licensed laboratories shall provide additional information of relevance to the investigation or control of reportable diseases or conditions (for example, reported signs and symptoms, laboratory test results (including negative results), potential exposures, contacts, and clinical outcomes).

Stat. Auth.: ORS 413.042 & 433.004
Stats. Implemented: ORS 433.004
Hist.: HD 15-1981, f. 8-13-81, ef. 8-15-81; HD 4-1987, f. 6-12-87, ef. 6-19-87; HD 13-1990(Temp), f. 5-25-90, cert. ef. 8-1-90; HD 5-1991, f. 3-29-91, cert. ef. 4-1-91; HD 10-1991, f. & cert. ef. 7-23-91; HD 29-1994, f. & cert. ef. 12-2-94; OHD 3-2002, f. & cert. ef. 3-4-02; PH 11-2005, f. 6-30-05, cert. ef. 7-5-05; PH 5-2010, f. & cert. ef. 3-11-10; PH 7-2011, f. & cert. ef. 8-19-11; PH 16-2013, f. 12-26-13, cert. ef. 1-1-14; PH 10-2015, f. 7-2-15, cert. ef. 7-3-15

333-018-0013
Electronic Laboratory Reporting

(1) A licensed laboratory that, pursuant to ORS 433.004 and OAR chapter 333, division 18, sends an average of greater than 30 records per month to the local public health administrator shall electronically send all reportable disease data to the Authority in accordance with the standards set forth in the Authority's Manual for Mandatory Electronic Laboratory Reporting, dated February 2009, and incorporated by reference.

(2) Prior to reporting data electronically, a licensed laboratory shall seek and obtain approval from the Authority for its electronic reporting, in accordance with the Authority's Manual for Mandatory Electronic Laboratory Reporting.

(3) A licensed laboratory that fails to seek approval from the Authority for electronic reporting or fails to obtain approval within one year from seeking approval from the Authority may be subject to civil penalties in accordance OAR 333-026-0030.

(4) A licensed laboratory that is required to report data electronically shall have a state-approved continuity of operations plan for reporting continuity in the event of emergency situations disrupting electronic communications. At least two alternative methodologies should be incorporated, such as facsimile, mail, or courier service.

(5) A licensed laboratory required to report data electronically shall participate fully in Oregon's Data Quality Control program, as specified in the Authority's Manual for Mandatory Electronic Laboratory Reporting.

(6) Electronic reports shall meet the reporting timelines in OAR chapter 333, division 18.

Stat. Auth.: ORS 413.042 & 433.004
Stats. Implemented: ORS 433.004
Hist.: PH 5-2010, f. & cert. ef. 3-11-10; PH 7-2011, f. & cert. ef. 8-19-11

333-018-0015
What Is to Be Reported and When

(1) Health care providers shall report all human cases or suspected human cases of the diseases, infections, microorganisms, and conditions specified below. The timing of health care provider reports is specified to reflect the severity of the illness or condition and the potential value of rapid intervention by public health agencies.

(2) When local public health administrators cannot be reached within the specified time limits, reports shall be made directly to the Authority, which shall maintain an around-the-clock public health consultation service.

(3) Licensed laboratories shall report all test results indicative of and specific for the diseases, infections, microorganisms, and conditions specified below for humans. Such tests include but are not limited to: microbiological culture, isolation, or identification; assays for specific antibodies; and identification of specific antigens, toxins, or nucleic acid sequences.

(4) Human reportable diseases, infections, microorganisms, intoxications, and conditions, and the time frames within which they must be reported are as follows:

(a) Immediately, day or night:

(A) Select biological agents and toxins: Avian influenza virus; Bacillus anthracis (anthrax); Botulinum neurotoxins; Botulinum neurotoxin-producing species of Clostridium; Brucella (brucellosis); Burkholderia mallei (glanders); Burkholderia pseudomallei (melioidosis); Conotoxins; Clostridium botulinum (botulism); Coxiella burnetii (Q fever); Crimean-Congo hemorrhagic fever virus; Diacetoxyscirpenol; Eastern Equine Encephalitis virus; Ebola virus; Francisella tularensis (tularemia); Hendra virus; Lassa fever virus; Lujo virus; Marburg virus; Monkeypox virus; Newcastle disease virus; Nipah virus; Reconstructed replication-competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus); Ruminants virus, Ricin; Rickettsia prowazekii (louse-borne typhus); Rift Valley fever virus; Severe Acute Respiratory Syndrome (SARS) and infection by SARS coronavirus; Saxitoxin (paralytic shellfish poisoning); South American Hemorrhagic Fever viruses (Chapare, Guanarito, Junin, Machupo, Sabia); Staphylococcal enterotoxins A,B,C,D,E subtypes; T-2 toxin; Tetrodotoxin (puffer fish poisoning); Tick-borne encephalitis complex (flavi) viruses (Far Eastern subtype, Siberian subtype); Kyasanur Forest disease virus; Omsk hemorrhagic fever virus, Variola major (Smallpox virus); Variola minor virus (Alastrim);

(B) The following other infections, microorganisms, and conditions: Corynebacterium diphtheriae (diphtheria); novel influenza; poliomyelitis; rabies (human); measles (rubeola); rubella; Vibrio cholerae O1, O139, or toxigenic (cholera); yellow fever; intoxication caused by marine microorganisms or their byproducts (for example, domoic acid intoxication, ciguatera, scombroid);

(C) Any known or suspected disease outbreak, including any outbreak associated with health care, regardless of whether the disease, infection, microorganism, or condition is specified in this rule; and

(D) Any uncommon illness of potential public health significance.

(b) Within 24 hours (including weekends and holidays): Haemophilus influenzae (any invasive disease; for laboratories, any isolation or identification from a normally sterile site); Neisseria meningitidis (any invasive disease; for laboratories, any isolation or identification from a normally sterile site); and pesticide poisoning.

(c) Within one local public health authority working day: amebic infection of the central nervous system (for example, by Naegleria or Balamuthia), Bordetella pertussis (pertussis); Borrelia (relapsing fever, Lyme disease); cadmium demonstrated by laboratory testing of urine; Campylobacter (campylobacteriosis); Chlamydophila (Chlamydia) psittaci (psittacosis); Chlamydia trachomatis (chlamydiosis; lymphogranuloma venereum); Clostridium tetani (tetanus); Coccidioides (coccidioidomycosis), Creutzfeldt-Jakob disease and other transmissible spongiform encephalopathies; Cryptococcus (cryptococcosis), Cryptosporidium (cryptosporidiosis); Cyclospora cayetanensis (cyclosporosis); bacteria of the Enterobacteriaceae family found to be resistant to any carbapenem antibiotic ; Escherichia coli (Shiga-toxigenic, including E. coli O157 and other serogroups); Giardia (giardiasis); Grimontia; Haemophilus ducreyi (chancroid); hantavirus; hepatitis A; hepatitis B (acute or chronic infection); hepatitis C; hepatitis D (delta); hepatitis E; HIV infection (does not apply to anonymous testing) and AIDS; death of a person <18 years of age with laboratory-confirmed influenza; lead poisoning; Legionella (legionellosis); Leptospira (leptospirosis); Listeria monocytogenes (listeriosis); mumps; Mycobacterium tuberculosis and M. bovis (tuberculosis); nonrespiratory infection with nontuberculous mycobacteria; Neisseria gonorrhoeae (gonococcal infections); Plasmodium (malaria); Rickettsia (other than prowazekii: Rocky Mountain spotted fever, typhus, others); Salmonella (salmonellosis, including typhoid); Shigella (shigellosis); Taenia solium (including cysticercosis and undifferentiated Taenia infections); Treponema pallidum (syphilis); Trichinella (trichinosis); Vibrio (other than Vibrio cholerae O1, O139, or toxigenic; vibriosis); Yersinia (other than pestis; yersiniosis); any infection that is typically arthropod vector-borne (for example: babesiosis, California encephalitis, Colorado tick fever, dengue, Eastern equine encephalitis, ehrlichiosis, Heartland virus infection, St. Louis encephalitis, West Nile fever, Western equine encephalitis, Zika, etc.); a human bitten by any other mammal; and hemolytic uremic syndrome.

(d) Within seven days: Any blood lead level tests including the result.

(5) Licensed laboratories shall report, within seven days, the results of all tests of CD4+ T-lymphocyte absolute counts and the percent of total lymphocytes that are CD4 positive, and HIV nucleic acid (viral load) tests.

Stat. Auth.: ORS 413.042, 433.004 & 433.006
Stats. Implemented: ORS 433.004 & 437.010
Hist.: HD 15-1981, f. 8-13-81, ef. 8-15-81; HD 20-1985(Temp), f. & ef. 9-30-85; HD 4-1987, f. 6-12-87, ef. 6-19-87; HD 15-1988, f. 7-11-88, cert. ef. 9-1-88; HD 13-1990(Temp), f. 5-25-90, cert. ef. 8-1-90; HD 5-1991, f. 3-29-91, cert. ef. 4-1-91; HD 10-1991, f. & cert. ef. 7-23-91; HD 9-1992, f. & cert. ef. 8-14-92; HD 29-1994, f. & cert. ef. 12-2-94; OHD 22-2001, f. & cert. ef. 10-19-01; OHD 3-2002, f. & cert. ef. 3-4-02; PH 11-2005, f. 6-30-05, cert. ef. 7-5-05; PH 7-2006, f. & cert. ef. 4-17-06; PH 13-2006(Temp), f. 6-27-06, cert. ef. 7-1-06 thru 12-27-06; PH 19-2006, f. & cert. ef. 9-13-06; PH 11-2007(Temp), f. & cert. ef. 8-22-07 thru 2-18-08; PH 13-2007, f. & cert. ef. 11-7-07; PH 8-2009(Temp), f. & cert. ef. 9-1-09 thru 2-26-10; PH 5-2010, f. & cert. ef. 3-11-10; PH 7-2011, f. & cert. ef. 8-19-11; PH 16-2013, f. 12-26-13, cert. ef. 1-1-14; PH 10-2015, f. 7-2-15, cert. ef. 7-3-15; PH 6-2016(Temp), f. & cert. ef. 2-18-16 thru 8-15-16; PH 24-2016, f. 8-8-16, cert. ef. 8-16-16

333-018-0017
Reporting of Veterinary Diseases

(1) Laboratories shall report to the Oregon Public Health Division all test results indicative of and specific for the following diseases, infections, microorganisms, and conditions, within the following time frames, as follows:

(a) Immediately, day or night: anthrax, rabies, and plague;

(b) Within one day: psittacosis, leptospirosis, Q fever, and tularemia; and

(c) Within one week: *Baylisascaris*, *Borrelia burgdorferii*, *campylobacteriosis*, *Cryptococcus*, *Cryptosporidium*, *Escherichia* coli O157:H7, giardiasis, lymphocytic choriomeningitis, methicillin-resistant *Staphylococcus aureus*, Rocky Mountain spotted fever, salmonellosis, toxoplasmosis, West Nile virus, yersiniosis; and any other disease that could potentially be a zoonotic illness.

(2) "Test" as used in this rule, includes but is not limited to:

(a) Microbiological culture, isolation, or identification;

(b) Assays for specific antibodies; and

(c) Identification of specific antigens, toxins, or nucleic acid sequences.

Stat. Auth.: ORS 413.042 & 433.004
Stats. Implemented: ORS 433.004
Hist.: PH 5-2010, f. & cert. ef. 3-11-10

333-018-0018
Submission of Organisms or Specimens to the Public Health Laboratory

Licensed laboratories are required to forward aliquots, specimens or cultures of the following organisms to the Oregon State Public Health Laboratory:

(1) Select biological agents and toxins: Avian influenza virus; Bacillus anthracis; Botulinum neurotoxins; Botulinum neurotoxin producing species of Clostridium; Brucella abortus; Brucella melitensis; Brucella suis; Burkholderia mallei; Burkholderia pseudomallei; Conotoxin; Coxiella burnetii; Crimean-Congo hemorrhagic fever virus; Diacetoxyscirpenol; Eastern Equine Encephalitis virus; Ebola virus; Francisella tularensis; Hendra virus; Lassa fever virus; Lujo virus; Marburg virus; Monkeypox virus; Newcastle disease virus; Nipah virus; Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus); Ruminants virus; Ricin; Rickettsia prowazekii; Rift Valley fever virus; SARS-associated coronavirus (SARS-CoV), Saxitoxin; Sheep pox virus; South American Hemorrhagic Fever viruses (Chapare, Guanarito, Junin, Machupo, Sabia); Staphylococcal enterotoxins A,B,C,D,E subtypes; T-2 toxin, Tetrodotoxin; Tick-borne encephalitis complex (flavi) viruses (Far Eastern subtype; Siberian subtype); Kyasanur Forest disease virus; Omsk hemorrhagic fever virus; Variola major virus (Smallpox virus); Variola minor virus (Alastrim); Venezuelan equine encephalitis virus; and Yersinia pestis.(2) Other organisms or specimens including:

(a) From persons of any age:

(A) All isolates of Corynebacterium diphtheriae, Grimontia spp., Listeria spp., Mycobacterium tuberculosis and M. bovis, Salmonella spp., Shigella spp., Vibrio spp., Yersinia spp. and suspected Shiga-toxigenic Escherichia coli (STEC), including E. coli O157;

(B) Isolates of the Enterobacteriaceae family resistant to any carbapenem antibiotic;

(C) Suspected Neisseria meningitidis and Haemophilus influenzae isolated from normally sterile sites;

(D) All novel and highly pathogenic avian influenza isolates, Measles (rubeola), poliomyelitis, rabies (human), rubella, and yellow fever; and

(E) All Coccidioides spp. and Cryptococcus spp. isolates.

(b) From persons under the age of 18 years who died with laboratory-confirmed influenza: respiratory specimens or viral isolates, any Staphylococcus aureus isolates, and, after consulting with the Oregon Public Health Division, autopsy specimens.

Stat. Auth.: ORS 413.042, 433.004 & 438.450
Stats. Implemented: ORS 433.004 & 438.310
Hist.: HB 248, f. 6-30-70, ef. 7-25-70; HD 28-1988, f. & cert. ef. 12-7-88; HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95; OHD 11-2001, f. & cert. ef. 5-16-01, Renumbered from 333-024-0050(5); OHD 3-2002, f. & cert. ef. 3-4-02; PH 11-2005, f. 6-30-05, cert. ef. 7-5-05; PH 28-2006, f. 11-30-06, cert. ef 12-18-06; PH 5-2010, f. & cert. ef. 3-11-10; PH 7-2011, f. & cert.

ef. 8-19-11; PH 16-2013, f. 12-26-13, cert. ef. 1-1-14; PH 10-2015, f. 7-2-15, cert. ef. 7-3-15; PH 24-2016, f. 8-8-16, cert. ef. 8-16-16

333-018-0020
Reports from Local Public Health Administrators

(1) The local public health administrator shall notify the Authority immediately of any reported cases of the following diseases and conditions: anthrax, botulism (foodborne), cholera, diphtheria, marine intoxications, measles, pesticide poisoning, plague, poliomyelitis, rabies; any uncommon illness of potential public health significance; any outbreak of disease.

(2) Animal bites that have been investigated by the local public health administrator and for which testing of the biting animal for rabies has been deemed unnecessary need not be reported to the Authority.

(3) For other reportable diseases and conditions, the local public health administrator shall notify the Authority no later than the end of each business week of all cases reported during that week. Reports shall be made by means approved by the Authority and in a format approved by the Authority.

Stat. Auth.: ORS 431.110, 431.120, 433.004, 437.010, 616.010 & 624.005
Stats. Implemented: ORS 433.004 & 437.010
Hist.: HD 15-1981, f. 8-13-81, ef. 8-15-81; HD 12-1983, f. & ef. 8-1-83; HD 4-1987, f. 6-12-87, ef. 6-19-87; HD 29-1994, f. & cert. ef. 12-2-94; OHD 3-2002, f. & cert. ef. 3-4-02; PH 7-2011, f. & cert. ef. 8-19-11; PH 16-2013, f. 12-26-13, cert. ef. 1-1-14

333-018-0035
Procedures Involving Emergency Response Employees

(1) Each person or local government employing persons to render emergency care shall designate a contact person or "designated officer" to receive reports from the local public health administrator made under ORS 433.006. The employer shall assure that the designated officer has sufficient training to carry out the duties as described below, which shall include appropriate procedures for follow-up after occupational exposures to specific diseases as specified below in section (2) and section (6).

(2) Sections (3) through (5) apply only to the following subset of reportable diseases: meningococcal disease, infectious pulmonary or laryngeal tuberculosis, diphtheria, plague (Yersinia pestis), rabies, hemorrhagic fevers (for example, Lassa, Marburg, and Ebola).

(3) Health care providers and health care facilities shall, when reporting this subset of diseases, determine and include as part of their report whether or not an emergency care provider was involved in pre-hospital care for this disease.

(4) Health care providers and facilities shall report to the local public health administrator and may relay the diagnosis of these diseases directly to the emergency care providers or the designated officer specified below in section (5), but shall not disclose the identity or addresses of the person having the disease or otherwise refer specifically to the person.

(5) Upon receiving a report of a reportable disease as defined in section (2) above, the designated officer shall notify all out-of-hospital caregivers, including but not limited to: first responders, emergency medical technicians, paramedics, firefighters, law enforcement officers, corrections officers, probation officers, or other current or former personnel of the employer who may have been exposed to the reportable disease. The designated officer shall inform the personnel only of the reportable disease and the fact of possible exposure and the appropriate follow-up procedures. The designated officer shall not inform the personnel of the identity or addresses of the individual having the reportable disease or otherwise refer specifically to the individual having the reportable disease.

(6) In the event of an occupational exposure to a bloodborne pathogen as defined by ORS 433.060, the designated officer shall also assist the exposed worker as defined in ORS 433.060 in implementing the provisions of ORS 433.065 through ORS 433.080 and associated Authority rules (chapter 333, division 22). These rules include provisions for determining HIV, hepatitis B and hepatitis C status of the source patient and soliciting HIV testing after an occupational exposure.

Stat. Auth.: ORS 433.045 - 433.080 & 431.110
Stats. Implemented: ORS 433.006 & 433.065
Hist.: HD 15-1981, f. 8-13-81, ef. 8-15-81; HD 12-1983, f. & ef. 8-1-83; HD 4-1987, f. 6-12-87, ef. 6-19-87; HD 29-1994, f. & cert. ef. 12-2-94; HD 8-1997, f. & cert. ef. 6-26-97; OHD 15-2001, f. & cert. ef. 7-12-01, Renumbered from 333-018-0023; OHD 3-2002, f. & cert. ef. 3-4-02; PH 7-2011, f. & cert. ef. 8-19-11; PH 16-2013, f. 12-26-13, cert. ef. 1-1-14

Health Care Acquired Infection Reporting and Public Disclosure

333-018-0100
Definitions

The following definitions apply to OAR 333-018-0100 through 333-018-0145:

(1) "Adult ICU" means all specialty and non-specialty intensive care units that care for adults as defined in the NHSN Manual.

(2) "ASC" means an ambulatory surgical center as defined in ORS 442.015 and that is licensed pursuant to ORS 441.015.

(3) "Authority" means the Oregon Health Authority.

(4) "CBGB" means coronary bypass graft surgery with both chest and graft incisions, as defined in the NHSN Manual.

(5) "CAUTI" means catheter-associated urinary tract infection as defined in the NHSN Manual.

(6) "CDC" means the federal Centers for Disease Control and Prevention.

(7) "CDI" means Clostridium difficile infection as defined in the NHSN Manual.

(8) "CLABSI" means central line associated bloodstream infection as defined in the NHSN Manual.

(9) "CMS" means the federal Centers for Medicare and Medicaid Services.

(10) "Collection Month" means the month in which an infection was identified.

(11) "COLO" means colon procedures as defined in the NHSN Manual.

(12) "Committee" means the Health Care Acquired Infections Advisory Committee established in section 4, chapter 838, Oregon Laws 2007.

(13) "Dialysis facility" means outpatient renal dialysis facility as defined in ORS 442.015.

(14) "Dialysis Event" means an event that occurs in individuals who receive dialysis as defined by the NHSN Manual.

(15) "Follow-up" means post-discharge surveillance intended to detect CBGB, COLO, HPRO, HYST, KRPO, and LAM surgical site infection (SSI) cases occurring after a procedure.

(16) "HAI" means health care acquired infection as defined in section 2, chapter 838, Oregon Laws 2007.

(17) "Health care facility" means a facility as defined in ORS 442.015.

(18) "Hospital" means a facility as defined in ORS 442.015 and that is licensed pursuant to ORS 441.015.

(19) "Hospital Inpatient Quality Reporting Program (HIQRP)" means the initiative administered by CMS that provides a financial incentive to hospitals to report designated quality measures, mandated by section 501(b) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003.

(20) "HPRO" means hip prosthesis procedure as defined in the NHSN Manual.

(21) "HYST" means abdominal hysterectomy procedure as defined in the NHSN Manual.

(22) "Inpatient rehabilitation ward" means an area within a hospital used for evaluation, treatment, and restoration of function to patients who have lost function due to acute or chronic pain, musculoskeletal problems, stroke, brain or spinal cord dysfunction, or catastrophic events resulting in complete or partial paralysis.

(23) "ICU" means an intensive care unit as defined in the NHSN Manual.

(24) "KPRO" means knee prosthesis procedure as defined in the NHSN Manual.

(25) "Lab ID" means laboratory-identified event as defined in the NHSN Manual.

(26) "LAM" means laminectomy procedure as defined in the NHSN Manual.

(27) "Licensed satellite" has the meaning given that term in OAR 333-500-0010.

(28) "LTCF" means a long term care facility as defined in ORS 442.015.

(29) "MDS" means the CMS minimum data set nursing home resident assessment and screening tool.

(30) "Medical ICU" means a non-specialty intensive care unit in which at least 80 percent of patients served are adult medical patients.

(31) "Medical/Surgical ICU" means a non-specialty intensive care unit in which less than 80 percent of patients served are adult medical, adult surgical, or specialty patients.

(32) "Medical ward" means an area within a hospital used for the evaluation and treatment of patients with medical conditions or disorders.

(33) "Medical/surgical ward" means an area within a hospital used for the evaluation of patients with medical or surgical conditions.

(34) "MRSA" means methicillin-resistant Staphylococcus aureus as defined in the NHSN Manual.

(35) "NHSN" means the CDC's National Healthcare Safety Network.

(36) "NHSN Inpatient" means a patient whose date of admission to the healthcare facility and the date of discharge are different days as defined in the NHSN Manual.

(37) "NHSN Manual" means the 2014 patient safety component protocols, established by the CDC's NHSN, which govern the HAIs and other information required by CMS to be reported by health care facilities, found at http://www.cdc.gov/nhsn/Training/patient-safety-component/, and incorporated by reference.

(38) "NICU" means a specialty intensive care unit that cares for neonatal patients.

(39) "Non-specialty ICU" means an intensive care unit in which patients are medical, surgical, or medical/surgical patients.

(40) "Oregon HAI group" means the NHSN group administered by the Authority.

(41) "Overall-facility wide" means data are collected for the entire facility as defined in the NHSN Manual.

(42) "Patient information" means individually identifiable health information as defined in ORS 179.505.

(43) "Pediatric inpatient rehabilitation ward" means an area within a hospital used for evaluation, treatment, and restoration of function to patients under 18 years of age who have lost function due to acute or chronic pain, musculoskeletal problems, stroke, brain or spinal cord dysfunction, or catastrophic events resulting in complete or partial paralysis

(44) "Pediatric ICU" means a specialty intensive care unit that cares for pediatric patients.

(45) "Pediatric medical ward" means an area within a hospital used for the evaluation and treatment of patients under 18 years of age with medical conditions or disorders.

(46) "Pediatric medical/surgical ward" means a hospital area where patients under 18 years of age with medical or surgical conditions are managed.

(47) "Pediatric surgical ward" means an area within a hospital used for the evaluation and treatment of patients under 18 years of age who have undergone a surgical procedure.

(48) "Person" has the meaning given that term in ORS 442.015.

(49) "Procedure" means an operative procedure as defined in the NHSN Manual.

(50) "Provider" means health care services provider as defined in ORS 179.505.

(51) "QIO" means the quality improvement organization designated by CMS for Oregon.

(52) "SCIP" means the Surgical Care Improvement Project, established through collaborative efforts of the Joint Commission and CMS.

(53) "SCIP-Inf-1" means the HAI process measure defined as prophylactic antibiotic received within one hour prior to surgical incision, published by SCIP effective July 1, 2006.

(54) "SCIP-Inf-2" means the HAI process measure defined as prophylactic antibiotic selection for surgical patients, published by SCIP effective July 1, 2006.

(55) "SCIP-Inf-3" means the HAI process measure defined as prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac patients), published by SCIP effective July 1, 2006.

(56) "SCIP-Inf-4" means the HAI process measure defined as cardiac surgery patients with controlled 6 a.m. postoperative serum glucose, published by SCIP effective July 1, 2006.

(57) "SCIP-Inf-6" means the HAI process measure defined as surgery patients with appropriate hair removal, published by SCIP effective July 1, 2006.

(58) "SCIP-Inf-9" means the HAI process measure defined as urinary catheter removed on postoperative day one or postoperative day two with day of surgery being day zero, published by SCIP effective July 1, 2006.

(59) "SCIP-Inf-10" means the HAI process measure defined as surgery patients with perioperative temperature management, published by SCIP effective July 1, 2006.

(60) "Specialty ICU" means an intensive care unit in which at least 80 percent of adult patients served are specialty patients, including but not limited to oncology, trauma, and neurology.

(61) "SSI" means a surgical site infection event as defined in the NHSN manual.

(62) "Staff" means any employee of a health care facility or any person contracted to work within a health care facility.

(63) "State agency" has the meaning given that term in ORS 192.410.

(64) "Surgical ICU" means a non-specialty intensive care unit in which at least 80 percent of patients served are adult surgical patients.

(65) "Surgical ward" means an area within a hospital used for the evaluation and treatment of patients who have undergone a surgical procedure.

Stat. Auth.: ORS 442.420 & OL 2007, Ch. 838 § 1-6 & 12
Stats. Implemented: ORS 179.505, 192.410, 192.496, 192.502, 441.015, 442.400, 442.405, & OL 2007, Ch. 838 § 1-6 &12
Hist.: OHP 1-2008, f. & cert. ef. 7-1-08; OHP 1-2009, f. & cert. ef. 7-1-09; OHP 4-2010, f. 6-30-10, cert. ef. 7-1-10; OHP 4-2011(Temp), f. 7-28-11, cert. ef. 8-1-11 thru 1-25-12; OHP 7-2011, f. 9-30-11, cert. ef. 10-1-11; Renumbered from 409-023-0000 by PH 13-2013, f. 12-26-13, cert. ef. 1-1-14; PH 17-2014, f. & cert. ef. 6-9-14; PH 24-2016, f. 8-8-16, cert. ef. 8-16-16

333-018-0105
Review

Unless otherwise directed by the Authority, the committee shall review these rules (OAR 333-018-0100 through 333-018-0145) at least biennially.

Stat. Auth.: ORS 442.420 & 2007 OL Ch. 838 § 1–6 & 12
Stats. Implemented: 2007 OL Ch. 838 § 1–6 & 12
Hist.: OHP 1-2008, f. & cert. ef. 7-1-08; Renumbered from 409-023-0005 by PH 13-2013, f. 12-26-13, cert. ef. 1-1-14

333-018-0110
HAI Reporting for Hospitals

(1) Hospitals must report to the Authority the following HAIs:

(a) CLABSI in:

(A) Adult, pediatric, and neonatal ICUs; and

(B) Adult and pediatric, medical, surgical, and medical/surgical wards.

(b) SSIs for inpatient CBGB, COLO, HPRO, HYST, KPRO and LAM procedures.

(c) CAUTI in:

(A) Adult and pediatric ICUs; and

(B) Adult and pediatric medical, surgical, medical/surgical wards, and inpatient rehabilitation wards.

(d) Inpatient CDI facility-wide lab ID events, excluding neonatal and well-baby units.

(e) Inpatient MRSA bacteremia lab ID events.

(2) Hospitals must report to the Authority all fields required to be reported by NHSN in accordance with the NHSN manual, including discharge dates.

(3) A hospital must report the information required in section (1) of this rule to the Authority no later than 30 days after the end of the collection month.

(4) A hospital must have an infection preventionist (IP) who actively seeks out HAIs required to be reported under this rule by screening a variety of data from various sources that may include but are not limited to:

(a) Laboratory;

(b) Pharmacy;

(c) Admission;

(d) Discharge;

(e) Transfer;

(f) Radiology;

(g) Imaging;

(h) Pathology; and

(i) Patient charts, including history and physical notes, nurses' and physicians' notes, and temperature charts.

(5) An IP shall use follow-up surveillance methods to detect SSIs for procedures listed in section (1) of this rule using at least one of the following:

(a) Direct examination of patients' wounds during follow-up visits to either surgery clinics or physicians' offices;

(b) Review of medical records, subsequent hospitalization records, or surgery clinic records;

(c) Surgeon surveys by mail or telephone;

(d) Patient surveys by mail or telephone; or

(e) Other facility surveys by mail or telephone.

(6) A hospital may train others employed by the facility to screen data sources for these infections required to be reported in section (1) of this rule but the IP must determine that the infection meets the criteria established by these rules.

(7) Hospitals that report the information in subsection (1)(a) to (e) of this rule through NHSN in order to meet CMS reporting requirements, may, in lieu of reporting this information directly to the Authority, permit the Authority to access the information through NHSN. A hospital that permits the Authority to access the information through NHSN must:

(a) Join the Oregon HAI group in NHSN;

(b) Authorize disclosure of NHSN data to the Authority as necessary for compliance with these rules, including but not limited to summary data and denominator data for all SSIs, the annual hospital survey and data analysis components for all SSIs, and summary data and denominator data for all adult, pediatric and neonatal ICUs; and

(c) Permit the Authority to access data reported through NHSN dating back to when reporting was first required by CMS for the different HAIs.

(8) All hospitals must report to the Authority on a quarterly basis the following HAI process measures, including but not limited to definitions, data collection, data reporting and training requirements:

(a) SCIP-Inf-1;

(b) SCIP-Inf-2;

(c) SCIP-Inf-3;

(d) SCIP-Inf-4;

(e) SCIP-Inf-6;

(f) SCIP-Inf-9; and

(g) SCIP-Inf-10.

(9) Hospitals that report the information in section (8) of this rule to CMS or the Joint Commission do not have to provide the information directly to the Authority; the Authority will access the information through CMS or the Joint Commission. If a hospital is not reporting the information in section (8) of this rule to CMS or the Joint Commission, in accordance with CMS or Joint Commission reporting requirements, it must provide the information to the Authority no later than on the 15th calendar day, four months after the end of the quarter. As CMS reporting requirements for SCIP measures are removed, reporting requirements for the Authority will change accordingly.

Stat. Auth.: ORS 442.420 & 2007 OL Ch. 838 § 1–6 & 12
Stats. Implemented: ORS 442.405 & 2007 OL Ch. 838 § 1–6 & 12
Hist.: OHP 1-2008, f. & cert. ef. 7-1-08; OHP 1-2009, f. & cert. ef. 7-1-09; OHP 4-2010, f. 6-30-10, cert. ef. 7-1-10; OHP 4-2011(Temp), f. 7-28-11, cert. ef. 8-1-11 thru 1-25-12; OHP 7-2011, f. 9-30-11, cert. ef. 10-1-11; Renumbered from 409-023-0010 by PH 13-2013, f. 12-26-13, cert. ef. 1-1-14; PH 17-2014, f. & cert. ef. 6-9-14; PH 8-2015, f. & cert. ef. 3-24-15; PH 24-2016, f. 8-8-16, cert. ef. 8-16-16

333-018-0115
HAI Reporting for Ambulatory Surgery Centers

All Ambulatory Surgical Centers must complete the Evidence-Based Elements of Patient Safety Performance (EBEPSP) Survey provided by the Authority, annually, no later than 30 days after receipt of the survey.

Stat. Auth.: ORS 442.420 & OL 2007, Ch. 838 § 1-6 and 12
Stats. Implemented: ORS 442.405 & OL 2007, Ch. 838 § 1-6 and 12
Hist.: OHP 1-2009, f. & cert. ef. 7-1-09; OHP 4-2011(Temp), f. 7-28-11, cert. ef. 8-1-11 thru 1-25-12; OHP 7-2011, f. 9-30-11, cert. ef. 10-1-11; Renumbered from 409-023-0012 by PH 13-2013, f. 12-26-13, cert. ef. 1-1-14; PH 17-2014, f. & cert. ef. 6-9-14

333-018-0120
HAI Reporting for Long Term Care Facilities

(1) All LTCFs must report urinary tract infections to the Authority except as provided in subsection (b) of this section.

(a) A LTCF must report infections to the Authority in the same manner established by MDS, including but not limited to reporting definitions, data collection, data submission, and administrative and training requirements.

(b) If a LTCF reports infections in accordance with MDS to CMS, the LTCF is not required to report that information directly to the Authority; the Authority will access the information through CMS.

(2) All LTCFs must submit the Evidence-Based Elements of Patient Safety Performance Survey to the Authority annually, no later than 30 days after receipt of the survey.

(3) All LTCFs must submit the Infection Prevention Program Survey to the Authority annually, no later than 30 days after receipt of the survey.

Stat. Auth.: ORS 442.420 & 2007 OL Ch. 838 § 1–6 & 12
Stats. Implemented: ORS 442.405 & 2007 OL Ch. 838 § 1–6 & 12
Hist.: OHP 1-2009, f. & cert. ef. 7-1-09; Renumbered from 409-023-0013 by PH 13-2013, f. 12-26-13, cert. ef. 1-1-14; PH 17-2014, f. & cert. ef. 6-9-14

333-018-0125
HAI Reporting for Other Health Care Facilities

(1) All dialysis facilities shall report dialysis events to the Authority.

(2) A dialysis facility that reports dialysis events to NHSN may, in lieu of reporting the information directly to the Authority, permit the Authority access to NHSN.

(3) All Inpatient Rehabilitation Facilities (IRF) shall report to the Authority CAUTIs for adult and pediatric wards.

(4) The reporting system for IRFs shall be NHSN.

(5) IRFs that report information in order to meet CMS reporting requirements, may, in lieu of reporting information directly to the Authority, permit the Authority to access the information through NHSN. An IRF that permits the Authority to access the information through NHSN must:

(a) Join the Oregon HAI group in NHSN;

(b) Authorize disclosure of NHSN data to the Authority as necessary for compliance with these rules, including but not limited to summary data and denominator data for all SSIs, the annual hospital survey and data analysis components for all SSIs, and summary data and denominator data for all adult, pediatric and neonatal ICUs; and

(c) Permit the Authority to access data reported through NHSN dating back to when reporting was first required by CMS for the different HAIs.

Stat. Auth.: ORS 442.420 & OL 2007, Ch. 838 § 1-6 and 12
Stats. Implemented: ORS 442.405 & OL 2007, Ch. 838 § 1-6 and 12

Hist.: OHP 1-2008, f. & cert. ef. 7-1-08; OHP 1-2009, f. & cert. ef. 7-1-09; OHP 4-2011(Temp), f. 7-28-11, cert. ef. 8-1-11 thru 1-25-12; OHP 7-2011, f. 9-30-11, cert. ef. 10-1-11; Renumbered from 409-023-0015 by PH 13-2013, f. 12-26-13, cert. ef. 1-1-14; PH 17-2014, f. & cert. ef. 6-9-14

333-018-0127
Annual Influenza Summary

Each hospital, including licensed satellites, ASC, Dialysis facility, LTCF, and IRF must submit an annual survey to the Authority, no later than May 31, on a form prescribed by the Authority, regarding influenza vaccination of staff. Facilities must report at least the following information:

(1) Number of staff with a documented influenza vaccination during the previous influenza season;

(2) Number of staff with a documented medical contraindication to influenza vaccination during the previous influenza season;

(3) Number of staff with a documented refusal of influenza vaccination during the previous influenza season; and

(4) Facility assessment of influenza vaccine coverage of facility staff during the previous influenza season and plans to improve vaccine coverage of facility staff during the upcoming influenza season.

Stat. Auth.: ORS 442.420 & OL 2007, Ch. 838 § 1-6 and 12
Stats. Implemented: ORS 442.405 & OL 2007, Ch. 838 § 1-6 and 12
Hist.: PH 17-2014, f. & cert. ef. 6-9-14; PH 8-2015, f. & cert. ef. 3-24-15; PH 24-2016, f. 8-8-16, cert. ef. 8-16-16

333-018-0130
HAI Public Disclosure

(1) The Authority shall disclose to the public facility-level and state-level HAI outcomes quarterly.

(2) The Authority may disclose state-level and facility-level HAI data, including but not limited to observed frequencies, expected frequencies, proportions, and ratios.

(3) The Authority shall summarize HAI data by facilities subject to this reporting in an annual report. The Authority shall publish the annual report no later than April 30 of each calendar year.

(4) The Authority shall disclose data and accompanying explanatory documentation to facilities and the general public.

(5) The Authority may use statistically valid methods to make comparisons by facility, and to state, regional, and national statistics.

(6) The Authority shall provide a maximum of 30 calendar days for facilities to review facility-reported data prior to public release of data.

(7) The Authority shall provide facilities the opportunity to submit written comments and may include any submitted information in the annual report.

(8) Pending recommendations from the committee, the Authority may publish additional reports intended to serve the public's interest.

Stat. Auth.: ORS 442.420 & 2007 OL Ch. 838 § 1–6 & 12
Stats. Implemented: ORS 442.405, 192.496, 192.502, 192.243, 192.245 & 2007 OL Ch. 838 § 1–6 & 12
Hist.: OHP 1-2008, f. & cert. ef. 7-1-08; Renumbered from 409-023-0020 by PH 13-2013, f. 12-26-13, cert. ef. 1-1-14; PH 17-2014, f. & cert. ef. 6-9-14

333-018-0135
HAI Data Security

The Authority shall undertake precautions to prevent unauthorized disclosure of the raw data files. These precautions include but are not limited to:

(1) Storing the raw data files on the internal storage hardware of a password-protected personal computer that is physically located within the Authority;

(2) Restricting staff access to the raw data files;

(3) Restricting network access to the raw data files; and

(4) If applicable, storing patient information within a strongly-encrypted and password-protected virtual drive or using other methods to reliably achieve the same level of security.

Stat. Auth.: ORS 442.420 & 2007 OL Ch. 838 § 1–6 & 12
Stats. Implemented: ORS 192.496, 192.502 & 2007 OL Ch. 838 § 1–6 & 12
Hist.: OHP 1-2008, f. & cert. ef. 7-1-08; Renumbered from 409-023-0025 by PH 13-2013, f. 12-26-13, cert. ef. 1-1-14; PH 17-2014, f. & cert. ef. 6-9-14

333-018-0140
Prohibited Activities

Unless specifically required by state or federal rules, regulations, or statutes, the Authority is prohibited from:

(1) Disclosing individually identifiable patient, health care professional, or health care facility employee information;

(2) Intentionally linking or attempting to link individual providers to individual HAI events; and

(3) Providing patient-level or provider-level reportable HAI data to any state agency for enforcement or regulatory actions.

Stat. Auth.: ORS 442.420 & 2007 OL Ch. 838 § 1–6 & 12
Stats. Implemented: ORS 192.496, 192.502 & 2007 OL Ch. 838 § 1–6 & 12
Hist.: OHP 1-2008, f. & cert. ef. 7-1-08; Renumbered from 409-023-0030 by PH 13-2013, f. 12-26-13, cert. ef. 1-1-14

333-018-0145
Compliance

(1) Health care facilities that fail to comply with these rules or fail to submit required data shall be subject to civil penalties not to exceed $500 per day per violation.

(2) The Authority shall annually evaluate the quality of data submitted, as recommended by the committee.

Stat. Auth.: ORS 442.445 & 442.420
Stats. Implemented: ORS 442.445
Hist.: OHP 1-2008, f. & cert. ef. 7-1-08; Renumbered from 409-023-0035 by PH 13-2013, f. 12-26-13, cert. ef. 1-1-14

DIVISION 19

INVESTIGATION AND CONTROL OF DISEASES: GENERAL POWERS AND RESPONSIBILITIES

333-019-0000
Responsibility of Public Health Authorities to Investigate Reportable Diseases

(1) The local public health administrator shall use all reasonable means to investigate in a timely manner all reports of reportable diseases, infections, or conditions. To identify possible sources of infection and to carry out appropriate control measures, the local public health administrator shall investigate each report following procedures outlined in the Authority's Investigative Guidelines or other procedures approved by the Authority. The Authority may provide assistance in these investigations.

(2) Investigations of outbreaks involving residents of multiple states or counties or exposures in multiple states of counties may be supervised by the Authority.

(3) Investigations by the Authority or local public health administrator shall be conducted in accordance with ORS 433.004 and these rules.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 413.042, 431.110, 433.004, 437.010, 616.010 & 624.005
Stats. Implemented: ORS 433.004 & 437.030
Hist.: HD 15-1981, f. 8-13-81, ef. 8-15-81; HD 4-1987, f. 6-12-87, ef. 6-19-87; HD 29-1994, f. & cert. ef. 12-2-94; OHD 4-2002, f. & cert. ef. 3-4-02; PH 7-2011, f. & cert. ef. 8-19-11; PH 10-2015, f. 7-2-15, cert. ef. 7-3-15

333-019-0002
Cooperation with Public Health Authorities

(1) Health care providers, health care facilities, and licensed laboratories shall cooperate with local public health administrators and the Authority in the investigation and control of reportable diseases and conditions.

(2) Every health care provider attending a person with a reportable disease, infection, or condition shall instruct the person in measures appropriate to controlling the spread of the disease.

Stat. Auth.: ORS 413.042, 431.110, 433.004, 437.010, 616.010 & 624.005
Stats. Implemented: ORS 433.004, 433.106 & 433.130
Hist.: OHD 4-2002, f. & cert. ef. 3-4-02; PH 11-2005, f. 6-30-05, cert. ef. 7-5-05; PH 7-2011, f. & cert. ef. 8-19-11

333-019-0003
Providing Information to the Oregon Health Authority or Local Public Health Administrator

(1) The Authority or local public health administrator (LPHA) may, as necessary to investigate a case of a reportable disease, disease outbreak or epidemic, require a health care provider, public or private entity, or an individual to permit the inspection or provide copies of information necessary to the investigation.

(2) Information that may be inspected or provided to the Authority or LPHA includes but is not limited to:

(a) Individually identifiable health information and contact information related to:

(A) The case;

(B) An individual who may be the potential source of exposure or infection;

(C) An individual who has been or may have been exposed to or affected by the disease; or

(D) A control.

(b) Policies, practices, systems or structures that may have affected the likelihood of disease transmission.

(c) Factors that may influence an individual's susceptibility to the disease or likelihood of being diagnosed with the disease.

(3) In addition to requesting information the Authority or LPHA may inspect, sample or test real or personal property. The Authority or LPHA will request permission to inspect, sample or test real or personal property prior to taking any action. If an individual or entity refuses to allow access to real or personal property for this purpose, the Authority or LPHA may seek an administrative warrant in order to obtain access.

(4) The Authority or LPHA shall request the information required to be submitted orally or in writing and shall inform the individual or entity from whom the information is sought when the information is required to be submitted. In lieu of requesting that information be provided to the Authority or LPHA, the Authority or LPHA may request access to the information at the location where the information is located.

(5) A person who provides information in accordance with these rules is immune from civil or criminal liability that might otherwise be incurred or imposed with respect to providing information under this section.

(6) Pursuant to ORS 433.008, all information obtained by the Authority or LPHA in the course of an investigation is confidential, may only be released in accordance with ORS 433.008(2) through (6), and except as required for the administration of public health laws or rules, a state or local public health official or employee may not be examined in any administrative or judicial proceeding about the existence or contents of a reportable disease report or other information received by the Authority or LPHA in the course of an investigation of a reportable disease or disease outbreak.

Stat. Auth.: ORS 433.004
Stats. Implemented: ORS 433.004
Hist.: PH 7-2011, f. & cert. ef. 8-19-11

333-019-0005
Conduct of Special Studies by Oregon Health Authority

The Authority may conduct special studies concerning the causes and prevention of diseases and other significant health conditions. Special studies include any collection of information about the health status or potential health risk factors of individuals or groups of individuals, other than the routine collection of birth, death, and marriage information, and are not restricted to reportable diseases, infections, or conditions. The Authority may collaborate with local public health authorities, other institutions, or other individuals in the conduct of these studies.

Stat. Auth.: ORS 413.042, 431.110, 433.004, 437.010, 616.010 & 624.005
Stats. Implemented: ORS 433.006 & 433.065
Hist.: HD 15-1981, f. 8-13-81, ef. 8-15-81; HD 4-1987, f. 6-12-87, ef. 6-19-87; HD 9-1997, f. & cert. ef. 6-26-97; OHD 4-2002, f. & cert. ef. 3-4-02; PH 11-2005, f. 6-30-05, cert. ef. 7-5-05; PH 7-2011, f. & cert. ef. 8-19-11

Disease-Related School, Child Care, and Worksite Restrictions

333-019-0010
Imposition of Restrictions

(1) For purposes of this rule:

(a) "Restrictable disease":

(A) As applied to food service facilities includes but is not limited to diphtheria, hepatitis A, measles, Salmonella enterica serotype Typhi infection, Shiga-toxigenic Escherichia coli (STEC) infection, shigellosis, tuberculosis disease, open or draining skin lesions infected with Staphylococcus aureus or Streptococcus pyogenes, and any illness accompanied by diarrhea or vomiting.

(B) As applied to schools, children's facilities, and health care facilities, includes but is not limited to chickenpox, diphtheria, hepatitis A, measles, mumps, pertussis, rubella, Salmonella enterica serotype Typhi infection, scabies, Shiga-toxigenic Escherichia coli (STEC) infection, shigellosis, and tuberculosis disease and may include a communicable stage of hepatitis B infection if, in the opinion of the local health officer, the child poses an unusually high risk to other children (for example, exhibits uncontrollable biting or spitting).

(C) Includes any other communicable disease identified in an order issued by the Authority or a local public health administrator as posing a danger to the public's health.

(b) "Susceptible" means being at risk of contracting a restrictable disease by virtue of being in one or more of the following categories:

(A) Not being complete on the immunizations required by OAR chapter 333, division 50;

(B) Possessing a medical exemption from any of the vaccines required by OAR chapter 333, division 50 due to a specific medical diagnosis based on a specific medical contraindication; or

(C) Possessing a nonmedical exemption for any of the vaccines required by OAR chapter 333, division 50.

(c) "Reportable disease" means a human reportable disease, infection, microorganism, or condition specified by OAR chapter 333, division 18.

(2) To protect the public health, an individual who attends or works at a school or child care facility, or who works at a health care facility or food service facility may not attend or work at a school or facility while in a communicable stage of a restrictable disease, unless otherwise authorized to do so under these rules.

(3) A susceptible child or employee in a school or children's facility who has been exposed to a restrictable disease that is also a reportable disease for which an immunization is required under OAR 333-050-0050 must be excluded by the school administrator, unless the local health officer determines, in accordance with section (4) of this rule, that exclusion is not necessary to protect the public's health.

(4) A school administrator may request that the local health officer determine whether an exclusion under section (3) of this rule is necessary. In making such a determination the local health officer may, in consultation as needed with the Authority, consider factors including but not limited to the following:

(a) The severity of the disease;

(b) The means of transmission of the disease;

(c) The intensity of the child's or employee's exposure; and

(d) The exposed child's or employee's susceptibility to the disease, as indicated by:

(A) A previous occurrence of the disease;

(B) Vaccination records;

(C) Evidence of immunity as indicated by laboratory testing;

(D) Year of birth; or

(E) History of geographic residence and the prevalence of the disease in those areas.

(5) The length of exclusion under section (3) of this rule is one incubation period following the child or employee's most recent exposure to the disease.

(6) A susceptible child or employee may be excluded under this rule notwithstanding any claim of exemption under ORS 433.267(1).

(7) Nothing in these rules prohibits a school or children's facility from adopting more stringent exclusion standards under ORS 433.284.

(8) The infection control committee at all health care facilities shall adopt policies to restrict the work of employees with restrictable diseases in accordance with recognized principles of infection control. Nothing in these rules prohibits health care facilities or the local public health authority from adopting additional or more stringent rules for exclusion from these facilities.

Stat. Auth.: ORS 413.042, 431.110, 433.004, 433.255, 433.260, 433.284, 433.329, 433.332, 616.750 & 624.005
Stats. Implemented: ORS 433.255, 433.260, 433.407, 433.411 & 433.419
Hist.: HD 15-1981, f. 8-13-81, ef. 8-15-81; OHD 4-2002, f. & cert. ef. 3-4-02; PH 11-2005, f. 6-30-05, cert. ef. 7-5-05; PH 7-2011, f. & cert. ef. 8-19-11; PH 16-2013, f. 12-26-13, cert. ef. 1-1-14; PH 1-2015(Temp), f. & cert. ef. 1-7-15 thru 7-5-15; PH 10-2015, f. 7-2-15, cert. ef. 7-3-15; PH 24-2016, f. 8-8-16, cert. ef. 8-16-16

333-019-0014
Removal of Restrictions

(1) Worksite, child care, and school restrictions can be removed by statement of the local public health administrator that the disease is no longer communicable to others or that adequate precautions have been taken to minimize the risk of transmission.

(2) School or child care restrictions for chickenpox, scabies, staphylococcal skin infections, streptococcal infections, diarrhea, or vomiting may also be removed by a school nurse or health care provider.

(3) Restrictions at health care facilities for chickenpox, scabies, staphylococcal skin infections, streptococcal infections, diarrhea, or vomiting may also be removed by the facility's infection control committee when sufficient measures have been taken to prevent or minimize the transmission of disease, in accordance with written procedures approved by the committee.

(4) In general, restrictions on persons diagnosed with shigellosis or Shiga-toxigenic Escherichia coli (STEC) infection, including E. coli O157 infection, shall not be lifted until no pathogens are identified by a licensed laboratory in two consecutive approved fecal specimens collected not less than 24 hours apart. Such restrictions may be waived or modified at the discretion of the local public health administrator.

(5) Individuals infected with Salmonella enterica serotype Typhi (with or without symptoms), hereinafter referred to as "typhoid cases," must, before having a restriction removed, submit fecal specimens and one urine specimen to a licensed laboratory for testing on a schedule specified by the local public health administrator.

(6) A restriction on a typhoid case who is not a chronic carrier must be lifted by the local public health administrator when Salmonella enterica serotype Typhi is not identified by a licensed laboratory in any of four successive approved fecal specimens, collected at least 24 hours apart and not earlier than one month after illness onset, and one urine specimen.

(7) A "chronic carrier" is an individual who has fecal specimens test positive for Salmonella enterica serotype Typhi more than one year after onset or first diagnosis or on two occasions at least one year apart. A restriction on a chronic carrier may only be removed when Salmonella enterica serotype Typhi is not identified by a licensed laboratory in any of six successive approved fecal specimens, collected at least 72 hours apart, and one urine specimen.

Stat. Auth.: ORS 413.042, 431.110, 433.004, 616.010 & 624.005
Stats. Implemented: ORS 433.004, 433.260 & 433.273
Hist.: OHD 4-2002, f. & cert. ef. 3-4-02; PH 7-2011, f. & cert. ef. 8-19-11; PH 16-2013, f. 12-26-13, cert. ef. 1-1-14; PH 10-2015, f. 7-2-15, cert. ef. 7-3-15

Pet Licensing, Animal Bites, and Rabies

333-019-0017
Rabies Vaccination for Animals

(1) Except where specifically exempt, all dogs at least three months old shall be immunized against rabies by the age of six months. The following are exempt:

(a) Dogs brought temporarily into the state for periods of less than 30 days and kept under strict supervision by their owners;

(b) Dogs for which rabies immunization is contraindicated for health reasons, as determined by a licensed veterinarian subsequent to an examination. The reasons for the exemption and a specific description of the dog, including name, age, sex, breed, and color, shall be recorded by the examining veterinarian on a Rabies Vaccination Certificate, which shall bear the owner's name and address. The veterinarian shall also record whether the exemption is permanent, and if it is not, the date the exemption ends;

(c) Dogs that are owned by dealers, breeders, or exhibitors exclusively for sale or exhibition purposes and that are confined to kennels except for transportation under strict supervision to and from dog shows or fairs.

(2) Vaccination of an animal against rabies is valid only when performed:

(a) By a licensed veterinarian as specified by ORS 686.350 through 686.370 and OAR 875-010-0006;

(b) By a veterinary technician (certified according to OAR 875-030-0010) under the direct supervision of a licensed veterinarian; or

(c) In the case of a need to vaccinate and the lack of an available veterinarian, by another person approved for this purpose by the State Public Health Veterinarian.

(3) To be considered immunized against rabies, dogs and cats must be vaccinated according to guidelines published by the U.S. Centers for Disease Control and Prevention in the Compendium of animal rabies prevention and control, 2016 from the National Association of State Public Health Veterinarians.

(4) A Rabies Vaccination Certificate shall be completed and signed by a licensed veterinarian; electronic signatures are acceptable. That individual shall give the original and one copy to the dog's owner and retain one copy for the period for which the vaccination is in force. The Certificate must include at least the following information: owner's name and address; dog description by age, sex, color, breed; date of vaccination; due date for revaccination; type and lot number of vaccine used; and name and address of vaccinator.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 413.042 & 433.365
Stats. Implemented: ORS 433.365
Hist.: OHD 4-2002, f. & cert. ef. 3-4-02; PH 6-2003, f. & cert. ef. 5-22-03; PH 11-2005, f. 6-30-05, cert. ef. 7-5-05; PH 5-2010, f. & cert. ef. 3-11-105; PH 24-2016, f. 8-8-16, cert. ef. 8-16-16

333-019-0019
Dog Licensing

(1) Each dog shall be licensed by the local animal control agency in whose jurisdiction its owner resides.

(2) No dog shall be licensed until the owner of a vaccinated dog presents, in person or by mail, the original Rabies Vaccination Certificate to the County Clerk or designated animal control officer serving that jurisdiction.

(3) Upon receipt of applicable fees (if any, pursuant to ORS 433.380), the local animal control agency shall issue a serially numbered tag legibly identifying an expiration date that may not exceed the vaccine coverage expiration date by more than two months. The tag shall be attached to a collar or harness that shall be worn by the dog at all times when off the premises of the owner.

(4) The local animal control agency may request and file the Rabies Vaccination Certificate, cross-referenced to the tag number.

(5) An unexpired tag shall be honored throughout Oregon.

(6) A dog's rabies vaccination tag may, at the discretion of the local animal control agency, serve as the dog license, but not for more than two months beyond the immunity expiration date.

(7) Nothing in these rules shall be construed to limit the power of any jurisdiction to enact more stringent requirements to regulate and control dogs.

Stat. Auth.: ORS 413.042, 431.110, 433.004, 433.340
Stats. Implemented: ORS 433.380
Hist.: OHD 4-2002, f. & cert. ef. 3-4-02

333-019-0022
Wolf-Dog Hybrids

For the purposes of dog licensing, immunization, and response to bites, wolf-dog hybrids shall be considered wild animals and not dogs. The status of an animal as a dog or as a wolf-dog hybrid shall be determined by a Licensed Veterinarian. Such determinations may consider descriptions of the animal in medical records and prior claims made by the owner, and shall be subject to review by the State Public Health Veterinarian or designee.

Stat. Auth.: ORS 413.042, 431.001, 433.004, 433.340, 686.010 & 686.020
Stats. Implemented: ORS 433.004, 433.380
Hist.: OHD 4-2002, f. & cert. ef. 3-4-02

333-019-0024
Management of Animal Bites

(1) The circumstances surrounding bites of humans by mammals shall be investigated by the local public health administrator in accordance with the Investigative Guidelines published by the Authority.

(2) Except as provided in section (3) of this rule, any dog, cat, or ferret that has bitten a person shall be held for observation until the 10th day following the bite. This observation shall be under the supervision of a licensed veterinarian or other person designated by the local public health administrator. Animals shall be held within an enclosure or with restraints deemed adequate by the local public health administrator to prevent contact with any person or other animals. At the discretion of the local public health administrator, properly vaccinated dogs used by public law enforcement agencies may be exempted from the observation period requirement; however, any law enforcement agency shall notify the local public health administrator immediately should any exempted dog develop abnormal behavior within 10 days of biting a person.

(3) The local public health administrator may order the euthanasia and rabies testing of animals that have bitten humans when these animals are:

(a) Inadequately vaccinated dogs, cats, or ferrets that have inflicted an unprovoked bite to the face, head, or neck of a person; or

(b) Any other mammal suspected of having rabies or that has been in contact with an animal suspected of having rabies.

(4) Because it is preferable to hold such animals for observation, no person shall either euthanize any dog, cat, or ferret that has bitten a human or destroy the head of any mammal that has bitten a person without authorization by the local public health administrator.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 413.042, 431.110, 433.004, 433.340, 433.350
Stats. Implemented: ORS 433.345, 433.350
Hist.: OHD 4-2002, f. & cert. ef. 3-4-02; PH 7-2011, f. & cert. ef. 8-19-11

333-019-0027
Management of Possibly Rabid Animals

(1) An animal is considered to have been in close contact with an animal suspected of having rabies when, within the past 180 days, it has been bitten, mouthed, mauled by, or closely confined with a rabid animal or any mammal suspected of having rabies.

(2) The disposition of such animals and of animals suspected of having rabies that have not bitten humans shall be determined by the local public health authority as follows:

(a) Inadequately vaccinated dogs, cats, and ferrets shall be destroyed immediately, if the owner permits. If the owner does not agree to this, the animal shall be confined as prescribed by the local public health authority for a period of four months for dogs and cats and six months for ferrets under the observation of a licensed veterinarian or a person designated by the local public health authority. A rabies vaccine must be administered at the time of entry into quarantine to bring the animal up to current rabies vaccination status.

(b) Dogs, cats, and ferrets that are adequately vaccinated shall be revaccinated immediately and observed in confinement for 45 days by a person designated by the local public health authority. If the owner prefers, such animals can be destroyed (in lieu of confinement) with the concurrence of the local public health authority.

(c) Unless the owner prefers to hold any unvaccinated livestock or wild animals born and raised in captivity in confinement for six months, such animals shall be destroyed. Livestock that are current on rabies vaccination with a USDA-licensed vaccine approved for that species should be given a booster vaccination immediately and observed for 45 days.

(d) Unless otherwise specified, all other mammals shall be destroyed.

(e) For the purposes of this rule, confinement shall be within an enclosure or with restraints deemed adequate by the local public health authority to prevent contact with any member of the public or any other animal. Nothing in these rules or in OAR 333-019-0024 shall be interpreted to require any public authority to bear the costs of such confinement.

(3) Nothing in these rules is intended or shall be construed to limit the power of any city, city and county, county or district in its authority to enact more stringent requirements to regulate and control animals within its jurisdiction.

Stat. Auth.: ORS 413.042 & 433.360
Stats. Implemented: ORS 433.360
Hist.: OHD 4-2002, f. & cert. ef. 3-4-02; PH 5-2010, f. & cert. ef. 3-11-10; PH 24-2016, f. 8-8-16, cert. ef. 8-16-16

Other Disease-Specific Provisions

333-019-0031
Acquired Immunodeficiency Syndrome/Human Immunodeficiency Virus

Investigation of cases of HIV infection or AIDS. Investigations of HIV infection or AIDS shall be conducted to the extent that resources permit. The Authority, or the local public health administrator, will ensure that each identified case is offered prevention, care, and partner counseling and referral services.

NOTE: Specific rules regarding reporting requirements for HIV and AIDS may be found in OAR 333-018-0015. Rules regarding informed consent for HIV testing and confidentiality of HIV test results may be found in OAR 333-022-0200 through 333-022-0315.

Stat. Auth.: ORS 431.110, 433.004
Stats. Implemented: ORS 431.110, 433.004
Hist.: HD 4-1987, f. 6-12-87, ef. 6-19-87; HD 15-1988, f. 7-11-88, cert. ef. 9-1-88; HD 29-1994, f. & cert. ef. 12-2-94; OHD 13-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0223; OHD 22-2001, f. & cert. ef. 10-19-01; OHD 4-2002, f. & cert. ef. 3-4-02; PH 7-2006, f. & cert. ef. 4-17-06; PH 7-2011, f. & cert. ef. 8-19-11; PH 16-2013, f. 12-26-13, cert. ef. 1-1-14

333-019-0036
Special Precautions Relating to Pregnancy and Childbirth

(1)(a) Blood samples drawn from women during pregnancy or at delivery pursuant to ORS 433.017 shall be submitted for standard tests for reportable infectious diseases or conditions which may affect a pregnant woman or fetus. Routine tests submitted shall include syphilis, hepatitis B, and HIV. Tests using bodily fluids other than blood that have equal or better sensitivity and specificity may be substituted for the blood test.

(b) "Consent of the patient to take a sample of blood" (as stated in ORS 433.017, section 3) or other bodily fluid, is defined as notifying the patient or her authorized representative of the tests which will be conducted on that specimen. The patient or her authorized representative shall be informed that she may decline any or all of the tests.

(c) If a patient declines any of the offered tests, documentation shall be included in the medical record.

(2) Any health care provider attending the birth of an infant shall evaluate whether the newborn is at risk for gonococcal oph-

thalmia neonatorum. The primary means of assessing risk shall be review of results of prenatal testing and maternal history of risk factors for gonococcal. If the infant is determined to be at risk, or risk cannot be adequately assessed, the person attending the birth shall ensure that the newborn receives erythromycin or tetracycline ophthalmic ointment or silver nitrate 1 percent aqueous solution into each eye within two hours after delivery.

Stat. Auth.: ORS 413.042 & 433.017
Stats. Implemented: ORS 433.017, 433.006 & 433.110
Hist.: OHD 4-2002, f. & cert. ef. 3-4-02; PH 20-2005, f. 12-30-05, cert. ef. 1-1-06; PH 5-2010, f. & cert. ef. 3-11-10

333-019-0039
Sudden Infant Death Syndrome

(1) In compliance with ORS 431.120(4), the Authority will conduct an epidemiologic investigation of each instance of sudden infant death syndrome.

(2) In order to promote support of this effort, the Authority will reimburse any county health department (or other agency providing public health services in lieu of a county health department for this purpose) to the extent of $25 to help defray the cost of one home visit by a public health nurse to any family who has lost a member of the family to SIDS.

(3) In order for the home visit to be reimbursed the following procedure will be required:

(a) On receiving the death investigation report in which the cause of death is SIDS, the administrator of the local public health authority receiving the report will, if possible, assure the arrangement of a home visit to the affected family by a public health nurse at an appropriate time;

(b) The home visit will include:

(A) A nursing assessment of family needs related to the SIDS event;

(B) Grief counseling;

(C) Education regarding the state of knowledge regarding the cause of SIDS;

(D) Discussion of other support resources available to help meet family needs;

(E) Information alerting the family to expect to receive in the mail an epidemiologic investigation questionnaire, including an explanation of its purpose, of its confidentiality, and assurance of assistance in completing the form if necessary.

(4) After the home visit has been completed, the local agency will notify the Authority in writing, including the name and birth date of the deceased infant, and the family name and address, and the date of the visit. This notice should be addressed to the Public Health Division, Center for Public Health Practice, 800 NE Oregon Street, Portland, OR 97232.

(5) On receipt of this written notice, the Authority will reimburse the agency in the amount of $25. Reimbursement for repeat visits to the same family will not be available.

(6) An epidemiologic questionnaire will be mailed by the Authority to the parent(s) (guardian) of the deceased infant, with instructions as to its purpose and means of completing and a request that it be completed and returned.

(7) In the event that the completed questionnaire has not been returned in a reasonable length of time, the Authority will notify the county health department (or agency acting in lieu of the county health department) with a request for a follow-up contact with the family to ensure the highest possible rate of return and of accuracy.

(8) Completed questionnaires will be collected and tabulated and the information analyzed by the Authority. A report of the findings will be published biennially beginning in 1985.

Stat. Auth.: ORS 431.001 & 433.004
Stats. Implemented: ORS 431.001 & 433.004
Hist.: HD 3-1983, f. & ef. 3-3-83; HD 16-1991, f. & cert. ef. 10-10-91; HD 29-1994, f. & cert. ef. 12-2-94; OHD 15-2001, f. & cert. ef. 7-12-01, Renumbered from 333-018-0025; OHD 4-2002, f. & cert. ef. 3-4-02; PH 7-2011, f. & cert. ef. 8-19-11

333-019-0041
Tuberculosis

(1) Each health care facility shall formally assess the risk of tuberculosis transmission among staff (professional and volunteer), residents, and patients at least annually and shall follow tuberculosis screening recommendations outlined in "Guidelines for preventing the transmission of Mycobacterium tuberculosis in Health-Care Settings," published by the Centers for Disease Control and Prevention (Morbidity and Mortality Weekly Report, Vol. 54, Number RR-17: 1-141; December 30, 2005) or otherwise approved by the Authority. For the purposes of this rule "health care facility" has the meaning given that term in ORS 442.015.

(2) Each facility specified below shall formally assess the risk of tuberculosis transmission among staff (professional and volunteer), residents, and patients at least annually and shall follow appropriate tuberculosis screening recommendations as outlined in the relevant publication or as otherwise approved by the Authority:

(a) Long Term Care Facilities for the Elderly: "Prevention and control of tuberculosis in facilities providing long-term care to the elderly. Recommendations of the Advisory Committee for Elimination of Tuberculosis," published by the Centers for Disease Control and Prevention (Morbidity and Mortality Weekly Report, Vol. 39, RR-10, pp. 7-20; July 13, 1990) and "Guidelines for preventing the transmission of Mycobacterium tuberculosis in Health-Care Settings," published by the Centers for Disease Control and Prevention (Morbidity and Mortality Weekly Report, Vol. 54, Number RR-17: 1-141; December 30, 2005).

(b) Homeless Shelters: "Prevention and control of tuberculosis among homeless persons," published by the Centers for Disease Control and Prevention (Morbidity and Mortality Weekly Report, Vol. 41, RR-5, pp. 13-23; April 17, 1992)

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 431.110, 432.060, 433.001–433.035, 433.110–433.220 & 437.030
Stats. Implemented: ORS 431.150, 431.155, 431.170, 433.001–433.035, 433.110–433.220 & 437.030
Hist.: OHD 4-2002, f. & cert. ef. 3-4-02; PH 10-2005, f. 6-15-05, cert. ef. 6-21-05; PH 9-2009, f. & cert. ef. 9-22-09; PH 7-2011, f. & cert. ef. 8-19-11; PH 12-2011, f. & cert. ef. 12-14-11

333-019-0042
Tuberculosis Screening in Correctional Facilities

(1) For purposes of this rule:

(a) "Correctional facility" means a facility operated by the Oregon Department of Corrections or a local correctional facility as that is defined in ORS 169.005; and

(b) "Symptoms of TB disease" means a cough longer than 3 weeks and/or coughing up blood in conjunction with fever, fatigue, night sweats or weight loss.

(2) A correctional facility shall screen all inmates upon admission for symptoms of tuberculosis (TB) disease. This screening and any follow-up shall be documented.

(3) Any inmate suspected of having TB disease or who has TB disease shall be isolated as appropriate and provided medical care and treatment that meets accepted standards of practice.

(4) Inmates detained or confined for 15 consecutive days or more in a correctional facility shall be screened for the following TB risk factors:

(a) HIV/AIDS;

(b) Immigration within the past five years from a country that has a high incidence of TB, including but not limited to immigration from Africa, Asia, Middle East, Latin America, Eastern Europe and South Pacific regions;

(c) Close contact to a person with infectious TB disease;

(d) History of injection drug use;

(e) History of homelessness; and

(f) Taking immunosuppressive medication.

(5) Inmates screened under section (4) of this rule who have TB risk factors and no documented history of prior positive screening tests for TB shall be screened with either a TB skin test or interferon gamma release assay (IGRA). Inmates with a documented previously positive TB skin test or IGRA, or a new positive result upon testing, shall receive a chest X-ray.

(6) Exceptions:

(a) A correctional facility is not required to retest an inmate at each admission under section (5) of this rule if:

(A) There is a documented record of a negative TB skin test or negative IGRA or normal chest X-ray within the past year; or

(B) There is a documented record of adequate TB treatment or compliance with a currently prescribed TB treatment.

(b) This exception does not apply if the inmate has symptoms of TB, evidence of new exposure to a person with infectious TB disease or a diagnosis of HIV/AIDS.

(7) Nothing in these rules prohibit any correctional facility from having more stringent TB screening requirements.

Stat. Auth.: ORS 431.110, 432.060, 433.001–433.035, 433.110–433.220 & 437.030

Stats. Implemented: ORS 431.150, 431.155, 431.170, 433.001–433.035, 433.110–433.220 & 437.030

Hist.: PH 12-2011, f. & cert. ef. 12-14-11

333-019-0052
Communication during Patient Transfer of Multidrug-Resistant Organisms

(1) As used in this rule:

(a) "Facility" means:

(A) A healthcare facility as that term is defined in ORS 442.015;

(B) An infirmary (for example, in a jail or prison);

(C) A residential facility or assisted living facility as those terms are defined in ORS 443.400;

(D) An adult foster home as that term is defined in ORS 443.705;

(E) A hospice program as that term is defined in ORS 443.850; and

(F) Any other facility that provides 24-hour patient care.

(b) "Multidrug-resistant organism" (MDRO) means an organism causing human disease which has acquired antibiotic resistance, as listed and defined in the Centers for Disease Control and Prevention's Antibiotic Resistance Threats in the United States, 2013 (Atlanta, GA; 2013). MDROs include but are not limited to:

(A) Methicillin-resistant Staphylococcus aureus (MRSA);

(B) Vancomycin-resistant Enterococcus (VRE);

(C) Carbapenem-resistant Enterobacteriaceae (CRE), as that term is defined in OAR 333-017-0000 sections (10) and (24);

(D) Multidrug-resistant Acinetobacter baumannii;

(E) Multidrug-resistant Pseudomonas aeruginosa;

(F) Drug-resistant Streptococcus pneumoniae;

(G) Other Gram-negative bacteria producing extended-spectrum beta-lactamases (ESBL); and

(H) Toxin-producing Clostridium difficile.

(c) "Receiving facility" means the facility receiving or admitting the case patient into their care from another facility's care.

(d) "Referring facility" means the facility transferring or discharging the case patient out of its care and into another facility's care.

(e) "Standard Precautions" means the minimum infection prevention measures that apply to all patient care, regardless of suspected or confirmed infection status of the patient, in any setting where healthcare is delivered. Standard Precautions include:

(A) Hand hygiene;

(B) Use of personal protective equipment (for example, gloves, gowns, facemasks), depending on the anticipated exposure;

(C) Respiratory hygiene and cough etiquette;

(D) Safe injection practices; and

(E) Safe handling of potentially contaminated equipment or surfaces in the patient environment.

(f) "Transmission Based Precautions" means infection control practices that are implemented in addition to Standard Precautions in patients with known or suspected colonization or infection of highly transmissible or epidemiologically important infectious pathogens (for example, CRE, norovirus, Neisseria meningitidis) or syndromes (for example, diarrhea) when there is strong evidence that the pathogen or syndrome may be transmitted from person to person via droplet, contact, or airborne routes in healthcare or non-healthcare settings (Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee. Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, 2007).

(2) When a referring facility transfers or discharges a patient who is infected or colonized with a multidrug-resistant organism (MDRO) or pathogen which warrants Transmission Based Precautions, it must include written notification of the infection or colonization to the receiving facility in transfer documents. The referring facility must ensure that the documentation is readily accessible to all parties involved in patient transfer (for example, referring facility, medical transport, emergency department, receiving facility).

(3) When a facility becomes aware that it received in transfer one or more patients with an MDRO or pathogen that warrants Transmission Based Precautions, and that was isolated from a patient specimen collected within 48 hours after transfer, it must notify the referring facility.

(4) When a facility becomes aware that it transferred or discharged one or more patients who have an MDRO or pathogen that warrants Transmission Based Precautions, the referring facility must notify the receiving facility.

(5) If a facility transfers or discharges a patient with laboratory-confirmed, carbapenemase-producing Enterobacteriaceae, the facility must notify the local health department communicable disease staff within one working day of the date and destination of the transfer or discharge.

Stat. Auth.: ORS 413.042, 431.110, 433.004, 433.010

Stats. Implemented: ORS 433.004, 433.006, 433.010, 433.110, 442.015, 443.400, 443.705, 443.850

Hist.: PH 16-2013, f. 12-26-13, cert. ef. 1-1-14

DIVISION 20

NEWBORN HEARING SCREENING TESTS

333-020-0125
Definitions

As used in these rules:

(1) "Advisory Committee" means the Newborn Hearing Advisory Committee appointed by the Director of the Oregon Health Authority to advise the Authority and the legislature on the implementation and evaluation of universal newborn hearing screening in Oregon and the state newborn hearing screening test registry, tracking and recall system.

(2) "Authority" means the Oregon Health Authority.

(3) "Automated auditory brainstem response" means a specific test method that elicits an objective electro-physiological measurement of the brainstem's response to acoustic stimulation of the ear, obtained with equipment that automatically provides a pass/refer outcome.

(4) "Birthing Center" means any health facility licensed by the State of Oregon for the primary purpose of performing low risk deliveries, as defined in ORS 442.015(14)(f).

(5) "Birthing Facility" means the location of a child's birth, including hospital, birthing center (or) in the case of a home or out-of-facility birth, the child's birthing attendant.

(6) "Child" (or plural "children") means any individual (or individuals) who is (are) less than 36 months of age.

(7) "Diagnostic Facility" means any facility or person, including hospitals, private audiology practices, licenses health care providers and educational facilities that conduct newborn hearing diagnostic testing.

(8) "Diagnostic Testing" means the performance of physiologically-based testing on children to determine the presence or absence and extent of a hearing loss, using procedures specified by the Authority, for the purposes of establishing a diagnosis and serving as a basis for initiating therapy and/or intervention.

(9) "Director" means the Assistant Director of Oregon Health Authority, Public Health Division.

(10) "Early intervention services" means services for children with disabilities from birth until three years of age that are

designed to meet the developmental needs of children with disabilities and the needs of the family related to enhancing the child's development, and that are selected in collaboration with the parents and caregivers.

(11) "Early intervention facility" is any public or private educational institution providing early intervention services.

(12) "EI" (or, alternately, "EI/ECSE") means the Early Intervention/Early Childhood Special Education Program of the Office of Special Education of the Oregon Department of Education. EI/ECSE provides early intervention services under public supervision by personnel qualified in accordance with criteria established by rules of the State Board of Education and in conformity with an individualized family service plan, as defined in ORS 343.035(6).

(13) "Follow-up Hearing Test" means any hearing screening or diagnostic test procedure that is conducted on a child who is enrolled in the Tracking and Recall System.

(14) "Hospital" means any health care facility licensed by the State of Oregon and meeting the definition of "hospital" in ORS 442.015(14)(a).

(15) "Newborn" means a child less than one month of age.

(16) "Newborn Hearing Screening Test" means a physiologically-based test procedure utilizing either otoacoustic emissions or automated auditory brainstem response technologies, or other technologies as approved by the Authority. If a newborn achieves a 'pass' on the first screening test, screening is completed. If a newborn does not pass, a second screening test is carried out immediately using a different technology or, after an interval of 12 hours, using the same technology.

(17) "Newborn hearing screening test registry" means a listing of newborn children and information related to their newborn hearing screening tests.

(18) "Otoacoustic emissions" means a specific test method that elicits a physiologic response from the cochlea, and may include Transient Evoked Otoacoustic Emissions and Distortion Product Otoacoustic Emissions.

(19) "Pass" means a newborn hearing screening result that indicates that a child's hearing is most likely within normal limits.

(20) "Private educational institution" means any private institution providing early intervention services as defined in ORS 343.035(6) or the equivalent and which have been accepted for the Office of Special Education of the Oregon Department of Education's "Approved Private Schools" list.

(21) "Public educational institution" means any public educational institution providing early intervention services, as defined in ORS 343.035(6).

(22) "Refer" means a newborn hearing screening test result that indicates that a child needs a follow-up hearing test.

(23) "Regional Program" means any one of the Low Incidence Regional Programs for the Deaf and Hard-of-Hearing.

(24) "Screening Facility" means any facility or person, including hospitals, birthing centers, private audiology practices, licensed health care providers and educational facilities that conduct newborn hearing screening tests.

(25) "Tracking and recall system" means a system attached to the newborn hearing test registry designed to identify and contact the parent or guardian of a newborn child listed in the newborn hearing screening test registry for the purposes of assisting in testing and in enrollment of the child in early intervention services in a timely manner.

Stat. Auth.: ORS 433.323
Stats. Implemented: ORS 433.321–433.327
Hist.: OHD 8-2000, f. & cert. ef. 7-20-00, PH 21-2003, f. & cert. ef. 12-16-03; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 11-2011, f. & cert. ef. 10-27-11

333-020-0127
Purpose and Intent

(1) The purpose of these rules is to implement ORS 433.321 et.seq., which:

(a) Authorizes the Authority to develop a newborn hearing screening test registry and tracking and recall system for all newborns in Oregon; and

(b) Requires the Authority to adopt rules to develop and implement the registry and recall system.

(2) In order to identify children with hearing loss as early as possible and assure timely entry into early intervention services, it is the intent that all Oregon newborns will be enrolled in the newborn hearing screening test registry using information derived from birth records and from screening facility reports to the Authority.

(3) It is the intent that all children who are identified in the newborn hearing screening test registry as not having completed a newborn hearing screening test (and) all children who received a result of "REFER" on the newborn hearing screening test shall be enrolled in the Tracking and Recall system. In addition, it is the intent that all children in the Newborn Hearing Screening Test Registry who are diagnosed with a hearing loss regardless of their initial newborn hearing screening test result shall be enrolled in the Tracking and Recall System.

(4) It is the intent that all screening facilities and diagnostic facilities that are conducting follow-up hearing tests on children enrolled in the tracking and recall system shall report child-specific information to the Authority for the purposes of assuring that children are receiving needed services in a timely manner.

Stat. Auth.: ORS 433.323
Stats. Implemented: ORS 433.321–433.327
Hist.: PH 21-2003, f. & cert. ef. 12-16-03

333-020-0130
Requirement for Hearing Loss Screening in Newborn Children

(1) In all hospitals or birthing centers with more than 200 live births per year, each newborn child shall receive a Newborn Hearing Screening Test within one month of the child's date of birth.

(2) The hospital or birthing center shall attempt to conduct the Newborn Hearing Screening Test prior to discharge of the child from the facility.

(3) No newborn child may be refused the Newborn Hearing Screening Testing because of an inability of the parent or guardian to pay for the testing.

(4) For hospitalized children, the timing of the Newborn Hearing Screening Test may be deferred if medically indicated.

(5) The hospital or birthing center shall notify the parent or guardian and the health care provider of the newborn child of the Newborn Hearing Screening Test results within 10 days of the test. This notification shall include a description of the meaning of a Pass result and a Refer result.

(6) The hospital or birthing center shall, with the results of the Newborn Hearing Screening Test, provide the parent or guardian of a child who needs follow-up testing and the health care provider with the names and contact information for diagnostic facilities and a description of the importance of timely diagnosis and intervention.

(7) The Authority will determine the number of live births per year by information provided by the Center for Health Statistics of the Authority.

(8) Hospitals or birthing centers which in the past have not had more than 200 births per year and which then report to the Authority more than 200 live births in a calendar year, shall be required to begin providing Newborn Hearing Screening Testing by July first of the following calendar year.

(9) Hospitals or birthing centers which in the past have had more than 200 live births per year and which then report to the Authority fewer than 200 live births in a calendar year may choose to discontinue providing Newborn Hearing Screening Testing on or after April first of the following calendar year.

(10) Hospitals or birthing centers with fewer than 200 live births per year, and which are not providing the Newborn Hearing Screening Test, shall provide the parent or guardian of a newborn child born in their facility with information furnished by the Authority including, but not limited to, a list of Authority recommended screening facility locations and contact information, and a statement indicating that newborn hearing screening is considered standard of care.

Stat. Auth.: ORS 433.321
Stats. Implemented: ORS 433.321

Hist.: OHD 8-2000, f. & cert. ef. 7-20-00; PH 21-2003, f. & cert. ef. 12-16-03

333-020-0135
Facility Responsible for Performing the Newborn Hearing Screening Test

(1) Should a newborn child be discharged from a hospital or birthing center with more than 200 live births in a calendar year before the Newborn Hearing Screening Test is performed or completed, it shall be the responsibility of the hospital to arrange for the provision of screening.

(2)(a) In all hospitals and birthing centers with more than 200 live births in a calendar year, the hospital or birthing center where a baby is born is responsible for assuring that the Newborn Hearing Screening Test is performed on that newborn child within one month of the child's date of birth, except that, for hospitalized children, the timing of the testing may be deferred past the one month time line, if medically indicated. If testing is deferred, the hospital shall be responsible for performing the Newborn Hearing Screening Test prior to the child's discharge to home.

(b) For purposes of this section, in the case of a newborn child admitted to a hospital as a result of transfer from another hospital or birthing center, the hospital from which the child is discharged to home shall be responsible for the performance of the Newborn Hearing Screening Test, if not done prior to transfer.

Stat. Auth.: ORS 433.321
Stats. Implemented: ORS 433.321
Hist.: OHD 8-2000, f. & cert. ef. 7-20-00; PH 21-2003, f. & cert. ef. 12-16-03

333-020-0140
Maintaining a List of Facilities Able to Perform Follow-up Diagnostic Testing

(1) The Authority shall maintain a list of licensed clinical audiologists or licensed physicians able to perform Diagnostic Testing, as follows:

(a) The Authority shall establish written criteria for placement on the list, including testing and reporting requirements.

(b) Individual audiologists or physicians may choose to be identified solely by the facility with which they are affiliated or by whom they are employed, if that facility accepts the testing requirements of 333-020-0145(1)(a).

(c) Audiologists or physicians who meet the criteria for inclusion on the list may notify the Authority that they wish to be included on the list, and upon verification of eligibility, the Authority shall immediately update the list.

(2) The list, and the criteria, shall be available at the Authority, upon request.

(3) The Authority shall provide the list, on at least an annual basis, no later than April first, to all hospitals or birthing centers.

Stat. Auth.: ORS 433.321
Stats. Implemented: ORS 433.321
Hist.: OHD 8-2000, f. & cert. ef. 7-20-00; PH 21-2003, f. & cert. ef. 12-16-03

333-020-0145
Maintaining and Distributing a List of Early Intervention Facilities

(1) The Authority shall maintain a list of early intervention facilities that provide early intervention services to infants who are deaf or hard-of-hearing, as follows:

(a) Each Regional Program.

(b) Each county office of the EI/ECSE program.

(c) Each private educational institution.

(d) The Authority may list the Regional Program in lieu of the EI county office(s) in that region, at the discretion of the Office of Special Education of the Oregon Department of Education, for the purpose of simplifying and facilitating the early intervention enrollment process for parents and guardians.

(2) The Authority shall provide this list of early intervention facilities to all individuals or facilities that are on the list of diagnostic facilities, as defined in OAR 333-020-0145, annually, no later than September first, to facilitate referrals.

Stat. Auth.: ORS 433.321
Stats. Implemented: ORS 433.321
Hist.: OHD 8-2000, f. & cert. ef. 7-20-00; PH 21-2003, f. & cert. ef. 12-16-03

333-020-0147
Newborn Hearing Screening Test Registry

Using information submitted by birthing facilities and screening facilities, including birth records and newborn hearing screening test results, the Authority shall establish a registry of all newborns and their hearing screening test results or status.

Stat. Auth.: ORS 433.323
Stats. Implemented: ORS 433.321–433.327
Hist.: PH 21-2003, f. & cert. ef. 12-16-03

333-020-0149
Tracking and Recall System

(1) In consultation with the Advisory Committee, the Authority shall establish and implement a tracking and follow-up protocol for newborns in the Newborn Hearing Screening Test Registry identified with hearing loss or at-risk of hearing loss, including, but not limited to:

(a) Newborns who have no recorded newborn hearing screening test results and/or no recorded newborn hearing screening status in the Newborn Hearing Screening Test Registry;

(b) Newborns who have newborn hearing screening test results or status of:

(A) "REFER";

(B) Unable to complete initial screen;

(C) Screening deferred for medical reasons.

(c) Newborns or children who have been diagnosed with hearing loss.

(2) At a minimum, the tracking and follow-up protocol shall include:

(a) Responsibilities of Authority staff for identifying children in need of follow-up testing and for contacting parents/guardians, health care providers and local public health staff regarding needed follow-up services;

(b) Recommended methods and time frames for contacting parents/guardians, health care providers and local public health agencies regarding needed follow-up services;

(c) Procedures to document contacts made and outcomes of contacts;

(d) Procedures to identify, document and comply with parent/family desire to opt-out of continued follow-up;

(e) Procedures to document and address barriers to timely follow-up services, including financial and geographic barriers;

(f) Procedures to document "Loss to follow-up" after reasonable attempts are made to contact family and/or health care provider;

(g) Procedures to assure child-specific and family information is used only for the purposes for which it is intended and is not disclosed for other unrelated purposes.

Stat. Auth.: ORS 433.323
Stats. Implemented: ORS 433.321–433.327
Hist.: PH 21-2003, f. & cert. ef. 12-16-03

333-020-0150
Collecting and Submitting Information Related to Newborn Hearing Screening

(1) By November 1, 2003, the Authority shall develop confidential reporting mechanisms and protocols for reporting newborn hearing screening test results to the Newborn Hearing Screening Test Registry. The reporting mechanisms and protocols shall be reviewed at least annually and modified as necessary.

(2) By November first of each year, or as necessary due to modifications, the Authority shall provide a written description of the reporting mechanisms and protocols, including reporting form templates if appropriate, to all screening facilities.

(3) Prior to the January 1, 2004 effective date of the law and as requested, the Authority shall offer training and technical assistance for screening facility staff to assure effective implementation of the newborn hearing screening reporting requirements.

(4) Beginning January 1, 2004, within 10 days of testing, each screening facility conducting newborn hearing screening tests shall report to the Authority, at a minimum, the following information about each newborn child receiving hearing screening in that facility.

(a) Name of the child;

(b) Child's date of birth;

(c) Birthing facility identifier;

(d) Screening facility identifier, if different than birthing facility;

(e) Newborn blood spot screening kit unique identification number, for matching purposes;

(f) Result of the newborn hearing screening test (or) status of the newborn hearing screening test, if not completed.

(5) The Authority may request that screening facilities report additional information deemed necessary to:

(a) Match the newborn hearing screening test result or status with the appropriate child in the Newborn Hearing Screening Test Registry;

(b) Identify children with risk factors for hearing loss.

Stat. Auth.: ORS 433.323
Stats. Implemented: ORS 433.321–433.327
Hist.: OHD 8-2000, f. & cert. ef. 7-20-00; PH 21-2003, f. & cert. ef. 12-16-03

333-020-0151
Collecting and Submitting Information Related to Diagnostic Testing for Hearing Loss in Newborns

(1) By November 1, 2003, the Authority shall develop and maintain confidential reporting mechanism (s) for child-specific diagnostic hearing test information.

(2) In consultation with the Advisory Committee, the Authority shall develop and distribute reporting form templates and protocols to approved diagnostic facilities, clinical audiologists and physicians conducting diagnostic hearing tests or other follow-up hearing testing on children.

(3) Prior to the January 1, 2004 effective date of the law and as requested, the Authority shall develop and offer training sessions for diagnostic facility staff to assure effective implementation of the reporting forms and protocols.

(4) The Authority shall review reporting forms and protocols at least annually, and as necessary, for effective management of the program. In the event of a modified form or protocol, the Authority shall give the diagnostic facility at least one full calendar month to incorporate the new form or protocol into practice.

(5) Within 10 days of testing of a child who has a "REFER" result on the newborn hearing screening test (or) who presents for an initial or completion of a newborn hearing screening test (or) who is diagnosed with a hearing loss, the diagnostic facility conducting the testing shall report, at a minimum, the following information to the Authority via the confidential reporting mechanism(s) established by the Authority:

(a) Name of the child;

(b) Child's date of birth;

(c) Birthing facility identifier, if known;

(d) Parent or guardian's name, address, and contact information;

(e) Child's primary health care provider;

(f) Newborn hearing screening results, if known;

(g) Diagnostic facility identifier;

(h) Diagnostic testing results, including type and degree of hearing loss and affected ear(s), if applicable;

(i) Disposition, including referrals made to early intervention services;

(j) Name and contact information for person completing diagnostic hearing test;

(k) Name and contact information for person completing form, if different than (j).

(6) The Authority may request that diagnostic facilities report additional information deemed necessary to:

(a) Match the follow-up test result or status with the appropriate child in the Newborn Hearing Screening Test Registry and Tracking and Recall System;

(b) Provide or offer follow-up services to children identified with hearing loss or at-risk of hearing loss and their families.

Stat. Auth.: ORS 433.323
Stats. Implemented: ORS 433.321–433.327
Hist.: PH 21-2003, f. & cert. ef. 12-16-03

333-020-0155
Responsibility for Issuing Reports

(1)(a) The Authority shall analyze the information collected under OAR 333-020-0160 through 333-020-0175:

(b) The Authority shall provide an individualized monthly report to each screening, diagnostic and early intervention facility detailing submissions from that facility from the previous month. Monthly reports to each facility shall include information about the follow-up status of individual children from that facility who are enrolled in the tracking and recall system as allowed by law.

(2) The Authority shall issue an annual report and analysis of aggregated data submitted by all screening, diagnostic and early intervention facilities, by July first of each year for the previous year's data.

(3) In consultation with the Advisory Committee, the Authority shall include in the annual report recommendations for improvement of the Early Hearing Detection and Intervention Program, including but not limited to improvement in the Newborn Hearing Screening Test Registry and Tracking and Follow-up System.

Stat. Auth.: ORS 433.323
Stats. Implemented: ORS 433.321–433.327
Hist.: OHD 8-2000, f. & cert. ef. 7-20-00; PH 21-2003, f. & cert. ef. 12-16-03

333-020-0160
Appointment of a Newborn Hearing Advisory Committee

(1) The Director shall appoint an Advisory Committee to:

(a) Provide policy level guidance and advice to the Authority on the implementation of the Newborn Hearing Screening Test Registry and Tracking and Recall system as defined by OAR 333-020-125 through 333-025-0180.

(b) Provide assistance in the preparation of a report to the biennial Legislative Assembly on the status of early hearing detection and intervention efforts in Oregon and the implementation and evaluation of the Newborn Hearing Screening Test Registry and Tracking and Recall System. The report will include but not be limited to strategies to increase the rate of early screening for children born in hospitals and birthing centers with less than 200 live births per year or born outside of hospitals and birthing centers.

(2) At a minimum, the Advisory Committee shall include at least one representative from each of the following categories:

(a) Parent of a child with hearing loss;

(b) Adult with hearing loss;

(c) Pediatric health care provider;

(d) Clinical audiologist;

(e) Hospital newborn hearing screening program representative;

(f) Diagnostic facility representative;

(g) Early intervention facility representative;

(h) Local public health agency representative;

(i) Speech-language pathologist.

(3) The Director shall establish by-laws of the Advisory Committee, including additional committee membership categories, committee duties and terms.

Stat. Auth.: ORS 433.323
Stats. Implemented: ORS 433.321–433.327
Hist.: OHD 8-2000, f. & cert. ef. 7-20-00; PH 21-2003, f. & cert. ef. 12-16-03

333-020-0165
Religious Exemption from Testing

(1) A hospital or birthing center directed to provide Newborn Hearing Screening Tests under these Administrative Rules is exempt from providing such services if the parent or guardian of the newborn child objects to the testing procedure on the grounds that the procedure conflicts with the religious tenets and practices of the parent or guardian.

(2) The parent or guardian must sign a statement that the newborn child is being so reared, using the following language: [Form not included. See ED. NOTE.]

[ED. NOTE: Forms referenced are available from the agency.]

Stat. Auth.: ORS 433.323
Stats. Implemented: ORS 433.321–433.327
Hist.: OHD 8-2000, f. & cert. ef. 7-20-00; PH 21-2003, f. & cert. ef. 12-16-03

DIVISION 21

PREVENTIVE MEDICINE

Artificial Insemination

333-021-0700
Form for Reporting Written Request and Consent to Performance of Artificial Insemination

The form, referred to as Exhibit 2 and by this reference made a part hereof, is adopted as the form for reporting written request and consent to performance of artificial insemination pursuant to ORS 677.365.

[ED. NOTE: Exhibits referenced are available from the agency.]

Stat. Auth.: ORS 677.365
Stats. Implemented: ORS 677.365
Hist.: HD 146(Temp), f. & ef. 11-7-77; HD 3-1978, f. & ef. 2-21-78

Newborns

333-021-0800
Administration of Vitamin K to Newborns

(1) The purpose of ORS 433.303 to 433.314 is to protect newborn infants against hemorrhagic disease of the newborn.

(2) The Vitamin K forms suitable for use are forms of Vitamin K_1 (Phytonadione), available in injectable or oral forms: as Mephyton for oral use, or as aquamephyton or konakion for injectable use. Menadione (Vitamin K_3) is not recommended for prophylaxis and treatment of hemorrhagic disease of the newborn:

(a) The dose of any of the Vitamin K_1 forms to be administered is one dose of 0.5 to 1.0 mg., if given by injection, or one dose of 1.0 to 2.0 mg. if given orally. Additional or larger doses may be administered on an individual basis as judged medically necessary;

(b) The Vitamin K dose is to be administered within the first 24 hours of delivery. If for any reason this is not done, the administration of Vitamin K_1 to the newborn at a later date is recommended.

(3) The forms of Vitamin K listed in section (2) of this rule are prescription drugs, and because no forms of Vitamin K_1 appropriate for oral administration to newborn infants which are not prescription drugs have been identified, Vitamin K may be administered only by persons authorized by law to administer prescription drugs.

(4) Physicians licensed under ORS Chapters 677, 684 and 685 (medical, osteopathic, naturopathic and chiropractic physicians) or midwives attending the mother at the birth of the child are responsible for ensuring that Vitamin K is administered to the newborn. This may be accomplished by a person legally authorized to administer Vitamin K, or by directing another person who is legally authorized and in a position to administer Vitamin K, or by referring the infant's family to the local health department, hospital, or practitioner legally authorized to obtain and administer Vitamin K.

(5) The person administering the Vitamin K to the newborn shall keep a record of the administration for a minimum of six months.

(6) A parent may, after being provided a full and clear explanation, decline to permit the administration of Vitamin K. In this event, the parent shall sign a form acknowledging his/her understanding of the reason or administration of Vitamin K and possible adverse consequences in the presence of a person who witnessed the instruction of the parent, and who will also sign the form. The form shall become a part of the medical record of the newborn infant.

Stat. Auth.: ORS 433.312
Stats. Implemented: ORS 433.303–433.314
Hist.: HD 20-1984, f. & ef. 10-22-84

DIVISION 22

HUMAN IMMUNODEFICIENCY VIRUS HIV TESTING AND CONFIDENTIALITY

333-022-0200
Definitions

For purposes of OAR 333-022-0205 through 333-022-0210, unless otherwise specified the following definitions shall apply:

(1) "Division" means the Public Health Division within Oregon Health Authority.

(2) "Health care provider" has the meaning given that term in ORS 433.045.

(3) "HIV test" has the meaning given that term in ORS 433.045.

(4) "HIV-positive test" means a positive result on the most definitive HIV test procedure used to test a particular individual. In the absence of any recommended confirming tests, this means the positive result of the initial test done.

(5) "Insurance producer" has the meaning given that term in ORS 746.600.

(6) "Insurance-support organization" has the meaning given that term in ORS 746.600.

(7) "Insurer" has the meaning given that term in ORS 731.106.

(8) "Licensed health care facility" means a health care facility as defined in ORS 442.015 and a mental health facility, alcohol treatment facility or drug treatment facility licensed or operated under ORS Chapters 426 or 430.

(9) "Local public health administrator" has the meaning given that term in ORS 433.060.

(10) "Local public health authority" has the meaning given that term in ORS 431.260.

(11) "Next of kin" means an individual within the first applicable class of the following listed classes:

(a) The spouse of the decedent;

(b) A son or daughter of the decedent 18 years of age or older;

(c) Either parent of the decedent;

(d) A brother or sister of the decedent 18 years of age or older;

(e) A guardian of the decedent at the time of death;

(f) A person in the next degree of kindred to the decedent;

(g) The personal representative of the estate of the decedent; or

(h) The person nominated as the personal representative of the decedent in the decedent's last will.

(12) "Personal representative" means a person who has authority to act on behalf of an individual in making decisions related to health care.

(13) "Substantial exposure" means an exposure to blood or certain body fluids that have a potential for transmitting the human immunodeficiency virus based upon current scientific information and may include but is not limited to contact with blood or blood components, semen, or vaginal/cervical secretions through percutaneous inoculation or contact with an open wound, non-intact skin, or mucous membrane of the exposed person.

Stat. Auth.: ORS 433.045 - 433.080
Stats. Implemented: ORS 433.006 & 433.065
Hist.: PH 6-2013, f. & cert. ef 2-4-13

333-022-0205
HIV Testing, Notification, Right to Decline

(1) Pursuant to ORS 433.045, a health care provider or the provider's designee shall, before subjecting an individual to an HIV test:

(a) Notify the individual being tested; and

(b) Allow the individual being tested the opportunity to decline the test.

(2) A health care provider or the provider's designee may provide an individual notice and the opportunity to decline testing verbally or in writing, including providing the notice and the opportunity to decline in a general medical consent form.

(3) Whenever an insurer, insurance producer or insurance-support organization asks an applicant for insurance to take an HIV test in connection with an application for insurance, the insurer, insurance producer or insurance-support organization must reveal the use of the test to the applicant and obtain the written consent of the applicant. The consent form must disclose the purpose of the test and to whom the results may be disclosed.

(4) Anyone other than those listed in sections (1) through (3) of this rule who wishes to subject an individual to an HIV test must reveal the use of the test to the individual and obtain written consent of the individual for the HIV test.

(5) If an individual is deceased, next of kin may consent to an HIV test pursuant to ORS 433.075.

(6) If an individual is incapable of consenting to an HIV test, the individual's personal representative may consent on the individual's behalf.

Stat. Auth.: ORS 433.045 – 433.080
Stats. Implemented: ORS 433.045, 433.055(3), 433.065 & 433.075
Hist.: PH 6-2013, f. & cert. ef 2-4-13

333-022-0210
Confidentiality

(1) General. Pursuant to ORS 433.045, a person may not disclose or be compelled to disclose the identity of any individual upon whom an HIV test is performed or the results of such a test in a manner that permits identification of the subject of the test, except as required or permitted by federal law, the law of this state, or these rules, or as authorized by the individual who is tested. The prohibitions on disclosure do not apply to an individual acting in a private capacity and not in an employment, occupational or professional capacity.

(2) Disclosure to or for a tested individual. The results of an HIV test may be disclosed to:

(a) The tested individual;

(b) The health care provider or licensed health care facility or person ordering the test; and

(c) Any individual to whom the tested individual has authorized disclosure.

(3) Medical records. When a health care provider or licensed health care facility obtains HIV test results of an individual, the test results may be entered into the routine medical record of that individual maintained by that health care provider or licensed health care facility. The information in the record may be disclosed in a manner consistent with ORS 192.553 to 192.581 and the Health Information Portability and Accountability Act (HIPAA) regulations, 45 CFR 160 to 164.

(4) Public health purposes.

(a) Anyone may report the identity and HIV-related test result of an individual to the local public health authority or Division for public health purposes.

(b) The Division or local public health authority may inform an individual who has had a substantial exposure to HIV of that exposure if the Division or local public health authority determines that there is clear and convincing evidence that disclosure is necessary to avoid an immediate danger to the individual or to the public.

(c) The Division or local public health authority may disclose the identity of an individual with an HIV-positive test to a health care provider for the purpose of referring or facilitating treatment for HIV infection.

(d) The Division or local public health authority may only disclose the minimum amount of information necessary to carry out the purposes of the disclosure.

(5) Anatomical donations. The identity of a HIV tested individual and that individual's HIV test results may be released to a health care provider or licensed health care facility to the minimum extent necessary to make medical decisions concerning organ or tissue transplants.

(6) Nothing in this rule is intended to limit the extent to which a licensed health care facility or health care provider can use or disclose HIV related health information in accordance with other state and federal laws.

Stat. Auth.: ORS 433.008, 433.045
Stats. Implemented: ORS 433.045 – 433.080
Hist.: PH 6-2013, f. & cert. ef 2-4-13

Occupational and Health Care Setting Exposures

333-022-0300
Procedures for Requesting a Source Person Consent to an HIV Test Following an Occupational Exposure

(1) For purposes of this rule the following definitions apply:

(a) "Exposure" means contact with a source person's body fluids.

(b) "Licensed health care provider" has the meaning given that term in ORS 433.060.

(c) "Local public health administrator (LPHA)" means the public health administrator of the county or district health department for the jurisdiction in which the reported substantial exposure occurred.

(d) "Next of kin" means an individual within the first applicable class of the following listed classes:

(A) The spouse of the decedent;

(B) A son or daughter of the decedent 18 years of age or older;

(C) Either parent of the decedent;

(D) A brother or sister of the decedent 18 years of age or older;

(E) A guardian of the decedent at the time of death;

(F) A person in the next degree of kindred to the decedent;

(G) The personal representative of the estate of the decedent; or

(H) The person nominated as the personal representative of the decedent in the decedent's last will.

(e) "Occupational exposure" means a substantial exposure of a worker in the course of the worker's occupation.

(f) "Qualified person" means an individual, such as a licensed health care provider, who has the necessary training and knowledge about infectious disease to make a determination about whether an exposure was substantial.

(g) "Source person" means a person whose body fluids may be the source of a substantial exposure.

(h) "Substantial exposure" means an exposure to blood or certain body fluids that have a potential for transmitting the human immunodeficiency virus based upon current scientific information and may include but is not limited to contact with blood or blood components, semen, or vaginal/cervical secretions through percutaneous inoculation or contact with an open wound, non-intact skin, or mucous membrane of the exposed person.

(i) "Worker" means a person who is licensed or certified to provide health care under ORS Chapters 677, 678, 679, 680, 684 or 685, or ORS 682.216, an employee of a health care facility, of a licensed health care provider or of a clinical laboratory, as defined in ORS 438.010, a firefighter, a law enforcement officer, as defined in ORS 414.805, a corrections officer or a parole and probation officer.

(2) The Division has determined that a worker who experiences an occupational exposure may benefit from requesting the mandatory testing of a source person because such testing may assist a worker in obtaining necessary prophylaxis or treatment for HIV.

(3) Pursuant to ORS 433.065, a worker who experiences an exposure may request that a determination be made as to whether the exposure was a substantial exposure.

(a) A worker may make a request for a determination to:

(A) If the source person is being treated at a licensed health care facility:

(i) The facility's infection control officer or other designated qualified person; or

(ii) The source person's treating health care provider;

(B) The worker's health care provider; or

(C) The LPHA.

(b) A request for a determination must include but is not limited to:

(A) The worker's name and contact information;

(B) Whether the worker has been tested for HIV and if so, when;

(C) The details of the exposure;

(D) The name, contact information, and current location of the source, if known;

(E) Information about the source person's HIV status, if known; and

(F) A citation to ORS 433.065 and these rules as authority for the request for a determination.

(4) The health care provider, infection control practitioner, designated qualified person or local public health administrator to whom the request is made must determine whether an exposure was a substantial exposure and an occupational exposure and provide that determination in writing to the worker within 24 hours of receiving the request. The individual making the determination may rely on the most recent guidance on this topic issued by the federal Centers for Disease Control and Prevention. The individual to whom the request is made may contact the worker to request additional information and may require the release of records related to the exposure from the worker, a licensed health care facility or a licensed health care provider in order to make his or her determination.

(5) If the health care provider, infection control officer, designated qualified person or LPHA to whom the request was made determines the worker experienced a substantial exposure and an occupational exposure the worker may request that the source person be tested for HIV.

(a) If the worker knows that the source person is under the care of a licensed health care facility or a licensed health care provider the worker may request that the health care facility or licensed health care provider ask the source person to consent to an HIV test. A health care facility or licensed health care provider who receives a request from a worker as described in section (5) of this rule is required to ask the source person to consent to an HIV test within 24 hours of receiving the request and to report to the worker immediately whether the source person has consented to an HIV test.

(b) If the worker does not know whether the source person is under the care of a licensed health care facility or a licensed health care provider the worker may contact the LPHA and ask for assistance in locating the source person. If the source person is located with assistance from the LPHA, the LPHA must request that the source person consent to an HIV test.

(c) In accordance with ORS 433.075(5) if the source person consents to the HIV test, the results of an HIV test shall be reported to the worker by the health care provider or licensed health care facility that ordered the test but the results may not identify the source person and the worker is prohibited from redisclosing any information about the test if the source person is known to the worker.

(d) A worker, or the exposed person's employer in the case of an occupational exposure, is responsible for the costs of the source person's HIV test in accordance with ORS 433.075.

(6) If the worker disagrees with a determination that an alleged occupational exposure was not a substantial exposure, the worker may request a second determination from the LPHA. If the LPHA determines that the exposure was substantial, the worker may request that the source person be tested for HIV according to the procedures detailed in subsections (5)(a) through (d).

(7) If the source person refuses to consent, the health care provider or licensed health care facility that requested that the source person be tested must document, in writing, the source person's refusal to consent to an HIV test and provide that documentation to the worker. The LPHA must also be notified by the health care provider, licensed health care facility, or the worker of the documentation of the refusal along with the determination that the exposure was substantial.

(8) If a source person refuses to consent to an HIV test or fails to obtain a test within 24 hours of his or her consent to the HIV test the worker may petition the circuit court in the county in which the occupational exposure occurred in accordance with ORS 433.080 and OAR 333-022-0305 to request mandatory testing of the source person. Before a worker may petition the court for mandatory testing the worker must agree to an HIV test and submit a specimen to a laboratory certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (P.L. 100-578,42 U.S.C. 201 and 263(a))(CLIA) and must notify the LPHA of the failure to obtain a test along with along with the determination that the exposure was substantial.

(9) If a source person is deceased or is unable to consent to an HIV test, consent shall be sought from the source person's next of kin.

(10) If a worker has an employer, the worker's employer shall be required to provide the worker with information about HIV infection, methods of preventing HIV infection, HIV tests and treatment and assistance in following the procedures outlined above. A worker who is self-employed may obtain this information and assistance from the LPHA.

Stat. Auth.: ORS 433.065
Stats. Implemented: ORS 433.065
Hist.: PH 6-2013, f. & cert. ef 2-4-13

333-022-0305
Petition for Mandatory Testing of Source Persons

(1) If a worker has complied with the process established in OAR 333-022-0300 and a source person has refused to consent to an HIV test or has failed to obtain a test within the time period established in that rule, the worker may petition the circuit court for the county in which the exposure occurred and seek a court order for mandatory testing in accordance with ORS 433.080.

(2) The form for the petition shall be as prescribed by the Division and shall be obtained from the LPHA.

(3) The petition shall name the source person as the respondent and shall include a short and plain statement of facts alleging:

(a) The petitioner is a worker subjected to an occupational exposure and the respondent is the source person;

(b) The petitioner meets the definition of worker in ORS 433.060;

(c) All procedures for obtaining the respondent's consent to an HIV test as described in OAR 333-022-0300 have been exhausted by the petitioner and the respondent has refused to consent to the test, or within the time period prescribed in OAR 333-022-0300 has failed to submit to the test;

(d) The petitioner has no knowledge that he or she has a history of a positive HIV test and has since the occupational exposure submitted a specimen for an HIV test to a laboratory certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (P.L. 100-578,42 U.S.C. 201 and 263(a))(CLIA).; and

(e) The injury that petitioner is suffering or will suffer if the source person is not ordered to submit to an HIV test.

(4) The petition shall be accompanied by the certificate of the LPHA declaring that, based upon information in the possession of the administrator, the facts stated in the allegations under subsections (3)(a), (b) and (c) of this rule are true.

(5) A LPHA must provide the petitioner a certificate as described in section (4) of this rule and must appear at any court hearing on the petition in accordance with ORS 433.080(7).

(6) The court is required to hold a hearing on the petition in accordance with ORS 433.080.

Stat. Auth.: ORS 433.080
Stats. Implemented: ORS 433.080
Hist.: PH 6-2013, f. & cert. ef 2-4-13

333-022-0310
Substantial Exposure While Being Administered Health Care

(1) For purposes of this rule the following definitions apply:

(a) "Exposure" means contact with a worker's body fluids.

(b) "Local public health administrator (LPHA)" means the public health administrator of the county or district health department for the jurisdiction in which the reported substantial exposure occurred.

(c) "Health care" has the meaning given that term in ORS 192.556.

(d) "Licensed health care provider" has the meaning given that term in ORS 433.060.

(e) "Patient" means an individual who has experienced an exposure or substantial exposure while being administered health care.

(f) "Qualified person" means an individual, such as a licensed health care provider, who has the necessary training and knowledge about infectious disease to make a determination about whether an exposure was substantial.

(g) "Substantial exposure" means an exposure to blood or certain body fluids that have a potential for transmitting the human immunodeficiency virus based upon current scientific information and may include but is not limited to contact with blood or blood components, semen, or vaginal/cervical secretions through percutaneous inoculation or contact with an open wound, non-intact skin, or mucous membrane of the exposed person.

(h) "Worker" means a person who is licensed or certified to provide health care under ORS Chapters 677, 678, 679, 680, 684 or 685, or ORS 682.216, an employee of a health care facility, of a licensed health care provider or of a clinical laboratory, as defined in ORS 438.010, a firefighter, a law enforcement officer, as defined in ORS 414.805, a corrections officer or a parole and probation officer

(2) If a patient has experienced an exposure by a worker the worker shall report that exposure immediately to one of the following:

(a) The worker's supervisor or employer, if applicable;

(b) The licensed health care facility's infection control officer or other designated qualified person if the exposure occurred in a licensed health care facility as that term is defined in ORS 442.015; or

(c) The LPHA if the worker does not have a supervisor or employer and the exposure did not occur in a licensed health care facility.

(3) If a witness to the incident has reason to believe the incident was not reported, the witness shall notify one of the individuals or entities listed in section (2) of this rule and provide details of the incident.

(4) The individual to whom a report was made under section (2) or (3) of this rule shall immediately make a determination whether the exposure was substantial and shall provide that determination to the worker in writing. The individual making the determination may rely on the most recent guidance on this topic issued by the federal Centers for Disease Control and Prevention. If the individual to whom the report was made is not qualified to make such a determination the individual must consult with a designated qualified person and that qualified person must then make the determination. The individual making a determination may require the release of records related to the exposure from the worker, a health care facility or a licensed health care provider in order to make his or her determination.

(5) If a determination is made that the exposure was substantial, the worker who was the source of the substantial exposure to a patient shall notify the patient in writing within 24 hours of the determination. The worker may request that his or employer, the health care facility if the exposure occurred in a health care facility, or the LPHA provide assistance in making the notification. The notice must include but is not limited to:

(a) Details of the exposure;

(b) Why it was determined to be substantial;

(c) Whether the worker is willing to consent to an HIV test;

(d) The worker's HIV status if the worker consents to that information being included in the notice;

(e) Information about how the patient may request the worker be tested for HIV and to whom the patient should make such a request; and

(f) A statement that the patient will be responsible for the costs of the worker's HIV test in accordance with ORS 433.075.

(6) If the patient disagrees with a determination that an alleged occupational exposure was not a substantial exposure, the patient may request a second determination from the LPHA. If the LPHA determines that the exposure was substantial, the patient may request that the source person be tested for HIV according to the procedures detailed in subsections (5)(a) through (f).

(7) A patient who has received notification in accordance with section (5) of this rule may make a written request for the worker to be tested for HIV to the individual or entity listed in the notice.

(8) The individual or entity to whom a request has been made under section (6) of this rule must:

(a) Immediately ask the worker to consent to an HIV test; and

(b) Inform the patient immediately whether the worker consented to the testing.

(9) If the worker consents to an HIV test the worker must submit to a test within 24 hours of being asked to consent.

(10) In accordance with ORS 433.075(5) if the worker consents to the HIV test the results of a HIV test shall be reported to the patient by the individual who ordered the test but the results may not identify the worker and the patient is prohibited from redisclosing any information about the results of the test if the worker is known to the patient.

(11) Pursuant to ORS 433.065, a patient who has experienced a substantial exposure by a worker shall be offered information about HIV infection, methods of preventing HIV infection, and HIV tests. This information must be provided by the patient's licensed health care provider. Upon request by the patient's health care provider, the LPHA must provide assistance in providing this information to the patient.

Stat. Auth.: ORS 433.065
Stats. Implemented: ORS 433.065
Hist.: PH 6-2013, f. & cert. ef 2-4-13

333-022-0315
Employer Program for Prevention, Education and Testing

(1) Pursuant to ORS 433.075(4), where an employer provides a program of prevention, education and testing for HIV exposures for its employees, the program will be considered to be approved by the Division if employees receive counseling regarding HIV infection control, uniform body fluids precautions, sexual/needle-sharing abstinence and safer sex practices including advice about precautionary measures to be taken with partners at risk of exposure to HIV while test results are pending.

(2) The Division may make the educational materials needed for such a program available to an employer who requests such materials in writing.

(3) An employer that provides HIV testing to employees must use a laboratory certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (P.L. 100-578,42 U.S.C. 201 and 263(a))(CLIA).

(4) If an employer does not have a testing program in place, the employer shall notify the exposed worker of a health care provider who will perform testing, or an exposed worker may seek medical treatment from a health care provider of his or her choice.

Stat. Auth.: ORS 433.075
Stats. Implemented: ORS 433.075
Hist.: PH 6-2013, f. & cert. ef 2-4-13

Infected Health Care Providers

333-022-0400
Definitions

For the purpose of OAR 333-022-0400 through 333-022-0460, the following definitions apply. Other definitions pertaining to these rules are listed in OAR 333-022-0200:

(1) "Health Care Provider" as defined in OAR 333-017-0000(25) means a person who has direct or supervisory responsibility for the delivery of health care or medical services. This shall include, but not be limited to: Licensed physicians, nurse practitioners, physician assistants, nurses, dentists, medical examiners, and administrators, superintendents and managers of clinics, health care facilities as defined in ORS 442.015(13) and licensed laboratories.

(2) "Reviewable Health Care Provider" means a health care provider who routinely performs or participates in the performance of surgical, obstetric, or dental procedures that:

(a) Pose a significant risk of a bleeding injury to the arm or hand of the health care provider; and

(b) Are of a nature that reasonably could result in the patient having an exposure to the health care provider's blood in a manner capable of effectively transmitting HIV or hepatitis B virus (HBV), for example, due to the inability of the health care provider to withdraw the injured limb. Examples of procedures that do not carry this significant risk include, but are not limited to: oral, rectal, or vaginal examinations; phlebotomy; administering intramuscular, intradermal, or subcutaneous injections; needle biopsies, needle aspirations, and lumbar punctures; cutdown and angiographic procedures; excision of epidermal or dermal lesions; suturing of superficial lacerations; endoscopy; placing and maintaining peripheral and central intravascular lines, nasogastric tubes, rectal tubes, and urinary catheters; or acupuncture.

(3) "HBsAg" means the surface antigen of the hepatitis B virus.

(4) "HBeAg" means the "e" antigen of the hepatitis B virus.

(5) "OR-OSHA" means the Oregon Occupational Safety and Health Division of the Oregon Department of Consumer and Business Services.

Stat. Auth.: ORS 431.110(1), 433.001 & 433.004
Stats. Implemented: ORS 431.110(1), 433.001 & 433.004
Hist.: HD 18-1993, f. 10-26-93, cert. ef. 10-28-93; HD 29-1994, f. & cert. ef. 12-2-94; Renumbered from 333-012-0280, PH 6-2013, f. & cert. ef. 2-14-13

333-022-0405
Preamble

(1) The purpose of OAR 333-022-0400 through 333-022-0460 is to prevent the transmission of hepatitis B virus and human immunodeficiency virus to patients from infected health care providers. The Division declares that strict adherence to proper infection control procedures by all health care providers is the primary way to prevent such transmission. The Division recognizes that when proper infection control procedures are used, the risk of transmission of HIV or hepatitis B virus from reviewable health care providers to their patients is negligible.

(2) In the event that an HIV-infected health care provider demonstrates symptoms of cognitive, emotional, behavioral or neurologic impairment, he or she should be treated like any other distressed and/or impaired health care provider, following the standards of the appropriate professional licensing board.

Stat. Auth.: ORS 431.110(1) & 433.004
Stats. Implemented: ORS 431.110(1) & 433.004
Hist.: HD 18-1993, f. 10-26-93, cert. ef. 10-28-93; Renumbered from 333-012-0290, PH 6-2013, f. & cert. ef. 2-14-13

333-022-0410
Infection Control

(1) All health care providers and health care facilities shall strictly adhere to the infection control requirements of OAR 333-017-0005(1) and applicable sections of the OSHA rules, "Occupational Exposure to Bloodborne Pathogens" (OAR 437-002 - 1910.1030). This includes the proper use of hand washing, protective barriers, and care in the use and sterilization or disposal of needles and other sharp instruments as described in the U.S. Public Health Service's Centers for Disease Control and Prevention recommendations found in "Recommendations for Prevention of HIV Transmission in Health Care Settings", Morbidity and Mortality Weekly Report 1987; 36 (supplement number 2S); 1-18S and "Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health Care Settings", Morbidity and Mortality Weekly Report 1988; 37:377-82, 387-88.

(2) Any health care provider who observes that another health care provider or health care facility is not practicing current infection control standards shall seek correction of that problem through procedures appropriate to the setting. Such procedures may include, for example, discussing the needed corrective actions directly with the health care provider, reporting the breaches of infection control practice to the health care facility's infection control committee, or other actions/reporting as recommended by the infection control committee or required by other regulations.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 431.110(1) & 433.004(1)(d)
Stats. Implemented: ORS 431.110(1) & 433.004(1)(d)
Hist.: HD 18-1993, f. 10-26-93, cert. ef. 10-28-93; Renumbered from 333-012-0300, PH 6-2013, f. & cert. ef. 2-14-13

333-022-0415
Infection Control Training

(1) All health care providers and health care facilities shall adhere to the infection control training requirements of the OSHA rules, "Occupational Exposure to Bloodborne Pathogens" (OAR 437-002 – 1910.1030). These include employers ensuring that all employees with potential occupational exposures to bloodborne pathogens participate in a training program at the time of initial assignment to the tasks where occupational exposure may take place and at least annually thereafter.

(2) Any institution in Oregon providing professional training leading to a degree or certificate as a health care provider shall provide formal training in infection control procedures as a prerequisite for graduation.

Stat. Auth.: ORS 431.110(1) & 433.004(1)
Stats. Implemented: ORS 431.110(1) & 433.004(1)
Hist.: HD 18-1993, f. 10-26-93, cert. ef. 10-28-93; Renumbered from 333-012-0310, PH 6-2013, f. & cert. ef. 2-14-13

333-022-0420
HIV and Hepatitis B Testing of Health Care Providers

(1) HIV testing and hepatitis B testing of health care providers is not required by the Division.

(2) All reviewable health care providers are encouraged to voluntarily undergo testing for HIV infection. Any reviewable health care provider is encouraged to either:

(a) Demonstrate serologic evidence of immunity to the hepatitis B virus from vaccination; or

(b) To know his or her HBsAg status and, if that status is positive, is encouraged to know his or her HBeAg status.

(3) The provisions of section (2) of this rule shall not be deemed to authorize any health care provider, health care facility, clinical laboratory, blood or sperm bank, insurer, insurance agent, insurance-support organization as defined in ORS 746.600, government agency, employer, research organization or agent of any of them to require HIV testing of any health care provider as a condition of practice. Nor shall such provisions be deemed to create a legal standard of care for reviewable health care providers.

Stat. Auth.: ORS 431.110(1) & 433.004(1)(d)
Stats. Implemented: ORS 431.110(1) & 433.004(1)(d)
Hist.: HD 18-1993, f. 10-26-93, cert. ef. 10-28-93; Renumbered from 333-012-0320, PH 6-2013, f. & cert. ef. 2-14-13

333-022-0425
Hepatitis B Immunization

Every reviewable health care provider, whether or not directly subject to regulation by OR-OSHA, is encouraged to determine whether he or she has serologic evidence of immunity to hepatitis B or to obtain complete hepatitis B immunization.

Stat. Auth.: ORS 431.110(1) & 433.004(1)(d)
Stats. Implemented: ORS 431.110(1) & 433.004(1)
Hist.: HD 18-1993, f. 10-26-93, cert. ef. 10-28-93; Renumbered from 333-012-0330, PH 6-2013, f. & cert. ef. 2-14-13

333-022-0430
Process for Initiating Review of the Professional Practice of a Reviewable Health Care Provider with a HIV-Positive Test or a Positive Test for HBsAg and HBeAg

(1) Any reviewable health care provider who learns that he or she has a HIV-positive test or a positive test for both HBsAg and HBeAg is encouraged to refrain from participating in the performance of procedures outlined in OAR 333-022-0400(2) until he or she ensures that his or her HIV and/or HBsAg/HBeAg infection status is reported to either:

(a) The Division for the purpose of undergoing a review of his or her professional practice as described in OAR 333-022-0435; or

(b) His or her own institution of employment for the purpose of undergoing a review of his or her professional practice, if such a process exists.

(2) Reports to the Division should be made directly to the State Epidemiologist, the Deputy State Epidemiologist, or the State Health Officer.

(3) Health care providers who are uncertain as to whether or not they are reviewable may seek anonymous guidance from the Division.

Stat. Auth.: ORS 431.110 & 433.004
Stats. Implemented: ORS 431.110 & 433.004
Hist.: HD 18-1993, f. 10-26-93, cert. ef. 10-28-93; HD 29-1994, f. & cert. 12-2-94; Renumbered from 333-012-0340, PH 6-2013, f. & cert. ef. 2-14-13

333-022-0435
Division Response to the Report of a Reviewable Health Care Provider with a HIV-Positive Test or Positive Tests for HBsAg and HBeAg

The following procedures shall be undertaken by the Division at the request of a reviewable health care provider with a positive test for HIV or positive tests for HBsAg and HBeAg:

(1) The Division shall interview the reviewable health care provider and his or her personal licensed physician or primary health care provider within two weeks of receipt of the report to determine:

(a) The date of the initial positive test result;

(b) An estimated date of initial infection, if available from clinical and exposure history information;

(c) The reviewable health care provider's current medical status with special emphasis on presence or absence of exudative lesions or weeping dermatitis, pulmonary tuberculosis, and cognitive, emotional, behavioral or neurologic impairment; and

(d) Whether the reviewable health care provider complies with standard infection control procedures and whether he or she has a history of incidents in which there was a substantial likelihood that a patient received a substantial exposure to the reviewable health care provider's blood;

(e) Pursuant to ORS 433.008 and 433.045, confidentiality of the reviewable health care provider's HIV or HBsAg/HBeAg status shall be maintained during this investigation.

(2) The Division shall convene an expert panel within two weeks of completion of the investigation to make recommendations regarding the reviewable health care provider's continued practice.

(3) The identity of the reviewable health care provider will not be revealed to the expert panel, unless the reviewable health care provider consents to this disclosure.

Stat. Auth.: ORS 431.110(1) & 433.004(1)
Stats. Implemented: ORS 431.110(1) & 433.004(1)
Hist.: HD 18-1993, f. 10-26-93, cert. ef. 10-28-93; HD 29-1994, f. & cert. 12-2-94; Renumbered from 333-012-0350, PH 6-2013, f. & cert. ef. 2-14-13

333-022-0440
Composition of the Expert Panel and Its Responsibilities

(1) The expert panel shall include: An infectious disease specialist, with expertise in the epidemiology of HIV and hepatitis B infections, who is not involved in the care of the reviewable health care provider; a health professional with expertise in the procedures performed by the reviewable health care provider; a representative of the Division; and others at the discretion of the Division. With the consent of the reviewable health care provider, the reviewable health care provider's personal licensed physician or primary health care provider shall also be offered a position on the panel. The reviewable health care provider shall have the right to review the composition of the panel.

(2) The expert panel shall consider all information obtained by the Division's investigation and may request further information of the Division or the reviewable health care provider as needed.

(3) The expert panel shall make recommendations to the Division regarding the reviewable health care provider's further practice. The panel will focus on the reviewable health care provider's ability to comply with infection control procedures and his or her ability to provide competent care. Restrictions in future practice will be recommended only if there are medical impairments, infection control breaches, or scientific evidence to indicate that, in the Division's judgment, the reviewable health care provider's current practice activities pose a significant risk of transmission to the patient. Job modifications, limitations, or other restrictions are warranted only if there is clear evidence that the reviewable health care provider's current practice activities pose a significant risk of transmitting infection to patients. If restrictions are recommended, the panel will recommend the least restrictive alternative. If warranted, the panel may recommend one or more of the following:

(a) Additional infection control procedures;

(b) Restrictions on specific procedures;

(c) Monitoring of the reviewable health care provider's practice for compliance with the recommendations of the expert panel;

(d) Medical monitoring (both content and frequency) of the reviewable health care provider; and

(e) Frequency with which the panel should reconvene to reconsider its recommendations in light of the changing medical condition of the reviewable health care provider.

(4) The expert panel shall furnish the reviewable health care provider with a draft of its recommendations and an opportunity for comment. Before finalizing its recommendations to the Division, the expert panel shall take into account any comments received from the reviewable health care provider or the provider's representative.

Stat. Auth.: ORS 431.110(1) & 433.004(1)
Stats. Implemented: ORS 431.110(1) & 433.004(1)
Hist.: HD 18-1993, f. 10-26-93, cert. ef. 10-28-93; HD 29-1994, f. & cert. 12-2-94; Renumbered from 333-012-0360, PH 6-2013, f. & cert. ef. 2-14-13

333-022-0445
Division Recommendations to Reviewable Health Care Provider

The Division shall consider the specific recommendations of the expert panel and comments, if any, of the reviewable health care provider or the provider's representative, and shall prepare written recommendations to the reviewable health care provider. These written recommendations shall be presented to the reviewable health care provider within one week after completion of the panel's recommendations.

Stat. Auth.: ORS 431.110 & 433.004
Stats. Implemented: ORS 431.110 & 433.004
Hist.: HD 18-1993, f. 10-26-93, cert. ef. 10-28-93; Renumbered from 333-012-0370, PH 6-2013, f. & cert. ef. 2-14-13

333-022-0450
Notification of the Appropriate Licensing Board

If the Division has reason to believe that the reviewable health care provider poses a significant risk of transmission of HIV or hepatitis B virus to the patient, whether or not an HIV-infected or HBsAg/HBeAg-positive reviewable health care provider has been reported to the Division and has consented to voluntary review as outlined above, the Division may notify the appropriate licensing board, and shall inform the reviewable health care provider, in writing, of this notification.

Stat. Auth.: ORS 431.110 & 433.004
Stats. Implemented: ORS 431.110 & 433.004
Hist.: HD 18-1993, f. 10-26-93, cert. ef. 10-28-93; Renumbered from 333-012-0380, PH 6-2013, f. & cert. ef. 2-14-13

333-022-0455
Notification and Counseling of Some or All Past or Present Patients of the Reviewable Health Care Provider

Notification of patients as to their possible exposure to HIV or hepatitis B shall not occur except in any of the following circumstances:

(1) HIV or hepatitis B transmission from reviewable health care provider to at least one of his or her patients has occurred;

(2) The patient to be notified has had a substantial exposure to the reviewable health care provider's blood or body fluids; or

(3) The reviewable health care provider has had significant violations of infection control practices that were standard at the time of the patient contact and which resulted in a significant risk of a substantial exposure to the patient being notified;

(4) The identity of the HIV-infected health care provider shall not be explicitly disclosed during the notification process.

Stat. Auth.: ORS 431.110(1) & 433.004(1)(d)
Stats. Implemented: ORS 431.110(1) & 433.004(1)(d)

Hist.: HD 18-1993, f. 10-26-93, cert. ef. 10-28-93; Renumbered from 333-012-0390, PH 6-2013, f. & cert. ef. 2-14-13

333-022-0460
Confidentiality

The report of a reviewable health care provider, the Division's investigation, the deliberations and recommendations of the expert panel, and the Division's recommendations pursuant to these rules shall be held in the strictest confidence under ORS 433.008 and 433.045, except as outlined in OAR 333-022-0450 and 333-022-0455.

Stat. Auth.: ORS 431.110(1) & 433.004(1)
Stats. Implemented: ORS 431.110(1) & 433.004(1)
Hist.: HD 18-1993, f. 10-26-93, cert. ef. 10-28-93; Renumbered from 333-012-0400, PH 6-2013, f. & cert. ef. 2-14-13

CAREAssist

333-022-1000
Purpose and Description of Program

(1) The CAREAssist program is Oregon's AIDS Drug Assistance Program (ADAP). The core purpose of CAREAssist is to ensure access to HIV-related prescription drugs to underinsured and uninsured individuals living with HIV/AIDS. CAREAssist also helps people living with HIV or AIDS pay for medical care expenses, including but not limited to medication, insurance premiums and medical services. The program is funded through Part B of the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87), which provides grants to states and territories.

(2) The Oregon Health Authority (Authority) shall make funds available for the CAREAssist program as long as it continues to receive grant funds from the federal government.

(3) If insufficient funds are available for the CAREAssist program the Authority may:

(a) Modify group benefits for approved clients; and

(b) Institute a waiting list in lieu of accepting applications.

(4) Ryan White funds may not be used for any item or service if payment has been made, or can reasonably be expected to be made by another payment source. ADAP is a last-resort payment source. As such, the Authority may require the applicant or client to enroll in the most cost-effective insurance available, as determined by the Authority. If the client or applicant refuses to enroll in health insurance that the Authority has identified as the most cost-effective plan for which he or she is eligible, the Authority shall only provide assistance with the cost of HIV antiretroviral, Hepatitis antiviral and opportunistic infection-related medications as identified in the formulary.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: HD 14-1987(Temp), f. & ef. 9-30-87; HD 9-1988, f. 5-11-88, cert. ef. 5-12-88; HD 1-1990(Temp), f. & cert. ef. 1-8-90; PH 9-2005, f. 6-15-05, cert. ef. 6-21-05; PH 25-2010(Temp), f. & cert. ef. 10-1-10 thru 3-29-11; Renumbered from 333-012-0250 by DMAP 5-2011, f. & cert. ef. 3-29-1; Renumbered from 410-121-3000, PH 30-2014, f. 11-10-14, cert. ef. 12-1-14; PH 23-2016, f. & cert. ef. 8-2-16

333-022-1010
Definitions

(1) "AIDS" means acquired immunodeficiency syndrome.

(2) "Authority" means the CAREAssist program, administered by the Oregon Health Authority.

(3) "CAREAssist" includes benefits provided to clients under Bridge, UPP, Group 1 or Group 2 as those terms are used in OAR 333-022-1000 through 333-022-1170.

(4) "CAREAssist formulary" or "formulary" means a list of medications available to enrolled clients of CAREAssist when the same drug or a therapeutically comparable medication is not available through the client's primary health insurance.

(5) "Federal Poverty Level" or "FPL" means the annual poverty income guidelines, published by the United States Department of Health and Human Services.

(6) "Family" means all individuals counted by the Authority in determining the applicant's or client's family size.

(7) "Monthly income" means the monthly average of any and all monies received on a periodic or predictable basis, which the family relies on to meet personal needs.

(8) "Gross monthly income" means income before taxes or other withholdings.

(9) "HIV" means the human immunodeficiency virus, the causative agent of AIDS.

(10) "OHP" means the Oregon Health Plan.

(11) "Oregon residency" means that an individual:

(a) Has a physical location to reside in Oregon; and

(b) Is in Oregon at least six months out of the year; and

(c) Is not absent from Oregon more than three consecutive months; or

(d) Is living out of state for more than three months due to temporary or seasonal employment outside of Oregon; or

(e) Is living out of state for more than three months while attending an education institution full time.

(12) "Refuses" means a client or applicant actively declines enrollment in the insurance identified by the Authority.

(13) "Seasonal worker" means the applicant performs work cyclically during the year and most often the work is defined by seasons and typically defined by the calendar year.

(14) "Special enrollment period" means a time period outside of open enrollment in which a client is eligible to apply for private insurance because they experienced a qualifying event as defined by the Affordable Care Act.

(15) "UPP" means the CAREAssist Uninsured Persons Program.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 30-2014, f. 11-10-14, cert. ef. 12-1-14; PH 23-2016, f. & cert. ef. 8-2-16

333-022-1020
Eligibility

To qualify for the CAREAssist program an individual must:

(1) Be HIV positive or have AIDS; and

(2) Reside in Oregon; and

(3) Have a monthly income based on family size which is at or below 500 percent of the FPL.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 30-2014, f. 11-10-14, cert. ef. 12-1-14; PH 23-2016, f. & cert. ef. 8-2-16

333-022-1030
Application Process

(1) An individual may apply for CAREAssist benefits by completing a form prescribed by the Authority and providing the documentation as instructed in the application so that the Authority can verify that the applicant:

(a) Has tested positive for HIV or has AIDS; and

(b) Has a monthly income based on family size at or below 500 percent of the FPL; and

(c) Is a resident of Oregon.

(2) An applicant must sign an authorization that permits the Authority to contact and exchange information with the applicant's health care providers, insurers, and any other individual or entity necessary to determine the applicant's eligibility for CAREAssist, process payments and facilitate care coordination for the client.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 30-2014, f. 11-10-14, cert. ef. 12-1-14; PH 23-2016, f. & cert. ef. 8-2-16

333-022-1040
Review of Applications

(1) The Authority must review an application to determine if it is complete.

(a) An applicant or the applicant's case manager shall be notified by the Authority if the application is incomplete. Notifications shall identify what information is missing and the deadline for submitting the missing information.

(b) If the applicant does not provide the requested information before the deadline the Authority must notify the applicant in writing that the application is incomplete, shall no longer be reviewed, and that the applicant may reapply at any time.

(2) Once an application is deemed complete the Authority must verify the information submitted and make a determination within 10 business days as to whether the applicant is eligible for CAREAssist benefits.

(3) Verification of Oregon residency.

(a) An applicant must provide documentation verifying Oregon residency, as outlined in the application.

(b) An applicant may be asked to appear at an Authority office or a local case management provider's office in person if the applicant's residency status is in question.

(c) If an applicant is a seasonal worker who must be out of state for more than three consecutive months for employment, the applicant may be considered to reside in Oregon but must receive prior authorization, in writing, from the program before leaving the state for work.

(4) Verification of HIV/AIDS status. The applicant must ensure that a form prescribed by the Authority that verifies an applicant's HIV/AIDS status is signed and submitted to the Authority by:

(a) The applicant's health care provider; or

(b) The applicant's HIV case manager, if the case manager has received documentation of HIV/AIDS status directly from a health care provider.

(5) Determination of family size. The Authority shall determine an applicant's family size by counting the individuals related by birth, marriage, adoption, or legally defined dependent relationships who either live in the same household as the applicant and for whom the applicant is financially responsible, or whom do not live in the same household as the applicant but fall within the categories listed in subsections (b), (c) or (d) of this section, including but not limited to:

(a) A legal spouse; or

(b) A child 18 years of age or younger who qualifies as a dependent for tax filing purposes; or

(c) A child age 19 to 26 who takes 12 or more credit hours in a school term, or its equivalent; or

(d) An adult for whom the applicant has legal guardianship.

(6) Determination of monthly income.

(a) An applicant must submit to the Authority income documentation for all family members and from all sources. The Authority shall use the documentation to calculate the total monthly income for a family. Income after taxes or other withholdings may only be used when:

(A) A self-employed applicant or the applicant's family member provides a copy of the most recent year's IRS Form 1040 (Schedule C) in which case the Authority may allow a 50 percent deduction from gross receipts or sales; or

(B) An applicant or applicant's family member has income from rental real estate and provides a copy of the most recent year's IRS Form 1040 (Schedule E). In this case the Authority may use the total rental real estate income, as reported on the Schedule E. If the Schedule E shows a loss, the applicant or applicant's family member shall be considered to have no income from this source.

(b) The Authority must determine an applicant's income by adding together all sources of family income, and dividing that number by the applicable FPL. The resultant sum is the applicant's percentage of the FPL. For example, if total annual income for a family of two is $31,460 and 100 percent FPL for a family of two is $15,730 for the current year: $31,460 divided by $15,730 equals two or 200 percent FPL.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 30-2014, f. 11-10-14, cert. ef. 12-1-14

333-022-1050
Approval or Denial of Application

(1) If the Authority determines that an applicant is eligible for CAREAssist benefits the applicant shall be notified in writing within 14 calendar days of the Authority's determination and be assigned to a benefit group as follows:

(a) Group 1: Clients who are enrolled in a private, group or individual insurance policy.

(b) Group 2: Clients whose primary prescription benefits are provided by OHP or the Department of Veterans Affairs (VA).

(2) A client's notification must describe:

(a) The eligibility effective date and end date;

(b) Group number and benefits associated with that group;

(c) A list of CAREAssist in-network pharmacies;

(d) Recertification date and process; and

(e) The repercussions of not recertifying.

(3) CAREAssist eligibility is for six months.

(4) If the Authority determines that an applicant is not eligible for CAREAssist benefits an applicant shall be notified in writing in accordance with ORS 183.415.

(5) An applicant who has been denied may reapply at any time.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 30-2014, f. 11-10-14, cert. ef. 12-1-14; PH 23-2016, f. & cert. ef. 8-2-16

333-022-1060
Group 1 and 2 Benefits

(1) Group 1 and 2 clients are eligible for assistance with:

(a) The cost of health insurance premiums if applicable, provided the coverage, at a minimum includes pharmaceutical benefits equivalent to the HIV antiretroviral and opportunistic infection-related medications on the CAREAssist formulary as well as coverage for other essential medical benefits as defined by the Affordable Care Act.

(b) Copays, coinsurance and deductibles on prescription drugs covered by the client's primary health insurance, with the exception of medications prescribed to treat erectile dysfunction.

(c) Copays, coinsurance and deductibles on medical services covered by the client's primary health insurance, up to a maximum amount set by the program each calendar year. Eligible medical services include but are not limited to laboratory tests, office visits, emergency room visits, X-rays, and hospital stays.

(d) The full cost of CAREAssist formulary prescriptions, filled at an in-network pharmacy when:

(A) The client has successfully enrolled in insurance but coverage is not yet active; or

(B) The client's insurance policy does not cover the cost of the prescription; and

(C) The prescribing provider submitted a Prior Authorization Request to the client's primary insurance, the request was denied and there is no acceptable therapeutic substitution.

(e) Prescription drugs if the required copay exceeds the cost of the prescription medication and the insurance policy therefore does not pay.

(f) Medication therapy management.

(2) CAREAssist clients who smoke or chew tobacco may be eligible to receive additional and enhanced services from the Oregon Tobacco Quit Line (1-800-QUIT-NOW), if funding is available.

(3) A client on restricted status may not be entitled to some of the benefits described in section (1) and (2) of this rule.

(4) The Authority shall only make payments directly to a service provider or benefits administrator. No reimbursements or direct payments may be made to a client or an individual who pays on behalf of a client.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 30-2014, f. 11-10-14, cert. ef. 12-1-14

333-022-1070
Prescriptions

(1) Unless an exception applies under subsections (3)(a) or (b) of this rule, CAREAssist clients must use an Authority-approved CAREAssist in-network pharmacy for all:

(a) Medications not designated as acute on the CAREAssist formulary;

(b) Chronic care medications; and

(c) Medications paid for in full by the Authority

(2) The Authority must provide to each client a list of approved pharmacies and post the information on the CAREAssist website.

(3) A CAREAssist client may use a non-CAREAssist in-network pharmacy if:

(a) His or her insurance carrier requires use of a pharmacy that is not a CAREAssist in-network pharmacy; and

(b) He or she has provided the Authority with a copy of the insurance summary of benefits for that insurance plan and the requirement to use a non-CAREAssist in-network pharmacy is explicitly stated in that insurance summary.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 30-2014, f. 11-10-14, cert. ef. 12-1-14

333-022-1080
Payments and Cost Coverage

(1) The Authority may only make insurance premium payments directly to the insurance carrier or benefits administrator. No direct payments may be made to a client.

(2) When no other payer for health coverage (public assistance or private) is available, CAREAssist may pay insurance premiums for a limited time for a client's insurance plan that covers his or her family members if the monthly premium cannot by divided, until the Authority determines that the client's family members can obtain their own policies.

(3) The Authority may not use CAREAssist funds to pay for any administrative costs, which are in addition to the premium payment.

(4) Authority payments for prescriptions follow the health insurance pharmacy benefits defined within the policy and may not pay for the cost to dispense a brand-name drug when a generic equivalent is the preferred option of the health insurance.

(5) The Authority shall only cover the costs of medications that are covered by the client's health insurance or those specifically listed on the CAREAssist formulary as additional benefits to the client, and prior to any payments being made by the Authority must receive a determination by the prescriber that no acceptable therapeutic equivalent is available through the primary insurance.

(6) The Authority may only pay for HIV medications or a combination of HIV drugs as approved in the federal Department of Health and Human Services (DHHS) Treatment Guidelines, which can be found at http://aidsinfo.nih.gov/guidelines.

(a) The CAREAssist Pharmacy Benefits Manager (PBM) clinical pharmacist team (team) assesses each client's medication regimen to ensure that it conforms to current DHHS guidelines. In the event that a treatment recommendation or guideline is not followed, the clinical pharmacist at the PBM shall notify the Authority that payment may not be made until the prescriber submits a prior authorization form to the PBM's clinical pharmacist.

(b) The Authority may deny payment for medications that are determined to be clinically inappropriate pursuant to the DHHS Treatment Guidelines.

(7) Medical Services.

(a) The Authority shall identify and inform clients of an amount to be provided within the calendar year for medical service copays and deductible. The annual financial amount shall be posted on the CAREAssist website at the beginning of each calendar year. All costs exceeding the published amount are the client's responsibility.

(b) The Authority may pay for a client's out-of-pocket medical service expense for an insurance-covered medical service or durable medical equipment, up to an annual maximum amount. The client's primary insurance must cover the service or device before CAREAssist assumes any financial cost unless the client is pre-approved for limited full-cost coverage under UPP or Bridge, as allowed under OARs 333-022-1140 and 333-022-1145.

(8) When the Authority acts as primary payer:

(a) Reimbursement to providers shall be 125 percent of the current Oregon Medicaid Fee for Service rate for the allowable Current Procedural Terminology (CPT) Code unless the provider bills for less. A list of allowable CPT Codes is posted on the CAREAssist website.

(b) Payments made by the Authority on behalf of clients must be accepted by the provider as payment in-full. Balance billing is prohibited.

(9) Clients who receive refunds for services paid by the Authority on the client's behalf must reimburse the program or develop a repayment plan within 60-days of receiving the refund. This includes but is not limited to refunds issued by pharmacies, medical providers, insurance carriers and the Internal Revenue Service.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 30-2014, f. 11-10-14, cert. ef. 12-1-14; PH 23-2016, f. & cert. ef. 8-2-16

333-022-1090
Client Eligibility Review

(1) The Authority must verify a client's eligibility every six months, but may conduct an eligibility review at any time and as many times as necessary within an eligibility period.

(2) The Authority must provide CAREAssist clients with a Client Eligibility Review (CER) form and instructions within 60 days of the expiration of their current eligibility period.

(3) A client must submit the CER and any other required documentation within the timeframe established by the Authority in the instructions. A deadline for submitting the CER or requested documentation may be extended at the discretion of the Authority.

(4) The Authority shall review a client's application and supporting documentation and verify the information in accordance with OAR 333-022-1040.

(5) The Authority must notify a client in writing whether his or her benefits continue and whether there are any changes. Notification shall include the effective date for the client's new enrollment status. If a client is not found eligible for continued benefits the client shall have a right to a hearing in accordance with ORS 183.415.

(6) A CAREAssist client who fails to submit the required renewal documents by the requested deadline shall be placed on a restricted status in accordance with OAR 333-022-1120. If the Authority has not received a complete CER at the end of three months, the client is no longer eligible to receive benefits. The Authority must inform the client that he or she is no longer eligible for benefits because the required information was not submitted, eligibility could not be verified and explain that benefits shall end effective the first day of the following month. An individual may reapply for benefits at any time under OAR 333-022-1030.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 30-2014, f. 11-10-14, cert. ef. 12-1-14; PH 23-2016, f. & cert. ef. 8-2-16

333-022-1100
Client Reporting Requirements

(1) A CAREAssist client is required to notify the Authority within 15 calendar days of any of the following:

(a) Receiving notification of changes to premium payments or benefits from his or her insurance company or a benefits administrator;

(b) Changes in contact information including address and phone number; or

(c) Changes in eligibility for group or individual insurance coverage, whether private or publicly funded.

(2) A client's failure to notify the Authority in accordance with section (1) of this rule may result in a client being terminated from the program in accordance with OAR 333-022-1160. A client who is terminated under this section because the client failed to notify the Authority that his or her insurance plan was cancelled may not be eligible to reapply until the client is enrolled in an insurance plan.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 30-2014, f. 11-10-14, cert. ef. 12-1-14

333-022-1120
Restricted Status

(1) The Authority may place a client on restriction if the client fails to return a complete Client Eligibility Review (CER) by the requested deadline.

(2) The effective date and duration of the restriction shall be as follows:

(a) Restriction takes effect on the first day of the client's new eligibility period.

(b) The restricted period shall not exceed three consecutive months. If the Authority has not received a complete CER at the end of three months, the client is no longer eligible for benefits and the client will be notified in accordance with OAR 333-022-1090.

(3) Ending restriction:

(a) Six full months of unrestricted benefits shall be approved if the Authority receives a complete CER before the end of the restricted period and determines the client eligible.

(b) The effective date for full benefits shall be the date of receipt of the complete CER.

(4) The Authority shall notify a client of the restricted status. The notice must comply with ORS 183.415 and explain:

(a) How long the restriction is in effect;

(b) How the client can come into compliance and have the restriction lifted; and

(c) The consequences of not coming into compliance within the specified time period.

(5) If a client is placed on restricted status the Authority may only provide the following benefits to the client:

(a) Payment of insurance premiums; and

(b) Payment of medications that treat HIV, viral hepatitis and opportunistic infections, as those are described in the CAREAssist restricted formulary, available on the CAREAssist website.

(6) Restricted clients are ineligible for assistance with the cost of:

(a) Prescriptions not listed on the Restricted Formulary; and

(b) All medical services, even when that service continues to be paid by the client's primary insurance.

(7) Restricted clients are required to recertify, as indicated in OAR 333-022-1090.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 30-2014, f. 11-10-14, cert. ef. 12-1-14; PH 23-2016, f. & cert. ef. 8-2-16

333-022-1130
Incarcerated Applicants or Clients

(1) A CAREAssist client who is incarcerated in a state or federal correctional institution is ineligible for CAREAssist and shall be terminated from the program in accordance with OAR 333-022-1160.

(2) A CAREAssist client who is incarcerated in a city or county correctional facility may remain enrolled in the program for up to 60 days from the first day of incarceration as long as:

(a) The client's primary insurance coverage is maintained and active; and

(b) The client completes recertification in accordance with OAR 333-022-1090 as scheduled.

(3) At the Authority's discretion, incarcerated clients, as described in section (2) may continue to receive CAREAssist benefits for an additional 30 days if the client is expected to be released within those additional 30 days.

(4) Pre-release application to CAREAssist. The Authority may accept an application and determine eligibility for an individual who is incarcerated but is expected to be released within 30 days of submitting the application.

Stat. Author.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 30-2014, f. 11-10-14, cert. ef. 12-1-14

333-022-1140
Bridge Program

(1) The Bridge Program provides limited benefits to an individual whose medical provider has applied for the program on the patient's behalf. The program provides payment for basic services and medications for an individual who is in the process of applying for CAREAssist and insurance.

(2) Bridge Program eligibility. In order to be eligible for the Bridge Program an individual must:

(a) Be HIV positive or have AIDS;

(b) Reside in Oregon;

(c) Have income at or below 500 percent of the FPL;

(d) Be in the process of applying for long-term medication assistance programs such as Medicaid, Medicare, or applying to CAREAssist; and

(e) Have not previously received Bridge Program benefits or have not been terminated from the CAREAssist program within the past 365 days.

(3) To apply for Bridge Program benefits a patient's medical provider must, on behalf of the patient, submit a form prescribed by the Authority and sign the form attesting that the individual is HIV positive or has AIDS. If the health care provider is licensed outside of Oregon, the Authority may request a copy of the applicant's most current laboratory results.

(4) The Authority must notify an applicant whether the patient's application has been approved or denied, in accordance with ORS 183.415.

(5) An individual enrolled in the Bridge Program is not guaranteed to be determined eligible for CAREAssist benefits.

(6) The Bridge Program benefits include:

(a) Assistance with the cost of a 30-day supply of prescription drugs listed on the CAREAssist formulary and designated as available to Bridge Program participants, only if dispensed by a CAREAssist contract in-network pharmacy.

(b) Payment of the costs of medical services and laboratory tests as defined by the list of approved Current Procedural Terminology (CPT) codes noted on the Bridge Program instructions and application forms.

(7) The Authority may only pay for an individual's medical visits or laboratory tests for dates of service that are on or after the individual's enrollment in the Bridge Program.

(8) Individuals enrolled in the Bridge Program must actively participate with an assigned CAREAssist caseworker to assure progress toward a sustainable means of medication access. Failure to do so may result in cancellation of enrollment. At a minimum, the client is expected to submit a full application for ongoing assistance with CAREAssist within the 30 days of Bridge Program enrollment.

(9) The Bridge Program is not available to an individual who has primary health insurance coverage.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 30-2014, f. 11-10-14, cert. ef. 12-1-14; PH 23-2016, f. & cert. ef. 8-2-16

333-022-1145
Uninsured Persons Program

(1) The Uninsured Persons Program (UPP) provides full-cost coverage for a limited number of medications and medical services for clients who are ineligible for insurance.

(2) In order to be eligible for UPP an individual must:

(a) Meet all eligibility requirements outlined in OAR 333-022-1020; and

(b) Be ineligible for public and private insurance that meets minimum essential coverage under the federal Affordable Care Act, Public Law 111–148; and

(c) Be enrolled in Ryan White community-based HIV Case Management Services.

(3) To apply for UPP an individual must comply with OAR 333-022-1030 and an application shall be reviewed by the Authority in accordance with OAR 333-022-1040, as applicable.

(4) If the Authority determines that an applicant is eligible for CAREAssist benefits the applicant shall be notified in writing within 10 business days of the Authority's determination. A client's notification must describe:

(a) The eligibility effective date and end date;

(b) Group number and benefits associated with that group;

(c) A list of CAREAssist in-network pharmacies;

(d) Recertification date and process; and

(e) The repercussions of not recertifying.

(5) UPP eligibility is for six months.

(6) If the Authority determines that an applicant is not eligible for UPP benefits an applicant will be notified in writing in accordance with ORS 183.415.

(7) An applicant who is denied may reapply at any time.

(8) UPP benefits include:

(a) Assistance with the cost of prescription drugs listed on the CAREAssist formulary, when dispensed by a CAREAssist contract in-network pharmacy;

(b) Full-cost laboratory and medical visits performed in an out-patient setting. Coverage is limited to allowable CPT codes, as designated by the program. The program may cover the cost of each allowable CPT code up to four times a year. Any additional coverage requires prior authorization initiated by the client's prescribing physician.

(c) Medication therapy management; and

(d) Tobacco cessation services.

(9) An UPP client must notify the Authority immediately if he or she becomes eligible for insurance or obtains insurance.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 30-2014, f. 11-10-14, cert. ef. 12-1-14; PH 23-2016, f. & cert. ef. 8-2-16

333-022-1147
Dental Benefits

(1) The CAREAssist Dental Program provides assistance with out-of-pocket dental expenses related to a specific dental plan or plans identified by the Authority.

(2) Clients are eligible for the CAREAssist Dental Program as long as their primary prescription coverage is not provided by the Oregon Health Plan at the time of application.

(3) The Dental Program provides assistance with the cost of:

(a) The monthly premium on a dental plan identified by the Authority, paid directly to the insurance carrier or benefits administrator.

(b) Out-of-pocket dental expenses for services approved by the identified plan. The plan must cover a portion of the specific procedure before CAREAssist assumes any financial cost.

(4) The Dental Program cannot provide assistance with the cost of:

(a) Out-of-pocket dental expenses related to any dental plan other than the plan or plans specified by the Authority.

(b) Dental services for which the CAREAssist-sponsored dental plan will not pay, either because the service is disallowed or the client has maximized the annual dental benefit, as determined by the dental plan administrator.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 23-2016, f. & cert. ef. 8-2-16

333-022-1150
Client Rights

Applicants and clients have the following rights:

(1) To receive CAREAssist services free of discrimination based on race, color, sex, gender, ethnicity, national origin, religion, age, class, sexual orientation, physical or mental ability.

(2) To be informed about services and options available in the CAREAssist programs for which they may be eligible.

(3) To have their CAREAssist records be treated confidentially in accordance with OAR chapter 943, division 14.

(4) To have access to a written grievance process posted on the CAREAssist website.

(5) To receive language assistance services, including access to translation and interpreter services at no cost if the individual has limited English proficiency.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 30-2014, f. 11-10-14, cert. ef. 12-1-14

333-022-1160
Termination from CAREAssist

(1) The Authority may terminate a client or restrict benefits for any of the following:

(a) Failure to continue to meet eligibility requirements;

(b) Submitting false, fraudulent or misleading information to the Authority in order to obtain or retain benefits;

(c) Placement in a custodial institution, such as a state or federal prison, that is legally obligated to provide medical services; or

(d) Failure to notify the Authority of changes in accordance with OAR 333-022-1100.

(2) The Authority must provide a notice of termination to a client in writing in accordance with ORS 183.415.

(3) An individual who is found to have provided false, fraudulent or misleading information to the Authority may not reapply for CAREAssist benefits for six months following the issuance of a final order of termination and may be required to repay the Authority for benefits provided.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 30-2014, f. 11-10-14, cert. ef. 12-1-14

333-022-1170
Hearings

A client who has benefits denied, restricted, or terminated has a right to a contested case hearing in accordance with ORS Chapter 183.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 30-2014, f. 11-10-14, cert. ef. 12-1-14

HIV Case Management

333-022-2000
Purpose

(1) The Oregon HIV Case Management Program provides case management and supportive services, through Ryan White Part B case management agencies, that include but are not limited to client-centered services that ensure timely and coordinated access to primary medical care, medications, treatment adherence counseling and other support services for HIV-positive individuals.

(2) Case management and supportive services will be available as long as the Oregon Health Authority (Authority) continues to receive Ryan White Program, Part B funds for this purpose.

(3) If insufficient funds are available for case management and supportive services, the Authority may reduce case management services or reduce funding for supportive services.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 29-2014, f. 11-10-14, cert. ef. 12-1-14

333-022-2010
Definitions

(1) "Agency" refers to a contracted provider delivering Ryan White funded services.

(2) "AIDS" means acquired immunodeficiency syndrome.

(3) "Authority" means the Oregon Health Authority.

(4) "Family" means all individuals counted by an agency in determining the individual or client's family size.

(5) "Federal Poverty Level" or "FPL" means the annual poverty income guidelines, published by the United States Department of Health and Human Services.

(6) "Gross monthly income" means income before taxes or other withholdings.

(7) "HIV" means the human immunodeficiency virus, the causative agent of AIDS.

(8) "HIV case management service area" means all Oregon counties except Multnomah, Washington, Clackamas, Columbia and Yamhill.

(9) "Ryan White Program, Part B" means The Ryan White HIV/AIDS Program authorized and funded under Title XXVI of the Public Health Services Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87, October 30, 2009).

(10) "Ryan White Part B case management services agency" or "agency" means a contractor of the Authority that is responsible for providing case management services and administering supportive services to individuals living with HIV/AIDS in a specific jurisdiction.

(11) "Supportive services" means financial assistance that can be authorized on behalf of an individual enrolled in Ryan White Part B case management services.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 29-2014, f. 11-10-14, cert. ef. 12-1-14

333-022-2020
Eligibility

To be eligible for the HIV Case Management Program an individual must:

(1) Be HIV positive or have AIDS; and

(2) Reside in an agency's jurisdiction within the HIV case management service area, unless another agency agrees to provide services and the Authority authorizes the provision of services by that other agency

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 29-2014, f. 11-10-14, cert. ef. 12-1-14

333-022-2030
Enrollment Process

(1) To enroll in the HIV Case Management Program an individual must go through an intake process with a local Ryan White Part B case management services agency. A list of the agencies may be obtained on the Authority's website at www.healthoregon.org/hiv.

(2) During the intake process an individual must provide information to an agency that enables the agency to verify at least the following:

(a) Identity;

(b) HIV status;

(c) Residency in the HIV case management service area;

(d) Income;

(e) Household member information; and

(f) Health insurance information, if applicable.

(3) Identity may be verified for an individual by providing one of the following:

(a) Oregon Driver License;

(b) Tribal identification (ID);

(c) State of Oregon ID card;

(d) Military ID;

(e) Passport;

(f) Student ID;

(g) Social Security Card;

(h) Citizenship/Naturalization documents;

(i) Student visa;

(j) Oregon Learner's Permit or Temporary License;

(k) Birth certificate; or

(l) Other form of verification determined appropriate by an agency.

(4) HIV/AIDS status must be verified within 30 days of intake by a physician or lab result.

(5) Documents that verify that an individual resides in the HIV case management service area include but are not limited to documents with the client's full legal name and an address, within the service area, that matches the residential address provided during the intake.

(6) Determination and verification of income:

(a) Family size will be determined by counting the individuals related by birth, marriage, adoption, or legally defined dependent relationships who either live in the same household as the individual seeking to enroll in the HIV Case Management Program and for whom that individual is financially responsible, or whom do not live in the same household as the individual but fall within the categories listed in subsections (b), (c) or (d) of this section, including but not limited to:

(A) A legal spouse; or

(B) A child 18 years of age or younger who qualifies as a dependent for tax filing purposes; or

(C) A child age 19 to 26 years of age who takes 12 or more credit hours in a school term, or its equivalent; or

(D) An adult for whom the individual has legal guardianship.

(b) Gross monthly income:

(A) An individual must submit documentation for all family members and from all sources to determine total monthly gross income for a family. Income after taxes or other withholdings may only be used when:

(i) A self-employed individual or the individual's family member files an Internal Revenue Service, Form 1040, Schedule C in which case the agency will allow a 50 percent deduction from gross receipts or sales; or

(ii) An individual or individual's family member has income from rental real estate and provides a copy of the most recent year's IRS Form 1040 (Schedule E). In this case the agency may use the total rental real estate income, as reported on the Schedule E. If the Schedule E shows a loss, the applicant or applicant's family member shall be considered to have no income from this source.

(B) The agency must determine an applicant's income by adding together all sources of family income, and dividing that number by the applicable FPL. The resultant sum is the applicant's percentage of the FPL.

(7) An individual must sign any authorization necessary to permit the agency to exchange information with the individual's health care providers, and any other individual or entity necessary to coordinate care and services.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 29-2014, f. 11-10-14, cert. ef. 12-1-14

333-022-2040
Approval or Denial of Enrollment

(1) The agency will make a determination as to whether the individual is eligible for case management services within 30 days of receiving all documentation in accordance with OAR 333-022-2030.

(2) If the agency determines that an individual cannot be enrolled in the HIV Case Management Program an individual will be notified in accordance with ORS 183.415.

(3) An individual who has been denied may reapply at any time.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 29-2014, f. 11-10-14, cert. ef. 12-1-14

333-022-2050
Determination of Service Needs

Once enrolled in the HIV Case Management Program, a client must participate in a screening and assessment process with an agency to review his or her needs and resources, for the purpose of developing a plan to address the needs identified. The purpose of this assessment is to identify actions to remove barriers to HIV care and treatment.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 29-2014, f. 11-10-14, cert. ef. 12-1-14

333-022-2060
Client Rights

Individuals applying for or clients enrolled in the HIV Case Management Program have the following rights:

(1) To receive HIV case management services free of discrimination based on race, color, sex, gender, ethnicity, national origin, religion, age, class, sexual orientation, physical or mental ability.

(2) To be informed about services and options available in the HIV Case Management Program.

(3) To have HIV case management services and other program records maintained confidentially in accordance with OAR chapter 943, division 14.

(4) To have access to a written grievance process provided by the agency.

(5) To receive language assistance services including access to translation and interpretation services, at no cost if the individual or client has limited English proficiency, in order to access HIV case management services.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 29-2014, f. 11-10-14, cert. ef. 12-1-14

333-022-2070
Client Responsibilities

A client enrolled in the HIV Case Management Program is expected to:

(1) Participate in screening, assessment, care plan development and implementation activities;

(2) Provide accurate eligibility information at all times;

(3) Inform the case manager of changes in address, phone number, income, family size, legal name change, or health insurance coverage within 15 days;

(4) Make and keep appointments, or cancel or change an appointment within 24 hours of the scheduled time; and

(5) Other responsibilities as designated by the agency.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 29-2014, f. 11-10-14, cert. ef. 12-1-14

333-022-2080
Supportive Services

(1) A client enrolled in the HIV Case Management Program may be eligible for supportive services if income is at or below 250 percent of the FPL.

(2) Authorization by an agency of supportive services is discretionary and a decision to provide such services will be based on the following factors:

(a) The agency is funded to provide the services;

(b) The funds are available in the agency budget;

(c) The services are allowable per the contract with the Authority;

(d) No other payer exists to provide the needed services, with the exception of those that qualify for Veteran's Administration or Indian Health Services who may still qualify to receive Ryan White services;

(e) The client is eligible and currently active in the HIV Case Management Program; and

(f) The client's need for the service has been determined by the agency and documented in the client's file.

(3) An agency may authorize supportive services for any of the following:

(a) Emergency financial assistance, per agency budget, including but not limited to assistance with short-term medical costs, food, utilities or housing;

(b) Housing assistance, including but not limited to short-term assistance to support emergency, temporary or transitional housing;

(c) Linguistics services, meaning interpretation and translation services;

(d) Medical nutritional therapy provided by a licensed registered dietitian outside of a primary care visit, including the provision of nutritional supplements;

(e) Oral health care, including but not limited to diagnostic, preventive, and therapeutic services provided by general dental practitioners, dental specialists, dental hygienists and auxiliaries, and other trained primary care providers;

(f) Outpatient substance abuse services, meaning the provision of medical or other treatment or counseling to address substance abuse problems in an outpatient setting, provided by a physician or under the supervision of a physician or other qualified/licensed personnel;

(g) Residential substance abuse services, meaning treatment to address substance abuse problems in a residential health service setting, provided by a physician or under the supervision of a physician or other qualified/licensed personnel;

(h) Home health care services provided in the home by licensed health care workers such as nurses, and the administration of intravenous and aerosolized treatment, parenteral feeding, diagnostic testing, and other medical therapies;

(i) Mental health services meaning psychological and psychiatric treatment and counseling services offered to individuals with a mental illness, conducted in a group or individual setting, and provided by a mental health professional licensed or authorized within the state to render such services;

(j) Medical transportation services necessary to access health care services; or

(k) Other services funded by the Authority.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 29-2014, f. 11-10-14, cert. ef. 12-1-14

333-022-2090
Client Enrollment Review

(1) A client must participate with the agency at least every six months in reviewing the client's eligibility and enrollment information for HIV case management services, and at any time the agency deems it necessary within an eligibility period.

(2) An individual who does not provide an agency with the information necessary to verify continued eligibility may not receive supportive services until continued eligibility is documented.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 29-2014, f. 11-10-14, cert. ef. 12-1-14

333-022-2100
Incarcerated Applicants or Clients

(1) An individual who is incarcerated may not be enrolled in the HIV Case Management Program and may not continue to be enrolled in the program except as described in section (2) of this rule.

(2) An agency may enroll or continue to provide services to an individual who is incarcerated in order to facilitate an HIV positive inmate's transition from a correctional facility to the community under the following circumstances:

(a) The incarcerated person will be released within 180 days; and

(b) There are no other transitional case management or discharge planning services provided by the correctional facility.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 29-2014, f. 11-10-14, cert. ef. 12-1-14

333-022-2110
Termination

(1) A client enrolled in the HIV Case Management Program may be terminated from the program for any of the following:

(a) Failure to continue to meet eligibility requirements;

(b) Placement in a custodial institution for more than 180 days, such as a state or federal prison that is legally obligated to provide medical services;

(c) Cannot be located or is unresponsive to program requests for more than 60 days;

(d) Submitting false, fraudulent or misleading information in order to obtain or retain benefits;

(e) Fraudulent use of supportive services; or

(f) Consistent documented violations of the responsibilities outlined in OAR 333-022-2070.

(2) If an agency proposes to terminate an individual from the program it must notify the individual in writing, and the individual must be informed of their hearing rights per ORS 183.415. An

appeal must be submitted to the local or state authority to arrange t h e hearing.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 29-2014, f. 11-10-14, cert. ef. 12-1-14

333-022-2120
Hearings

A client who has been terminated has a right to a contested case hearing in accordance with ORS Chapter 183.

Stat. Auth.: ORS 413.042, 431.250, 431.830
Stats. Implemented: ORS 431.250, 431.830
Hist.: PH 29-2014, f. 11-10-14, cert. ef. 12-1-14

333-022-3000
Oregon Housing Opportunity in Partnership Program

(1) The Oregon Housing Opportunities in Partnership (OHOP) program provides housing services to eligible applicants who have received a medical diagnosis of HIV or AIDS. OHOP assists clients in achieving and maintaining housing stability so as to avoid or reduce homelessness and improve their access to, and engagement in, HIV care and treatment. OHOP is designed to promote client housing stability and act as a bridge to long-term assistance programs, such as Section 8, or to self-sufficiency. Participation in OHOP is voluntary and conditional.

(2) The OHOP program is funded through grants from the U.S. Department of Housing and Urban Development and other funds. OHOP is a needs-based program and not an entitlement program.

(3) The OHOP program is administered and operated in accordance with the OHOP Program Policy and Procedures manual, dated July 1, 2015, adopted and incorporated by reference. The manual may be obtained by visiting www.healthoregon.org/hiv.

Stat. Auth.: ORS 413.014, 431.250
Stats Implemented: ORS 431.250
Hist.: PH 14-2015, f. 8-28-15, cert. ef. 9-3-15

DIVISION 23

PRESCRIPTION DRUG MONITORING PROGRAM

333-023-0800
Purpose

The purpose of the Prescription Drug Monitoring Program rules (OAR 333-023-0800 through 333-023-0820) is to define operational processes of a prescription drug monitoring program.

Stat. Auth.: ORS 431.962
Stats. Implemented: ORS 431.962
Hist,: DMAP 6-2011, f. & cert. ef. 5-5-11; Renumbered from 410-121-4000, PH 28-2015, f. 12-29-15, cert. ef. 1-1-16

333-023-0805
Definitions

Unless otherwise stated in OAR 333-023-0800 through 333-023-0820, or the context of OAR 333-023-0800 through 333-023-0820 requires otherwise, the following definitions apply to OAR 333-023-0800 through 333-023-0820:

(1) "Authority" means the Oregon Health Authority.

(2) "Controlled substance" means a prescription drug classified in Schedules II through IV under the Federal Controlled Substances Act, 21 U.S.C. 811 and 812, as modified under ORS 475.035.

(3) "Delegate" means a member of staff of a practitioner or pharmacist who is authorized by the practitioner or pharmacist to access the system on his or her behalf.

(4) "Dispense" and "dispensing" have the meaning given those terms in ORS 689.005.

(5) "Health professional regulatory board" has the meaning given that term in ORS 676.160.

(6) "Pharmacy" has the meaning given that term in ORS 689.005 but does not include a pharmacy in an institution as defined in ORS 179.010.

(7) "Practitioner" has the meaning given that term in ORS 431.960.

(8) "Prescription drug" has the meaning given that term in ORS 689.005.

(9) "System" means the secure electronic system used to monitor reported prescription drug information.

(10) "Unsecure data" means data that is electronic and is not encrypted at the level established by the National Institute of Standards and Technology.

(11) "Vendor" means the private entity under contract with the Authority to operate the system.

Stat. Auth.: ORS 431.962
Stats. Implemented: ORS 431.962 - 431.978 & 431.992
Hist,: DMAP 6-2011, f. & cert. ef. 5-5-11; DMAP 64-2013, f. & cert. ef. 11-19-13; Renumbered from 410-121-4005, PH 28-2015, f. 12-29-15, cert. ef. 1-1-16

333-023-0810
Reporting Requirements

(1) Not later than 72 hours after dispensing a controlled substance a pharmacy shall electronically report to the Authority the following information for prescription drugs dispensed that are classified in schedules II through IV under the federal Controlled Substances Act, 21 U.S.C. 811 and 812, as modified by the State Board of Pharmacy by rule under ORS 475.035:

(a) Patient's full name, address, date of birth, and sex;

(b) Pharmacy Drug Enforcement Administration Registration Number (or other identifying number in lieu of such registration number);

(c) Prescriber name and Drug Enforcement Administration Registration Number (or other identifying number in lieu of such registration number);

(d) Identification of the controlled substance using a national drug code number;

(e) Prescription number;

(f) Date the prescription was written;

(g) Date the drug was dispensed;

(h) Number of metric units dispensed;

(i) Number of days supplied; and

(j) Number of refills authorized by the prescriber and the number of the fill of the prescription.

(2) A pharmacy located outside of the state and licensed by the Oregon Board of Pharmacy shall electronically report the required information for controlled substances dispensed to residents of Oregon.

(3) A pharmacy shall submit data formatted in the American Society for Automation in Pharmacy (ASAP) 2007 version 4 release 1 specification standard.

(4) Data submitted by a pharmacy shall meet criteria prescribed by the Authority before it is uploaded into the system.

(5) A pharmacy shall be responsible for the correction of errors in the submitted data. Corrections shall be submitted no later than one week after the data was submitted.

(6) A pharmacy that has not dispensed any controlled substances during a seven-day reporting period must submit a zero report to the Authority at the end of the reporting period.

(7) A pharmacy that does not dispense any controlled substances or any controlled substances directly to a patient may request a waiver from the Authority for exemption from the reporting requirement. A pharmacy requesting a no reporting waiver shall submit to the Authority a written waiver request form provided by the Authority.

(8) If the Authority approves or denies the no reporting waiver request, the Authority shall provide written notification of approval or denial to the pharmacy. The duration of the waiver shall be two years at which time the pharmacy must reapply.

(9) A pharmacy may request a waiver from the Authority for exemption from the electronic reporting method. A pharmacy requesting an electronic reporting waiver shall submit to the Authority a written waiver request form provided by the Authority that contains the reason for the requested waiver.

(10) The Authority may grant a waiver of the electronic reporting requirement for good cause as determined by the

Authority. Good cause includes financial hardship and not having an automated recordkeeping system.

(a) If the Authority approves the electronic reporting waiver, the Authority shall provide written notification to the pharmacy. The Authority shall determine an alternative reporting method for the pharmacy granted a waiver. The duration of the waiver shall be two years at which time the pharmacy must reapply.

(b) If the Authority denies the electronic reporting waiver, the Authority shall provide written notification to the pharmacy explaining why the request was denied. The Authority may offer alternative suggestions for reporting to facilitate participation in the program.

Stat. Auth.: ORS 431.962
Stats. Implemented: ORS 431.962 & 431.964
Hist,: DMAP 6-2011, f. & cert. ef. 5-5-11; DMAP 64-2013, f. & cert. ef. 11-19-13; Renumbered from 410-121-4010, PH 28-2015, f. 12-29-15, cert. ef. 1-1-16

333-023-0815
Notification to Patients

Using language provided by the Authority, a pharmacy shall notify each patient receiving a controlled substance about the Prescription Drug Monitoring Program before or when the controlled substance is dispensed to the patient. The notification shall include that the prescription will be entered into the system.

Stat. Auth.: ORS 431.962
Stats. Implemented: ORS 431.962
Hist,: DMAP 6-2011, f. & cert. ef. 5-5-11; Renumbered from 410-121-4015, PH 28-2015, f. 12-29-15, cert. ef. 1-1-16

333-023-0820
Information Access

(1) System Access. Only the following individuals or entities may access the system:

(a) Practitioners and pharmacists authorized to prescribe or dispense controlled substances;

(b) Delegates;

(c) Designated representatives of the Authority and any vendor contracted to establish or maintain the system; and

(d) State Medical Examiner and designees of the State Medical Examiner.

(2) All entities or individuals who request access from the Authority for the creation of user accounts shall agree to terms and conditions of use of the system.

(3) All delegates must be authorized by a practitioner or pharmacist with an active system account.

(4) The Authority shall monitor the system for unusual and potentially unauthorized use. When such use is detected, the user account shall be immediately deactivated.

(5) The vendor, a practitioner, a pharmacist or a pharmacy shall report to the Authority within 24 hours any suspected breach of the system or unauthorized access.

(6) When the Authority is informed of any suspected breach of the system or unauthorized access, the Authority shall notify the Authority's Information Security Office and investigate.

(7) If patient data is determined to have been breached or accessed without proper authorization, the Authority shall notify all affected patients, the Attorney General, and the applicable health professional regulatory board as soon as possible but no later than 30 days from the date of the final determination that a breach or unauthorized access occurred. Notice shall be made by first class mail to a patient or a patient's next of kin if the patient is deceased. The notice shall include:

(a) The date the breach or unauthorized access was discovered and the date the Authority believes the breach or unauthorized access occurred;

(b) The data that was breached or accessed without proper authorization;

(c) Steps the individual can take to protect him or herself from identity or medical identity theft;

(d) Mitigation steps taken by the Authority; and

(e) Steps the Authority will take to reasonably ensure such a breach does not occur in the future.

(8) Practitioner, Pharmacist, and Delegate Access. A practitioner, pharmacist, or delegate who chooses to request access to the system shall apply for a user account as follows:

(a) Complete and submit an application provided by the Authority that includes identifying information and credentials;

(b) Agree to terms and conditions of use of the system that defines the limits of access, allowable use of patient information, and penalties for misuse of the system; and

(c) Mail to the Authority a notarized application.

(9) State Medical Examiner Access. The State Medical Examiner or his or her designee shall apply for a user account as required in section (8) of this rule and indicate their license type as Medical Examiner.

(10) The Authority shall compare the licensure requirements between Oregon practitioners and similarly licensed professionals in California, Idaho, and Washington. The Authority's determination of similar licensure requirements shall be based upon scope of practice and formulary.

(11) The Authority shall review each application to authenticate before granting approval of a new account.

(12) If the Authority learns that an applicant has provided inaccurate or false information on an application, the Authority shall deny access to the system or terminate access to the system if access has already been established. The Authority may send written notification to the appropriate health professional regulatory board or oversight entity.

(13) A practitioner or pharmacist who is an authorized system user shall notify the Authority when his or her license or DEA registration has been limited, revoked, or voluntarily retired. A practitioner or pharmacist who changes or terminates employment shall notify the Authority of that change.

(14) When the Authority learns that a practitioner or pharmacist's license has been limited or revoked, the Authority shall deny further access to the system.

(15) When a delegate for any reason is no longer authorized as a delegate by a practitioner or pharmacist, the practitioner or pharmacist shall revoke the delegation and notify the Authority.

(16) When the account of a delegate is inactive for more than six months, the account shall be deactivated by the Authority.

(17) When for any reason access of a designee of the State Medical Examiner must be revoked, the State Medical Examiner shall notify the Authority.

(18) Each time a practitioner or pharmacist makes a patient query he or she shall certify that requests are in connection with the treatment of a patient in his or her care and agree to terms and conditions of use of the system.

(19) Each time the State Medical Examiner or designee of the State Medical Examiner makes a patient query he or she shall certify that requests are for the purpose of conducting a specific medicolegal investigation or autopsy where there is reason to believe controlled substances contributed to the death and agree to terms and conditions of use of the system.

(20) Each time a delegate makes a patient query he or she shall certify that requests are in connection with the treatment of a patient of the practitioner or pharmacist for whom the delegate is conducting the query, agree to terms and conditions of use, and indicate the authorizing practitioner or pharmacist for whom the delegate is conducting the query.

(21) Practitioners and pharmacists with delegates must conduct monthly audits of delegate use to monitor for potential misuse of the system.

(22) When a practitioner or pharmacist learns of any potential unauthorized use of the system or system data by a delegate, the practitioner or pharmacist shall:

(a) Revoke the delegation; and

(b) Notify the Authority of the potential unauthorized use.

(23) When the State Medical Examiner learns of any potential unauthorized use of the system or system data by a designee, the State Medical Examiner shall notify the Authority.

(24) When the Authority learns of any potential unauthorized use of the system or system data, the Authority shall revoke the

user's access to the system, notify the Authority's Information Security Office, and investigate.

(a) If the Authority determines unauthorized use occurred, the Authority shall send written notification to the appropriate health professional regulatory board, the Attorney General and all affected individuals.

(b) If the Authority determines unauthorized use did not occur, the Authority shall reinstate access to the system.

(25) The Authority shall send written notification to a user or a potential user when an account has been deactivated or access has been denied.

(26) Patient Access. A patient may request a report of the patient's own controlled substance record. The patient shall mail to the Authority a request that contains the following documents:

(a) A signed and dated patient request form provided by the Authority; and

(b) A copy of the patient's current valid U.S. driver's license or other valid government issued photo identification.

(27) The Authority shall review the personal information submitted and verify that the patient's identification and request match before taking further action.

(28) If the Authority cannot verify the information, the Authority shall send written notification to the patient explaining why the request cannot be processed.

(29) After the Authority has verified the request, the Authority shall query the system based upon the patient information provided in the request and securely send the report to the patient at no cost to the patient. The report shall include:

(a) A list of controlled substances dispensed to the patient including the dates of dispensation, the practitioners who prescribed the controlled substances, and the pharmacies that dispensed them; and

(b) A list of users who accessed the system for information on that specific patient with the date of each instance of access.

(30) If no data is found that matches the patient identified in the request, the Authority shall send written notification to the patient explaining possible reasons why no patient data was identified.

(31) A patient may send written notification to the Authority if he or she believes unauthorized access to his or her information has occurred. The notification shall include the patient's name, who is suspected to have gained unauthorized access to the patient's information, what information is suspected to have been accessed by unauthorized use, when the suspected unauthorized access occurred, and why the patient suspects the access was unauthorized. The Authority shall treat such patient notifications as potential unauthorized use of the system.

(32) A patient may request that the Authority correct information in a patient record report as follows:

(a) The patient shall specify in writing to the Authority what information in the report the patient considers incorrect.

(b) When the Authority receives a request to correct a patient's information in the system, the Authority shall make a note in the system that the information is contested and verify the accuracy of the system data with the vendor. The vendor shall verify that the data obtained from the query is the same data received from the pharmacy.

(c) If the data is verified incorrect, the Authority shall correct the errors in consultation with the vendor and document the correction. The Authority shall send to the patient the corrected report.

(d) If the vendor verifies the data is correct, the Authority shall send written notification informing the patient that the request for correction is denied. The notice shall inform the patient of his or her rights as are applicable to the prescription drug monitoring program, the process for filing an appeal, and if there are no appeal rights, how to otherwise address or resolve the issue.

(33) The Authority shall respond to all patient requests within 10 business days after the Authority receives a request. Each response shall include information that informs the patient of his or her rights as are applicable to the prescription drug monitoring program.

(34) If the Authority denies a patient's request to correct information, or fails to grant a patient's request within 10 business days after the Authority receives the request, a patient may appeal the denial or failure by requesting a contested case hearing. The appeal shall be filed within 30 days after the request to correct information is denied. The appeal process is conducted pursuant to ORS Chapter 183 and the Attorney General's Uniform and Model Rules of Procedure for the Office of Administrative Hearings (OAH), OAR 137-003-0501 through 137-003-0700.

(35) Law Enforcement Access. A federal, state, or local law enforcement agency engaged in an authorized drug-related investigation of an individual may request from the Authority controlled substance information pertaining to the individual to whom the information pertains. The request shall be pursuant to a valid court order based on probable cause.

(36) A law enforcement agency shall submit to the Authority a request that contains the following:

(a) A form provided by the Authority specifying the information requested; and

(b) A copy of the court order documents.

(37) The Authority shall review the law enforcement request.

(a) If the form is complete and the court order is valid, the Authority shall query the system for the requested information and securely provide a report to the law enforcement agency.

(b) If the request or court order is not valid, the Authority shall respond to the law enforcement agency providing an explanation for the denial.

(38) Health Professional Regulatory Board Access. A health professional regulatory board investigating an individual regulated by the board may request from the Authority controlled substance information pertaining to the member.

(a) A health professional regulatory board shall submit to the Authority a form provided by the Authority specifying the information requested. The board's executive director shall certify that the requested information is necessary for an investigation related to licensure, renewal, or disciplinary action involving the applicant, licensee, or registrant to whom the requested information pertains.

(b) The Authority shall review the regulatory board request.

(A) If a request is valid, the Authority shall query the system for the requested information and securely provide a report to the health professional regulatory board.

(B) If a request is not valid, the Authority shall respond to the health professional regulatory board providing an explanation for the denial.

(39) Researcher Access. The Authority may provide de-identified data for research purposes to a researcher. A researcher shall submit a research data request form provided by the Authority.

(a) The request shall include but is not limited to a thorough description of the study aims, data use, data storage, data destruction, and publishing guidelines.

(b) The Authority shall approve or deny research data requests based on application merit.

(c) If a request is approved, the requestor shall sign a data use agreement provided by the Authority.

(d) The Authority shall provide the minimum data set necessary that does not identify individuals.

(e) The Authority may charge researchers a reasonable fee for services involved in data access.

Stat. Auth.: ORS 431.962

Stats. Implemented: ORS 431.962 & 431.966

Hist.: DMAP 6-2011, f. & cert. ef. 5-5-11; DMAP 64-2013, f. & cert. ef. 11-19-13; Renumbered from 410-121-4020, PH 28-2015, f. 12-29-15, cert. ef. 1-1-16

DIVISION 24

CLINICAL LABORATORIES

333-024-0005
Purpose

These rules (OAR 333-024-0005 through 333-024-0055 and 333-024-0260 and 333-024-0265) are for the purpose of carrying out ORS Chapter 438, the declarative purpose of which is to insure

the quality of medical laboratory work in order to protect the health and welfare of the people of the State of Oregon by establishing a regulatory program for clinical laboratories.

Stat. Auth.: ORS 438.450
Stats. Implemented: ORS 438.030 & 438.450
Hist.: HB 248, f. 6-30-70, ef. 7-25-70; HD 28-1988, f. & cert. ef. 12-7-88

333-024-0010
Definitions

(1) "Accredited college or university" as used in the Act and OAR 333-024-0021 means the accreditation by a nationally recognized accrediting agency or association as determined by the U.S. Commissioner of Education.

(2) "Approved accreditation organization" for laboratories means a private, nonprofit association that has formally received the Health Care Financing Administration's approval.

(3) "Accreditation" means a certificate obtained from a nonprofit organization that has met the standards as established by the Health Care Financing Administration and approved by the Division.

(4) "Clinical laboratory" or "laboratory" means a facility where the microbiological, serological, toxicological, chemical, hematological, immunological, immunohematological, cytological, pathological, histological, cytogenetical, or other examinations are performed on materials derived from the human body, for the purpose of diagnosis, prevention of disease or treatment of patients by physicians, dentists and other persons who are authorized by license to diagnose or treat humans.

(5) "CLIA 88" means the **Clinical Laboratory Improvement Amendments of 1988** including the rules that implement the law as published in **Section 42 Code of Federal Regulations**, **Part 493**, **Laboratory Requirements**, February 28, 1992 and January 19, 1993 as amended and revised.

(6) "Clinical laboratory specialty" or "laboratory specialty" means the examination of materials derived from the human body for the purpose of diagnosis and treatment of patients, or assessment of health, employing one of the following sciences: microbiology, chemistry, diagnostic immunology, toxicology, cytogenetics, hematology, immunohematology, histocompatibility, cytology, histopathology, or oral pathology.

(7) "Clinician" means a nurse practitioner licensed and certified by the Oregon State Board of Nursing, or a physician assistant licensed by the Board of Medical Examiners for the State of Oregon.

(8) "Dentist" means a person licensed to practice dentistry by the Oregon Board of Dentistry.

(9) "Director of clinical laboratory" or "Director" means the person who plans, organizes, directs and participates in any or all of the technical operations of a clinical laboratory, including but not limited to reviewing laboratory procedures and their results, training and supervising laboratory personnel, and evaluating the technical competency of such personnel.

(10) "Division" means the Public Health Division of the Oregon Health Authority.

(11) "Health Screen Testing" means tests performed for the purpose of identifying health risks, providing health information and referring the person being tested to medical care.

(12) "High complexity laboratory" means a facility that performs testing classified as highly complex in the specialties of microbiology, chemistry, hematology, diagnostic immunology, immunohematology, clinical cytogenetics, cytology, histopathology, oral pathology, radiobioassay and histocompatibility and may also perform moderate complexity tests, physician performed microscopy procedures and waived tests.

(13) "High complexity test" means a procedure performed on materials derived from the human body that meet the criteria for this category of testing in the specialties of microbiology, chemistry, hematology, immunohematology, diagnostic immunology, clinical cytogenetics, cytology, histopathology, oral pathology, radiobioassay and histocompatibility as established by the Health Care Financing Administration and the Centers for Disease Control and Prevention.

(14) "Laboratory evaluation system" means a system of testing clinical laboratory methods, procedures and proficiency by periodic performance and reporting on test specimens submitted for examination.

(15) "Moderate complexity laboratory" means a facility that performs testing classified as moderately complex in the specialties of microbiology, hematology, chemistry, immunohematology or diagnostic immunology and may also perform any physician performed microscopy procedure and waived test.

(16) "Moderate complexity test" means a procedure performed on materials derived from the human body that meet the criteria for this category of testing in the specialties of microbiology, hematology, chemistry, immunohematology or diagnostic immunology as established by the Health Care Financing Administration and the Centers for Disease Control and Prevention.

(17) "Owner of a clinical laboratory" means the individual(s), corporation, association, firm, partnership, joint stock companies, or a county, state or municipality owning and operating a clinical laboratory.

(18) "Pertinent clinical laboratory experience" or "pertinent experience" as used in the Act and OAR 333-024-0021 and 333-024-0022 means laboratory experience gained in a clinical laboratory performing or supervising the same types of laboratory tests as those in common use for the specific specialty involved.

(19) "Physician" means a person licensed to practice medicine by the Board of Medical Examiners for the State of Oregon.

(20) "Physician performed microscopy procedure" means a test as defined in OAR 333-024-0016(1)(b) which is personally performed by a physician or other clinician during a patient's visit on a specimen obtained during the examination of the patient.

(21) "Specimen" means materials derived from a human being or body.

(22) "The Act" as used in OAR 333-024-0005 through 333-024-0055 and 333-024-0260 and 333-024-0265 means Oregon Revised Statutes, Chapter 438.

(23) "Waived laboratory" means a facility that performs only tests as defined in OAR 333-024-0016(1)(a) that are so simple and accurate as to render the likelihood of erroneous results negligible.

(24) "Waived test" means tests that are so simple and accurate as to render the likelihood of erroneous results negligible, or tests which are categorized as waived for CLIA laboratories, by the Health Care Financing Administration and Centers for Disease Control and Prevention.

Stat. Auth.: ORS 433.017 & 438.010
Stats. Implemented: ORS 438.010-320, 438.430, 438.435 & 438.510
Hist.: HB 248, f. 6-30-70, ef. 7-25-70; HD 28-1988, f. & cert. ef. 12-7-88; HD 7-1990, f. & cert. ef. 3-21-90; HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95

333-024-0012
Licensure

(1) It shall be unlawful:

(a) For any Owner or Director of a clinical laboratory to operate or maintain a clinical laboratory without a license or without a temporary permit issued under this rule or to perform or permit the performance of any laboratory specialty for which the laboratory is not licensed, unless the laboratory has been issued a valid certificate from the federal government under the **Clinical Laboratory Improvement Amendments of 1988**, **Public Law 100-578**, **42.U.S.C. 201** and **263a**, except as specified herein;

(b) For any person to serve in the capacity of Director of a high complexity clinical laboratory without being qualified as a Clinical Laboratory Director under OAR 333-024-0021;

(c) For any person to serve in the capacity of Director of a moderate complexity clinical laboratory without being qualified as a Clinical Laboratory Director under OAR 333-024-0022; and

(d) For any person other than a physician or clinician to direct or perform microscopic procedures listed in OAR 333-024-0016(1)(b) in a Physician Performed Microscopy Laboratory.

(2) OAR 333-024-0005 through 333-024-0055 and 333-024-0260 and 333-024-0265 apply to all clinical laboratories and laboratory personnel within the State of Oregon, except:

(a) Clinical laboratories operated by the United States Government;

(b) Clinical laboratories operated and maintained purely for research or teaching purposes, and that involve no patient or public health services.

(3) It shall be unlawful for an out-of-state laboratory to perform health screen testing in Oregon without a permit issued as provided in OAR 333-024-0380.

(4) The Division shall issue and renew waived, physician performed microscopy, moderate and high complexity licenses for any or all clinical laboratory specialties to the Owners of clinical laboratories who demonstrate to the satisfaction of the Division that:

(a) The clinical laboratory is in compliance with OAR 333-024-0005 through 333-024-0055, 333-024-0260, 333-024-0265, 333-024-0305 through 333-024-0360 and 333-024-0370 through 333-024-0400;

(b) The laboratory is equipped to perform within the scope of its license;

(c) The clinical laboratory retains complete laboratory records as stated in OAR 333-024-0050;

(d) The clinical laboratory meets the standards of the Division for safety, disposal of hazardous and infectious waste, ventilation, handling of specimens, and maintenance of equipment to ensure protection of the public health.

(5) Requirements for license application, fees, exemptions, expiration, and renewal are as follows:

(a) The application for a license for a clinical laboratory shall be made on forms provided by the Division and shall be executed by the Owner or one of the Owners or by an officer of the firm or corporation owning the clinical laboratory, or in the case of a county or municipality, by the public official responsible for operation of the laboratory, or in the case of an institution, by the administrator of the institution. The application shall contain the names of the Owner, the Director or Directors of the clinical laboratory, the location and physical description of the clinical laboratory, the laboratory specialties for which a license is requested, and such other information as the Division may require:

(A) Not-for-profit, or state, or local government laboratories that engage in limited public health testing may file a single application, provided they have the same owner and director. They may perform a combined total of fifteen test methods listed in the waived, physician performed microscopy and moderate complexity category.

(B) Laboratories that are located at the same site and are under the same director may file a single application.

(b) Laboratories must pay an annual or biennial, nonrefundable license fee prior to issuance of a license or permit. Numbers in the fee category indicate the number of tests performed annually; count tests on patient/client specimens only. Count the number of tests in each profile. Do not count waived tests, physician-performed microscopy by physicians and clinicians, standards, controls, calculated tests, or proficiency testing samples. Effective July 1, 1999, the annual fees are:

(A) Waived — Accredited and Non-Accredited — $71;

(B) Physician Performed Microscopy (PPM) — Accredited and Non-Accredited — $95;

(C) Non-Accredited Moderate and High Complexity:

(i) Low Volume A (LVA) 1–2,000 tests — $261;

(ii) A — 2,001 to 10,000 tests; ≤ 3 specialties — $517;

(iii) B — 2,001 to 10,000 tests; ≥ 4 specialties — $650;

(iv) C — 10,001 to 25,000 tests; ≤ 3 specialties — $916;

(v) D — 10,001 to 25,000 tests; ≥ 4 specialties — $1,037;

(vi) E — 25,001 to 50,000 tests — $1,254;

(vii) F — 50,001 to 75,000 tests — $1,584;

(viii) G — 75,001 to 100,000 tests — $1,914;

(ix) H — 100,001 to 500,000 tests — $2,263;

(x) I — 500,001 to 1,000,000 tests — $4,365;

(xi) J — > 1,000,000 tests — $5,298.

(D) Accredited Moderate and High Complexity:

(i) Low Volume A (LVA) 1–2,000 tests — $118;

(ii) A — 2,001 to 10,000 tests; ≤ 3 specialties — $138;

(iii) B — 2,001 to 10,000 tests; ≥ 4 specialties — $145;

(iv) C — 10,001 to 25,000 tests; ≤ 3 specialties — $285;

(v) D — 10,001 to 25,000 tests; ≥ 4 specialties — $295;

(vi) E — 25,001 to 50,000 tests — $401;

(vii) F — 50,001 to 75,000 tests — $620;

(viii) G — 75,001 to 100,000 tests — $840;

(ix) H — 100,001 to 500,000 tests — $1,078;

(x) I — 500,001 to 1,000,000 tests — $3,070;

(xi) J — > 1,000,000 tests — $3,893.

(c) Laboratories must pay an annual or biennial, nonrefundable license fee prior to issuance of a license or permit. Numbers in the fee category indicate the number of tests performed annually; count tests on patient/client specimens only. Count the number of tests in each profile. Do not count waived tests, physician-performed microscopy by physicians and clinicians, standards, controls, calculated tests, or proficiency testing samples. Effective July 1, 2000, the annual fees are:

(A) Waived — Accredited and Non-Accredited — $75;

(B) Physician Performed Microscopy (PPM) — Accredited and Non-Accredited — $100;

(C) Non-Accredited Moderate and High Complexity:

(i) Low Volume A (LVA) 1–2,000 tests — $275;

(ii) A — 2,001 to 10,000 tests; ≤ 3 specialties — $545;

(iii) B — 2,001 to 10,000 tests; ≥ 4 specialties — $685;

(iv) C — 10,001 to 25,000 tests; ≤ 3 specialties — $965;

(v) D — 10,001 to 25,000 tests; ≥ 4 specialties — $1,092;

(vi) E — 25,001 to 50,000 tests — $1,320;

(vii) F — 50,001 to 75,000 tests — $1,667;

(viii) G — 75,001 to 100,000 tests — $2,015;

(ix) H — 100,001 to 500,000 tests — $2,382;

(x) I — 500,001 to 1,000,000 tests — $4,595;

(xi) J — > 1,000,000 tests — $5,577.

(D) Accredited Moderate and High Complexity:

(i) Low Volume A (LVA) 1–2,000 tests — $125;

(ii) A — 2,001 to 10,000 tests; ≤ 3 specialties — $146;

(iii) B — 2,001 to 10,000 tests; ≥ 4 specialties — $153;

(iv) C — 10,001 to 25,000 tests; ≤ 3 specialties — $300;

(v) D — 10,001 to 25,000 tests; ≥ 4 specialties — $311;

(vi) E — 25,001 to 50,000 tests — $422;

(vii) F — 50,001 to 75,000 tests — $653;

(viii) G — 75,001 to 100,000 tests — $884;

(ix) H — 100,001 to 500,000 tests — $1,136;

(x) I — 500,001 to 1,000,000 tests — $3,232;

(xi) J — > 1,000,000 tests — $4,098.

(d) A prorated fee may be assessed for a license that will be in effect for a year or less;

(e) Unless sooner voided, suspended or revoked, all licenses issued under this section expire on June 30 of the one or two year cycle following the date of issuance and shall be renewable in the manner prescribed by the Division;

(f) All monies received by the Division for the licensure of clinical laboratories shall be credited to the Division account and shall be used for payment of the expenses of the Division in administering OAR 333-024-0005 through 333-024-0055 and 333-024-0260 and 333-024-0265.

(6) A license issued to the Owner of a clinical laboratory shall show on its face the names of the Owners and Directors, the location of the laboratory and the clinical laboratory specialties authorized under the license. The license shall be displayed at all times in a prominent place in the laboratory.

(7) A license issued to the Owner of a clinical laboratory is not transferable. The license of the laboratory is voided 30 days after a change of its Director if it has only one Director or if all Directors change or a change in the ownership or in the location of the laboratory. Upon the death of a laboratory's Director and the immediate notification to the Division, the Division shall be empowered to issue, after the payment of the proper fee, a special temporary permit. This permit shall be of 30 days' duration and issued to an approved substitute Director. If a license is voided or a special temporary permit is issued under this rule, a new license application,

accompanied by the non-refundable license fee prescribed in subsection (4)(b) of this rule shall be filed with the Division.

(8) Temporary permit requirements are as follow:

(a) In addition to the license of a clinical laboratory required by this rule, the Division may issue a temporary permit, valid for 45 days from the date of issuance, in any or all clinical laboratory specialties upon payment of the respective required fees as prescribed in subsection (5)(b) or (5)(c) of this rule;

(b) In issuing the temporary permit, the Division may require that:

(A) Plans for compliance with applicable laws and rules be submitted with the application for temporary permit;

(B) During the period in which the temporary permit is in effect, periodic reports be submitted on the progress of the plans for compliance; and

(C) Temporary provisions specified by the Division upon application of the temporary permit be maintained for the protection of the public.

(c) If at any time the Division determines that the clinical laboratory can no longer operate in a manner which protects the public health and safety or that the requirements imposed under paragraphs (7)(b)(A), (B) and (C) of this rule are not being maintained, the Division shall cancel the temporary permit;

(d) One renewal of the temporary permit may be granted if deemed to be in the best interest of public health by the Division. The fee for renewal is the respective required fee as prescribed in subsection (4)(b) of this rule.

(9) Subject to ORS 183.310 to 183.550, the Division may refuse to issue or renew the license or may suspend or revoke the license of any clinical laboratory, if it finds that the Owner or Director has:

(a) Intentionally made false statements on an application for a clinical laboratory license or any other documents required by the Division, or made any misrepresentation in seeking to obtain or retain a license;

(b) Demonstrated incompetence as defined in OAR 333-024-0055;

(c) Intentionally falsified any report;

(d) Referred a specimen for examination to an unlicensed clinical laboratory in this State unless the laboratory is exempt from the application of this rule, or a clinical laboratory not certified or accredited under the provisions of CLIA 88, or other authorized CLIA exempt state laboratory certification program;

(e) Misrepresented the scope of laboratory service offered by the clinical laboratory or the clinical laboratory specialties authorized by the license;

(f) Rendered a report on clinical laboratory work actually performed in another clinical laboratory without designating the name and address of the clinical laboratory in which the test was performed;

(g) Knowingly had professional connection with or permitted the use of the name of the licensed clinical laboratory or its Director by a clinical laboratory that is required to but has not obtained a license;

(h) Failed to perform or cause to be performed within the time specified analysis of test samples as stated in OAR 333-024-0040(1) or failed to report on the results of such analysis within the specified time;

(i) Failed to permit within a reasonable time the entry or inspection as stated in OAR 333-024-0040(4), (6), (7), (9), (10), (11) and (12);

(j) Failed to continue to meet requirements of this rule, inclusive;

(k) Violated any provision of OAR 333-024-0005 through 333-024-0055 and 333-024-0260 and 333-024-0265.

(10) The owner or director must notify the Division within 30 days of a change of laboratory name and technical supervisor.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 433.017, 438.010, 438.040 & 438.055

Stats. Implemented: ORS 438.040 - 438.055 & 438.110 - 438.160

Hist.: HD 28-1988, f. & cert. ef. 12-7-88; HD 7-1990, f. & cert. ef. 3-21-90; HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95; OHD 5-1999, f. & cert. ef. 7-30-99

333-024-0016
Licensure Categories

(1) The four categories of clinical laboratories are:

(a) A waived laboratory which may perform only the following; dipstick or tablet reagent urinalysis (nonautomated), fecal occult blood, ovulation test-visual color comparison tests for human luteinizing hormone, urine pregnancy test-visual color comparison tests, erythrocyte sedimentation rate (nonautomated), hemoglobin-copper sulfate (nonautomated), blood glucose (by glucose monitoring devices cleared by the Food and Drug Administration specifically for home use), spun microhematocrit, and hemoglobin and glucose by Hemocue, Chemtrak Accumeter cholesterol, body fluid occult blood, nitrazine pH paper for all body fluids except blood or any other tests which are categorized as waived for CLIA laboratories, by the Health Care Financing Administration and Centers for Disease Control and Prevention:

(A) A waived laboratory is exempt from personnel requirements, proficiency testing and routine on-site inspections;

(B) A waived laboratory shall follow manufacturer's instructions for test performance:

(b) A physician performed microscopy procedure laboratory which may perform only tests in the waived category and the following: wet mounts (for presence or absence of bacteria, fungi, parasites and human cellular elements), all potassium hydroxide (KOH) preparations, pinworm examinations, fern tests, post-coital direct examinations of vaginal or cervical mucus, nasal smears for granulocytes, qualitative post-vasectomy semen analysis limited to presence or absence of sperm and motility, fecal leukocyte examinations, and urine sediment examinations, or any other tests which are categorized as provider-performed microscopy procedures for CLIA laboratories, by the Health Care Financing Administration and Centers for Disease Control and Prevention:

(A) A physician performed microscopy laboratory is exempt from routine on-site inspections;

(B) A physician performed microscopy laboratory shall follow manufacturer's instructions for test performance;

(C) A physician performed microscopy laboratory shall meet the applicable requirements for quality control, proficiency testing, quality assurance, records and reports.

(c) A moderate complexity laboratory which may perform waived, physician performed microscopy procedures, and tests identified as moderate complexity by the Health Care Financing Administration and the Centers for Disease Control and Prevention;

(d) A high complexity laboratory which may perform all categories of testing including the specialties of cytogenetics, cytology, pathology, histocompatibility and radiobioassay.

(2) Any test not listed in the waived, physician performed microscopy procedures or moderate complexity category is high complexity.

(3) The category of any test may be obtained from the Division.

Stat. Auth.: ORS 438.110

Stats. Implemented: ORS 438.110

Hist.: HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95

333-024-0020
Licensure for Performance of Laboratory Specialties

(1) Licensure for the performance of surgical pathology, autopsy pathology, exfoliative cytology, and immunohematology (except as provided in section (4) of this rule) shall be granted only to a laboratory whose Director is a physician or dentist specifically qualified in these fields.

(2) A clinical laboratory testing for substances of abuse shall be licensed under ORS 438.435(4) and comply with OAR 333-024-0305 through 333-024-0350, except when performing tests for the purpose of diagnosis, prevention of disease or treatment of patients by physicians, dentists and other persons who are authorized by license to diagnose or treat humans.

(3) Licensure for the performance of substances of abuse testing in clinical laboratories shall be granted only to a laboratory whose Director qualifies under OAR 333-024-0320(1).

Stat. Auth.: ORS 438.120
Stats. Implemented: ORS 438.120
Hist.: HB 248, f. 6-30-70, ef. 7-25-70; HD 28-1988, f. & cert. ef. 12-7-88

333-024-0021
Qualifications and Responsibilities of Directors for High Complexity Laboratories

(1) The Director shall meet at least one of the qualifications defined by the following:

(a) Is a pathologist certified in clinical or anatomical pathology by the American Board of Pathology, the American Osteopathic Board of Pathology, or is eligible for such certification (Board eligible);

(b) Is certified or board eligible by the American Board of Oral Pathology. An oral pathologist shall only direct an oral pathology laboratory;

(c) Is a physician who:

(A) Is eligible for certification by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Society of Cytology, the American Board of Dermatology, or other national accrediting board related to a laboratory specialty as may be approved by the Division; and

(B) Has had two or more years of general laboratory training and experience.

(d) Has an earned degree of Doctor of Science, Doctor of Public Health, or Doctor of Philosophy or an acceptable degree, as determined by the Division, from an accredited college or university with a major in the chemical, physical, or biological sciences and possesses special qualifications as follows: is certified or is eligible for certification by the American Board of Medical Microbiology, American Board of Bioanalysis, the American Board of Clinical Chemistry, or other national accrediting board related to a laboratory specialty or possesses other special qualifications as approved by the Division; and has one or more years experience supervising high complexity testing;

(e) Was responsible for the direction of a clinical laboratory for at least 12 months within the five years preceding January 1, 1970, and has had at least two years of pertinent clinical laboratory experience as determined by the Division;

(f) Was serving as a laboratory director in Oregon and either previously qualified or could have qualified as a laboratory director in Oregon on or before February 28, 1992, and is a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine, and has two or more years of general laboratory training or experience;

(g) Was qualified as a clinical laboratory director under federal regulations prior to February 28, 1992.

(2) A person is qualified to act as the laboratory Director of the clinical laboratory only at any accredited chiropractic college in this State for the benefit of chiropractic patients if that person is a chiropractic physician licensed by the State Board of Chiropractic Examiners, and possesses special qualifications, as determined by the State Board of Chiropractic Examiners, which enable that person to perform as a laboratory Director.

(3) The Director shall supervise or perform only in those specialties for which qualified.

(4) The Director is responsible for the overall operation and administration of the laboratory, including the employment of competent personnel, equipment, safety, quality assurance, all testing (including proficiency testing) and test reports.

(a) The laboratory director may, if qualified, perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities in writing to other qualified individuals; and ensure that all duties are properly performed; and must be accessible to provide on site, telephone or electronic consultation;

(b) The laboratory director may direct no more than five laboratories;

(c) The laboratory director must ensure:

(A) Quality services for all aspects of test performance;

(B) Environmental conditions provide a safe testing site;

(C) Test methodologies provide accurate results;

(D) Verification procedures are used to determine the accuracy, precision, and other pertinent performance characteristics of the method;

(E) Laboratory personnel perform only director approved methods;

(F) The laboratory is enrolled in an approved proficiency testing program if required;

(G) The proficiency test samples shall be tested in the same manner as patient specimens, results returned within established time frames, reviewed by the director or designate, and corrective action taken, if necessary.

(H) Quality control and quality assurance programs are established and maintained;

(I) Acceptable levels of analytical performance for each test are established and maintained;

(J) That all necessary remedial actions are taken and documented whenever necessary and patient test results are reported only when the system is functioning properly;

(K) That test results include pertinent information required for interpretation;

(L) That consultation is available to the laboratory's clients, if applicable;

(M) That a general supervisor provides on-site supervision of high complexity test performance by qualified testing personnel;

(N) The employment of a sufficient number of qualified personnel to provide consultation, supervision and accurate test performance and report test results in accordance with their personnel responsibilities;

(O) That policies and procedures are established to monitor the competency of the individuals performing the testing and provide remedial training or education as needed;

(P) That an approved procedure manual is available to all testing personnel; and

(Q) The duties and responsibilities of each consultant, supervisor and each testing personnel are specified in writing; and

(R) All personnel have appropriate training.

Stat. Auth.: ORS 438.210 & 438.220
Stats. Implemented: ORS 438.210 & 438.220
Hist.: HB 248, f. 6-30-70, ef. 7-25-70; HD 28-1988, f. & cert. ef. 12-7-88, Renumbered from 333-024-0015; HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95

333-024-0022
Qualifications and Responsibilities for Director of Moderate Complexity Laboratories

(1) The director shall meet at least one of the qualifications in 333-024-0021 or one of the following:

(a) Is a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine; and

(A) Has one or more years of directing or supervising non-waived laboratory testing; or

(B) Has at least 20 continuing medical education credit hours in laboratory practice; or

(C) Has 1 year of laboratory training in non-waived testing during a residency.

(b) Has earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(A) Has at least one year of pertinent laboratory training or experience; and

(B) Has at least one year of supervisory laboratory experience in non-waived testing.

(c) Has earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and

(A) Has at least 2 years of laboratory training or experience, or both in non-waived testing; and

(B) Has at least 2 years of supervisory laboratory experience in non-waived testing.

(2) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of competent personnel, equipment, safety, quality assurance, all testing including proficiency testing, and test reports:

(a) The laboratory director may, if qualified, perform the duties of the technical consultant, clinical consultant, and testing personnel or delegate these responsibilities in writing to other qualified individuals; and must ensure that all duties are properly performed, and must be accessible to provide on site, telephone or electronic consultation;

(b) The laboratory director may direct no more than five laboratories;

(c) The director must ensure:

(A) Quality services for aspects of test performance;

(B) Environmental conditions provide a safe testing site;

(C) Test methodologies provide accurate results;

(D) Verification procedures are used to determine the accuracy, precision, and other pertinent performance characteristics of the method;

(E) Laboratory personnel perform only director approved methods;

(F) The laboratory is enrolled in an approved proficiency testing program if required;

(G) The proficiency test samples shall be tested in the same manner as patient specimens, results returned within established time frames, reviewed by the director or designate, and corrective action taken, if necessary;

(H) Quality control and quality assurance programs are established and maintained;

(I) Acceptable levels of analytical performance for each test are established and maintained;

(J) That all necessary remedial actions are taken and documented whenever necessary and patient test results are reported only when the system is functioning properly;

(K) That test results include pertinent information required for interpretation;

(L) That consultation is available to the laboratory's clients, if applicable;

(M) The employment of a sufficient number of qualified personnel to provide consultation, supervision and accurate test performance and report test results in accordance with their personnel responsibilities;

(N) That policies and procedures are established to monitor the competency of the individuals performing the testing and provide remedial training, or education as needed;

(O) That an approved procedure manual is available to all testing personnel;

(P) The duties and responsibilities of each consultant and each testing personnel are specified in writing; and

(Q) All personnel have appropriate training.

Stat. Auth.: ORS 438.210 & 438.220
Stats. Implemented: ORS 438.210 & 438.220
Hist.: HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95

333-024-0023
Qualifications and Responsibilities of Consultants, Supervisors and Testing Personnel for Moderate and High Complexity Laboratories

(1) Moderate complexity laboratory technical and clinical consultants shall meet the minimal qualifications and fulfill the responsibilities described in the **Clinical Laboratory Improvement Amendments of 1988, 42 CFR, Part 493, Subpart M**.

(2) High complexity laboratory clinical consultants, general and technical supervisors, and cytology general supervisors shall meet the minimal qualifications and fulfill the responsibilities as described in the **Clinical Laboratory Improvement Amendments of 1988, 42 CFR, Part 493, Subpart M**.

(3) All testing personnel shall meet the minimal qualifications and fulfill the responsibilities as described in the **Clinical Laboratory Improvement Amendments of 1988, 42 CFR, Part 493, Subpart M**.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 438.070
Stats. Implemented: ORS 438.070
Hist.: HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95

333-024-0026
Equipment and Facilities

(1) All equipment shall be maintained in good working order, checked routinely, and precisely calibrated according to manufacturer's requirements or a minimum of every six months.

(2) Work bench space shall be ample, clean, well-organized, well-lighted, and convenient to sink, water and electrical outlets.

(3) The laboratory shall be ventilated to protect the health of the personnel and patients against accidental release of hazardous vapors or aerosols.

(4) Laboratory procedure manuals and policies shall be available for the use of the personnel in the laboratory and shall be reviewed by the Director initially and when there is a change in methods or policy.

(5) The premises shall be free from unnecessary physical, chemical, and biological hazards. All materials containing pathogenic organisms shall be:

(a) Autoclaved at 121°C for 30 minutes to ensure nonviability prior to being discarded; or

(b) Incinerated in a State-approved incinerator; or

(c) Disposed using another Division approved method.

(6) Safety precautions must be posted and observed.

(7) Glassware shall be free from excessive scratches and cloudiness and graduations must be legible. "To contain" and "to deliver" pipettes are to be kept separated. Cleanliness of glassware must be adequate for the purpose for which it is used.

(8) Blood-letting lancets, needles, and syringes, if not sterile and disposable, shall be sterilized prior to each use by standard and accepted methods. Each sterilizing cycle shall contain a satisfactory indicating device to assure proper sterilization.

(9) Electrical equipment shall be maintained in a safe condition with regards to shock and fire hazards. All electrical equipment, except battery operated, shall be grounded. Protective fuses shall not be bypassed.

(10) Caustic, explosive, and flammable materials shall carry labels to indicate their nature and shall be placed in containers and stored in locations which are suitable to ensure stability, purity, and safety as is necessary regarding the material involved.

(11) The laboratory shall define, establish and document a function check and maintenance protocol that ensures equipment, instrument, and test system performance necessary for accurate and reliable test results and result reporting.

(12) Requirements for calibration and calibration verification for unmodified moderate complexity test procedures that are performed using instruments, kits, or test systems that have been cleared by the Food and Drug Administration (FDA) through the 510(k) or Premarket Approval (PMA) process:

(a) Until September 1, 1996, the laboratory must meet the requirements in OAR 333-024-0035(1)(e) and (f);

(b) After September 1, 1996, the laboratory must meet the requirements in OAR 333-024-0026(13).

(13) Requirements for calibration and calibration verification for laboratories performing high complexity testing procedures, tests not cleared by the FDA through the 510(k) or PMA process, modified moderate complexity testing:

(a) The laboratory must:

(A) Establish the number, type, and concentration of calibration materials required to assure accurate and reliable test results;

(B) Establish the frequency and acceptable limits for calibration and calibration verification, if not provided by the manufacturer;

(C) Use calibration materials appropriate for the methodology, and if possible, traceable to a reference method or reference material of known value; and

(b) The laboratory must perform and document calibration:

(A) At the frequency required by the manufacturer;

(B) In accordance with criteria established by the laboratory, if more frequent than manufacturer's requirements; and

(C) When calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

(c) The laboratory must perform calibration verification to verify the laboratory's established reportable range for patient test values using calibration or control materials, including at least a minimal value (zero), a mid-point value, and a maximum value at the upper limit of that range:

(A) When a complete change of reagents is introduced;

(B) When there is a major preventative maintenance or replacement of critical parts that may influence test performance;

(C) When controls reflect an unusual trend or shift or are outside the laboratory's acceptable limits and other means of assessing and correcting unacceptable control values have failed to identify and correct the problem;

(D) At least once every six months, unless the laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

(d) Calibration and calibration verification must meet the laboratory's acceptable ranges prior to patient test reporting;

(e) Calibration and calibration verification documentation must be maintained for a minimum of two years.

Stat. Auth.: ORS 438.110 & 438.320

Stats. Implemented: ORS 438.110 & 438.320

Hist.: HB 248, f. 6-30-70, ef. 7-25-70; HD 28-1988, f. & cert. ef. 12-7-88, Renumbered from 333-024-0025; HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95

333-024-0035
Internal Quality Control for Moderate and High Complexity Laboratories

(1) Laboratories that perform testing using unmodified, moderate complexity test systems, cleared by the Food and Drug Administration (FDA) through the 510(k) or Premarket Approval (PMA) process must, until September 1, 1996:

(a) Follow the manufacturer's instructions for test system operation and test performance;

(b) Have a procedure manual as defined in OAR 333-024-0035(4);

(c) Perform and document control procedures using at least two levels of control materials each day of testing;

(d) Perform and document applicable specialty and subspecialty control procedures as specified in OAR 333-024-0037;

(e) Follow the manufacturer's instructions for calibration:

(A) Calibration must be performed at least once every six months, or more frequently if required by manufacturers;

(B) Use calibration materials specified by the manufacturer;

(C) Maintain documentation of all calibration and calibration verification for a minimum of two years. Documentation must define the number, type, concentration of calibration materials, and frequency required;

(f) Perform calibration verification at least every 6 months to verify the laboratory's established reportable range for patient test values using calibration or control materials, including at least a minimal value (zero), a mid-point value, and a maximum value at the upper limit of that range;

(g) Perform and document that remedial action has been taken when problems or errors are identified as specified in OAR 333-024-0035(19); and

(h) Comply with requirements as specified in OAR 333-024-0035(4)–(8), (11)–(13) and (16).

(2) After September 1, 1996, unmodified moderate complexity test systems cleared by the Food and Drug Administration (FDA) through the 510(k) or Premarket Approval (PMA) process, must comply with quality control requirements in OAR 333-024-0035(2)–(22) and 333-024-0037.

(3) After final rule adoption, high complexity testing, methods developed in house, devices not subject to clearance by the FDA through the 510(k) or PMA process, or modified test systems must comply with quality control requirements in OAR 333-024-0035(4) through 333-024-0035(22) and 333-024-0037.

(4) The procedure manual must include, when applicable to the test procedure:

(a) Requirements for specimen collection and processing, and criteria for specimen rejection;

(b) Procedures for microscopic examinations, including the detection of inadequately prepared slides;

(c) Step-by-step performance of the procedure, including test calculations and interpretation of results;

(d) Preparation of slides, solutions, calibrators, controls, reagents, stains and other materials used in testing;

(e) Calibration and calibration verification procedures;

(f) The reportable range for patient test results;

(g) Control procedures;

(h) Remedial action to be taken when calibration or control results fail to meet the laboratory's criteria for acceptability;

(i) Limitations in methodologies, including interfering substances;

(j) Reference range (normal values);

(k) Imminent life-threatening laboratory results or "panic values";

(l) Pertinent literature references;

(m) Appropriate criteria for specimen storage and preservation to ensure specimen integrity until testing is completed;

(n) The laboratory's system for reporting patient results including, when appropriate, the protocol for reporting panic values;

(o) Description of the course of action to be taken in the event that a test system becomes inoperable;

(p) Criteria for the referral of specimens including procedures for specimen submission and handling;

(q) Manufacturers' package inserts or operator manuals may be used. Any of the required items for procedure manuals not provided by the manufacturer must be written by the laboratory;

(r) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance. These records must be retained for two years after a procedure has been discontinued; and

(s) Textbooks may be used as a supplement to these written descriptions but may not be used in lieu of the laboratory's written procedures for testing or examining specimens.

(5) Laboratory procedure manuals and relevant texts shall be reviewed, approved and signed by the Director, initially and whenever there is a change in method or policy.

(6) The laboratory must define and document criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation to include water quality, temperature, humidity, protection of test equipment, test result reporting and remedial action taken to correct any conditions that fail to meet the laboratory's criteria.

(7) Reagents, solutions, culture media, control materials, calibration materials and other supplies, as appropriate, must be labeled to indicate:

(a) Identity and, when significant, titer, strength or concentration;

(b) Recommended storage requirements;

(c) Preparation and expiration date; and

(d) Other pertinent information required for proper use.

(8) Reagents, solutions, culture media, control materials, calibration materials and other supplies must be prepared, stored, and handled in a manner to ensure that:

(a) They are not used when they have exceeded their expiration date, have deteriorated or are of substandard quality; and

(b) Components of reagent kits of different lot numbers are not interchanged unless otherwise specified by the manufacturer.

(9) Prior to reporting patient test results, the laboratory must verify or establish, for each method; accuracy, precision, analytical sensitivity and specificity, the reportable range of patient test results, the reference range (normal values) and any other applicable performance characteristic.

(a) The provisions of this section are not retroactive. Laboratories are not required to verify or establish performance specifications for any test method of moderate or high complexity in use prior to date of final rule adoption;

(b) Each laboratory that introduces a new procedure for patient testing using a device (instrument, kit, or test system) must assure that it meets the requirements for quality control;

(c) The laboratory must have documentation of the verification or establishment of all applicable test performance specifications;

(d) Perform function checks including background or baseline, verifying that they are within established limits and document results;

(e) The manufacturer's reference range for each test is appropriate for the laboratory's patient population.

(10) A laboratory that introduces a new procedure must, prior to reporting patient test results:

(a) Verify or establish for each method the performance specifications for the following performance characteristics:

(A) Accuracy;

(B) Precision;

(C) Analytical sensitivity;

(D) Analytical specificity to include interfering substances;

(E) Reportable range of patient test results;

(F) Reference ranges; and

(G) Any other performance characteristic required for test performance.

(b) Establish calibration and control procedures for the tests as required in OAR 333-024-0026;

(c) Document the verification or establishment of all applicable test performance specifications.

(11) The laboratory must have available written policies and procedures for the preparation of patients, specimen collection, specimen labeling, specimen preservation, conditions for specimen transportation, specimen processing and rejection of unacceptable specimens.

(12) The laboratory must assure the identification and integrity of the patient specimen(s) from collection until testing has been completed and the results reported.

(13) The laboratory must have written instructions for the handling of referral specimens.

(14) For qualitative tests, the laboratory must include a positive and negative control each day of testing, unless the manufacturer's instructions, or the laboratory's method validation indicates the need for more frequent control checks to assure accurate testing.

(15) For quantitative tests, the laboratory must include at least two samples of different concentrations of either calibration materials, control materials, or a combination thereof at least each day of testing, unless the manufacturer's instructions, or the laboratory's method validation indicates the need for more frequent control checks to assure accurate testing.

(16) Limits for controls shall be clearly stated and recorded. The course of action taken when analyses are outside these control limits shall be clearly stated and recorded. The control limits shall be set so that clinically reliable results are assured. Values for standards shall be clearly stated and recorded.

(17) The manufacturer's instructions shall be followed unless there is documentation available showing the changes made, and proof these changes do not adversely affect the reliability of the test result.

(18) All test methods shall meet the following quality control requirements:

(a) The laboratory must follow the manufacturer's instructions for control procedures;

(b) Each day of use, the laboratory must evaluate the detection phase of direct antigen systems using an appropriate positive and negative control material (organism or antigen extract). When direct antigen systems include an extraction phase, the system must be checked each day of use using a positive organism;

(c) If calibration or control materials are not available, the laboratory must have an alternative mechanism to assure the validity of patient test results;

(d) Control samples must be tested in the same manner as patient specimens;

(e) When calibration or control materials are used, statistical parameters (e.g., mean and standard deviation) for each lot number of calibration material and each lot of control material must be determined through repetitive testing:

(A) The stated values of an assayed control material may be used as the target values provided the stated values correspond to the methodology and instrumentation employed by the laboratory and are verified by the laboratory;

(B) Statistical parameters for unassayed materials must be established over time by the laboratory through concurrent testing with calibration materials or control materials having previously determined statistical parameters.

(f) Control results must meet the laboratory's criteria for acceptability prior to reporting patient test results;

(g) Reagent and supply checks.

(A) The laboratory must check each batch or shipment of reagents, discs, stains, antisera and identification systems (systems using two or more substrates) when prepared or opened for positive and negative reactivity, as well as graded reactivity if applicable;

(B) Each day of use (unless otherwise specified in OAR 333-024-0037), the laboratory must test staining materials for intended reactivity to ensure predictable staining characteristics;

(C) The laboratory must check fluorescent stains for positive and negative reactivity each time of use (unless otherwise specified);

(D) The laboratory must document that the physical characteristics of the media are not compromised and report any deterioration in the media to the manufacturer;

(E) The laboratory must follow the manufacturer's specifications for using the media and be responsible for the test results;

(F) The laboratory must check each batch or shipment of media for sterility, ability to support growth, and as appropriate, selectivity/inhibition and/or biochemical response;

(G) The laboratory may use manufacturer's control checks of media provided the manufacturer's product insert specifies that the manufacturer's quality control checks meet the National Committee for Clinical Laboratory Standards (NCCLS) for media quality control, except for the following media:

(i) Campylobacter agar;

(ii) Chocolate agar;

(iii) Pathogenic Neisseria selective isolation media;

(iv) Media used for the isolation of parasites, viruses, mycoplasmas, chlamydia;

(v) Mueller Hinton media used for susceptibility tests; and

(vi) Commercially prepared media packaged as a unit or system consisting of two or more different substrates.

(19) Remedial action policies and procedures must be established, implemented and documented when:

(a) The test systems do not meet the laboratory's established performance specifications;

(b) Patient test values are outside of the laboratory's reportable range of patient test results;

(c) The laboratory's reference range for a test procedure is inappropriate for the laboratory's patient population;

(d) Results of control, calibration or calibration verification materials fail to meet the laboratory's established criteria;

(e) The laboratory cannot report patient test results within its established time frames; and must notify the appropriate individual of the delayed testing;

(f) Errors are detected in the reported patient test results:

(A) The laboratory must promptly notify the authorized person ordering or individual utilizing the test results of the reporting error;

(B) Issue a corrected report to the authorized person ordering or individual utilizing the test report; and

(C) Maintain exact duplicates of the original and the corrected report for two years.

(20) For electrophoretic determinations:

(a) At least one control sample must be used in each electrophoretic cell; and

(b) The control sample must contain fractions representative of those routinely reported in patient specimens.

(21) If an initial screen for Substances of Abuse is positive and confirmatory testing is required as directed under OAR 333-024-0345(1), it must be confirmed by a principle stated in OAR 333-024-0345(3).

(22) Additional Quality Control practices may be required by the Division for specialized categories of testing.

Stat. Auth.: ORS 438.320

Stats. Implemented: ORS 438.320

Hist.: HB 248, f. 6-30-70, ef. 7-25-70; HD 28-1988, f. & cert. ef. 12-7-88; HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95

333-024-0037

Specialty and Subspecialty Quality Control

(1) *Bacteriology* quality control requirements are:

(a) The laboratory must check positive and negative reactivity with control organisms:

(A) Each day of use for catalase, coagulase, betalactamase, oxidase reagents and DNA probes;

(B) Each week of use for Gram and acid-fast stains, bacitracin, optochin, ONPG, X and V discs or strips; and

(C) Each month of use for antisera.

(b) Each week of use, the laboratory must check XV discs or strips with a positive control organism;

(c) For antimicrobial susceptibility tests, the laboratory must check each new lot shipment of media and each lot of antimicrobial discs before, or with initial use, using approved reference organisms, following the **National Committee for Clinical Laboratory Standards (NCCLS)** approved procedures for antimicrobial susceptibility quality control:

(A) The laboratory's zone sizes or minimum inhibitory concentration for reference organisms must be within established quality control limits before reporting patient results;

(B) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

(d) The laboratory must check each batch or lot shipment of media for sterility. Media must also be checked for its ability to support growth, and as appropriate, selectivity/inhibition and/or biochemical response.

(2) *Mycobacteriology* quality control requirements are:

(a) Each day of use, the laboratory must check the iron uptake test with at least one acid-fast organism that produces a positive reaction and with an organism that produces a negative reaction and check all other reagents or test procedures used for mycobacteria identification with at least one acid-fast organism that produces a positive reaction;

(b) The laboratory must check fluorochrome acid-fast stains for positive and negative reactivity each week of use;

(c) The laboratory must check acid-fast stains each week of use with an acid-fast organism that produces a positive reaction; and

(d) For susceptibility tests performed on *Mycobacterium tuberculosis* isolates, the laboratory must check the procedure each week of use with a strain of *Mycobacterium tuberculosis* susceptible to all antimycobacterial agents tested.

(3) *Mycology* quality control requirements are:

(a) Each day of use, the laboratory using the auxanographic medium for nitrate assimilation must check the nitrate reagent with a peptone control;

(b) Each week of use, the laboratory must check all reagents used with biochemical tests and other test procedures for mycological identification with an organism that produces a positive reaction;

(c) Each week of use, the laboratory must check acid-fast stains for positive and negative reactivity; and

(d) For susceptibility tests, the laboratory must test each drug each day of use with at least one control strain that is susceptible to the drug. The laboratory must establish control limits. Criteria for acceptable control results must be met prior to reporting patient results.

(4) *Parasitology* quality control requirements are:

(a) The laboratory must have available a reference collection of slides or photographs, and, if available, gross specimens for identification of parasites;

(b) The laboratory must calibrate the ocular micrometer for determining the size of ova and parasites; and

(c) Each month of use, the laboratory must check permanent stains using a fecal sample control that will demonstrate staining characteristics.

(5) *Virology* quality control requirements are:

(a) The laboratory must have available host systems for the isolation of viruses and test methods for the identification of viruses that cover the entire range of viruses that are etiologically related to clinical diseases for which services are offered;

(b) The laboratory must maintain records that reflect the systems used and the reactions observed; and

(c) In tests for the identification of viruses, the laboratory must simultaneously culture uninoculated cells or cell substrate controls as a negative control to detect erroneous identification results.

(6) *Syphilis Serology* quality control requirements are:

(a) The equipment, glassware, reagents, controls, and techniques for tests for syphilis must conform to manufacturers' specifications;

(b) The laboratory must run serologic tests on patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity plus a negative control;

(c) The laboratory must employ positive and negative controls that evaluate all phases of the test system to ensure reactivity and uniform dosages; and

(d) The laboratory must not report test results unless the predetermined reactivity pattern of the controls is observed.

(7) *General Immunology* quality control requirements are:

(a) The laboratory must run serologic tests on patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity, if applicable, plus a negative control;

(b) The laboratory must employ controls that evaluate all phases of the test system (antigens, complement, erythrocyte indicator systems, etc.) to ensure reactivity and uniform dosages when positive and negative controls alone are not sufficient; and

(c) The laboratory must not report test results unless the predetermined reactivity pattern of the controls is verified.

(8) *Routine Chemistry and Endocrinology* quality control requirements are:

(a) A minimum of two different levels of controls covering the full range of expected results shall be tested with each run of patient specimens, each change of reagents or major maintenance performed;

(b) Control samples must be tested in the same manner, if applicable, as a patient specimen; and

(c) The laboratory must not report test results unless the control results are within the laboratory's acceptable limits.

(9) *Blood Gas Analysis* quality control requirements are:

(a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer;

(b) Test one sample of control material each eight hours of testing;

(c) Use a combination of calibrators and control materials that include both low and high values on each day of testing; and

(d) Include one sample of calibration material or control material each time patients are tested unless automated instrumentation internally verifies calibration at least every thirty minutes.

(10) *Toxicology* quality control requirements are those listed in general chemistry, in addition, for drug abuse screening using thin layer chromatography:

(a) Each plate must be spotted with at least one sample of calibration material containing all drug groups identified by thin layer chromatography which the laboratory reports; and

(b) At least one control sample must be included in each chamber, and the control sample must be processed through each step of patient testing, including extraction procedures.

(11) *Urinalysis* quality control requirements are those listed in general chemistry, except for those tests categorized as waived.

(12) *Hematology* quality control requirements are:

(a) Cell counts performed manually using a hemocytometer must be tested in duplicate. One control is required for each eight hours of operation;

(b) For non-manual hematology testing systems, excluding coagulation, the laboratory must include two levels of controls each eight hours of operation;

(c) For all non-manual coagulation testing systems, the laboratory must include two levels of control each eight hours of operation and each time a change in reagents occurs;

(d) For manual coagulation tests:

(A) Each individual performing tests must test two levels of controls before testing patient samples and each time a change in reagents occurs; and

(B) Patient and control specimens must be tested in duplicate.

(13) *Cytology* quality control requirements are:

(a) All gynecologic smears are stained using a Papanicolaou or modified Papanicolaou staining method;

(b) Effective measures are taken to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process;

(c) Nongynecologic specimens that have a high potential for cross-contamination must be stained separately from other nongynecologic specimens, and the stains are filtered or changed following staining;

(d) Diagnostic interpretations must not be reported on unsatisfactory smears; and

(e) All cytology slide preparations must be evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.

(14) A cytology laboratory is responsible for ensuring that:

(a) Each individual engaged in the evaluation of cytology preparations by nonautomated microscopic technique examines no more than 100 slides (one patient per slide, gynecologic or nongynecologic, or both) in a 24 hour period, irrespective of the site or laboratory. Previously examined gynecologic and nongynecologic cytology preparations, and tissue pathology slides examined by a technical supervisor are not included in the 100 slide limit;

(b) For purposes of workload calculations, each slide preparation (nongynecologic) made using automated, semi-automated, or other liquid-based slide preparatory techniques which result in cell dispersion over one-half or less of the total available slide area and which is examined by nonautomated microscopic technique counts as one-half slide; and

(c) Records are maintained of the total number of slides examined by each individual during each 24 hour period, irrespective of the site or laboratory, and the number of hours each individual spends examining slides in the 24 hour period:

(A) The maximum number of 100 slides described in this section is examined in no less than an 8 hour workday;

(B) For the purposes of establishing workload limits for individuals examining slides by nonautomated microscopic technique on other than an 8 hour workday basis (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours must be used to prorate the number of slides that may be examined.

(15) The individual who provides technical supervision of cytology must ensure that:

(a) All gynecologic smears interpreted to be showing reactive or reparative changes, atypical squamous or glandular cells of undetermined significance, or to be in the premalignant (dysplasia, cervical intraepithelial neoplasia or all squamous intraepithelial lesions including human papillomavirus-associated changes) or malignant category are confirmed and signed by a technical supervisor in cytology;

(b) All nongynecologic cytologic preparations are reviewed and signed by the technical supervisor in cytology;

(c) The slide examination performance of each cytotechnologist is evaluated and documented, including performance evaluation through the re-examination of normal and negative cases and feedback on the reactive, reparative, atypical, malignant or premalignant cases; and

(d) A maximum number of slides, not to exceed the maximum workload limit, is established by the technical supervisor for each individual examining slide preparations by nonautomated microscopic technique.

(A) The actual workload limit must be documented for each individual;

(B) Records are available to document that each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.

(16) The laboratory must establish and follow a program designed to detect errors in the performance of cytologic examinations and the reporting of results:

(a) The laboratory must establish a program that includes a review of slides from at least 10 percent of the gynecologic cases interpreted to be negative for reactive, reparative, atypical, premalignant or malignant conditions. This review must be done by a technical supervisor in cytology, a cytology general supervisor, or a qualified cytotechnologist:

(A) The review must include negative cases selected at random from the total caseload and from patients or groups of patients that are identified as having a high probability of developing cervical cancer, based on available patient information;

(B) Records of initial examinations and rescreening results must be available; and

(C) The review must be completed before reporting patient results on those cases selected.

(b) The laboratory must compare clinical information, when available, with cytology reports and must compare all malignant and premalignant gynecology reports with the histopathology report, if available in the laboratory (either on-site or in storage), and determine the causes of any discrepancies;

(c) For each patient with a current high grade intraepithelial lesion or above (moderate dysplasia or CIN-2 or above), the laboratory must review all normal or negative gynecologic specimens received within the previous five years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that would affect patient care, the laboratory must notify the patient's physician and issue an amended report;

(d) The laboratory must establish and document an annual statistical evaluation of the number of cytology cases examined, number of specimens processed by specimen type, volume of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation), number of gynecologic cases where cytology and available histology are discrepant, the number of gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as malignant or premalignant, and the number of gynecologic cases for which histology results were unavailable to compare with malignant or premalignant cytology cases;

(e) The laboratory must evaluate the case reviews of each individual examining slides against the laboratory's overall statistical values, document any discrepancies, including reasons for the deviation, and document corrective action, if appropriate;

(f) The laboratory report must:

(A) Clearly distinguish specimens or smears, or both, that are unsatisfactory for diagnostic interpretation; and

(B) Contain narrative descriptive nomenclature for all results.

(g) Corrected reports issued by the laboratory must indicate the basis for correction;

(h) The laboratory must retain all slide preparations for five years from the date of examination, or slides may be loaned to proficiency testing programs, in lieu of maintaining them for this time

period, provided the laboratory receives written acknowledgement of the receipt of slides by the proficiency testing program and maintains the acknowledgement to document the loan of such slides. Documentation for slides loaned or referred for purposes other than proficiency testing must also be maintained. All slides must be retrievable upon request;

(i) The technical supervisor must ensure that reports are signed, or if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor in cytology.

(17) *Histopathology* quality control requirements are:

(a) A control slide of known reactivity must be included with each slide or group of slides for differential or special stains;

(b) The laboratory must retain stained slides, and test reports at least ten years from the date of examination and retain specimen blocks at least two years from the date of examination;

(c) The laboratory must retain remnants of tissue specimens in a manner that assures proper preservation of the tissue specimens until the portions submitted for microscopic exam ination have been examined and a diagnosis made by a qualified individual;

(d) Only those individuals who meet the specific requirements in OAR 333-024-0023 for histology, dermatopathology, opthalmic pathology or oral pathology may examine and provide reports in these subspecialties;

(e) All tissue pathology reports must be signed by a qualified individual. If a computer report is generated with an electronic signature, it must be authorized by a qualified individual; and

(f) The laboratory must utilize acceptable terminology of a recognized system of disease nomenclature in reporting results.

(18) *Oral Pathology* quality control requirements are the same as those for histopathology.

(19) *Radiobioassay* quality control requirements are: the laboratory must comply with the applicable requirements of OAR 333-024-0035 and 333-024-0037.

(20) *Histocompatibility* quality control for renal allotransplantation includes the requirements for OAR 333-024-0035, 333-024-0037(7) and (23); and

(a) The laboratory must have available and follow criteria for:

(A) Selecting appropriate patient serum samples for crossmatching;

(B) The technique used in crossmatching;

(C) Preparation of donor lymphocytes for crossmatching; and

(D) Reporting crossmatch results.

(b) The laboratory must:

(A) Have available results of final crossmatches before an organ or tissue is transplanted; and

(B) Make a reasonable attempt and document efforts to have available serum specimens for all potential transplant recipients at initial typing, for periodic screening, for pre-transplantation crossmatch and following sensitizing events, such as transfusion and transplant loss.

(c) The laboratory's storage and maintenance of both recipient sera and reagents must:

(A) Be at an acceptable temperature range for sera and components;

(B) Use a temperature alarm system and have an emergency plan for alternate storage; and

(C) Ensure that all specimens are properly identified and easily retrievable.

(d) The laboratory's reagent typing sera inventory (applicable only to locally constructed trays) must indicate source, bleeding date and identification number, and volume remaining.

(e) The laboratory must properly label and store cells, complement, buffer and dyes.

(f) The laboratory must:

(A) HLA type all potential transplant recipients;

(B) Type cells from organ donors referred to the laboratory; and

(C) Have available and follow a policy that establishes when antigen redefinition and retyping are required.

(g) The laboratory must have available and follow criteria for:

(A) The preparation of lymphocytes for HLA-A, B and DR typing;

(B) Selecting typing reagents, whether locally or commercially prepared;

(C) The assignment of HLA antigens; and

(D) Assuring that reagents used for typing recipients and donors are adequate to define all major and International Workshop HLA-A, B and DR specificities for which reagents are readily available.

(h) The laboratory must:

(A) Screen potential transplant recipient sera for preformed HLA-A and B antibodies with a suitable lymphocyte panel on sera collected:

(i) At the time of the recipient's initial HLA typing; and

(ii) Thereafter, following sensitizing events and upon request.

(B) Use a suitable cell panel for screening patient sera (antibody screen), a screen that contains all the major HLA specificities and common splits.

(i) If the laboratory does not use commercial panels, it must maintain a list of individuals for fresh panel bleeding;

(j) If the laboratory uses frozen panels, it must have a suitable storage system;

(k) The laboratory must check:

(A) Each typing tray using positive and negative control sera;

(B) Positive controls for specific cell types when applicable (i.e., T cells, B cells, and monocytes); and

(C) Each compatibility test (i.e. mixed lymphocyte cultures, homozygous typing cells or DNA analysis) and typing for disease-associated antigens using controls to monitor the test components and each phase of the test system to ensure an acceptable performance level.

(l) Compatibility testing for cellularly-defined antigens must utilize techniques such as the mixed lymphocyte culture test, homozygous typing cells or DNA analysis;

(m) If the laboratory reports the recipient's or donor's, or both, ABO blood group and D(Rho) typing, the testing must be performed in accordance with the applicable requirements of OAR 333-024-0035, and 333-024-0037(23);

(n) If the laboratory utilizes immunologic reagents (such as antibodies or complement) to remove contaminating cells during the isolation of lymphocytes or lymphocyte subsets, the efficacy of the methods must be verified with appropriate quality control procedures;

(o) At least once each month, the laboratory must have each individual performing tests evaluate a previously tested specimen as an unknown to verify his or her ability to reproduce test results. Records of the results for each individual must be maintained;

(p) The laboratory must participate in at least one national or regional cell exchange program, if available, or develop an exchange system with another laboratory in order to validate interlaboratory reproducibility.

(21) *Histocompatibility*, other testing for:

(a) Transfusions and other non-renal transplantation, excluding bone marrow and living transplants, all the requirements specified in this section and OAR 333-024-0035 and 333-024-0037(20), as applicable, except for the performance of mixed lymphocyte cultures, must be met;

(b) Bone marrow transplantation, all the requirements specified in this section and OAR 333-025-0035 and 333-024-0037(20), including the performance of mixed lymphocyte cultures or other augmented testing to evaluate class II compatibility, must be met;

(c) Non-renal solid organ transplantation, the results of final crossmatches must be available before transplantation when the recipient has demonstrated presensitization by prior serum screening except for emergency situations. The laboratory must document the circumstances, if known, under which emergency transplants are performed, and records must reflect any information concerning the transplant provided to the laboratory by the patient's physician;

(d) HLA typing for disease-associated studies must meet all the requirements specified in this section and OAR 333-024-0035

and 333-024-0037(20), except for the performance of mixed lymphocyte cultures, antibody screening and crossmatching;

(e) Organ donor HIV testing, the requirements of general immunology in OAR 333-024-0035 and 333-024-0037(7) must be met.

(22) Clinical Cytogenetics quality control requirements are:

(a) When determination of sex is performed by X and Y chromatin counts, these counts must be based on an examination of an adequate number of cells. Confirmatory testing such as full chromosome analysis must be performed for all atypical results;

(b) The laboratory must have records that reflect the media used and document the reactions observed, number of cells counted, the number of cells karyotyped, the number of chromosomes counted for each metaphase spread, and the quality of the banding; that the resolution is sufficient to support the reported results; and that an adequate number of karyotypes are prepared for each patient;

(c) The laboratory also must have policies and procedures for assuring an accurate and reliable patient sample identification during the process of accessioning, cell preparation, photographing or other image reproduction technique, and photographic printing, and storage and reporting of results or photographs;

(d) The laboratory report must include the summary and interpretation of the observations, number of cells counted and analyzed, and the use of appropriate nomenclature.

(23) Immunohematology quality control requirements are:

(a) The laboratory must perform ABO group and D(Rho) typing, unexpected antibody detection, antibody identification and compatibility testing in accordance with manufacturer's instructions;

(b) The laboratory must perform ABO group by concurrently testing unknown red cells with anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells;

(c) The laboratory must determine the D(Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent;

(d) If required in the manufacturer's package insert for anti-D reagents, the laboratory must employ a control system capable of detecting false positive D(Rho) test results;

(e) If a facility provides services for the transfusion of blood and blood products, the facility must be under the adequate control and technical supervision of a pathologist or other qualified doctor of medicine or osteopathy. The facility must ensure that there are facilities for procurement, safekeeping and transfusion of blood and blood products and that blood and blood products must be available to meet the needs of the physicians responsible for the diagnosis, management, and treatment of patients;

(f) The requirements for blood and blood products storage facilities are:

(A) The blood and blood products must be stored under appropriate conditions, which include an adequate temperature alarm system that is regularly inspected:

(i) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period; and

(ii) Inspections of the alarm system must be documented.

(B) If blood is stored or maintained for transfusion outside of a monitored refrigerator, the facility must ensure and document that storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.

(g) In the case of services provided outside the blood bank, the facility must have an agreement reviewed and approved by the director that governs the procurement, transfer and availability of blood and blood products;

(h) There must be provision for prompt ABO blood group, D(Rho) type, unexpected antibody detection and compatibility testing in accordance with the requirements in immunohematology and for laboratory investigation of transfusion reactions, either through the facility or under arrangement with an approved facility on a continuous basis, under the supervision of a pathologist or other qualified doctor of medicine or osteopathy;

(i) According to the facility's established procedures, samples of each unit of transfused blood must be retained for further testing in the event of reactions. The facility must promptly dispose of blood not retained for further testing that has passed its expiration date;

(j) The facility, according to its established procedures, must promptly investigate all transfusion reactions occurring in all facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. The facility must document that all necessary remedial actions are taken to prevent future recurrences of transfusion reactions and that all policies and procedures are reviewed to assure that they are adequate to ensure the safety of individuals being transfused within the facility;

(k) Policies to ensure positive identification of a blood or blood product recipient must be established, documnented and followed.

Stat. Auth.: ORS 438.320
Stats. Implemented: ORS 438.320
Hist.: HD 6-1995, f. & cert. ef. 9-13-95

333-024-0040
External Quality Control (Proficiency Testing Programs and On-Site Inspections)

(1) Physician performed microscopy, moderate and high complexity laboratories shall:

(a) At the laboratory's own expense, be required to participate successfully in a proficiency testing program approved by the Health Care Financing Administration. Lists of currently approved programs are available from the Division. Continued or consistent failure, two out of three testing events, may result in the laboratory's license for that specialty, subspecialty or test being suspended or revoked by the Division;

(b) Authorize release of proficiency test results and provide documentation of corrective action to the Division;

(c) Assure proficiency testing is performed on each physician performed microscopy, moderate and high complexity regulated analyte listed in the **Clinical Laboratory Improvement Amendments of 1988, 42 CFR, Part 493, subpart I**, available on request from the Division;

(d) Meet the proficiency testing requirements as described in the **Clinical Laboratory Improvement Amendments of 1988, 42 CFR, Part 493, subpart H**, available on request from the Division;

(e) Notify the Division within six months if the analysis of a specialty, subspecialty or test has been discontinued or added to patient testing;

(f) Assure that individuals performing gynecologic cytology participate successfully in a proficiency testing program approved by the Health Care Financing Administration;

(g) Be required to participate successfully in the proficiency testing programs conducted by the Division involving the laboratory specialty, subspecialty or tests in which the laboratory performs tests;

(h) Analyze test samples submitted by the Division prior to, during, or subsequent to inspection.

(2) A laboratory shall have their license suspended or revoked for one year, pursuant to ORS 438.160, if it submits a proficiency testing sample to another laboratory for analysis prior to reporting to the proficiency testing program.

(3) Any laboratory that knowingly receives proficiency testing samples from another laboratory prior to the reporting deadline must notify the Division.

(4) On-site inspections and testing may be conducted by representatives of the Division or Federal Government at reasonable times during the laboratory's normal business hours without advance notice. The representative shall inspect the facilities, personnel policies, procedures, materials, staff qualifications, equipment, and records:

(a) Routine inspections of moderate and high complexity laboratories shall occur at a minimum of every two years.

(b) Laboratories accredited by a Health Care Financing Administration approved accreditation organization are exempt from routine, on site inspection provided the laboratory submits a copy of their accreditation certificate and authorizes its accreditation organization to release inspection data to the Division. The accreditation organization shall make available, upon request, a copy of the laboratory's statement of deficiencies, plan of correction and proof of accreditation to the Division.

(5) The Owner or Director may be required to submit reports on the operations and procedures of the laboratory to the Division or the Federal Government.

(6) Additional inspections may be performed without notice to verify correction of deficiencies, investigate complaints, validation of accrediting organizations' inspections, review unsatisfactory proficiency testing and verify personnel qualifications or other monitoring of compliance with OAR 333-024-0005 through 333-024-0050 and 333-024-0260 and 333-024-0265.

(7) Inspection of waived and physician performed microscopic procedures laboratories:

(a) The Division shall conduct inspections of any laboratory during routine hours of operation only to assess validation, complaint, and compliance with the applicable requirements of these rules;

(b) The laboratory is required to:

(A) Allow the Division or Federal Government to interview all employees of the laboratory concerning compliance with these rules;

(B) Allow the Division or Federal Government access to all areas of the facility including specimen procurement and processing areas, storage facilities for specimens, reagents, supplies, records and reports, testing and reporting areas;

(C) Permit employees to be observed performing tests, data analysis and reporting;

(D) Allow the Division to review all information and data necessary to evaluate complaints, determine immediate and serious risk to public health, and confirm that the laboratory is only performing tests within the scope of their license;

(E) Provide copies of all records and data that the Division or Federal Government requires under these rules; and

(F) Provide all information and data needed by the Division or Federal Government to make a determination of compliance with these rules.

(8) Failure to permit an inspection under these rules will result in the suspension of the laboratory's license.

(9) A waived laboratory conducting moderate and/or high complexity tests shall be considered a moderate or high complexity laboratory and the Division shall:

(a) Conduct an on-site survey;

(A) Examine the records of the laboratory;

(B) Give written notice of any deficiencies;

(C) Require the laboratory to return a written plan of correction, and verify that the corrections have occurred; and

(D) The time frames for the plan of correction and verification are the same as a moderate or high complexity laboratory.

(b) Require compliance with Division directives when there is an immediate threat to life, health, or safety.

(c) Charge the laboratory the appropriate fee.

(10) A physician performed microscopy procedure laboratory conducting additional moderate complexity or high complexity tests shall be considered a moderate or high complexity laboratory and the Division shall:

(a) Conduct an on-site survey:

(A) Examine the records of the laboratory;

(B) Give written notice of any deficiencies;

(C) Require the laboratory to return a written plan of correction, and verify that the corrections have occurred; and

(D) The time frames for the plan of correction and verification are the same as a moderate or high complexity laboratory.

(b) Require compliance with Division directives when there is an immediate threat to life, health, or safety.

(11) Inspection of non-accredited, moderate and high complexity laboratories:

(a) The Division will conduct inspections on at least a biennial basis of any laboratory at any time during routine hours of operation;

(b) The Division will conduct an on-site inspection prior to the issuance of a license;

(c) The laboratory may be required to:

(A) Test samples or perform procedures as the Division or Federal Government requires;

(B) Allow the Division or Federal Government to interview all employees of the laboratory concerning the laboratory's compliance with these rules;

(C) Permit employees to be observed performing tests, data analysis and reporting;

(D) Allow the Division or Federal Government access to all areas of the facility including: specimen procurement and processing areas, storage facilities for specimens, reagents, supplies, records and reports, testing and reporting areas;

(E) Provide copies to the Division or Federal Government of all records and data it requires.

(d) The laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection;

(e) The laboratory must provide, upon request, all information and data needed by the Division or Federal Government to make a determination of the laboratory's compliance with these rules;

(f) The Division or Federal Government may reinspect a laboratory at any time necessary to evaluate the ability of the laboratory to provide accurate and reliable test results;

(g) The laboratory must retain records as specified in OAR 333-024-0050.

(12) Inspection of accredited laboratories:

(a) The Division and the Federal government may conduct random validation inspections of any accredited laboratory at any time during its hours of operation;

(b) The Division and the Federal government may conduct complaint inspections of an accredited laboratory at any time during its hours of operation upon receiving a complaint about that laboratory;

(c) The laboratory may be required to comply with OAR 333-024-0040(11)(c)–(f).

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 438.320

Stats. Implemented: ORS 438.320

Hist.: HB 248, f. 6-30-70, ef. 7-25-70; HD 28-1988, f. & cert. ef. 12-7-88; HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95

333-024-0043
Quality Assurance

(1) Each laboratory performing physician performed microscopy, moderate or high complexity testing must establish and follow written policies and procedures for a comprehensive quality assurance program which is designed to monitor and evaluate the ongoing and overall quality of the total testing process (pre-analytic, analytic, post-analytic).

(2) The laboratory's quality assurance program must evaluate the effectiveness of its policies and procedures; identify and correct problems; assure the accurate, reliable and prompt reporting of test results; and assure the adequacy and competency of the staff.

(3) The laboratory must meet the requirements of this rule as they apply to the services offered, complexity of testing performed, test results reported, and the unique practices of each testing entity.

(4) The laboratory must monitor, evaluate, and revise, if necessary, based on the results of its evaluations, the following:

(a) The criteria established for patient preparation, specimen collection, labeling, preservation and transportation;

(b) The information solicited and obtained on the laboratory's test requisition for its completeness, relevance, and necessity for the testing of patient specimens;

(c) The use and appropriateness of the criteria established for specimen rejection;

(d) The completeness, usefulness, and accuracy of the test report information necessary for the interpretation or utilization of test results;

(e) The timely reporting of test results based on testing priorities (STAT, routine, etc.); and

(f) The accuracy and reliability of test reporting systems, appropriate storage of records and retrieval of test results.

(5) The laboratory must have an ongoing mechanism to evaluate the corrective actions taken under remedial action.

(6) Ineffective policies and procedures must be revised based on the outcome of the evaluation. The mechanism must evaluate and review the effectiveness of corrective actions taken for:

(a) Problems identified during the evaluation of calibration and control data for each test method;

(b) Problems identified during the evaluation of patient test values for the purpose of verifying the reference range of a test method; and

(c) Errors detected in reported results.

(7) The corrective actions taken for any unacceptable, unsatisfactory, or unsuccessful proficiency testing result(s) must be evaluated for effectiveness.

(8) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

(9) If a laboratory performs tests that are not included in an approved proficiency testing program, the laboratory must have a system for verifying the accuracy of its test results at least twice a year.

(10) The laboratory must have a mechanism to identify and evaluate patient test results that appear inconsistent with relevant criteria including:

(a) Patient age;

(b) Sex;

(c) Diagnosis or pertinent clinical data, when provided;

(d) Distribution of patient test results, when available; and

(e) Relationship with other test parameters, when available within the laboratory.

(11) The laboratory must have an ongoing mechanism to evaluate the effectiveness of its policies and procedures for assuring employee competence and, if applicable, consultant competence:

(a) The assessment of employee competence must be biannually the first year of employment; and

(b) Annually thereafter.

(12) The laboratory must have a system in place to document problems that occur as a result of breakdowns in communication between the laboratory and the authorized individual who orders or receives the results of test procedures or examinations; Corrective actions must be taken and documented, as necessary, to resolve the problems and minimize communications breakdowns.

(13) The laboratory must have a system in place to assure that all complaints and problems are documented. Investigations of complaints must be made and appropriate corrective actions instituted.

(14) The laboratory must have a mechanism for documenting and assessing problems identified during quality assurance reviews and discussing them with the staff. The laboratory must take corrective actions necessary to prevent recurrences.

(15) The laboratory must maintain documentation of all quality assurance activities including problems identified and corrective actions taken.

(16) All quality assurance records must be available to the Division and maintained for a period of 2 years.

Stat. Auth.: ORS 438.010 & 438.320
Stats. Implemented: ORS 438.320
Hist.: HD 6-1995, f. & cert. ef. 9-13-95

333-024-0045
Venereal Disease Testing

Tests for syphilis approved by the Division are as follow:

(1) Venereal Disease Research Laboratory (VDRL) slide tests;

(2) Fluorescent Treponemal Antibody — Absorption (FTA-ABS) test;

(3) Rapid Plasma Reagin (RPR) and Reagin Screen Test (RST) macroscopic flocculation card tests;

(4) Hemagglutination-Treponemal Test for Syphilis (HATTS);

(5) Microhemagglutination Assay for Antibodies to *Treponema pallidum* (MHA-TP) test;

(6) Unheated Serum Reagin (USR) test;

(7) Toluidine Red Unheated Serum Test (TRUST).

Stat. Auth.: ORS 433.017 & 438.010
Stats. Implemented: ORS 438.010
Hist.: HB 248, f. 6-30-70, ef. 7-25-70; HD 3-1982, f. & ef. 2-25-82; HD 28-1988, f. & cert. ef. 12-7-88; HD 7-1990, f. & cert. ef. 3-21-90

333-024-0050
Records and Reports

(1) Personnel policies, practices, and procedures that support sound laboratory practice shall be available in written form. A current record shall be maintained on each employee and shall include a resume of training and experience.

(2) Complete records for each specimen examined, including quality control, shall be kept for not less than two years, immunohematology records not less than five years, cytology and pathology records not less than ten years. Such records shall contain:

(a) Laboratory number or other identification of the specimen;

(b) The name or other identifier of the person from whom the specimen was taken, if available;

(c) The name of the physician or other authorized person or clinical laboratory submitting the specimen;

(d) The date and time the specimen was collected or date and time it was received in the laboratory;

(e) The type of test performed;

(f) The results of the tests in units of measurement where applicable;

(g) The signature, initials, or identification of the examiner;

(h) The date and time the test results were reported; and

(i) Other information as needed to aid in the interpretation of laboratory results.

(3) Cytology slides must be maintained for a minimum of 5 years, histology slides 10 years, and tissue blocks 2 years.

(4) The Owner or Director of each clinical laboratory licensed under the Act shall report communicable disease according to OAR 333-018-0000 through 333-018-0015, and shall maintain a separate log of such reporting:

(a) Reports shall not be interpreted as constituting a diagnosis nor shall any laboratory making such report be held liable under the laws of this State for having violated a trust or confidential relationship;

(b) Information contained in such reports may be used in compiling statistical and other data in which persons are not identified by name or otherwise.

(5) Requests for examinations of specimens and reporting of test results shall be as follows:

(a) The clinical laboratory shall examine specimens only at the oral, written or electronic request of a physician, dentist or other person authorized by law to use the findings of laboratory examinations;

(b) Oral requests for laboratory tests are permitted only if the laboratory subsequently requests written authorization for testing within 30 days;

(c) No person shall report the result of any test, examination, or analysis of a specimen submitted for evidence of human disease except to a physician, dentist, their agents, or other person authorized by law to employ the results thereof in the conduct of their practice or in the fulfillment of their official duties. Reports shall not be issued to the patient concerned except with the written consent of the physician or other authorized person;

(d) The clinical laboratory may examine specimens for substance of abuse submitted by persons other than medical personnel

authorized by law and shall report the result of any test to the person who submitted the specimen.

(6) The laboratory must maintain the written test authorization or documentation of efforts made to obtain a written authorization for a minimum of two years.

(7) The laboratory must assure that the requisition or test authorization includes:

(a) The name and address or other identifiers of the authorized person requesting the test or the name and address of the laboratory submitting the specimen;

(b) For Pap smears, the patient's last menstrual period, age or date of birth, and indication of whether the patient had a previous abnormal report, treatment or biopsy; and

(c) Any additional information relevant and necessary to a specific test to assure accurate and timely testing and reporting of results.

(8) The laboratory must have adequate systems in place to report results in a timely, accurate, reliable and confidential manner.

(9) The test report must indicate the name and address of the laboratory location at which the test was performed, the test performed, the test result, and if applicable, the units of measurement.

(10) The laboratory must indicate on the test report any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

(11) Pertinent "reference" or "normal" ranges, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests or the individual responsible for utilizing the test results.

(12) The laboratory must develop and follow written procedures for reporting imminent life-threatening laboratory results or panic values.

(13) The original report or exact duplicates of test reports must be maintained by the laboratory.

(14) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory.

(15) The referring laboratory may permit each testing laboratory to send an additional test result directly to the authorized person who initially requested the test.

(16) The authorized person who orders a test or procedure must be notified by the referring laboratory of the name and address of each laboratory location at which a test was performed.

(17) The test records of the laboratory must include:

(a) The patient identification number, accession number, or other unique identification of the specimen;

(b) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability;

(c) The records and dates of all specimen testing, including the identity of the personnel who performed the tests.

(18) The laboratory must, upon request, make available to clients:

(a) A list of test methods employed by the laboratory;

(b) If applicable, the performance specifications of each method used;

(c) Information that affect the interpretation of test results such as interferences;

(d) Pertinent updates on testing information whenever changes occur that affect the test results or its interpretation.

(19) A laboratory must refer specimens only to a Division licensed laboratory authorized to perform testing in that specialty or subspecialty at that complexity level; except referral specimens may be sent to laboratories outside the state of Oregon to a laboratory operating in compliance with the provisions of CLIA 88.

Stat. Auth.: ORS 438.310

Stats. Implemented: ORS 438.310

Hist.: HB 248, f. 6-30-70, ef. 7-25-70; HD 28-1988, f. & cert. ef. 12-7-88; HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95; OHD 11-2001, f. & cert. ef. 5-16-01, 333-024-0050(5) Renumbered to 333-018-0018

333-024-0053

Accreditation Organizations and Accredited Laboratories

(1) Accreditation organizations shall:

(a) Provide the Division with;

(A) Documentation of current deemed status from the Health Care Financing Administration;

(B) A list of all laboratories and accreditation expiration dates;

(C) A list of scheduled surveys and proposed survey dates;

(D) Copies of routine survey findings, upon request;

(E) Copies of all complaint investigations performed.

(b) Allow the Division to investigate complaints, conduct complaint or random on-site validation surveys and take disciplinary action;

(c) Provide a detailed description of the organization's survey process, including:

(A) Frequency of surveys performed;

(B) Copies of survey forms and guidelines;

(C) Accreditation survey review process;

(D) Deficiency writing and monitoring process;

(E) Policy on facility notification prior to survey;

(F) Surveyor qualifications;

(G) Policy for the investigation of complaints on accredited laboratories;

(H) Description of all types and categories of accreditation offered; and

(I) Procedure for proficiency testing monitoring including;

(i) Frequency of monitoring;

(ii) Correlation of proficiency testing with subspecialties, specialties, and analytes performed by the laboratory;

(iii) Definition of unsuccessful performance; and

(iv) Action to be taken regarding unsuccessful performance.

(d) Notify all of their accredited laboratories within 10 days of the loss of accreditation authority in Oregon;

(e) Notify the Division:

(A) Within 30 days of any changes in accreditation requirements;

(B) Verbally, within 5 days of identifying any deficiency posing an immediate and serious risk to patient or staff safety or health in an accredited laboratory, to be followed by a written notification within 14 days of the verbal notification;

(C) Of actions taken due to unsuccessful proficiency testing performance;

(D) Within 30 days of enforcement or sanction actions taken against their accredited laboratories;

(E) Within 30 days if a laboratory terminates its accreditation; and

(F) Within 30 days if the organization revokes a laboratory's accreditation.

(2) Accredited laboratories shall:

(a) Notify the Division of accreditation or changes in accreditation status within 30 days of occurrence;

(b) Authorize proficiency testing providers to submit copies of all proficiency testing results to the Division;

(c) Allow the Division to investigate complaints, conduct complaint or random on-site validation surveys, and take disciplinary action;

(d) Have a valid State License;

(e) Reapply for licensure within 60 days after the accrediting organization's deeming authority has been withdrawn:

(A) Pay applicable fees;

(B) Submit to survey by the Division; and

(C) Meet all applicable requirements for non-accredited laboratories in the appropriate licensure categorization.

(f) Reapply for licensure within 30 days after the withdrawal or revocation of the laboratory's accreditation by the accrediting organization:

(A) Pay applicable fees;

(B) Submit to survey by the Division; and

(C) Meet all applicable requirements for non-accredited laboratories in the appropriate licensure categorization.

(3) The Division may deny or terminate the license of a laboratory if the owner fails to authorize the accrediting organization to notify the Division of the laboratory's compliance with the accrediting organization requirements.

Stat. Auth.: ORS 438.310
Stats. Implemented: ORS 438.310
Hist.: HD 6-1995, f. & cert. ef. 9-13-95

333-024-0055
Incompetence

A clinical laboratory Owner or Director has "demonstrated incompetence" if there is:

(1) Repeated error demonstrated in the performance of laboratory tests or procedures or the results thereof;

(2) Failure to comply with the requirements of these rules relating to internal and external quality control;

(3) Failure to comply with the ORS 438 or OAR 333-024-0005 through 333-024-0055 and 333-024-0260 and 333-024-0265;

(4) Work assigned to personnel not qualified to perform in that specialty;

(5) Repeated erroneous reporting of test results.

Stat. Auth.: ORS 438.160
Stats. Implemented: ORS 438.160
Hist.: HB 248, f. 6-30-70, ef. 7-27-70; HD 28-1988, f. & cert. ef. 12-7-88

Laboratory Testing

333-024-0205
Definitions

As used in these rules:

(1) "Colorimetric assay" means a qualitative laboratory procedure to detect the presence of the enzyme biotinidase which, when present, produces a color change.

(2) "Congenital disorder" means a condition that is present at birth. This includes but is not limited to cystic fibrosis, endocrine, hemoglobinopathy, metabolic, and immunodeficiency disorders.

(3) "County health department" means those county and district health departments formed under ORS 431.416.

(4) "Cystic fibrosis" means a disorder, usually due to a single enzyme deficiency of genetic origin, in which the individual is completely or partially unable to produce a functioning transmembrane conductance regulator protein that results in progressive multi-organ dysfunction and the accumulation of trypsinogen in the blood during the newborn period.

(5) "Diagnostic laboratory" means a laboratory approved to perform testing for the congenital disorders listed herein to rule out a specific disorder suspected by newborn screening or for screening infants older than six months of age.

(6) "Division" means the Public Health Division of the Oregon Health Authority.

(7) "Dried blood specimen" means a blood specimen obtained from an infant by means of capillary-puncture or skin-puncture (heel stick), not by means of venipuncture or any other method, which is placed on special filter paper kits and allowed to air dry.

(8) "Endocrine disorders" means disorders related to hormone production or utilization resulting in abnormal growth and development, fluid and electrolyte imbalance or other disturbance, including hypothyroidism and congenital adrenal hyperplasia.

(9) "Fluorescent immunoassay" means a competitive binding or direct assay creating specific antibody-antigen reactions to detect thyroxin, thyroid stimulating hormone, 17-alpha-hydroxyprogesterone and immunoreactive trypsinogen.

(10) "Fluorescent spot test" means a biochemical laboratory test procedure utilizing certain naturally occurring enzymes in erythrocytes and added chemicals used to detect galactose in blood specimens as a screening test for galactosemia. It is described occasionally in the scientific literature as a "Hill test."

(11) "Hemoglobinopathy" means one of a group of disorders which results in abnormal structure and function of hemoglobin that leads to variable degrees of anemia, hemolysis and other complications. These include sickle cell disease and other clinically significant hemoglobinopathies.

(12) "High performance liquid chromatography" means the utilization of a separation column to detect various hemoglobin proteins based on their retention time.

(13) "Immunodeficiency disorders" means a group of disorders in which the immune system is not functioning properly. This includes severe combined immunodeficiency (SCID), a primary immune disorder characterized by a defect in T-cell production and function. SCID is also described as the "bubble boy disease".

(14) "Isoelectric focusing" means a laboratory procedure in which protein, hemoglobin in blood, is subjected to an electric field in a gel medium with a gradient pH causing it to migrate to its pH and isoelectric point, revealing specific patterns for each type of hemoglobin.

(15) "Kit" means any or all parts of the combined materials, laboratory slips, tubes, mailing containers, or other components provided by the state public health laboratory for the purposes of collection or submission of specimens for laboratory tests.

(16) "Metabolic disorders" means those disorders of intermediary metabolism and hormone production, regulation, or utilization in which the individual is completely or partially incapable of normal metabolism of biotin, single amino acids, galactose, or fatty acids resulting in the abnormal accumulation of those and other metabolites in the blood. These include phenylketonuria and medium-chain acyl-CoA dehydrogenase deficiency.

(17) "Newborn screening panel" means those disorders identified by the Oregon Health Authority in these rules for which all infants shall be tested, except if the infant is being reared as an adherent to a religion the teachings of which are opposed to such testing.

(18) "Practitioner" means a person duly and regularly licensed by the proper authority to practice medicine, naturopathy or chiropractic or to be a nurse practitioner. For purposes of OAR 333-024-0215(1) only, this definition is extended to include the licensed or unlicensed person who takes responsibility for delivery or the health care of the baby; or being none, the person responsible for the health care of the mother prior to birth of the baby.

(19) "Precision" of an assay means a quantitative measure of reproducibility of a laboratory procedure in assaying a particular chemical under defined conditions. Examples include, but are not limited to, statistically determined values of standard deviations from the mean and coefficients of variation.

(20) "Sensitivity" of an assay means the lowest concentration or quantity of a particular chemical that can be reliably detected or measured by a laboratory assay procedure under defined conditions.

(21) "Specificity" of an assay means the accuracy with which a laboratory assay procedure can reliably identify or measure the quantity of a particular chemical to distinguish it from other related or unrelated chemicals under defined conditions.

(22) "Specimen for newborn screening" means a dried blood specimen from an infant submitted to the state public health laboratory to detect congenital disorders included on the newborn screening test panel.

(23) "State public health laboratory" means the Oregon State Public Health Laboratory of the Public Health Division, 3150 NW 229th Avenue, Hillsboro, Oregon 97124.

(24) "Tandem mass spectrometry" means a laboratory procedure in which amino acids and acylcarnitines are detected and quantified in a sample taken from a dried blood spot.

(25) "These rules" means OAR 333-024-0205 through 333-024-0240.

(26) "TREC assay" means a DNA polymerase chain reaction method to detect T-cell receptor excision circles. An absence or reduction in TRECs can be used as an indicator for severe combined immunodeficiency or other primary immune deficiencies.

Stat. Auth.: ORS 431.310
Stats. Implemented: ORS 433.285, 433.290 & 433.295
Hist.: HD 18-1981(Temp), f. & ef. 9-11-81; HD 3-1982, f. & ef. 2-25-82; HD 10-1986, f. & ef. 6-11-86; PH 11-2014, f. 4-15-14, cert. ef. 5-1-14

Testing for Metabolic Diseases

333-024-0210
Infants Tested for Metabolic Diseases

Every infant born in Oregon on or after May 1, 2014, shall be tested for at least the following congenital disorders by the state public health laboratory:

(1) Cystic fibrosis (CF).
(2) Endocrine disorders:
(a) Congenital hypothyroidism (CH); and
(b) Congenital adrenal hyperplasia (CAH).
(3) Galactosemia (GALT).
(4) Hemoglobin disorders:
(a) Sickle cell disease (Hb S/S);
(b) Sickle cell/beta thalassemia (Hb S/A); and
(c) Sickle cell/hemoglobin C disease (Hb S/C).
(5) Metabolic disorders:
(a) Amino acid disorders:
(A) Homocystinuria (HCY);
(B) Phenylketonuria (PKU); and
(C) Tyrosinemia (TYR).
(b) Biotinidase deficiency;
(c) Fatty acid oxidation disorders:
(A) Carnitine uptake defect (CUD);
(B) Carnitine/acylcarnitine translocase deficiency (CT);
(C) Carnitine palmitoyl transferase deficiency (CPT), Types I and II;
(D) Glutaric acidemia, Type II (GA-II);
(E) Long-chain L-3 hydroxyacyl-CoA dehydrogenase deficiency (LCHAD);
(F) Medium-chain acyl-CoA dehydrogenase deficiency (MCAD);
(G) Short-chain acyl-CoA dehydrogenase deficiency (SCAD);
(H) Trifunctional protein deficiency (TFP); and
(I) Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD).
(d) Organic acid disorders:
(A) Beta-ketothiolase deficiency (BKT);
(B) Glutaric acidemia, Type I (GA-I);
(C) Isobutryl-CoA dehydrogenase deficiency (IBG);
(D) Isovaleric acidemia (IVA);
(E) Malonic aciduria (MAL);
(F) Maple syrup urine disease (MSUD);
(G) Methylmalonic acidemia (MMA);
(H) Propionic acidemia (PA);
(I) 2-Methyl-3-hydroxybutyryl CoA dehydrogenase deficiency (2M3HBA);
(J) 2-Methylbutyryl CoA dehydrogenase deficiency (2MBG);
(K) 3-hydroxy-3-methylglutaryl-CoA lyase deficiency (HMG);
(L) 3-methylcrotonyl-CoA carboxylase deficiency (3-MCC);
(M) 3-methylglutaconyl-CoA hydratase deficiency (3MGA); and
(N) Multiple carboxylase deficiency (MCD).
(e) Urea Cycle Disorders:
(A) Arginase deficiency (ARG);
(B) Argininosuccinate lyase deficiency (ASA); and
(C) Citrullinemia, Type I (CIT I).
(6) Other disorders as defined by Oregon Health Authority.
(7) Severe combined immunodeficiencies (SCID).

Stat. Auth.: ORS 433.285
Stats. Implemented: ORS 433.285
Hist.: HD 18-1981(Temp), f. & ef. 9-11-81; HD 3-1982, f. & ef. 2-25-82; HD 17-1983, f. & ef. 10-12-83; HD 10-1986, f. & ef. 6-11-86; HD 28-1994, f. 10-28-1994, cert. ef. 11-1-94; OHD 15-2002, f. & cert. ef. 10-4-02; PH 30-2004(Temp), f. & cert. ef. 9-17-04 thru 3-13-05; PH 37-2004, f. & cert. ef. 12-7-04; PH 11-2014, f. 4-15-14, cert. ef. 5-1-14

333-024-0215
Person Responsible for Submitting Specimens for Newborn Screening Testing

(1)(a) The person responsible for assuring that specimens are submitted for testing the infant for congenital disorders shall be in order of responsibility:

(A) The hospital, freestanding birthing center, or other health care facility licensed under ORS Chapter 441, or if the infant is not in such a facility;
(B) The practitioner, or if no practitioner is in attendance;
(C) The parent or legal guardian.

(b) For purposes of this section and OAR 333-024-0225, in the case of infants entering a health care facility before 48 hours of age as a result of transfer from another health care facility or from out-of-hospital birth, the receiving health care facility shall be responsible for the timely collection of specimens.

(2) The state public health laboratory may perform tests for certain congenital disorders for patients from outside Oregon.

Stat. Auth.: ORS 433.285
Stats. Implemented: ORS 433.285
Hist.: HD 18-1981(Temp), f. & ef. 9-11-81; HD 3-1982, f. & ef. 2-25-82; HD 17-1983, f. & ef. 10-12-83; HD 10-1986, f. & ef. 6-11-86; OHD 15-2002, f. & cert. ef. 10-4-02; PH 30-2004(Temp), f. & cert. ef. 9-17-04 thru 3-13-05; PH 37-2004, f. & cert. ef. 12-7-04; PH 11-2014, f. 4-15-14, cert. ef. 5-1-14

333-024-0220
Manner of Submitting Specimens

(1) All specimens submitted to the state public health laboratory for testing for congenital disorders shall be collected using kits available from the state public health laboratory according to procedures, protocols, and shipping instructions specified in the Newborn Screening Practitioner's Manual or on the website maintained by the state public health laboratory.

(2) Specimens collected for newborn screening testing shall be sent to the state public health laboratory within 24 hours of collection.

(3) Specimens shall be transmitted to the state public health laboratory in such a manner that they are received by the laboratory no later than five days after collection, preferably within 24 to 48 hours.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 433.285
Stats. Implemented: ORS 433.285
Hist.: HD 18-1981(Temp), f. & ef. 9-11-81; HD 3-1982, f. & ef. 2-25-82; HD 17-1983, f. & ef. 10-12-83; HD 10-1986, f. & ef. 6-11-86; OHD 15-2002, f. & cert. ef. 10-4-02; PH 30-2004(Temp), f. & cert. ef. 9-17-04 thru 3-13-05; PH 37-2004, f. & cert. ef. 12-7-04; PH 11-2014, f. 4-15-14, cert. ef. 5-1-14

333-024-0225
Time of Collecting Specimens for Testing Infants

A specimen for newborn screening testing shall be collected within five days after birth from every infant surviving more than two days, as follows:

(1) In the case of infants born outside a hospital or other health care facility and of infants who will remain in the hospital or health care facility for 24 hours or more, a specimen shall be collected after 24 hours but before five days after birth, preferably between 24 and 48 hours after birth. A second specimen shall be collected between 10 and 14 days but before one month of age.

(2) In the case of infants discharged from a hospital or other health care facility before 24 hours of age, a specimen shall be collected just prior to discharge from the facility, and a second specimen shall be collected from such infants 10 to 14 days after birth.

(3) In the case of infants who are preterm, low birth weight or ill and are admitted to a special care baby unit or neonatal intensive care unit, a specimen shall be collected at admission, a second specimen collected between 48 and 72 hours of age and a third specimen collected at discharge or 28 days of life, whichever comes first.

(4) In the case of infants up to six months of age entering the care of a practitioner and for whom the screening status is unknown or cannot be determined, a specimen shall be collected within two weeks of the first visit to the practitioner and sent to the state public health laboratory for screening.

(5) In the case of infants over six months of age entering the care of a practitioner and for whom the screening status is unknown or cannot be determined, a specimen shall be collected within two weeks of the first visit and sent to a diagnostic laboratory providing screening services for older infants.

Stat. Auth.: ORS 433.285
Stats. Implemented: ORS 433.285
Hist.: HD 18-1981(Temp), f. & ef. 9-11-81; HD 3-1982, f. & ef. 2-25-82; HD 17-1983, f. & ef. 10-12-83; HD 10-1986, f. & ef. 6-11-86; OHD 15-2002, f. & cert. ef. 10-4-02; PH 30-2004(Temp), f. & cert. ef. 9-17-04 thru 3-13-05; PH 37-2004, f. & cert. ef. 12-7-04; PH 11-2014, f. 4-15-14, cert. ef. 5-1-14

333-024-0230
Methods of Testing

(1) Infants shall be tested for congenital disorders on the newborn screening test panel by methods approved by rule of the Oregon Health Authority. The following laboratory procedures are approved. No other method shall be approved unless it meets or exceeds these methods in respect to specificity, sensitivity, and precision of the assay. Persons wanting amendment of this rule to include another method must provide technical data to the state public health laboratory showing to the satisfaction of the state public health laboratory that the proposed method meets or exceeds the approved methods in these respects.

(2) Laboratory methods for detecting congenital disorders shall be performed upon dried blood specimens and be as follows:

(a) Amino acid and urea cycle disorders: Quantitative measurement of amino acids by tandem mass spectrometry.

(b) Biotinidase deficiency: Colorimetric assay for biotinidase activity.

(c) Congenital adrenal hyperplasia: Fluorescent immunoassay of 17-alpha hydroxyprogesterone (17-OHP).

(d) Congenital hypothyroidism: Fluorescent immunoassay of thyroxine (T4) with secondary assay of thyroid stimulating hormone (thyrotropin or TSH).

(e) Cystic fibrosis: Fluorescent immunoassay for the presence or absence of immunoreactive trypsinogen (IRT).

(f) Fatty acid oxidation disorders: Quantitative measurement of acylcarnitines by tandem mass spectrometry.

(g) Galactosemia: Fluorescent immunoassay for the presence or absence of detectable galactose uridyl transferase in erythrocytes and galactose.

(h) Hemoglobinopathies: Primary screening by isoelectric focusing and confirmation by high performance liquid chromatography to detect hemoglobin variants.

(i) Severe combined immunodeficiencies: DNA polymerase chain reaction (PCR) to detect the absence or presence of T-cell receptor excision circles (TREC assay).

Stat. Auth.: ORS 433.285
Stats. Implemented: ORS 433.285
Hist.: HD 18-1981(Temp), f. & ef. 9-11-81; HD 3-1982, f. & ef. 2-25-82; HD 17-1983, f. & ef. 10-12-83; HD 10-1986, f. & ef. 6-11-86; HD 28-1994, f. 10-28-1994, cert. ef. 11-1-94; OHD 15-2002, f. & cert. ef. 10-4-02; PH 30-2004(Temp), f. & cert. ef. 9-17-04 thru 3-13-05; PH 37-2004, f. & cert. ef. 12-7-04; PH 11-2014, f. 4-15-14, cert. ef. 5-1-14

333-024-0231
Procedures for Follow-Up of Specimens Administered Too Early, Improperly Collected, and Those That Show Abnormal Results

(1) Improperly collected specimens. Where specimens contain insufficient blood, are contaminated or are found to be otherwise unsuitable for testing (refer to Newborn Screening Specimen Collection in the state public health laboratory's Practitioner's Manual or website), a repeat specimen will be requested. A letter will be mailed or faxed by the state public health laboratory to the practitioner who submitted the original specimen within two to four working days after receiving the sample. If there is no response after 10 working days, the state public health laboratory will send a follow-up letter. If there is no response within 21 working days after the second letter, a certified letter will be sent indicating that the state public health laboratory will no longer be tracking that infant and that the responsibility for further screening rests with the practitioner and the parents.

(2) Specimens that show anomalous results. The state public health laboratory will refer anomalous results to the screening program's medical consultants. Reports of anomalous findings will be made by the medical consultants to individual practitioners. Requests for repeat or diagnostic specimens will be made through the medical consultants by letter or telephone call, depending upon the urgency of the situation. The practitioner will inform the state public health laboratory of the final resolution or confirmation of each case to ensure timely and complete follow-up.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 433.285
Stats. Implemented: ORS 433.285
Hist.: HD 6-1985, f. 4-26-85, ef. 5-1-85; HD 10-1986, f. & ef. 6-11-86; OHD 15-2002, f. & cert. ef. 10-4-02; PH 30-2004(Temp), f. & cert. ef. 9-17-04 thru 3-13-05; PH 37-2004, f. & cert. ef. 12-7-04; PH 11-2014, f. 4-15-14, cert. ef. 5-1-14

333-024-0232
Demographic Data

The state public health laboratory will maintain demographic data records on infants to be used for the purposes of monitoring statistical trends and screening practices in hospitals, birthing facilities, and individual practices. This monitoring will enable the state public health laboratory to:

(1) Identify facilities and health care providers that submit inadequate specimens;

(2) Evaluate the overall effectiveness of the screening program;

(3) Monitor and ensure timely and complete follow-up; and

(4) Ensure that the most effective newborn screening program for the State of Oregon will be maintained.

Stat. Auth.: ORS 433.285 & 433.290
Stats. Implemented: ORS 433.285 & 433.290
Hist.: HD 6-1985, f. 4-26-85, ef. 5-1-85; OHD 15-2002, f. & cert. ef. 10-4-02; PH 30-2004(Temp), f. & cert. ef. 9-17-04 thru 3-13-05; PH 37-2004, f. & cert. ef. 12-7-04; PH 11-2014, f. 4-15-14, cert. ef. 5-1-14

333-024-0235
Religious Exemption from Newborn Screening Testing

(1) A religious exemption from testing for congenital disorders may be claimed if the infant is being reared as an adherent to a religion the teachings of which are opposed to such testing.

(2)(a) In the event a religious exemption is claimed from the requirements for testing for congenital disorders, the person otherwise responsible for submitting the specimen for testing shall be responsible for submitting a completed statement to the state public health laboratory signed by the infant's parent or legal guardian using the following language:

STATEMENT OF RELIGIOUS EXEMPTION

The undersigned parent or legal guardian of_____, born on_____, states that this child is exempt from newborn screening testing for detection of congenital disorders in that the child is being reared as an adherent to a religion the teachings of which are opposed to such testing. _____
(Signature of parent or legal guardian)

_____
(Date)

(b) The completed statement in subsection (a) of this section may be made on the reverse side of the original specimen identification form which otherwise accompanies the dried blood specimen used to test the infant for congenital disorders.

Stat. Auth.: ORS 431.180
Stats. Implemented: ORS 433.285
Hist.: HD 18-1981(Temp), f. & ef. 9-11-81; HD 3-1982, f. & ef. 2-25-82; HD 17-1983, f. & ef. 10-12-83; HD 10-1986, f. & ef. 6-11-86; HD 8-1991, f. & cert. ef. 6-19-91; OHD 15-2002, f. & cert. ef. 10-4-02; PH 30-2004(Temp), f. & cert. ef. 9-17-04 thru 3-13-05; PH 37-2004, f. & cert. ef. 12-7-04; PH 11-2014, f. 4-15-14, cert. ef. 5-1-14

Fees for Tests Performed in the State Laboratory

333-024-0240
Fees

(1)(a) The person responsible for submitting specimens for those tests performed on specimens received in the state public health laboratory on or after March 1, 2014, shall pay a test fee upon billing by the Authority, in accordance with the August 2013 Division of Medical Assistance Programs Fee for Service Fee Schedule.

(b) Public and private non-profit agencies may apply for a reduction or waiver of the test fees stated in subsection (2)(a) of this rule. Reduction or waiver requests must be sent to the director

of the state public health laboratory and be accompanied by proof of non-profit status. Requests should include the estimated number and type of tests anticipated per year. The decision to reduce or waive fees is discretionary with the state public health laboratory.

(3) For Oregon practitioners, newborn screening test kits purchased by prepayment on or after May 1, 2014:

(a) $32 per one-specimen kit; or

(b) $64 per two-specimen kit; or

(c) $64 per three-specimen kit (neonatal intensive care unit (NICU) and special baby care unit (SBCU) use only).

(4) Specimens which are submitted in an inadequate quantity or any unsatisfactory condition shall be subject to the fee of $5 per repeat specimen except for newborn screening specimens, which may be subject to a charge of $32 per specimen. Additional specimens from the same infant or patient specifically required or requested by the state public health laboratory, but not because the original specimen was inadequate or unsatisfactory, shall be exempt from additional fees.

(5) Kits requested for testing for congenital disorders shall be prepaid by the requestor in the amount as specified in section (3) of this rule. Kit requests must be accompanied by payment for the full amount of the order.

(6) No Oregon infant shall be denied testing for congenital disorders because of inability of the infant's parent or legal guardian to pay the fee for a test or kit:

(a) A practitioner or parent or legal guardian requesting exemption from fees shall complete a statement indicating the following:

STATEMENT OF FEE EXEMPTION

The undersigned parent or legal guardian of_____, born on_____, attests that they are unable to pay the fee/charge for labor and delivery services and for testing for congenital disorders because of lack of sufficient funds, insurance or Medicaid coverage.

_____

(Signature of parent or legal guardian)

_____

(Date)

(b) The above completed statement shall be completed by the parent or legal guardian on the original specimen identification form which accompanies the dried blood specimen used to test the infant for congenital disorders.

(c) Exemption statements must be received by the state public health laboratory within 90 days of the first newborn screening.

(d) Upon receipt of the statement in subsection (6)(a) of this rule, and confirmation of Oregon Health Authority records, the Oregon Health Authority will issue a refund check. The state public health laboratory will issue a refund check to the payer of record. The state public health laboratory will replace kits, damaged or unused, which are returned to the laboratory.

(7) For tests performed for or on behalf of Oregon state or local government agencies, as determined by the administrator to have a significant public health impact, a lesser fee, calculated to recover costs, may be charged.

(8) All specimens submitted to the state public health laboratory shall be collected according to procedures, protocols, and shipping instructions specified on the Oregon State Public Health Laboratory's website.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 431.310 & 433.285

Stats. Implemented: ORS 431.310 & 433.285

Hist.: HB 18-1981(Temp), f. & ef. 9-11-81; HB 3-1982, f. & ef. 2-25-82; HD 12-1982, f. 6-11-82, ef. 7-1-82; HD 27-1982(Temp), f. 12-15-82, ef. 12-16-82; HD 9-1983, f. 6-24-83, ef. 7-1-83; HD 11-1983(Temp), f. & ef. 7-11-83; HD 17-1983, f. & ef. 10-12-83; HD 10-1986, f. & ef. 6-11-86; HD 7-1987, f. & ef. 7-15-87; HD 12-1990, f. & cert. ef. 5-22-90; HD 8-1991, f. & cert. ef. 6-19-91; HD 28-1994, f. 10-28-1994, cert. ef. 11-1-94; HD 12-1997, f. 9-26-97, cert. ef. 10-1-97; OHD 3-1998, f. 3-31-98, cert. ef. 4-1-98; OHD 15-2002, f. & cert. ef. 10-4-02; PH 30-2004(Temp), f. & cert. ef. 9-17-04 thru 3-13-05; PH 37-2004, f. & cert. ef. 12-7-04; PH 7, 2014, f. & cert. ef. 1-30-14; PH 11-2014, f. 4-15-14, cert. ef. 5-1-14

Alpha-Fetoprotein Testing and Other Serum and Amniotic Fluid Based Markers for Congenital/Genetic Defects

333-024-0260
Purpose

(1) OAR 333-024-0260 through 333-024-0265 shall apply to the assay of Maternal Serum Alpha-Fetoprotein (MSAFP), Amniotic Fluid Alpha-Fetoprotein (AFAFP), Serum Human Chorionic Gonadotropin, Unconjugated Estriol, Amniotic Fluid Acetylcholinesterase or other related markers for the purposes of congenital/genetic screening.

(2) All sections of Clinical Laboratory OAR 333-024-0005 through 333-024-0055 shall apply.

Stat. Auth.: ORS 438.320

Stats. Implemented: ORS 438.320

Hist.: HD 28-1988, f. & cert. ef. 12-7-88; HD 6-1995, f. & cert. ef. 9-13-95

333-024-0265
Procedure

(1) Prior to performing patient screening, the laboratory shall have available documentation of its expertise with the assays of MSAFP, AFAFP, Serum Human Chorionic Gonadotropin, Unconjugated Estriol, Amniotic Fluid Acetylcholinesterase or other related markers for the purposes of congenital/genetic screening.

(2) Each laboratory shall establish reference data based on the laboratory's own test results for normal MSAFP, AFAFP, Serum Human Chorionic Gonadotropin, Unconjugated Estriol, Amniotic Fluid Acetylcholinesterase or other related markers for medically applicable times throughout the pregnancy.

(3) When required for calculation or interpretation of results, protocols shall be developed and implemented for adjusting test values for variables such as: gestational age, maternal weight, diabetic status, race or other factors.

(4) At least annually, the laboratory shall:

(a) Review the most recent patient test results;

(b) Compare current patient test data to previous results to ascertain changes in the median and dispersion of values;

(c) Investigate the causes of variation;

(d) Make corrections as needed; and

(e) Calculate and review percentages of abnormal results.

(5) Laboratories shall obtain and use in the calculation and interpretation, where applicable, at least the following information on each patient:

(a) Date of birth;

(b) An accurate estimation of gestational age, and method used for this determination;

(c) Patient's weight at the time the sample was obtained;

(d) Whether the patient is an insulin-dependent diabetic (IDDM);

(e) Patient's racial extraction;

(f) Date sample was collected;

(g) Patient history of multiple gestations; and

(h) Other pertinent medical information.

(6) The multiples of the median (MOM) shall be calculated using the laboratory's own reference data for each medically applicable time during gestation.

(7) Patient reports shall include information as indicated in section (5) of this rule. Additional information shall include:

(a) Defects screened for;

(b) Risk or cutoff used for determination of abnormal results;

(c) Interpretation of results; and

(d) Any other medically relevant information necessary for the interpretation of results.

(8) Policies shall be established for timely reporting of all results to the individual authorized to receive the patient's results.

Stat. Auth.: ORS 438.320

Stats. Implemented: ORS 438.320

Hist.: HD 28-1988, f. & cert. ef. 12-7-88; HD 6-1995, f. & cert. ef. 9-13-95

Testing for Substances of Abuse

333-024-0305
Purpose and Scope

OAR 333-024-0305 through 333-024-0365 are for the purpose of carrying out ORS 438.435 regarding substance of abuse testing in order to protect the people of the State of Oregon. OAR 333-024-0315 through 333-024-0350 establishes a regulatory program for laboratories performing medical testing or non-medical testing by automated methods to ensure the quality of testing. OAR 333-024-0360 sets standards for substance of abuse testing in correctional institutions or programs. OAR 333-024-0365 establishes a registry for entities performing non-medical substance of abuse screening using easily portable screening tests.

Stat. Auth.: ORS 438.050, 438.130, 438.435(2), (4), (5) & (6)
Stats. Implemented: ORS 438.050, 438.130 & 438.435
Hist.: HD 28-1988, f. & cert. ef. 12-7-88; HD 5-1992, f. & cert. ef. 5-15-92; HD 13-1997, f. & cert. ef. 10-16-97

333-024-0310
Definitions

(1) "Benefit" means, but is not limited to, eligibility for insurance or employment, access to or participation in a drug rehabilitation or mental health program, parole or probation, school attendance or attendance in school activities.

(2) "Chain of custody" or "custody chain" means the handling of specimens in a way which supports legal testimony to prove that the sample integrity and identification of the sample have not been violated, as well as the documentation describing these procedures from specimen collection to final report.

(3) "Confirmatory test" means a highly specific test to identify a substance of abuse or metabolite after a positive screening, based on a different analytical method than that of the initial screening test, at or below the cutoff concentration used for the screening test.

(4) "Control" means a material, the expected testing results of which are known, which is analyzed to ensure that the expected results are obtained.

(5) "Cutoff concentration" means the mass of a substance of abuse per unit volume of specimen, at or above which a test result is considered positive.

(6) "Director of a substances of abuse screening laboratory" or "Director" means the person who plans, organizes, directs and participates in any or all of the technical and administrative operations of a substances of abuse laboratory, including but not limited to reviewing laboratory procedures and their results, and the training and supervising of laboratory personnel.

(7) "Drug control manager" means the individual who works for the inspector general of the Department of Corrections, and oversees drug interdiction efforts of the Oregon Department of Corrections. This includes supervision of urine drug screening.

(8) "Easily portable screening test" means manual, non-automated, substance of abuse methods\kits.

(9) "Entity" means an individual, partnerships, corporation, company, district, local\county\state agency. An entity may be multiple sites under common ownership.

(10) "Local correctional facility" means any institution or facility used specifically for the confinement of inmates operated by a city or county.

(11) "Medical testing" means any test performed at the request of a physician, dentist, or other licensed health care professional for diagnosis and treatment or assessment of health, including testing for rehabilitation or placement into a rehabilitation or mental health program.

(12) "Non-medical testing" means substance of abuse (SOA) screening not for diagnosis and treatment or assessment of health, with or without an order from a physician, dentist or other licensed health care professional, including but not limited to, employment, pre-employment, on the job accident or injury, screening of students in schools, testing for insurance eligibility or eligibility for plasmapheresis.

(13) "Operator of a substance of abuse on-site screening facility" or "operator" means the person who plans, organizes, directs and participates in any or all of the technical and administrative operations.

(14) "Owner of a substances of abuse screening laboratory" or "Owner" means a person who owns the laboratory, or the State, county or municipality operating the laboratory, or the owner of any institution operating the laboratory or any non-profit organization operating the laboratory.

(15) "Parole, probation and post-prison supervision" means any program operated for offenders by the Department of Corrections or local correctional agencies.

(16) "Proficiency testing" means performance of tests on specimens whose expected results are unknown to anyone in the laboratory, known only to an external agency, and later revealed to the laboratory as an aid to laboratory improvement and/or a condition of licensure.

(17) "Quality control" means methods used to monitor the performance of laboratory tests to detect errors and prevent the reporting of incorrect results.

(18) "Screening" means performing initial tests designed to separate substances of abuse at a particular minimum concentration from those below that minimum concentration (positive versus negative).

(19) "Special category laboratory" means a laboratory that initially screens urine, blood, or other body fluids for substance of abuse, but does not perform confirmation testing by any method.

(20) "Specimen" means body fluids obtained from a live person.

(21) "Standard" means an authentic sample of the analyte of known purity, or a solution of the analyte of a known concentration.

(22) "State correctional facility" means any institution operated by the Oregon Department of Corrections.

(23) "Substances of abuse" or "SOA" means ethanol and controlled substances, except those used as allowed by law and as defined in ORS Chapter 475 or as used in ORS 689.005.

(24) "Substances of abuse on-site screening facility" or "on-site facility" means a location where on-site tests are performed on specimens for the purpose of screening for the detection of substances of abuse.

(25) "Substances of abuse on-site screening test" or "on-site test" means a substance of abuse test that is easily portable and is approved by the Food and Drug Administration for commercial distribution or an alcohol screening test that meets the requirements of the conforming products list found in the **United States Department of Transportation National Highway Traffic Safety Administration Docket No. 94-004** and meets the standards of the **United States Department of Transportation Alcohol Testing Procedure**, **49 C.F.R. part 40**, in effect on October 23, 1999.

(26) "Substances of abuse screening laboratory" or "SOA laboratory" means a facility where initial biochemical examinations are performed on a specimen for the purpose of screening for the detection of substances of abuse for medical purposes or non-medical purposes by automated methods. This includes licensed clinical laboratories screening for substances of abuse.

(27) "Substance of abuse testing program manager" means an individual who is responsible for all aspects of SOA testing in the facility including the quality control, proficiency testing, method selection, equipment maintenance, training, record keeping, and qualifications of individuals performing substance of abuse testing at each state or local correctional facility or parole, probation office site.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 438.050, 438.130, 438.435(4), 438.435(5) & 438.435(6)
Stats. Implemented: ORS 438.050, 438.130, 438.320 & 438.435
Hist.: HD 28-1988, f. & cert. ef. 12-7-88; HD 5-1992, f. & cert. ef. 5-15-92; HD 20-1994, f. & cert. ef. 7-20-94; HD 13-1997, f. & cert. ef. 10-16-97; OHD 10-1999(Temp), f. & cert. ef. 11-26-99 thru 2-22-00; administrative correction 3-17-00; OHD 4-2000, f. & cert. ef. 4-27-00; OHD 9-2000, f. & cert. ef. 11-3-00

333-024-0315
Licensure

(1) It shall be unlawful:

(a) For any owner or director of a SOA or a clinical laboratory to perform medical or automated non-medical SOA screening tests without a license issued under this rule unless they have been certified for that testing under the Clinical Laboratory Improvement Amendments of 1988, Public Law 100-578, 42.U.S.C. 201 and 263a;

(b) For any person to serve in the capacity of director of an SOA screening laboratory without being qualified as a laboratory director under OAR 333-024-0320(1).

(2) OAR 333-024-0305 through 333-024-0350 apply to all SOA screening laboratories and laboratory personnel within the State of Oregon, except:

(a) Laboratories screening for SOA operated by the United States Government;

(b) Laboratories screening for SOA operated and maintained solely for research or teaching purposes, and that involve no direct patient or public health services;

(c) State Police laboratories screening for SOA as a part of the criminal justice system;

(d) Special category laboratories operated by state or local correctional agencies to monitor inmates and offenders on parole, probation, or post-prison supervision. These special category laboratories must follow the provisions of OAR 333-024-0360.

(3) The Division shall issue and renew licenses to the owners of laboratories screening for SOA who demonstrate to the satisfaction of the Division that:

(a) The SOA laboratory is in compliance with ORS 438.435;

(b) The SOA laboratory is equipped to perform within the scope of its license;

(c) The SOA laboratory meets the standards of the Division for safety, sanitary conditions, plumbing, ventilation, handling of specimens, maintenance of equipment and requirements of general hygiene to ensure protection of the public health.

(4) Requirements for license application; fees, exemptions, expiration; and renewal are as follows:

(a) The application for a license for an SOA screening laboratory shall be made on forms provided by the Division and shall be executed by the owner or one of the owners or by an officer of the firm or corporation owning the laboratory, or in the case of a county or municipality, by the public official responsible for operation of the SOA laboratory, or in the case of an institution, by the administrator of the institution. The application shall contain the names of the owner, the director or directors of the laboratory, the location and physical description of the SOA laboratory, and such other information as the Division may require;

(b) Laboratories must pay an annual or biennial, nonrefundable license fee, prior to issuance of a license, as described in OAR 333-024-0012(5)(c);

(c) A laboratory certified in toxicology for medical substance of abuse testing under the **Clinical Laboratory Improvement Amendments of 1988, Code of Federal Regulations, Part 493 — Laboratory Requirements**, may also perform that testing for non-medical purposes. No separate substance of abuse screening license or registry is required;

(d) Unless sooner voided, suspended or revoked, all licenses issued under this section expire on June 30 of the one or two year cycle following the date of issuance and shall be renewable in the manner prescribed by the Division;

(e) All monies received by the Division for the licensure of SOA screening laboratories shall be credited to the Division account and shall be used for payment of the expenses of the Division in administering OAR 333-024-0005 through 333-024-0350.

(5) A license issued to the owner of an SOA screening laboratory shall show on its face the names of the owners and directors, the location of the laboratory and the laboratory specialty authorized under the license. The license shall be displayed at all times in a prominent place in the laboratory.

(6) A license issued to the owner of an SOA screening laboratory is not transferable. The license of the SOA laboratory is voided 30 days after a change of its director if it has only one director or if all directors change or a change in the ownership or in the location of the laboratory. In the case of death of a director, the Division shall be notified within five working days. The laboratory shall have 30 days to obtain another qualified director.

(7) Subject to ORS 183.310 to 183.550, the Division may refuse to issue or renew the license or may suspend or revoke the license of any SOA laboratory, if it finds that the owner or director has:

(a) Intentionally made false statements on an application for an SOA laboratory license or any other documents required by the Division, or made any misrepresentation in seeking to obtain or retain a license;

(b) Demonstrated incompetence as defined in OAR 333-024-0325;

(c) Intentionally falsified any report;

(d) Referred a specimen, for examination, to an unlicenced clinical or SOA laboratory in this state, or a laboratory out of state not certified by the **Clinical Laboratory Improvement Amendments of 1988, Code of Federal Regulations, Part 493 — Laboratory Requirements**, or an equivalent out of state laboratory, unless the laboratory is exempt under section (2) of this rule;

(e) Misrepresented the scope of laboratory service offered by the SOA laboratory or the laboratory specialty authorized by the license;

(f) Rendered a substances of abuse report performed in another laboratory without designating the name and address of the laboratory in which the test was performed;

(g) Knowingly had professional connection with or permitted the use of the name of the licensed laboratory or its director by a laboratory which is required to but has not obtained a license;

(h) Failed to perform or cause to be performed within the time specified, analysis of test samples as stated in OAR 333-024-0340 or failed to report on the results of such analysis within the specified time;

(i) Failed to permit within a reasonable time the entry or inspection as stated in OAR 333-024-0340(2) and (4);

(j) Failed to continue to meet the requirements of this rule, inclusive; and

(k) Violated any provision of OAR 333-024-0305 through 333-024-0350.

(8) Owner shall be responsible for all aspects of the laboratory.

(9) The substance of abuse screening laboratory must be in compliance with requirements of the **Clinical Laboratory Improvement Amendments of 1988, Code of Federal Regulations, Part 493 — Laboratory Requirements**, if medical testing for substances of abuse is performed.

(10) Entities performing only manual, non-automated SOA screens using easily portable screening tests must register with the Division and meet the requirements at OAR 333-024-0365.

(11) Licensed clinical laboratories or SOA screening laboratories performing a combination of medical and manual, non-medical SOA screens are not required to register with the Division and must meet the requirements of OAR 333-024-0365(5)(e) when performing tests which qualify for SOA registration.

(12) Licensed clinical laboratories performing only manual, non-medical SOA screens using easily portable screening tests must register with the Division and meet the requirements of OAR 333-024-0365.

(13) Laboratories certified under the **Clinical Laboratory Improvement Amendments of 1988, Code of Federal Regulations, Part 493 — Laboratory Requirements**, that perform medical and non-medical substance of abuse screening, must comply with 333-024-0305 through 333-024-0350 and 333-024-0365(5)(e).

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 438.050, 438.130, 438.435(4), (5) & (6) & 438.040
Stats. Implemented: ORS 438.050, 438.130 - 438.160 & 438.435

Hist.: HD 28-1988, f. & cert. ef. 12-7-88; HD 5-1992, f. & cert. ef. 5-15-92; HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95; HD 13-1997, f. & cert. ef. 10-16-97; OHD 5-1999, f. & cert. ef. 7-30-99; OHD 9-2000, f. & cert. ef. 11-3-00

333-024-0320
Qualifications and Responsibilities of Directors

(1) The director of a substances of abuse screening laboratory shall meet one of the following qualifications:

(a) Is a pathologist certified in clinical pathology by the American Board of Pathology, the American Osteopathic Board of Pathology, or is eligible for such certification;

(b) Is a physician with two or more years of clinical chemistry experience, with one year in toxicology;

(c) Has an earned degree of Doctor of Science (ScD), Doctor of Public Health (DrPH) or Doctor of Philosophy (PhD) in chemistry or biochemistry and has two or more years of clinical chemistry training or experience with one year in toxicology;

(d) Is certified or is eligible for certification by the American Board of Clinical Chemistry or by the American Board of Forensic Toxicology;

(e) Has an earned master of science degree in medical technology, chemistry, or biochemistry and has three or more years of clinical chemistry training or experience, with one year of pertinent experience in toxicology;

(f) Has a bachelor of science, bachelor of technology or bachelor of arts degree in medical technology, chemistry or biochemistry, and has four or more years of clinical chemistry training or experience, with one year experience in toxicology;

(g) Has directed substance of abuse screening for at least 12 months within the four years preceding January 1, 1987, and has at least two years of pertinent experience in toxicology.

(2) The director of an SOA screening laboratory shall be responsible for the quality of the work. This shall include, but not be limited to, the following:

(a) Monthly review and documentation of quality control data;

(b) Review and documentation of external proficiency testing within 30 days of receipt of the final report;

(c) Review and documentation of procedure manuals and relevant texts initially and also whenever there is a change in method or policy;

(d) Validation of new procedures prior to reporting test results;

(e) Review and documentation of preventive maintenance of equipment;

(f) Review of additional quality assurance items;

(g) Assure that qualified technical personnel perform the tests; and

(h) Assure the competency of all testing personnel annually.

(3) The director of an SOA screening laboratory shall require the submitter to indicate the need for confirmatory testing as described in ORS 438.435(6).

(4) A person shall not serve individually as director of more than five substances of abuse screening laboratories.

(5) Those individuals qualifying under 333-024-0320(1)(g) must have applied to the Division by January 1, 1989.

Stat. Auth.: ORS 438.050, 438.130, 438.435(4), 438.435(5) & 438.435(6)
Stats. Implemented: ORS 438.210, 438.220 & 438.435
Hist.: HD 28-1988, f. & cert. ef. 12-7-88; HD 5-1992, f. & cert. ef. 5-15-92; HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95; HD 13-1997, f. & cert. ef. 10-16-97

333-024-0325
Incompetence

An SOA laboratory owner or director has "demonstrated incompetence" if there is:

(1) Repeated error demonstrated in the performance of laboratory tests or procedures or the results thereof;

(2) Failure to comply with the requirements of OAR 333-024-0335 and 333-024-0340 relating to internal and external quality control;

(3) Failure to comply with ORS 438.435 or any regulations pertaining to the laboratory;

(4) Work assigned to personnel not qualified to perform in that specialty;

(5) Repeated erroneous reporting of test results.

Stat. Auth.: ORS 438.050, 438.130, 438.435(4), 438.435(5) & 438.435(6)
Stats. Implemented: ORS 438.160 & 438.435
Hist.: HD 28-1988, f. & cert. ef. 12-7-88; HD 5-1992, f. & cert. ef. 5-15-92

333-024-0330
Specimen Collection, Chain of Custody, Records, and Reports

(1) The specimen container shall be clean, tightly sealed and free of any interfering substance. It shall be transported and stored in such a manner as to preserve the integrity and security of the specimen.

(2) The specimen container shall be permanently labeled with time and date of collection and atleast one of the following:

(a) The name of the person from whom the specimen was taken, if available;

(b) Social security number;

(c) Employee number;

(d) Unique identifying number.

(3) The initial request form, used by the person requesting the test, must have a statement indicating whether, if positive, the test results are to be confirmed as required under ORS 438.435(7).

(4) For those specimens requiring a confirmatory test, a record shall be made of the following:

(a) Time and date of collection;

(b) Identity of the individual receiving the specimen; and

(c) Manner by which the specimen was sent to the laboratory, including the name of the commoncourier or the individual delivering the specimen.

(5) Any laboratory receiving or referring the specimen shall keep for a minimum of two years a record of the following:

(a) The condition under which the specimen was collected or received and results of tests or information to rule out adulteration of the specimen;

(b) The date, time and one of the unique identifications from the specimen label;

(c) Time and date received and referred;

(d) Laboratory accession number;

(e) Condition of the specimen;

(f) The name of the company or individual requesting the test; and if positive, whether the specimen requires confirmatory testing as described in OAR 333-024-0345(1);

(g) The type of test performed;

(h) The results of the tests and controls in units of measurement where applicable; and the type and concentration of standard(s) used in testing;

(i) Storage of specimen before and after screening;

(j) The signature, initials, or identification of the testing personnel;

(k) Date and time the tests were completed; and

(l) The name of the clinical laboratory performing the confirmatory testing if required under OAR 333-024-0345(1).

(6) Clinical and substance of abuse screening laboratories may examine specimens submitted by persons other than medical personnel authorized by law and shall report the result of any test to the person or company who requested the test except as indicated in number (7) of this rule.

(7) A copy of the SOA test results must be provided to the employee or pre-employee from whom the specimen was collected, after the employee or pre-employee submits a written request and proof of identity to the laboratory.

(a) When a written request is given to the laboratory in person:

(A) The employee or pre-employee must present two proofs of identity to the laboratory, which must include one of the following picture identification cards: state driver's license, state identification card, passport or a resident alien card from the U.S. Department of Immigration and Naturalization Service.

(B) The employee or pre-employee must sign and date a form for release of laboratory records.

(b) When a written request for SOA test results is received by mail:

(A) The request must be accompanied by a signed and dated form for release of laboratory test results and a notarized statement of the employee's or pre-employee's identity and mailing address.

(B) The laboratory will make a copy of the pertinent SOA test results and send this copy by registered or certified mail, or other bonded courier that would assure the confidentiality of the results, to the address requested by the notarized statement.

(c) A copy of the signed release form and picture identification, or the notarized statement, shall be maintained by the laboratory for two years.

Stat. Auth.: ORS 438.435
Stats. Implemented: ORS 438.310, 438.320 & 438.435
Hist.: HD 28-1988, f. & cert. ef. 12-7-88; HD 13-1997, f. & cert. ef. 10-16-97; OHD 10-1999(Temp), f. & cert. ef. 11-26-99 thru 2-22-00; administrative correction 3-17-00; OHD 4-2000, f. & cert. ef. 4-27-00; OHD 9-2000, f. & cert. ef. 11-3-00

333-024-0335
Internal Quality Assurance

(1) Laboratory procedure manuals and relevant texts of appropriate current laboratory methods shall be available for the use of the personnel in the laboratory.

(2) Each instrument system shall be calibrated according to the manufacturer's specifications and the calibrations shall be checked and recorded at intervals compatible with the proper operation of that instrument.

(3) Quality control requirements:

(a) Automated: At least one positive and one negative standard or control shall be included with the frequency recommended by the manufacturer; or at a frequency documented to assure the stability of the analytical method; but no less than once per day of testing.

(b) Manual:

(A) Test kits without positive and negative procedural controls, the laboratory must run at least one positive and one negative standard or control each day of testing for each analyte;

(B) Test kits with positive and negative procedural controls, the laboratory must run at least one positive and one negative standard or control with each lot/shipment and at least once per month for each analyte tested. Results of internal procedural controls must be documented with each sample tested.

(4) A permanent logbook or computer printout shall be kept and include patient/client name or unique identifier, date of test performance, quality control, reagent lot number, temperature, testing analyst, screening result and evidence for referral for confirmation, if applicable.

(5) Each analyst must annually demonstrate testing proficiency and interpretive competency for each analyte tested by proficiency testing internal blind samples.

(6) For each method, the minimum detectable limit for each substance tested must be on the report or in a letter of agreement between the laboratory and the client.

(7) Cutoffs at the minimal detectable range must be verified with a control when there is a lot change or major instrument maintenance.

(8) For each method, whether automated or manual, data shall be recorded and available to document the results on routine precision.

(9) Limits for controls shall be clearly stated and recorded. The corrective action taken when analyses are outside these control limits shall be clearly stated and recorded. The control limits shall be set so that reliable results are assured. Values for standards shall be clearly stated and recorded.

(10) Quality control results shall be recorded and retained in the laboratory for 2 years.

(11) Solid and liquid reagents, reagent solutions, standards and controls, if prepared in the laboratory, shall be calibrated and dispensed in a manner so as to ensure accuracy of results.

(12) All reagents and solutions shall be labeled to indicate identity, preparation date, expiration date, lot number, and storage conditions. No reagents or solutions may be used beyond their expiration date.

(13) The laboratory shall have a written procedure for chain of custody.

Stat. Auth.: ORS 438.435
Stats. Implemented: ORS 438.320 & 438.435
Hist.: HD 28-1988, f. & cert. ef. 12-7-88; HD 20-1994, f. & cert. ef. 7-20-95; HD 6-1995, f. & cert. ef. 9-13-95; HD 13-1997, f. & cert. ef. 10-16-97; OHD 9-2000, f. & cert. ef. 11-3-00

333-024-0340
External Quality Control (Proficiency Testing Program and On-Site Inspections)

(1) Licensed SOA laboratories shall:

(a) At the laboratory's own expense, be required to participate satisfactorily in the proficiency testing programs of the College of American Pathologists, or the American Association of Bioanalysts, or such other substantially equivalent testing program as may be approved by the Division involving substances of abuse testing and make available to the Division all test results;

(b) Be required to participate satisfactorily if required in the proficiency testing programs conducted by the Division involving substances of abuse testing;

(c) Analyze test samples submitted by the Division prior to, during, or subsequent to inspection if requested to the Division;

(d) Achieve satisfactory results on test samples in agreement with reference laboratories or within stated acceptable limits and which results shall be reviewed by the Division. Continued or consistent failure two out of three periods may result in the laboratory's license being withdrawn by the Division until satisfactory performance is demonstrated; and

(e) Ensure that proficiency samples are tested by regularly assigned personnel using routine methods. A specified time shall be allowed for such testing and reporting of results.

(2) Biennial on-site inspections may be conducted by representatives of the Division at reasonable times during the laboratory's normal business hours without advance notice. The representative shall inspect the facilities, personnel policies, procedures, materials, staff qualifications, equipment and records.

(3) The owner or director of an SOA laboratory may be required to submit reports on the operations and procedures of the laboratory.

(4) Additional inspections may be performed without notice to verify correction of deficiencies, investigate complaints, review unsatisfactory proficiency testing and verify personnel qualifications or other monitoring of compliance with OAR 333-024-0305 through 333-024-0350.

Stat. Auth.: ORS 438.320 & 438.435
Stats. Implemented: ORS 438.320 & 438.435
Hist.: HD 28-1988, f. & cert. ef. 12-7-88; HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95; HD 13-1997, f. & cert. ef. 10-16-97

333-024-0345
Confirmatory Testing

(1) When the substances of abuse screening laboratory obtains a positive test result and the submitter indicates the result is to be used to deprive or deny any person any employment or any benefit, that same specimen must be submitted and confirmed prior to the release of the screening results. When performed within the State of Oregon, the confirmatory testing shall be by a clinical laboratory licensed under ORS 438.110 and 438.150 or certified under the **Clinical Laboratory Improvement Amendments of 1988**, **Public Law 100-578**, **42 U.S.C. 201 and 263a** for that testing. The confirmatory testing shall be as described in section (4) of this rule.

(2) The administrator of the Division shall appoint a substances of abuse methods panel to recommend approval of methods used to confirm the presence of substances of abuse. The panel shall be composed of individuals from laboratories performing substances of abuse testing and shall include, but not be limited to, representatives from the Oregon State Police Crime Laboratory, laboratories

licensed under ORS Chapter 438, and the Oregon Health Sciences University.

(3) Any scientifically tested method for substances of abuse analysis may be submitted to the Division, for approval, by written request from a manufacturer, laboratory, or other party. Each candidate method shall be evaluated as to its capacity for accuracy by the panel, with recommendation based thereon, by one or more of the following means:

(a) Government or independent studies of the method's accuracy;

(b) Comparative data on proficiency test performance of various methods;

(c) Application of the method by panel members in performance of analysis; or

(d) Other means as determined by the Division.

(4) The following methods of chemical analysis to determine substances of abuse have been approved:

(a) Chromatography;

(b) Immunoassay;

(c) Spectroscopy;

(d) Mass spectroscopy.

(5) The confirmatory test shall be performed by a different analytical method from that used for the initial screening test.

Stat. Auth.: ORS 438.050, 438.130, 438.435(4), 438.435(5) & 438.435(6)
Stats. Implemented: ORS 438.435
Hist.: HD 28-1988, f. & cert. ef. 12-7-88; HD 5-1992, f. & cert. ef. 5-15-92; OHD 9-2000, f. & cert. ef. 11-3-00

333-024-0350
Equipment and Facilities

(1) All equipment shall be maintained in good working order, checked routinely, and precisely calibrated.

(2) Work bench space shall be ample, clean, well-organized, well-lighted, and convenient to sink, water and electrical outlets.

(3) The SOA laboratory shall be ventilated to protect the health of the personnel and patients against accidental release of hazardous vapors or aerosols.

(4) The premises shall be free from unnecessary physical, chemical, and biological hazards.

(5) Electrical equipment shall be maintained in a safe condition with regards to shock and fire hazards. All electrical equipment, except battery operated, shall be grounded. Protective fuses shall not be bypassed.

(6) Caustic, explosive and flammable materials shall carry labels to indicate their nature and shall be placed in containers and stored in locations which are suitable to ensure stability, purity, and safety as is necessary regarding the material involved.

Stat. Auth.: ORS 438.110, 438.320 & 438.435
Stats. Implemented: ORS 438.110, 438.320 & 438.435
Hist.: HD 28-1988, f. & cert. ef. 12-7-88; HD 6-1995, f. & cert. ef. 9-13-95

333-024-0360
Special Category Laboratories

(1) The rules in this section set standards for special category screening laboratories, as authorized in ORS 438.435(4), (6) and (7). These rules apply to the testing of inmates within state and local correctional facilities and to the testing of offenders on parole, probation, or under post-prison supervision.

(2) Special category laboratories as defined in this rule must use only manual or automated substance of abuse screening methods approved by the U.S. Food and Drug Administration. Any alcohol screening test must meet the requirements of the conforming products list found in the **United States Department of Transportation National Highway Traffic Safety Administration Docket No. 94-004** and meets the standards of the **United States Department of Transportation Alcohol Testing Procedure**, **49 C.F.R. part 40**, in effect on October 23,1999.

(3) Individuals who perform screening tests for substances of abuse must complete a training course offered by the manufacturer or provider of the test, an educational facility, or training provided by the Department of Corrections Drug Control Unit with curriculum acceptable to the Public Health Division. No testing is to be performed prior to the completion of this training. A certificate of satisfactory completion, including the dates and hours of training completed, shall be kept by the SOA testing program manager at each facility and parole office. A copy shall also be on file with the Drug Control Manager at the Department of Corrections.

(4) Protocols, procedures, and records of all testing shall be maintained as described in this section and shall be followed:

(a) Each local and state correctional facility or parole office shall have a designated substance of abuse program manager who shall assure that:

(A) Written policies established by the Department of Corrections are followed regarding specimen collection, specimen identification, and chain of custody, as defined in OAR 333-024-0310(2);

(B) Written procedure manuals are available to testing individuals, and that the written procedures require following the manufacturer's testing protocol. The written procedures must describe the test limitations and the use of approved standards and quality control, as defined in OAR 333-024-0310(4) and (21).

(C) There is a written record of the:

(i) Date and time the specimen was obtained;

(ii) Date and time the test was performed;

(iii) Lot number of the test kit used, test results, including the results of controls;

(iv) Signature or initials of the analyst.

(b) Quality control procedures as described in this subsection shall be followed:

(A) Each instrument shall be calibrated according to the manufacturer's specifications, with each new lot or shipment of reagents, and after major maintenance;

(B) For manual methods, known positive and negative controls, as defined in OAR 333-024-0310(4), shall be included with each batch of tests or with every ten samples for each analyte of each kit. Known positive and negative controls must be run with each lot shipment, and at least once per month, if internal procedural controls are included with each test;

(C) For automated instruments, a positive and negative control, as defined in OAR 333-024-0310(4) shall be included at least once per day of use, or following each tenth sample analyzed;

(D) All calibration and control data shall be recorded;

(E) The minimum detectable limit of the analytical method for each substance tested shall be available;

(F) Limits for controls shall be clearly stated and recorded. The corrective action taken when analyses are outside these control limits shall be clearly stated and recorded;

(G) No reagent shall be used beyond its expiration date;

(H) A record shall be kept of each testing individuals' quality control performance. This record will be reviewed by the SOA program manager at least every six months;

(I) Each local and state correctional facility, parole, probation, and post prison program shall be required to participate satisfactorily in a proficiency testing program, as defined in OAR 333-024-0310(16). The proficiency testing programs available from the College of American Pathologists, or the American Association of Bioanalysts, or other proficiency testing program acceptable to the Public Health Division may be used;

(J) Proficiency testing results and control data shall be reviewed every six months by the SOA program testing manager, and corrective action shall be taken and documented when appropriate. A copy of the report and corrective action must be sent to the Drug Control Manager of the Department of Corrections for review.

(c) If an initial test shows a result indicating the presence of a substance of abuse in the body, a confirmatory test shall be conducted in a licensed clinical laboratory, or a laboratory certified for that testing under the **Clinical Laboratory Improvement Amendments of 1988**, **Code of Federal Regulations Part 493 — Laboratory Requirements**, or an equivalent out of state laboratory, if the results are to be used to deprive or deny any person of any benefit, probation, or parole except as described in ORS 438.435(7).

(d) If any test for substances of abuse is performed outside this state the results of which are used to deprive or deny any person any benefit, the person desiring to use the test shall have the burden to show that the testing procedure used meets or exceeds the testing standards of this state.

Stat. Auth.: ORS 438.050, 438.130, 438.435(4), 438.435(5) & 438.435(6)
Stats. Implemented: ORS 438.435
Hist.: HD 5-1992, f. & cert. ef. 5-15-92; HD 5-1995, f. & cert. ef. 9-13-95; OHD 4-2000, f. & cert. ef. 4-27-00; OHD 9-2000, f. & cert. ef. 11-3-00

333-024-0365
Substance of Abuse Registration

(1) It shall be unlawful for any entity to perform any on-site test for non-medical substance of abuse screening tests prior to filing a registration form with the Division and payment of the registration fee, except laboratories:

(a) Owned and operated by the U.S. Government;

(b) Performing pure research;

(c) Performing substance of abuse tests for forensic purposes only;

(d) Performing substance of abuse tests from autopsy specimens;

(e) Identified as teaching facilities only training students in test performance;

(f) Owned and operated by the Oregon State Police performing substance of abuse screens for forensic purposes.

(2) SOA registration is not transferable to another entity.

(3) It shall be unlawful for a registered substance of abuse entity to perform medical testing.

(4) Clinical and SOA screening laboratories must meet the requirements under (5)(e) of this rule when performing tests which qualify for SOA registration.

(5) Registration shall be on a form provided by the Division and shall contain:

(a) The entity name and address;

(b) Name of legal owner and tax identification number;

(c) Telephone number;

(d) Name of individual contact at each on-site facility operated by the entity; and

(e) Signature of the operator certifying that:

(A) Only SOA kits approved by the Food and Drug Administration (FDA) or alcohol screening tests that meet the requirements of the conforming products list found in the **United States Department of Transportation National Highway Traffic Safety Administration Docket No. 94-004** and meet the standards of the **United States Department of Transportation Alcohol Testing Procedure**, **49 C.F.R. part 40**, in effect on October 23, 1999, are used;

(B) Tests are administered according to the manufacturer's package insert;

(C) Custody chain procedures are written and followed;

(D) Operators of the SOA on-site screening facility are trained in the use of the SOA screening tests by the manufacturer; and

(E) When the SOA on-site facility obtains a positive result on a specimen and the entity indicates that the test result is to be used to deny or deprive any person of employment or any benefit, or may otherwise result in adverse employment action, the same specimen shall be submitted to a clinical laboratory licensed under ORS 438.110 or 438.150, or certified under the **Clinical Laboratory Improvement Amendments of 1988, Public Law 100-578**, **42 .U.S.C. 201 and 263a** for that testing, or an equivalent out of state laboratory and the presence of a substance of abuse confirmed, using a different analytical method, prior to the release of the on-site test result.

(6) Evidence of registration with the Division shall be posted at the entity location shown on the registration form and at each on-site facility.

(7) The annual fee for filing a registration form with the Division is $50 for each entity. The fee cycle shall be January 1 through December 31, beginning 1998.

(8) All monies received by the Division for the registration of SOA entities shall be credited to the Division account and shall be used for payment of the expenses of the Division in administering OAR 333-024-0365.

(9) A list of registered entities is available, upon request, from the Division.

(10) SOA entities may examine specimens submitted by persons other than medical personnel and shall report the result of any SOA test to the person or company who requested the test except as indicated in number (11) of this rule.

(11) A copy of the SOA test results must be provided to the employee or pre-employee from whom the specimen was collected, after the employee or pre-employee submits a written request and proof of identity to the registered SOA entity.

(a) When a written request is given to the SOA entity in person:

(A) The employee or pre-employee must present two proofs of identity to the registered SOA entity, which must include one of the following picture identification cards: state driver's license, state identification card, passport or a resident alien card from the U.S. Department of Immigration and Naturalization Service.

(B) The employee or pre-employee must sign and date a form for release of laboratory records.

(b) When a written request for SOA test results is received by mail:

(A) The request must be accompanied by a signed and dated form for release of laboratory test results and a notarized statement of the employee's or pre-employee's identity and mailing address.

(B) The laboratory will make a copy of the pertinent SOA test results and send this copy by registered or certified mail, or other bonded courier that would assure the confidentiality of the results, to the address requested by the notarized statement.

(C) A copy of the signed release form and picture identification or the notarized statement, shall be maintained by the registered SOA entity for two years.

Stat. Auth.: ORS 438.435
Stats. Implemented: ORS 438.435
Hist.: HD 13-1997, f. & cert. ef. 10-16-97; OHD 10-1999(Temp), f. & cert. ef. 11-26-99 thru 2-22-00; Administrative correction 3-17-00; OHD 4-2000, f. & cert. ef. 4-27-00; OHD 9-2000, f. & cert. ef. 11-3-00

Health Screen Testing

333-024-0370
Purpose

OAR 333-024-0370 through 333-024-0400 are for the purpose of carrying out ORS 438.010(8); 438.060; 438.130(2); 438.150(5), (6) and (7). The purpose of the rules is to regulate the quality of health screen testing and to govern the issuance of permits to perform this type of testing.

Stat. Auth.: ORS 438.010(10), 438.060, 438.130(2), 438.150(5), (6) & (7)
Stats. Implemented: ORS 438.060, 438.130, 438.150 & 438.310
Hist.: HD 16-1990, f. & cert. ef. 6-15-90; OHD 9-2000, f. & cert. ef. 11-3-00

333-024-0375
Definitions

Except as provided in this section, definitions in OAR 333-024-0010 are applicable to OAR 333-024-0370 through 333-024-0400. Additionally:

(1) "Clinician" means a nurse practitioner licensed and certified by the Oregon State Board of Nursing, or a physician assistant licensed by the Board of Medical Examiners for the State of Oregon.

(2) "Health Screen Testing" means tests performed without a physician's or clinicians's order for the purpose of identifying health risks, providing health information, and referring the person being tested to medical care.

(3) "Health Screen Testing Service" means a service providing health screen testing.

(4) "Health Screen Testing Site" means the permanent location, temporary site or mobile vehicle where health screen testing is performed.

(5) "Human Chorionic Gonadotropin (HCG)" means a hormone produced by the placenta which appears in serum and urine and may be an indication of pregnancy.

(6) "Operator" means the person (e.g., individual, corporation, political subdivision, etc.) which operates the health screen testing service.

(7) "Person" includes individuals, corporations, associations, firms, partnerships and joint stock companies.

(8) "Pertinent Laboratory Experience" means the activity of performing laboratory testing or directing the performance of testing in human clinical chemistry.

(9) "Site Day" means the 24-hour period during which, either all or part of the time, testing is performed at a specific location.

Stat. Auth.: ORS 438.010(10), 438.060, 438.130(2), 438.150(5), (6) & (7)
Stats. Implemented: ORS 438.010, 438.060, 438.130 & 438.150
Hist.: HD 16-1990, f. & cert. ef. 6-15-90; HD 6-1995, f. & cert. ef. 9-13-95; OHD 9-2000, f. & cert. ef. 11-3-00

333-024-0380
Permits

(1) Any person who operates a health screen testing service must obtain a permit from the Division.

(2) OAR 333-024-0370 through 333-024-0400 apply to all health screen testing services and their personnel within the State of Oregon except:

(a) Health screen testing services operated by the United States Government;

(b) Health screen testing performed in a physician's, or clinician's office for the purpose of diagnosis and treatment of their own patients;

(c) Health screen testing provided by an employer to employees if such employer contracts for the testingthrough a licensed physician, a clinical laboratory or a hospital, which is a health screen testing permittee of the Division;

(d) Screening provided by blood banks solely for assuring blood donor suitability;

(e) Health screen testing provided by local health departments; and

(f) Testing by grantee agencies for the purpose of establishing eligibility for programs administered by Oregon Health Authority, Public Health Division.

(3) All out-of-state laboratories performing health screen testing services in Oregon must obtain a permit and meet requirements of OAR 333-024-0370 through 333-024-0400.

(4) The Division will, upon application and payment of the required fee, issue and renew permits to the operators of health screen testing services who demonstrate to the satisfaction of the Division that:

(a) The health screen testing service is equipped to perform within the scope of its permit; and

(b) The health screen testing service meets the rules of the Division for quality assurance procedures, proficiency testing, personnel qualification and standards of counseling and referral of persons being served, as more particularly set out in OAR 333-024-0370 through 333-024-0400.

(5) The permit authorizes the operation of the health screen testing service at those health screen testing sites identified in the application and at those sites identified in compliance with OAR 333-024-0385.

(6) The health screen testing service must have a permanent location in Oregon where the Division may review records, policies and testing procedures. The permit shall be kept at the permanent location. A copy of the permit shall be displayed at each testing site.

(7) A clinical laboratory certified under the **Clinical Laboratory Improvement Amendments of 1988 Code of Federal Regulations**, **Part 493 — Laboratory Requirements**, must meet the requirements of 333-024-0370 through 333-024-0400 for health screen testing, and pay the fee as required in (10)(c) of this rule, in order to perform testing in Oregon without a physician's or clinician's order.

(8) All health screen testing performed outside of a licensed clinical laboratory must have a permit, with the exception of those who qualify for exemption under section (2) of this rule.

(9) Unless sooner suspended or revoked, all permit(s) issued under this section expire on June 30 of even numbered years.

(10) Requirements for permit application and renewal are as follows:

(a) Beginning on and after January 1, 2000, the application for a permit to operate a health screen testing service shall be received by the Division at least 45 days prior to initial testing;

(b) The application for a permit shall be made on forms provided by the Division and shall be executed by the operator or authorized representative of the operator of the health screen testing service. The application shall contain the name(s) of the operator, and officers if applicable, of the health screen testing service, the director, the permanent location, health screen testing sites then known and other information as the Division may require;

(c) Health screen testing services must pay a biennial, nonrefundable permit fee of $150; and

(d) The health screen testing service must notify the Division of a change in owner, name or address of the permanent location within 30 days of the change.

(11) Permits may be suspended or revoked if the Division finds after hearing in accordance with ORS Chapter 183 for contested cases that:

(a) The facts represented to and relied upon by the Division in issuing the permit are other than represented and relied on;

(b) The required fee has not been paid; or

(c) The operator or director of the health screen testing service has violated any provision of OAR 333-024-0375 through 333-024-0400.

(12) The health screen testing service must also be in compliance with requirements of the **Clinical Laboratory Improvement Amendments of 1988**, **42 Code of Federal Regulations**, **Part 493 — Laboratory Requirements**.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 438.010(10), 438.060, 438.130(2) & 438.150(5), (6) & (7) & 341, 1999 OL
Stats. Implemented: ORS 438.010, 438.050, 438.055, 438.060, 438.130 & 438.150
Hist.: HD 16-1990, f. & cert. ef. 6-15-90; HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95; OHD 5-1999, f. & cert. ef. 7-30-99; OHD 9-2000, f. & cert. ef. 11-3-00

333-024-0385
Testing Site Schedule

The health screen testing service shall, in writing, notify the Oregon Health Authority, Oregon State Public Health Laboratory (OSPHL) of the proposed testing site schedule. The schedule must be received at the OSPHL, at least 15 days prior to testing at each site. All changes and cancellations regarding this schedule must be reported to the OSPHL prior to testing date.

Stat. Auth.: ORS 438.010(10), 438.060, 438.130(2), 438.150(5), (6) & (7)
Stats. Implemented: ORS 438.150
Hist.: HD 16-1990, f. & cert. ef. 6-15-90; HD 20-1994, f. & cert. ef. 7-20-94

333-024-0390
Personnel Qualifications and Responsibilities

(1) Each health screen testing service shall have a director who shall meet at least one of the following qualifications:

(a) Is a Medical Doctor (MD) or a Doctor of Osteopathy (DO) licensed to practice in Oregon and has one or more years of pertinent clinical laboratory experience;

(b) Has an earned Doctor of Science (ScD) or Doctor of Public Health (DrPH) or Doctor of Philosophy (PhD) degree in chemistry, biochemistry, or other closely related science from an accredited institution, and has one or more years of pertinent clinical laboratory experience;

(c) Has an earned Master of Science degree in medical technology, chemistry, biochemistry, or other closely related science from an accredited institution, and has two or more years of pertinent clinical laboratory experience;

(d) Has a Bachelor of Science, Bachelor of Technology, or Bachelor of Arts degree in Medical Technology, Chemistry, or Biochemistry, from an accredited institution, or is a licensed phar-

macist, and has four or more years of pertinent clinical laboratory experience; or

(e) Has performed the duties of Director of a health screen testing service for at least six site days during the 12 months prior to January 1, 1990.

(2) The Director of a health screen testing service shall be responsible for the quality of the work. This shall include, but not be limited to:

(a) Monthly review and documentation of quality control data and instrument maintenance;

(b) The review and documentation of all external proficiency testing, if applicable;

(c) Review and sign procedure manuals and relevant texts initially, and also whenever there is a new procedure, change in method or policy;

(d) Validation of new procedures prior to reporting test results;

(e) Assurance that personnel have received the training in the tests they perform. This shall include documentation of:

(A) Procedure Manual review;

(B) Collection techniques;

(C) Observation and performance of test procedures;

(D) Calibration, quality control, and routine maintenance of equipment;

(E) Waste disposal;

(F) Infection control;

(G) Emergency procedures;

(H) Methods to maintain patient confidentiality;

(I) Patient counseling; and

(J) Proficiency testing.

(f) Assurance that each person tested receives counseling and referral.

(3) Persons wishing to qualify as Director under subsection (1)(e) of this rule must apply to the Division by December 31, 1990.

(4) The laboratory director may direct no more than a total of five laboratories.

(5) Moderate complexity testing requires a technical and clinical consultant as defined in OAR 333-024-0023(1).

(a) A director qualifying under OAR 333-024-0022(1)(a), (b), or (c) may act as the technical consultant.

(b) A director qualifying under OAR 333-024-0022(1)(a) may act as the clinical consultant.

(6) Technical and clinical consultants must fulfill the responsibilities listed in OAR 333-024-0023(1).

(7) All testing personnel must have at least an academic high school diploma or equivalent.

Stat. Auth.: ORS 438.010(10), 438.060, 438.130(2), 438.150(5), (6) & (7)
Stats. Implemented: ORS 438.150
Hist.: HD 16-1990, f. & cert. ef. 6-15-90; HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95; OHD 9-2000, f. & cert. ef. 11-3-00

333-024-0395
Tests Performed

(1) The health screening testing service may perform only test procedures of waived or moderate complexity, as defined in OAR 333-024-010(24) and (16), from the following list of allowed tests.

(a) Blood hemoglobin;

(b) Packed red cell volume;

(c) Total cholesterol;

(d) Blood glucose;

(e) Blood in feces;

(f) Human chorionic gonadotropin;

(g) High density lipoprotein cholesterol. If the test is performed outside of a licensed clinical laboratory, only procedures not requiring a pre-precipitation step may be used;

(h) Triglyceride, only after an individual has fasted for 12 to 16 hours;

(i) Low density lipoprotein cholesterol by automated calculation using the Friedenwald equation.

(2) Permitted or licensed health screen testing services may perform testing defined in OAR 333-024-0395(1) at the patient's request, without an order from a physician or clinician.

Stat. Auth.: ORS 438.010(10), 438.060, 438.130(2), 438.150(5), (6) & (7)
Stats. Implemented: ORS 438.150
Hist.: HD 16-1990, f. & cert. ef. 6-15-90; HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95; OHD 20-2001, f. & cert. ef. 9-14-01

333-024-0400
Quality Assurance

Quality Assurance shall be comprised of Internal Quality Control, Tests Reports and Records, Quality Assurance Activities, Safety, External Quality Control, Counseling and Referral:

(1) Internal Quality Control:

(a) Documentation of training of testing personnel as specified in OAR 333-024-0390(2)(e) shall be kept on file at the permanent location and made available to the Authority at the health screen testing site;

(b) Laboratory procedure manuals and relevant reference materials for current screening methods shall be available for the use of the personnel at the health screen testing site and permanent location and include:

(A) Specimen collection requirements;

(B) Specimen labeling requirements;

(C) Specimen preservation requirements;

(D) Principle and instructions for test performance;

(E) Quality control requirements, including criteria for reporting tests;

(F) Equipment calibration and maintenance procedures;

(G) Normal ranges and test limitations.

(c) Procedure manuals shall be reviewed by the Director;

(d) Performance of each instrument shall be validated according to the manufacturer's specification at each new site;

(e) At each site, standards or controls shall be run which cover the range of expected results and be included at least once per day of use per instrument, per each reagent lot in use, unless the instrument is not moved, in which case it may qualify for external controls with each lot shipment of reagent cartridges per manufacturer's instructions;

(f) When control values are outside the established acceptable range, patient test results shall not be reported;

(g) The following shall be clearly stated and recorded: limits for controls; correction action taken when analyses are outside control limits, and the values for the standards;

(h) For each screening test, data shall be recorded and available to document confirmation of accuracy and precision at least once every six months for each instrument;

(i) Instrument maintenance, reagent storage, and test performance shall be performed according to manufacturer's instructions and recommendations;

(j) Records shall be recorded and retained at each site, with each instrument, for six site days, then transferred to the permanent location for a period of at least two years for:

(A) Client results;

(B) Instrument performance and calibration if applicable;

(C) Quality control; and

(D) Preventive maintenance.

(k) If an instrument is borrowed, the testing permittee shall have the following information (for the past six site days) on each instrument:

(A) Instrument performance to include, but not be limited to, wavelength verification, linearity, and calibration, if applicable;

(B) Quality control; and

(C) Preventive maintenance.

(l) All reagents and solutions shall be labeled to indicate identity, preparation date, lot number, expiration date, and storage conditions as appropriate. No reagents or solutions may be used beyond their expiration date;

(m) All quality control and equipment maintenance records shall be reviewed by the Director each month of operation;

(2) Test reports and records shall include:

(a) Name and address of health screen testing service;

(b) Patient name and results of tests performed;
(c) Date test performed;
(d) Expected ranges;
(e) Initials of individual performing tests;
(f) If indicated, fasting or non-fasting;
(g) Documentation of referral to a licensed physician or clinician for counseling per section (6) of this rule if results are outside expected normal ranges;
(h) Health Screen Testing services must maintain records of patient name, address and test values for at least 2 years;
(i) Health Screen Testing laboratories performing moderate complexity testing must comply with the rules in OAR 333-024-0026(12) & (13) and 333-024-0035(1) and (2).
(3) Quality assurance activities:
(a) If the laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.
(b) If a laboratory performs tests that are not included in an approved proficiency testing program, the laboratory must have a system for verifying the accuracy of its test results at least twice a year.
(c) The health screen testing service shall establish a quality assurance plan and monitors; and document quality assurance activities for test reporting and referral, quality control assessment and annual personnel competency.
(d) Any health screen testing service which tests for triglycerides must clearly display at the testing site a notice that triglyceride testing can only be performed after an individual has fasted for 12 to 16 hours.
(4) Safety: Permitted health screen testing services shall assure that:
(a) Eating, drinking, smoking, or applying cosmetics are prohibited at the bench where specimen collection and sample testing is performed;
(b) Laboratory coats or other protective clothing are worn by health screen testing personnel;
(c) Skin puncture sites are cleansed with an appropriate disinfectant;
(d) Gloves designed for medical use for bloodborne pathogen protection are worn during the skin puncture and changed between clients;
(e) Gloves designed for medical use for bloodborne pathogen protection are worn during specimen handling and testing;
(f) Used lancets, needles and blood tubes are disposed of in impervious biohazard labeled containers;
(g) Other potentially infectious materials are disposed of in a biohazard labeled container; refer to the infectious waste rules under 333-018-0040 through 333-018-0070;
(h) Electrical equipment is maintained in a safe condition with regards to shock and fire hazards;
(i) Work surfaces are disinfected with a virucidal reagent after each blood spill, and prior to and after each day of testing.
(5) External Quality Control:
(a) Permitted health screen testing services shall:
(A) Assure proficiency testing is performed on each moderate or high complexity regulated analyte listed in the **Clinical Laboratory Improvement Amendments of 1988 (CLIA)**, **Subpart I**, available on request from the Authority.
(B) Meet the proficiency testing requirements as described in **CLIA 88**, **42 CFR**, **Part 493**, **Subpart H,** available on request from the Authority.
(C) Analyze test samples submitted by the Authority prior to, during, or subsequent to inspection if requested by the Authority and achieve a score of at least 80 percent.
(D) Notify the Authority within six months if the analysis of a test has been discontinued or added to patient testing.
(E) Notify the Authority of change of director, owner, name, and address of the permanent location within 30 days of the change.
(b) Surveys for compliance will be performed either onsite or as paper surveys and the entity will be required to submit documentation to the Authority that quality control and quality assurance activities and test records meet this rule. Onsite inspections may be conducted by representatives of the Authority at reasonable times during the health screen testing service's normal business hours without advance notice. The representative shall review the personnel policies, procedures, staff qualifications/training, equipment records, quality control, reports, specimen handling and waste disposal, as related to health screen testing activities.
(c) Additional inspections may be performed by the Authority or HCFA without notice to verify correction of deficiencies, investigate complaints, review unsatisfactory proficiency testing, perform validation surveys, verify personnel qualifications or other monitoring of compliance with OAR 333-024-0370 through 333-024-0400.
(6) Counseling and Referral: The health screen testing service shall provide or contract for counseling and medical referral policies for each person tested and shall include:
(a) The ranges of results expected for that test;
(b) The value or test range that is recommended nationally for each test performed;
(c) A list of possible health risks associated with abnormal results;
(d) The recommended action which a person should follow if the test results are outside the expected value or range; and
(e) Procedures and follow-up for critical values.

Stat. Auth.: ORS 438.010(10), 438.060, 438.130(2), 438.150(5), (6) & (7)
Stats. Implemented: ORS 438.150
Hist.: HD 16-1990, f. & cert. ef. 6-15-90; HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f & cert. ef. 9-13-95; OHD 9-2000, f. & cert. ef. 11-3-00; OHD 20-2001, f. & cert. ef. 9-14-01

DIVISION 25

GENETIC INFORMATION AND PRIVACY

333-025-0100
Definitions

As used in these rules:
(1) "Anonymous research" means scientific or medical genetic research conducted in such a manner that any DNA sample or genetic information used in the research is unidentified. "Anonymous research" does not include research conducted in such a manner that the identity of such an individual, or the identity of the individual's blood relatives, can be determined by use of a code, encryption key or other means of linking the information to a specific individual.
(2) "Biological sample" means any human biological specimen that may be used as a DNA sample.
(3) "Blanket informed consent" means that the individual has consented to the use of that individual's DNA sample or health information for any future research, but has not been provided with a description of or consented to the use of the sample in genetic research or any specific genetic research project.
(4) "Blood relative" means a person who is:
(a) Related by blood to an individual; and
(b) A parent, sibling, son, daughter, grandparent, grandchild, aunt, uncle, first cousin, niece or nephew of the individual.
(5) "Clinical" means relating to or obtained through the actual observation, diagnosis, or treatment of patients and not through research.
(6) "Coded" means identifiable only through the use of a system of encryption that links a DNA sample or genetic information to an individual or the individual's blood relative. A coded DNA sample or genetic information is supplied by a repository to an investigator with a system of encryption.
(7) "Covered entity," as applied to a health care provider, means a health care provider that transmits any health information in electronic form to carry out financial or administrative activities in connection with a transaction covered by ORS 192.518 to 192.524.

(8) "Deidentified" means lacking, or having had removed, the identifiers or system of encryption that would make it possible for a person to link a biological sample or health information to an individual or the individual's blood relative, and neither the investigator nor the repository can reconstruct the identity of the individual from whom the sample or information was obtained. DNA samples and genetic information will be considered deidentified only if they meet the following standards provided in the Federal Privacy Rule:

(a) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:

(A) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and

(B) Documents the methods and results of the analysis that justify such determination; or

(b) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

(A) Names;

(B) All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

(i) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

(ii) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

(D) Telephone numbers;

(E) Fax numbers;

(F) Electronic mail addresses;

(G) Social security numbers;

(H) Medical record numbers;

(I) Health plan beneficiary numbers;

(J) Account numbers;

(K) Certificate/license numbers;

(L) Vehicle identifiers and serial numbers, including license plate numbers;

(M) Device identifiers and serial numbers;

(N) Web Universal Resource Locators (URLs);

(O) Internet Protocol (IP) address numbers;

(P) Biometric identifiers, including finger and voice prints;

(Q) Full face photographic images and any comparable images; and

(R) Any other unique identifying number, characteristic, or code; and

(c) The investigator and repository do not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

(9) "Direct provider" means a health care provider that is not an indirect treatment provider.

(10) "Disclose" means to release, publish, or otherwise make known to a third party a biological sample or health information.

(11) "DNA" means deoxyribonucleic acid.

(12) "DNA sample" means any human biological specimen that is obtained or retained for the purpose of extracting and analyzing the individual's DNA to perform a genetic test. "DNA sample" includes DNA extracted from the specimen.

(13) "Federal Common Rule" means the Federal Policy for the Protection of Human Subjects, as adopted by the following federal agencies and as revised through November 13, 2001: 7 CFR Part 1c, Department of Agriculture; 10 CFR Part 745, Department of Energy; 14 CFR Part 1230, National Aeronautics and Space Administration; 15 CFR Part 27, Department of Commerce; 16 CFR Part 1028, Consumer Product Safety Commission; 21 CFR Parts 50 and 56, Food and Drug Administration; 22 CFR Part 225, International Development Cooperation Agency, Agency for International Development; 24 CFR Part 60, Department of Housing and Urban Development; 28 CFR Part 46, Department of Justice; 32 CFR Part 219, Department of Defense; 34 CFR Part 97, Department of Education; 38 CFR Part 16, Department of Veterans Affairs; 40 CFR Part 26, Environmental Protection Agency; 45 CFR Part 690, National Science Foundation; 45 CFR Part 46, Department of Health and Human Services; 49 CFR Part 11, Department of Transportation. In the case of research not subject to federal regulation under one of these provisions, "Federal Common Rule" means 45 CFR Part 46.

(14) "Federal Privacy Rule" means the federal regulations under the Health Insurance Portability and Accountability Act, 45 CFR parts 160 and 164.

(15) "Genetic characteristic" includes a gene, chromosome or alteration thereof that may be tested to determine the existence or risk of a disease, disorder, trait, propensity or syndrome or to identify an individual or a blood relative. "Genetic characteristic" does not include family history or a genetically transmitted characteristic whose existence or identity is determined other than through a genetic test.

(16) "Genetic information" means information about an individual or the individual's blood relatives obtained from a genetic test.

(17) "Genetic research" means research using human DNA samples, genetic testing or genetic information.

(18) "Genetic test" means a test for determining the presence or absence of genetic characteristics in a human individual or the individual's blood relatives, including tests of nucleic acids such as DNA, RNA, and mitochondrial DNA, chromosomes or proteins in order to diagnose or determine a genetic characteristic.

(19) "Health care facility" means a hospital, long term care facility, an ambulatory surgical center, a freestanding birthing center or an outpatient dialysis center. "Health care facility" does not mean:

(a) An establishment furnishing residential care or treatment not meeting federal intermediate care standards, not following a primarily medical model of treatment, prohibited from admitting persons requiring 24-hour nursing care and licensed or approved under the rules of Oregon Health Authority, Department of Human Services or the Department of Corrections; or

(b) An establishment furnishing primarily domiciliary care.

(20) "Health care provider" has the meaning given in ORS 192.519(5).

(21) "Health information" means any information in any form or medium that:

(a) Is created or received by a health care provider, a state health plan, a health insurer, a healthcare clearinghouse, a public health authority, an employer, a life insurer, a school, or a university; and

(b) Relates to:

(A) The past, present or future physical or mental health or condition of an individual;

(B) The provision of health care to an individual; or

(C) The past, present or future payment for the provision of health care to an individual.

(22) "Human biological specimen" means any material derived from human subjects, such as blood, urine, tissues, organs, hair, nail clippings, or any other cells or fluids, whether collected for research purposes or as residual specimens from diagnostic, therapeutic, or surgical procedures.

(23) "Identifiable" or "Individually identifiable" means capable of being linked to the individual or a blood relative of the

individual from whom the biological sample or health information was obtained, including demographic information that identifies the individual, or for which there is a reasonable basis to believe the information can be used to identify an individual.

(24) "Identified" means having an identifier that links, or that could readily allow the recipient to link, a DNA sample or genetic information directly to the individual or a blood relative of the individual from whom the sample or information was obtained.

(25) "Identifier" means data elements that directly link a DNA sample or genetic information to the individual or a blood relative of the individual from whom the sample or information was obtained. Identifiers include, but are not limited to, names, telephone numbers, electronic mail addresses, Social Security numbers, driver license numbers and fingerprints.

(26) "Indirect provider" means a health care provider having a relationship with an individual in which:

(a) The health care provider delivers health care to the individual based on the orders of another health care provider; and

(b) The health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the individual.

(27) "Institutional Review Board" or "IRB" means an Institutional Review Board established in accord with and for the purposes expressed in the Federal Common Rule.

(28) "IRB approval" means the determination of the IRB that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other institutional and Federal and State requirements.

(29) "Limited data set" means protected health information that, in accordance with the Federal Privacy Rule, excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

(a) Names;

(b) Postal address information, other than town or city, state, and zip code;

(c) Telephone numbers;

(d) Fax numbers;

(e) Electronic mail addresses;

(f) Social security numbers;

(g) Medical record numbers;

(h) Health plan beneficiary numbers;

(i) Account numbers;

(j) Certificate/license numbers;

(k) Vehicle identifiers and serial numbers, including license plate numbers;

(l) Device identifiers and serial numbers;

(m) Web Universal Resource Locators (URLs);

(n) Internet Protocol (IP) address numbers;

(o) Biometric identifiers, including finger and voice prints; and

(p) Full face photographic images and any comparable images.

(30) "Obtain genetic information" means performing or getting the results of a genetic test.

(31) "Opt-out statement" means a written expression of an individual's desire to withhold his or her own biological specimen or clinical individually identifiable health information from use and disclosure for the purpose of anonymous research or coded research.

(32) "Person" includes but is not limited to any health care provider, health care facility, clinical laboratory, blood or sperm bank, insurer, insurance agent, insurance-support organization, as defined in ORS 746.600, government agency, employer, research organization or agent of any of them.

(33) "Personal representative" includes but is not limited to:

(a) A person appointed as a guardian under ORS 125.305, 419B.370, 419C.481 or 419C.555 with authority to make medical and health care decisions;

(b) A person appointed as a health care representative under ORS 127.505 to 127.660 or a representative under ORS 127.700 to 127.737 to make health care decisions or mental health treatment decisions; and

(c) A person appointed as a personal representative under ORS Chapter 113.

(34) "Recontact" means disclosure of genetic research findings to a research subject or the subject's physician through use of personal identifiers.

(35) "Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.

(36) "Retain a DNA sample" means the act of storing the DNA sample.

(37) "Retain genetic information" means making a record of the genetic information.

(38) "Specific informed consent for genetic research" means the individual or the individual's representative has consented to the use of that individual's DNA sample or genetic information for genetic research or for a specified genetic research project.

(39) "Unidentified" means deidentified or not identifiable.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 192.531

Stats. Implemented: ORS 192.531

Hist.: OHD 14-2002, f. & cert. ef. 9-27-02; PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04; PH 9-2004, f. & cert. ef. 3-23-04; PH 21-2005, f. 12-30-05, cert. ef. 1-1-06; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 11-2011, f. & cert. ef. 10-27-11

Research Involving Human Genetic Materials

333-025-0105
Scope

(1) OAR 333-025-0100 to 0165 apply to all genetic research subject to the law of the State of Oregon.

(2) All genetic research must comply with the applicable standards set forth in the Federal Common Rule. Additional protections for subjects of research are authorized by ORS 192.531 et seq. and these rules. These rules set state standards that are in addition to, and not intended to alter, any requirements under the Federal Common Rule or the Federal Privacy Rule.

Stat. Auth.: ORS 192.531–192.549

Stats. Implemented: ORS 192.531–192.549

Hist.: OHD 14-2002, f. & cert. ef. 9-27-02; PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04; PH 9-2004, f. & cert. ef. 3-23-04; PH 21-2005, f. 12-30-05, cert. ef. 1-1-06

333-025-0110
Institutional Review Boards (IRBs) and Approval for Research

(1) An IRB must conform to the organizational and operational standards contained in the Federal Common Rule.

(2) All proposed genetic research, including anonymous research, or research otherwise exempt from IRB approval, must first be submitted to an IRB for explicit prior approval or an explicit determination that the research is anonymous or otherwise exempt.

(3) A researcher must disclose to the IRB the intended use of human DNA samples, genetic tests or other genetic information for every proposed research project, including anonymous or otherwise exempt research.

(4) A researcher must follow the requirements of OAR 333-025-0115 and 333-025-0120 and provide assurances to the IRB that these requirements have been met.

Stat. Auth.: ORS 192.547

Stats. Implemented: ORS 192.533 & 192.547

Hist.: OHD 14-2002, f. & cert. ef. 9-27-02; PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04; PH 9-2004, f. & cert ef 3-23-04; PH 21-2005, f. 12-30-05, cert. ef. 1-1-06

333-025-0115
Informed Consent for Non-Exempt Genetic Research

(1) Except as provided in OAR 333-025-0120, a researcher may use an identified human biological sample or genetic information obtained on or after June 25, 2001, for genetic research only with specific informed consent for genetic research.

(2) Except as provided in OAR 333-025-0120, a researcher may use an identified human biological sample or genetic informa-

tion obtained prior to June 25, 2001, for genetic research with blanket informed consent or specific informed consent for genetic research.

Stat. Auth.: ORS 192.535 & 192.547
Stats. Implemented: ORS 192.535 & 192.547
Hist.: OHD 14-2002, f. & cert. ef. 9-27-02; PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04; PH 9-2004, f. & cert. ef 3-23-04; PH 21-2005, f. 12-30-05, cert. ef. 1-1-06

333-025-0120
Anonymous, Coded, or Exempt Genetic Research

(1) Any person proposing to conduct genetic research that is thought to be anonymous shall obtain from an IRB, prior to conducting such research, a determination that the research is anonymous. The person shall furnish the IRB with assurances that the criteria in (3) below are met.

(2) Any person proposing to conduct research that is thought to be exempt from review shall obtain an IRB determination that the research is exempt from review under 45 CFR 46.101(b) or other applicable exemption from the Federal Common Rule.

(3) A human biological sample or clinical individually identifiable health information may be used in anonymous or coded genetic research only if prior to the time the research is conducted:

(a) The subject has granted informed consent for the specific anonymous or coded research project; or

(b) The subject has granted consent for genetic research generally; or

(c) The subject was notified in accordance with OAR 333-025-0165 that the individual's sample or information may be used for anonymous or coded research, and before the sample or information was obtained, the subject did not request that the sample or information be withheld from anonymous or coded research; or

(d) The subject was not notified, due to emergency circumstances, in accordance with OAR 333-025-0165, that the individual's sample or information may be used for anonymous research or coded research, and the individual died before receiving the notice; or

(e) The subject has granted blanket informed consent and the sample or information was obtained before June 25, 2001; or

(f) The subject was deceased when the sample or information was obtained; or

(g) An Institutional Review Board:

(A) Waives or alters the consent requirements pursuant to the Federal Common Rule; and

(B) Waives authorization pursuant to the Federal Privacy Rule.

(4) In addition to the requirements of section (3) of this rule, genetic research in which the DNA sample or genetic information is coded shall satisfy the following requirements:

(a) The research has been approved by an Institutional Review Board after disclosure by the investigator to the board of risks associated with the coding;

(b) The code is:

(A) Not derived from individual identifiers;

(B) Kept securely and separately from the DNA samples and genetic information; and

(C) Not accessible to the investigator unless specifically approved by the Institutional Review Board.

(c) Data is stored securely in password protected electronic files or by other means with access limited to necessary personnel;

(d) The data is limited to elements required for analysis and is a limited data set; and

(e) The investigator is a party to a data use agreement with any limited data set recipient. The data use agreement must:

(A) Establish the permitted uses and disclosures of such information by the limited data set recipient, limited to research uses. The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that would violate the requirements of the Federal Privacy Rule, if done by the investigator;

(B) Establish who is permitted to use or receive the limited data set; and

(C) Provide that the limited data set recipient will:

(i) Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;

(ii) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;

(iii) Report to the investigator any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;

(iv) Ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and

(v) Not identify the information or contact the individuals.

Stat. Auth.: ORS 192.537 & 192.547
Stats. Implemented: ORS 192.535, 192.537 & 192.547
Hist.: OHD 14-2002, f. & cert. ef. 9-27-02; PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04; PH 9-2004, f. & cert. ef 3-23-04; PH 21-2005, f. 12-30-05, cert. ef. 1-1-06

333-025-0125
IRB Registry

(1) The Oregon Health Authority, Public Health Division shall establish and maintain a registry of IRBs that review research conducted in Oregon or that involves research subjects living in Oregon.

(2) By October 1, 2002, each existing IRB must register with Oregon Health Authority, Public Health Division on registration forms provided by the Authority.

(3) The Authority will update its registry annually. Each IRB will be required to renew its registration each year, or sooner if there exists material changes in the terms of registration.

Stat. Auth.: ORS 192.547
Stats. Implemented: ORS 192.547
Hist.: OHD 14-2002, f. & cert. ef. 9-27-02; PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04; PH 9-2004, f. & cert. ef 3-23-04

333-025-0130
Recontact

(1) Recontact of a research subject should not occur unless the subject was informed during the initial consent process that recontact may occur under specified circumstances and with this understanding, the research subject consented to participate in the study.

(2) If recontact of subjects is contemplated, the researcher must provide research protocols to the IRB describing the circumstances that might lead to recontact, as well as a plan for managing the process. If a subject declines the possibility of recontact, the researcher may not recontact the subject.

(3) Notwithstanding (1) above, in order to consider recontact in a situation where recontact was not contemplated and therefore not addressed in research protocols a researcher must seek approval from the IRB for re-contact and must assure the following conditions exist:

(a) The findings are scientifically valid and confirmed;

(b) The findings have significant implications for the subject's or the public's health; and

(c) A course of action to ameliorate or treat the subject's or the public's health concerns is readily available.

(4) Under conditions described in (3), the researcher shall determine and adhere to the expressed wishes and desires of the research subject in relation to disclosure of genetic information to that individual.

(5) When research results are disclosed to a subject, appropriate medical advice and referral must be provided.

(6) In all cases, a decision to recontact research subjects must have prior approval of the IRB.

Stat. Auth.: ORS 192.547
Stats. Implemented: ORS 192.547
Hist.: OHD 14-2002, f. & cert. ef. 9-27-02; PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04; PH 9-2004, f. & cert. ef 3-23-04

Obtaining Genetic Information for Identification of Deceased Individuals

333-025-0135
Information Concerning Deceased Individuals

(1) Anyone permitted by Oregon law to dispose of the body of a deceased individual or who is authorized by ORS 146.113 to 146.117 to submit the DNA sample of an unidentified deceased individual to a DNA diagnostic laboratory may obtain or retain genetic information for the purpose of identification of the deceased. After identification, relevant information concerning the death shall be submitted into the permanent medical record of the deceased.

(2) A DNA sample of or genetic information about a deceased individual may be used for medical diagnosis of blood relatives of the individual and for no other purpose except as otherwise authorized by law. A request to use a sample or information for such purpose may be made by:

(a) A representative designated by the decedent to act on the individual's behalf after death;

(b) The closest surviving blood relative of the decedent; or

(c) If there is more than one surviving blood relative of the same degree of relationship to the decedent, by the majority of the surviving closest blood relatives of the decedent.

(3) A DNA sample sent to a diagnostic laboratory for testing under Section (1) or (2) of this rule must be accompanied by an affidavit stating that the specific purpose for obtaining the DNA sample is to identify the deceased individual or is for medical diagnosis of blood relatives of the decedent, and for no other purpose.

(4) A person may use an individual's DNA sample or genetic information that is derived from a biological specimen or clinical individually identifiable health information for anonymous research or coded research, if the individual was deceased when the individual's biological specimen or clinical individually identifiable health information was obtained (OAR 333-025-0120).

Stat. Auth.: ORS 192.535, 192.537 & 192.539
Stats. Implemented: ORS 192.535, 192.537 & 192.539
Hist.: HD 1-1997, f. & cert. ef. 1-10-97; Renumbered from 333-024-0500 by OHD 14-2002, f. & cert. ef. 9-27-02; Renumbered from 333-024-0500 by PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04; Renumbered from 333-024-0500 by PH 9-2004, f. & cert. ef. 3-23-04; PH 21-2005, f. 12-30-05, cert. ef. 1-1-06

Informed Consent for Obtaining Genetic Information

333-025-0140
Informed Consent Procedures

(1) Unless exempted by ORS 192.535(1)(a)–(f), all persons collecting genetic information must conform to standards of informed consent as follows:

(a) Physicians licensed under ORS Chapter 677, and any other licensed health care providers or facilities, shall obtain informed consent according to ORS 677.097;

(b) Except as provided in OAR 333-025-0120, a person conducting research shall obtain informed consent according to the procedure given in OAR 333-025-0115; and

(c) If genetic information is collected in connection with an insurance transaction governed by ORS 746.135, informed consent will be conducted in the manner described by the Department of Consumer and Business Services under authority of ORS 746.135(1).

(2) For persons not described in (1) above, informed consent must be obtained using the form and process contained in Appendix 1 of these rules or a form which is substantively similar.

(3) Elements to be contained in a consent form for obtaining genetic information include:

(a) The name of the individual whose DNA sample is to be tested;

(b) The name of the individual, company, or organization requesting the genetic test for the purpose of obtaining genetic information;

(c) A statement signed by the individual whose DNA sample is to be tested indicating that he/she authorizes the genetic test; and

(d) A statement that specifies the purpose of the test and the genetic characteristic for which the DNA sample will be tested.

(4) Process for obtaining informed consent using the form contained in **Appendix 1** or a form that is substantively similar:

(a) Explain that the genetic test is voluntary;

(b) Inform the individual that he/she may choose not to have his/her DNA sample tested;

(c) Inform the individual that he/she has the option of withdrawing consent at any time;

(d) Explain the risks and benefits of having the genetic test, including:

(A) A description of the provisions of Oregon law pertaining to individual rights with regard to genetic information and the confidential nature of the genetic information;

(B) A statement of potential consequences with regard to insurability, employability, and social discrimination if the genetic test results or genetic information become known to others;

(C) The implications of both positive and negative test results; and

(D) The availability of support services, including genetic counseling.

(e) Inform the individual that it may be in his/her best interest to retain his/her DNA sample for future diagnostic testing, but that he/she has the right to have his/her DNA sample promptly destroyed after completion of the specific genetic test which was authorized;

(f) Inform the individual about the implications, including potential insurability, of authorizing disclosure to a third party payer that the genetic test was performed, and that he/she has the option of paying the cost of the genetic test out of pocket rather than filing an insurance claim;

(g) Ask the individual whether he/she has any further questions, and if so, provide the individual with the opportunity to ask questions and receive answers from either a genetic counselor or another person who is sufficiently knowledgeable to give accurate, understandable and complete answers to his/her questions;

(h) Request that the individual read, complete, sign and date the consent form; and

(i) Provide the individual with a copy of the completed form for his/her personal records.

[Forms and Appendices referenced are available from the agency.]
Stat. Auth.: ORS 192.535
Stats. Implemented: ORS 192.535
Hist.: HD 1-1997, f. & cert. ef. 1-10-97; Renumbered from 333-024-0510 by OHD 14-2002, f. & cert. ef. 9-27-02; Renumbered from 333-024-0510 by PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04; Renumbered from 333-024-0510 by PH 9-2004, f. & cert. ef 3-23-04; PH 21-2005, f. 12-30-05, cert. ef. 1-1-06

Retention of Genetic Information

333-025-0145
Retention for the Purpose of Identification of Deceased Individuals

(1) Any person who is permitted by Oregon law to dispose of the body of a deceased individual, or anyone who is authorized by ORS 146.113–117 may retain the genetic information obtained from an unidentified deceased individual's DNA sample without specific authorization for the purpose of identification of the deceased individual.

(2) Upon identification of the deceased individual, persons so authorized in Section (1) shall convey the deceased individual's genetic information to his/her permanent medical record.

Stat. Auth.: ORS 192.537 & 192.539
Stats. Implemented: ORS 192.537 & 192.539
Hist.: HD 1-1997, f. & cert. ef. 1-10-97; Renumbered from 333-024-0520 by OHD 14-2002, f. & cert. ef. 9-27-02; Renumbered from 333-024-0520 by PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04; Renumbered from 333-024-0520 by PH 9-2004, f. & cert. ef 3-23-04

333-025-0150
Retention for the Purpose of Testing to Benefit Blood Relatives of Deceased Individuals

Any person may retain the genetic information of a deceased individual indefinitely for the sole purpose of benefiting blood relatives of the deceased individual without specific authorization.

Stat. Auth.: ORS 192.535 & 192.537
Stats. Implemented: ORS 192.535 & 192.537
Hist.: HD 1-1997, f. & cert. ef. 1-10-97; Renumbered from 333-024-0530 by OHD 14-2002, f. & cert. ef. 9-27-02; Renumbered from 333-024-0530 by PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04; Renumbered from 333-024-0530 by PH 9-2004, f. & cert. ef 3-23-04

333-025-0155
Retention for the Purpose of Newborn Screening Procedures

The Oregon Health Authority may retain the blood samples of newborns collected for the control of metabolic diseases, as provided in ORS 433.285, for up to one year.

Stat. Auth.: ORS 433.285, 192.535 & 192.537
Stats. Implemented: ORS 192.535 & 192.537
Hist.: HD 1-1997, f. & cert. ef. 1-10-97; Renumbered from 333-024-0540 by OHD 14-2002, f. & cert. ef. 9-27-02; Renumbered from 333-024-0540 by PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04; Renumbered from 333-024-0540 by PH 9-2004, f. & cert. ef 3-23-04

Disclosure of Genetic Information

333-025-0160
Procedure for Authorization of Disclosure by the Tested Individual or the Tested Individual's Representative

Except as provided in ORS 192.539, and except for research disclosures authorized by an Institutional Review Board in accordance with these rules, any person shall be required to obtain specific authorization from the individual on whose sample a genetic test was conducted, or an individual's representative, to disclose genetic information, by completing the consent form specified in ORS 192.522, or a form that is substantively similar and by using the following procedure:

(1) Request that the tested individual, or his/her representative, read, sign and date the prescribed consent form; and

(2) Read, sign, and date the prescribed consent form on behalf of the individual or organization requesting the release of genetic information; and

(3) Provide the tested individual, or his/her representative, with a copy of the completed consent form for his/her personal records.

Stat. Auth.: ORS 192.539
Stats. Implemented: ORS 192.539
Hist.: HD 1-1997, f. & cert. ef. 1-10-97; Renumbered from 333-024-0550 by OHD 14-2002, f. & cert. ef. 9-27-02; Renumbered from 333-024-0550 by PH 16-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04; Renumbered from 333-024-0550 by PH 9-2004, f. & cert. ef 3-23-04; PH 21-2005, f. 12-30-05, cert. ef. 1-1-06

333-025-0165
Provider Notification and Opt Out

(1) A direct provider that is a covered entity and who obtains a biological specimen or clinical individually identifiable health information from an individual must:

(a) Notify the individual or his/her personal representative, in accordance with this rule, that the individual's biological specimen or clinical individually identifiable health information may be used or disclosed for anonymous or coded research; and

(b) Give the individual the opportunity to make an opt-out statement.

(2) Any health care provider that is not described in Section (1) of this rule may, but is not required to, furnish the notification and opportunity for an opt-out statement described in Section (1) of this rule.

(3) A health care provider described in Section (1) of this rule must provide notification no later than the time required for federal privacy notices by the Federal Privacy Rule for services rendered on or after July 1, 2006 (see 45 CFR 164.520).

(4) If a health care provider is required to provide notification pursuant to Section (1) of this rule, the health care provider must provide notification at least once per individual, regardless of how many times the provider obtains the individual's biological specimen or clinical individually identifiable health information.

(5) If a health care facility provides the notice pursuant to Section (1) of this rule, a health care provider providing care to patients in the health care facility is not required to provide an additional notice with respect to services provided in the facility.

(6) Notification may be delivered in a manner determined by the health care provider within the requirements of this rule, including but not limited to any manner permitted for the provision of the notice of privacy practices required under the Federal Privacy Rule.

(7) Notification must include:

(a) A place where the individual may mark to indicate the individual's opt-out statement;

(b) A general explanation of the meaning of anonymous and coded research;

(c) A statement describing that the biological specimen or clinical individually identifiable health information may be used at some undetermined point in the future without further notice to the individual;

(d) A statement that a refusal to allow use of biological specimens or clinical individually identifiable health information will not affect access to or provision of health care by the provider originally providing notice;

(e) A statement specifying that the individual retains the right to make or revoke an opt-out statement by submitting in writing such a request to the health care provider originally providing notice;

(f) A statement indicating that an opt-out statement will be valid from the date received by the health care provider;

(g) A prominent heading indicating the purpose of the notice; and

(h) The name, or title, and telephone number or other contact information of a person or office to contact for further information.

(8) If a health care provider is required to provide notification pursuant to Section (1) of this rule, notification may be, but is not required to be, provided using the form contained in Appendix 2 of these rules.

(9) Any health care provider described by Section (1) of this rule that receives an opt-out statement of an individual must, at the time of disclosure of a biological specimen or clinical individually identifiable health information, inform the indirect provider that is the intended recipient that the individual's biological specimen or clinical individually identifiable health information is subject to an opt out statement.

(a) Methods to inform the indirect provider may include, but shall not be limited to, marking or noting the biological specimen container or clinical individually identifiable health information as subject to an opt-out statement. The mark or notation may be in any form that can be understood by the intended recipient.

(b) If an opt-out statement is received after the completion of the first service delivery and within the first fourteen (14) days from the completion of the first service delivery, a health care provider is encouraged, but is not required, to make a good faith effort to inform the indirect health care provider of the opt-out statement.

(c) Any recipient of an individual's biological specimen or clinical individually identifiable health information from a health care provider described by Section (1) of this rule that is not informed of the individual's opt-out statement within fourteen (14) calendar days of receipt may presume that the individual has not made an opt-out statement.

(10) Any health care provider subject to Section (1) of this rule must have a process in place to demonstrate compliance with this rule.

[ED. NOTE: Forms and appendices referenced are available from the agency.]
Stat. Auth.: ORS 192.547
Stats. Implemented: ORS 192.531 - 192.549
Hist.: PH 21-2005, f. 12-30-05, cert. ef. 1-1-06

DIVISION 26

ENFORCEMENT OF PUBLIC HEALTH RULES

333-026-0030
Civil Penalties for Violations of OAR Chapter 333, Divisions 18 and 19

(1) A civil penalty may be imposed against a person or entity for a violation of any provision in OAR chapter 333, division 18 or 19, including but not limited to:

(a) Failing to report a reportable disease in accordance with OAR chapter 333, division 18;

(b) Reporting to work in a communicable stage of any restrictable disease in violation of OAR 333-019-0010 or 333-019-0046;

(c) Permitting a child to attend school in violation of OAR 333-019-0010;

(d) Failing to immunize an animal against rabies in accordance with OAR 333-019-0017;

(e) Failing to license a dog in accordance with OAR 333-019-0019;

(f) Failing to euthanize an animal in accordance with OAR 333-019-0024 or 333-019-0027;

(g) Euthanizing an animal or destroying the head of a mammal that has bitten a person without authorization under OAR 333-019-0024 from the local public health authority; and

(h) Failing to confine an animal in accordance with OAR 333-019-0027.

(2) Prior to issuing a notice of imposition of civil penalty, the Oregon Health Authority or the local public health authority shall send a written warning letter advising the person or entity that they are not in compliance with a rule in OAR chapter 333, division 18 or 19 and that continued noncompliance may result in the issuance of a notice of imposition of civil penalty. A person or entity's assertion that they did not receive the warning letter is not a defense to a notice of imposition of civil penalty.

(3) Civil penalties shall be imposed as follows:

(a) First violation: $100;

(b) Second violation: $200;

(c) Third or subsequent violation: $500.

(4) Each day a person or entity is out of compliance with a provision of OAR chapter 333, division 18 or 19 will be considered a new violation.

(5) A civil penalty may not exceed $500 a day per violation.

(6) A notice of imposition of civil penalty shall comply with ORS 183.745.

Stat. Auth.: ORS 431.262
Stats. Implemented: ORS 431.262 & 433.040
Hist.: PH 5-2010, f. & cert. ef. 3-11-10

DIVISION 27

HOME HEALTH AGENCIES

333-027-0000
Purpose

The purpose of these rules is to establish the standards for licensure of home health agencies.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.005 - 443.090
Hist.: HD 19-1987, f. 11-10-87, ef. 12-1-87; HD 22-1988, f. & cert. ef. 9-16-88; OHD 13-1998, f. & cert. ef. 11-6-98; PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0005
Definitions

The following definitions shall apply in OAR 333-027-0000 through 333-027-0190:

(1) "Admission" means acceptance of a patient for the provision of services by an agency.

(2) "Authority" means the Oregon Health Authority.

(3) "Agency" means Home Health Agency.

(4) "Branch Office" means a location or site from which a home health agency provides services to patients within a portion of the total geographic area served by the parent agency and does not exceed 60 miles from the parent agency.

(5) "Clinical Note" means a dated, written, and signed notation by a member of the home health agency team of a contact with the patient that describes care rendered, signs and symptoms, treatment and/or drugs given, patient's reaction, and any changes in patient's physical or mental condition.

(6) "Clinical Record" means all information and documentation pertaining to the care of a patient.

(7) "Division" means the Public Health Division of the Oregon Health Authority.

(8) "Governing Body" means the designated person(s) having ultimate responsibility for the home health agency.

(9) "Home Health Agency" means a public or private entity providing coordinated home health services on a home visiting basis.

(10) "Home Health Aide" means a person who is certified as a nursing assistant by the Oregon State Board of Nursing in accordance with OAR chapter 851, division 062 and who assists licensed nursing personnel in providing home health services.

(11) "Home Health Service" means items and services furnished to an individual by a home health agency, or by others under arrangement with such agency, on a visiting basis in a place of temporary or permanent residence used as the individual's home for the purpose of maintaining that individual at home.

(12) "Licensed Practical Nurse" means a person licensed as such by the Oregon State Board of Nursing in accordance with ORS Chapter 678.

(13) "Nurse Practitioner" has the meaning given that term in ORS 678.010.

(14) "Occupational Therapist" has the meaning given that term in ORS 675.210.

(15) "Occupational Therapy Assistant" has the meaning given that term in ORS 675.210.

(16) "Parent Home Health Agency" ("Parent Agency") means an agency that has branches or subunits.

(17) "Physical Therapist Assistant" has the meaning given that term in ORS 688.010 and is licensed in accordance with 688.020

(18) "Physical Therapist" has the meaning given that term in ORS 688.010.

(19) "Physician" means a person who is licensed by the Oregon Medical Board and that meets the definition in ORS 677.010(13) and (14).

(20) "Plan of treatment" means a document developed by the treating physician or nurse practitioner in consultation with agency staff after a patient assessment that identifies the patient's medical status and needs, and outlines the services that will be provided to the patient to meet identified needs. The plan of treatment may also be referred to as the plan of care.

(21) "Primary Agency" means the agency that admits the patient for the provision of curative, rehabilitative, and/or preventive services in the patient's home by home health professionals.

(22) "Professional Policy-Making Committee" (Committee) means a group of individuals who are appointed by the governing body of an agency, and who has authority and responsibility for the development and monitoring of all professional policies pertaining to the home health agency.

(23) "Progress Note" means a documented summary of a patient's response to care provided during a specific period of time.

(24) "Registered Nurse" means a person licensed as such by the Oregon State Board of Nursing in accordance with ORS Chapter 678.

(25) "Skilled Nursing" means the patient care services pertaining to the curative, rehabilitative, or preventive aspects of nursing performed by, or under the supervision of, a registered nurse pursuant to the plan of treatment.

(26) "Social Worker" means a person who has a master's degree from a school of social work accredited by the Council on Social Work Education and has one year of social work experience in a health care setting.

(27) "Social Work Assistant" means a person who has a baccalaureate degree in social work, psychology, or another field related to social work and has at least one year of social work experience in a health care setting.

(28) "Speech Pathologist" means a person who is licensed in accordance with ORS 681.250 and has a Certificate of Clinical Competence in speech pathology or audiology from the American-Speech-Language-Hearing Association.

(29) "Stable and predictable condition" means a situation where the patient's clinical or behavioral state is known, not characterized by rapid changes, and does not require continuous reassessment and evaluation.

(30) "Subunit" means an agency that provides services for a parent agency in a geographic area different from that of the parent agency and at a distance that exceeds 60 miles from the parent agency.

(31) "Survey" means an inspection of an applicant for a home health agency license or licensed home health agency to determine the extent to which the applicant or agency is in compliance with ORS Chapter 443 and these rules.

(32) "Therapeutic services" means services provided for curative, rehabilitative, or preventive purposes.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.005 & 443.085
Hist.: HD 151, f. & ef. 12-30-77; HD 1-1982, f. & ef. 2-4-82; HD 19-1987, f. 11-10-87, ef. 12-1-87; HD 22-1988, f. & cert. ef. 9-16-88; HD 20-1993, f. & cert. ef. 10-28-93; OHD 13-1998, f. & cert. ef. 11-6-98; OHD 9-2002, f. & cert. ef. 7-2-02; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 11-2011, f. & cert. ef. 10-27-11; PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

Services and Administration

333-027-0010
Application for Licensure

(1) An agency that establishes, purports to manage or operate as a home health agency must be licensed by the Division and comply with ORS 443.005–443.095 and OAR chapter 333, division 027.

(2) An applicant wishing to apply for a license to operate a home health agency shall submit an application on a form prescribed by the Division and pay the applicable fee as specified in OAR 333-027-0025.

(3) If an owner or administrator will have direct contact with a patient, the owner or administrator must submit background information to the Division, in accordance with OAR 333-027-0064 for the purposes of conducting a criminal records check.

(4) If any of the information delineated in the agency's most recent application changes at a time other than the annual renewal date, the agency shall notify the Division in writing within 30 days.

(5) A subunit must independently comply with all licensure requirements.

(6) A branch office is part of the parent agency and therefore need not independently comply with these licensure requirements. The Division shall determine on a case-by-case basis exceptions to the 60 mile travel distance from the parent agency requirement for a branch office and subunits as defined in OAR 333-027-0005.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.015 & 443.065
Hist.: HD 151, f. & ef. 12-30-77; HD 19-1987, f. 11-10-87, ef. 12-1-87; OHD 13-1998, f. & cert. ef. 11-6-98; OHD 9-2002, f. & cert. ef. 7-2-02; PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0015
Review of License Application

(1) In reviewing an application for a home health agency license, the Division shall verify that the agency:

(a) Is primarily engaged in providing skilled nursing and at least one of the following other services: physical therapy, occupational therapy, speech therapy, medical social services, home health aide, or other therapeutic services;

(b) Has a governing body established pursuant to ORS 443.055 and OAR 333-027-0060;

(c) Has policies established by professional personnel associated with the entity, including one or more physicians and one or more registered nurses, at least two of whom are neither owners or employees of the agency, and two consumers, to govern the services that it provides;

(d) Has a physician, a nurse practitioner or registered nurse supervise all services provided by the agency as described under subsection (1)(a) of this rule;

(e) Maintains clinical and financial records on all patients; and

(f) Has an overall plan and budget in effect.

(2) The Division shall conduct a survey in accordance with OAR 333-027-0035 of the agency, and may include subunits or branch locations, to determine if the agency is in compliance with ORS Chapter 443 and OAR chapter 333, division 027 and has the intent to provide home health services. If an agency is in compliance and has the intent to provide home health services to patients, a license may be issued for the operation of the agency.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.015
Hist.: HD 151, f. & ef. 12-30-77; HD 1-1982, f. & ef. 2-4-82; HD 19-1987, f. 11-10-87, ef. 12-1-87; HD 3-1989, f. & cert. ef. 5-24-89; HD 20-1993, f. & cert. ef. 10-28-93; OHD 13-1998, f. & cert. ef. 11-6-98; OHD 9-2002, f. & cert. ef. 7-2-02; PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0017
Approval of License Application

(1) The Division shall notify an applicant in writing if a license application is approved.

(2) A license shall be issued only for the agency and person(s) named in the application and may not be transferred or assigned.

(3) The license shall be conspicuously posted in an office that is viewable by the public.

(4) A licensed home health agency that provides personal care services that are necessary to assist an individual's daily needs, but do not include curative or rehabilitative services is not required to be licensed as an in-home care agency. Such agencies shall comply with ORS 443.305 through 443.355 and OAR 333-536-0000 through 333-536-0125 with the exception of the licensing requirements.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.015, 443.085 & 443.090
Hist.: PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0018
Denial of License Application

If the Division intends to deny a license application, it shall issue a Notice of Proposed Denial of License Application in accordance with ORS 183.411 through 183.470.

Stat. Auth: ORS 443.085
Stats. Implemented: ORS 443.045
Hist.: PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0020
Expiration and Renewal of License

(1) Each license shall expire on the 31st day of December of each calendar year.

(2) An agency shall submit a completed application for renewal on a form prescribed by the Division, accompanied by the required fee, to the Division not less than 30 days prior to the license expiration date.

(3) The Division may issue a renewal license contingent upon evidence of the agency's compliance with ORS Chapter 443 and OAR chapter 333, division 027; attestation to the delivery of agency services to patient(s) during the last calendar year; and, if requested, receipt of an annual statistical report containing such information as may be prescribed by the Division.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.015
Hist.: HD 151, f. & ef. 12-30-77; HD 19-1987, f. 11-10-87, ef. 12-1-87; HD 20-1993, f. & cert. ef. 10-28-93; OHD 13-1998, f. & cert. ef. 11-6-98, Renumbered from 333-027-0095; OHD 9-2002, f. & cert. ef. 7-2-02; PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

Organization and Quality of Patient Care

333-027-0025
Fees

(1) The fee for an initial agency license shall be $1,600 plus an additional $1,600 for each subunit of a parent agency.

(2) If the ownership of an agency changes, other than at the time of the annual renewal, the agency's licensure fee shall be $500, plus an additional $500 for each subunit. If the change of ownership of the agency does not involve the majority owner or partner, or the administrator operating the agency, the license fee shall be $100.

(3) The annual license renewal fee for an agency shall be $850 plus an additional $850 for each subunit.

(4) A hospital exempted under ORS 443.025 may provide home health services without maintaining a separate governing body and administrative services so long as the services provided meet the requirements of 443.005 through 443.095 and the hospital pays the home health licensing fee under 443.035.

(5) License fees will not be prorated and are non-refundable.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.015 & 443.035
Hist.: HD 151, f. & ef. 12-30-77; HD 20-1981, f. & ef. 10-9-81; HD 21-1986(Temp), f. & ef. 12-24-86; HD 19-1987, f. 11-10-87, ef. 12-1-87; HD 20-1993, f. & cert. ef. 10-28-93; OHD 13-1998, f. & cert. ef. 11-6-98, Renumbered from 333-027-0075; PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0029
Denial, Suspension, or Revocation of License

(1) The Division may deny an agency's initial or renewal application, and may suspend or revoke an agency's license for failure to comply with ORS 443.004, 443.005 through 443.105 or OAR chapter 333, division 027.

(2) If the Division intends to suspend or revoke an agency license, it shall do so in accordance with ORS Chapter 183.411 through 183.470.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.045
Hist.: PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0033
Return of Agency License

Each license certificate in the licensee's possession shall be returned to the Division immediately upon the suspension or revocation of the license, failure to renew the license by the date of expiration, or if operation is discontinued by the voluntary action of the licensee.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.085
Hist.: PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0036
Surveys

(1) The Division shall, in addition to any investigations conducted pursuant to OAR 333-027-0038, conduct at least one on-site inspection of each agency prior to licensure and once every three years thereafter as requirement of licensing and at such other times as the Division deems necessary.

(2) In lieu of the on-site inspection required by section (1) of this rule, the Division may accept a certification or accreditation from a federal agency or an accrediting body approved by the Division that the state licensing standards have been met if the agency:

(a) Notifies the Division to participate in any exit interview conducted by the federal agency or accrediting body; and

(b) Provides copies of all documentation concerning the certification or accreditation requested by the Division.

(3) An agency shall permit Division staff access to any location from which it is operating its agency or providing services during a survey.

(4) A survey may include but is not limited to:

(a) Interviews of patients, patient family members, agency management and staff;

(b) On-site observations of patients and staff performance;

(c) Review of documents and records;

(d) Patient audits.

(5) An agency shall make all requested documents and records available to the surveyor for review and copying.

(6) Following a survey, Division staff may conduct an exit conference with the agency owner or his or her designee. During the exit conference, Division staff shall:

(a) Inform the agency representative of the preliminary findings of the inspection; and

(b) Give the person a reasonable opportunity to submit additional facts or other information to the surveyor in response to those findings.

(7) Following the survey, Division staff shall prepare and provide the agency owner or his or her designee specific and timely written notice of the findings.

(8) If the findings result in a referral to another regulator agency, Division staff shall submit the applicable information to that referral agency for its review and determination of appropriate action.

(9) If no deficiencies are found during a survey, the Division shall issue written findings to the agency owner indicating that fact.

(10) If deficiencies are found, the Division shall take informal or formal enforcement action in compliance with OAR 333-027-0180 or 333-027-0185.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.019 & 443.085
Hist.: PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0037
Complaints

(1) Any person may make a complaint verbally or in writing to the Division regarding an allegation as to the care or services provided by a home health agency or violations of home health agency laws or regulations.

(2) The identity of a person making a complaint will be kept confidential.

(3) Information obtained by the Division during an investigation of a complaint or reported violation under this section is confidential and not subject to public disclosure under ORS 192.410 through 192.505.

(4) Upon the conclusion of the investigation, the Division may publicly release a report of its findings but may not include information in the report that could be used to identify the complainant or any patient of a home health agency. The Division may use any information obtained during an investigation in an administrative or judicial proceeding concerning the licensing of a home health agency.

(5) An employee or contract provider with knowledge of a violation of ORS Chapter 443 or OAR chapter 333, division 027, shall use the reporting procedures established by the home health agency before notifying the Division or other state agency of the inappropriate care or violation, unless the employee or contract provider:

(a) Believes a patient's health or safety is in immediate jeopardy; or

(b) Files a complaint in accordance with section (1) of this rule.

(6) If the complaint involves an allegation of criminal conduct or an allegation that is within the jurisdiction of another local, state, or federal agency, the Division will refer the matter to that agency.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.355
Hist.: PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0038
Investigations

(1) An unannounced complaint investigation will be carried out within 45 calendar days of the receipt of the complaint and may include, but is not limited to:

(a) Interviews of the complainant, caregivers, patients, a patient's representative, a patient's family members, witnesses, and agency management and staff;

(b) On-site observations of the patient(s), staff performance, patient environment; and

(c) Review of documents and records.

(2) Should the complaint allegation represent an immediate threat to the health or safety of a patient, the Division will notify appropriate authorities to ensure a patient's safety, and an investigation will be commenced within two working days.

(3) An agency shall permit Division staff access to the agency during an investigation.

(4) The agency shall cooperate with investigations of allegations of client abuse and neglect conducted by the Department of Human Services, Oregon Health Authority, Adult Protective Services, and other agencies such as law enforcement.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.355
Hist.: PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0040
Services and Supplies

If services or supplies are required by law to be prescribed by a physician or a nurse practitioner, the agency shall offer or provide such services and supplies only under an order for treatment and plan of treatment. Services and supplies offered or provided by an agency shall include only the following:

(1) Nursing care provided by or under the supervision of a registered nurse;

(2) Physical, occupational, or speech therapy, or medical social services;

(3) Other therapeutic services conforming to generally accepted and established standards;

(4) Home health aide services; and

(5) Medical supplies, other than drugs and biologicals, and medical appliances. When patient care supplies are stored in the agency, the agency shall store such supplies in a manner that prevents their contamination and ensures that the supplies do not exceed the manufacturer's expiration date.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.075
Hist.: HD 151, f. & ef. 12-30-77; HD 19-1986, f. & ef. 12-9-86; HD 19-1987, f. 11-10-87, ef. 12-1-87; HD 20-1993, f. & cert. ef. 10-23-93; OHD 13-1998, f. & cert. ef. 11-6-98; OHD 9-2002, f. & cert. ef. 7-2-02; PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0050
Changes in Services Provided

(1) An agency must obtain written approval from the Division prior to the implementation of the provision of additional services. When an agency applies for approval of additional services, the agency must provide evidence of:

(a) Governing body approval of addition of the services and all revisions in agency policies pertaining to the new services;

(b) The agency's professional policy-making committee development and approval of all policies and procedures pertaining to the new services; and

(c) Adherence to agency personnel policies and ORS Chapter 443 and OAR chapter 333, division 027 by all individuals providing services through the agency. If a new service is provided under the designation of "other therapeutic services" and is not in a category of licensure/certification covered by Oregon law, the governing body must designate and approve standards of educational or technical qualifications of personnel providing the services.

(2) An agency must notify the Division if it no longer provides a service listed on its current license.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.085
Hist.: HD 151, f. & ef. 12-30-77; HD 1-1982, f. & ef. 2-4-82; HD 19-1987, f. 11-10-87, ef. 12-1-87; HD 20-1993, f. & cert. ef. 10-28-93; OHD 13-1998, f. & cert. ef. 11-6-98; OHD 9-2002, f. & cert. ef. 7-2-02; PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0060
Administration of Home Health Agency

An agency shall clearly set forth in writing the organization, services provided, administrative control, and lines of authority for the delegation of responsibility to the patient care level. An agency shall not delegate administrative and supervisory functions to another agency, individual, or organization.

(1) The primary agency shall monitor and control all services provided through contractual agreements between the primary agency and any patient service provider.

(2) An agency shall maintain appropriate administrative records for each of its offices. If an agency has any branch offices, it shall ensure that each branch office is part of the agency and shares administration, supervision, and services on a daily basis.

(3) If an agency chooses to provide professional students with a practicum in home health, the governing body must ensure that:

(a) A contract between the agency and the accredited educational institution is in effect and it includes at a minimum, a description of:

(A) Program objectives;

(B) Program coordination;

(C) Student supervision;

(D) Adherence to agency policy; and

(E) Conformance with applicable professional practice laws, rules, and regulations.

(b) The agency maintains documentation of each practicum and the student's activities, supervision and the evaluation of these activities.

(c) The agency maintains documentation of patient care services provided by the student.

(4) An agency's governing body, or its designee, shall assume full legal and fiscal responsibility for the agency's operation. The agency's governing body shall provide for effective communication with administration of the agency and the owner of the agency.

(5) An agency's governing body shall:

(a) Employ a qualified administrator, unless exempted under ORS 443.025, who may also serve as Director of Professional Services;

(b) Regularly monitor the performance of the administrator;

(c) Appoint a professional policy-making committee;

(d) Adopt and annually review its written by-laws or acceptable equivalent; and

(e) Document all decisions affecting home health services.

(6) The Administrator shall have the following qualifications:

(a) A physician or registered nurse, currently licensed in Oregon, who has education, experience, and knowledge in community health service systems appropriate to the fulfillment of his/her responsibilities; or

(b) An individual who has education, experience, and knowledge in a related community health service systems and at least one year overall administrative experience in home health care or related community health program appropriate to the fulfillment of his/her responsibilities.

(7) The Administrator shall:

(a) Have authority and responsibility for the agency's overall management and operation;

(b) Organize and direct the agency's ongoing functions;

(c) Maintain ongoing communication between agency's governing body, professional policy-making committee, and staff;

(d) Employ qualified personnel and ensure the provision of adequate staff education and the completion of performance evaluations;

(e) Involve the Director of Professional Services in health care decisions;

(f) Ensure the accuracy of information provided to the public regarding the agency and its services;

(g) Implement an effective budgeting and accounting system;

(h) Designate, in writing, an individual qualified to serve as acting administrator in the administrator's absence; and

(i) Ensure that adequate and appropriate staff resources are available and used to meet the care needs of the agency's patients as identified in the plans of treatment.

(8) The agency shall employ a Director of Professional Services who must be a physician or registered nurse. The agency shall ensure that the Director of Professional Services or a similarly

qualified alternate, designated in writing, is available for consultation at all times during operating hours of the agency. The Director of Professional Services or designee shall have written authority, responsibility, and accountability for:

(a) Functions, activities, and evaluations of all health care personnel;

(b) The quality of home health services;

(c) Orientation and in-service education for all agency health care personnel;

(d) Coordination of home health services;

(e) Development and documentation of all written material related to agency services, including policies, procedures, and standards;

(f) Participation and involvement in employment decisions affecting home health care personnel;

(g) Assignment of adequate and appropriate staff resources to meet the home health care needs of the agency's patients; and

(h) Designating, in writing, a person qualified to serve as acting Director of Professional Services in the Director's absence.

(9)(a) The agency shall develop personnel policies which must be appropriate to the agency, be documented, and include:

(A) Hours of work;

(B) Orientation that is appropriate to the classification of the employee. The following portions of the orientation shall be completed within two weeks of employment; and shall include at a minimum: policies and procedures of the agency; job description and responsibility; role as team member providing services in the home setting; and information regarding other community agencies, infection control, ethics and confidentiality.

(C) An inservice program that provides ongoing education to ensure that staff skills are maintained for the responsibilities assigned and ensures that staff are educated in their responsibility in infection control;

(D) Work performance evaluations;

(E) Employee health program;

(F) Provisions for tuberculosis screening in accordance with OAR 333-019-0041; and

(G) Provisions for the completion of criminal records checks in accordance with ORS 443.004 and OAR 333-027-0064.

(b) Personnel records shall include job descriptions, personnel qualifications, evidence of any required licensure or certification, evidence of orientation and performance evaluations, evidence of a completed criminal records check and fitness determination.

(c) An agency may provide services by agency personnel working out of their individual homes within a portion of the geographic area served by an agency. The individual homes are not construed to be a branch. These services must be controlled, supervised, and evaluated by the agency, in accordance with all written agency policies. Such policies shall, at a minimum require documentation of:

(A) A meeting at least every two weeks of the supervisor and the individual to review the plan(s) of treatment;

(B) A telephone conference on at least a weekly basis between meetings;

(C) Supervisor participation in the development of each plan of treatment; and

(D) Procedures for submitting clinical and progress notes, summary reports, schedule of visits and periodic evaluations.

(10) An agency contracting with individual personnel or public or private entities for home health care services shall maintain written contracts and shall clearly designate:

(a) That patients are accepted for care only by the primary agency;

(b) The services to be provided;

(c) The rights and responsibilities of the contracting individual or entity in the coordination, supervision, and evaluation of the care or service provided;

(d) The obligation to comply with all applicable agency policies;

(e) The party with responsibility for development and revisions of the plan of treatment, patient assessment, progress reports, and patient care conferences, scheduling of visits or hours, and discharge planning;

(f) Appropriate documentation of services provided on record forms provided by the agency; and

(g) The terms of the agreement and basis for renewal or termination.

(11) An agency, under the direction of the governing body, shall prepare and document an overall program plan and annual operating budget. The agency's operating budget shall include all anticipated income and expenses related to items that would, under generally accepted accounting principles, be considered income and expense items. The agency's overall program plan and budget shall be reviewed and updated at least annually by a committee consisting of representatives of the governing body, the administrative staff, and the professional staff of the agency.

(12) An agency's governing body shall appoint a professional policy-making committee composed of professional personnel associated with the agency.

(a) The committee shall include one or more physicians and one or more registered nurses, at least two of whom are neither owners nor employees of the agency, and two consumers.

(b) The committee shall establish in writing and review annually, the agency's policies governing scope of services, admission and discharge policies, medical supervision, plans of treatment, emergency care, clinical records, personnel qualifications, and program evaluation.

(c) The committee shall meet as needed to advise the agency on other professional issues.

(d) The committee members shall participate with the agency staff in the annual evaluation of the agency's program.

(e) The agency shall document the committee's systematic involvement and effective communication with the governing body and the management of the agency.

Stat. Auth.: ORS 443.085

Stats. Implemented: ORS 443.004, 443.055, 443.065 & 443.085

Hist.: HD 151, f. & ef. 12-30-77; HD 19-1987, f. 11-10-87, ef. 12-1-87; HD 22-1988, f. & cert. ef. 9-16-88; HD 20-1993, f. & cert. ef. 10-28-93; OHD 13-1998, f. & cert. ef. 11-6-98; PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0064
Criminal Records Check

(1) For the purposes of this rule, the following definitions apply:

(a) "Direct contact with" means to provide home health services and includes meeting in person with a potential or current patient to discuss services offered by an agency or other matters relating to the business relationship between an agency and client;

(b) "Disqualifying condition" means a non-criminal personal history issue that makes an individual unsuitable for employment, contracting or volunteering for an agency, including but not limited to discipline by a licensing or certifying agency, or drug or alcohol dependency;

(c) "Subject Individual" (SI) means an individual on whom an agency may conduct a criminal records check and from whom an agency may require fingerprints for the purpose of conducting a national criminal records check, including:

(A) An employee or prospective employee;

(B) A contractor, temporary worker, volunteer or owner of an agency who has direct contact with an agency client or potential client; and

(C) A prospective contractor, temporary worker, or volunteer or owner who may have direct contact with an agency client.

(d) "Vendor" means a researcher or company hired to provide a criminal records check on a subject individual.

(2) An agency shall conduct a criminal records check before hiring or contracting with an SI and before allowing an SI to volunteer to provide services on behalf of the agency, if the SI will have direct contact with a patient of the agency.

(3) An SI who has or will have direct contact with a recipient of home health services may not be employed, contract with, or volunteer with an agency in any capacity if the criminal records

check conducted reveals the SI has been convicted of a crime as described in ORS 443.004(3).

(4) An agency shall have a policy on criminal records check requirements which shall include weighing test actions should the background check screening indicate that an SI has been convicted for crimes against an individual or property other than those identified in ORS 443.004(3). The policy must include the following provisions for performing a weighing test:

(a) The agency shall consider circumstances regarding the nature of potentially disqualifying convictions and conditions including but not limited to:

(A) The details of incidents leading to the charges of potentially disqualifying convictions or resulting in potentially disqualifying conditions;

(B) Age of the SI at time of the potentially disqualifying convictions or conditions;

(C) Facts that support the convictions or potentially disqualifying conditions; and

(D) Passage of time since commission of the potentially disqualifying convictions or conditions.

(b) Other factors which should be considered when available include but are not limited to:

(A) Other information related to criminal activity including charges, arrests, pending indictments and convictions. Other behavior involving contact with law enforcement may also be reviewed if information is relevant to other criminal records or shows a pattern relevant to criminal history;

(B) Periods of incarceration;

(C) Status of and compliance with parole, post-prison supervision or probation;

(D) Evidence of alcohol or drug issues directly related to criminal activity or potentially disqualifying conditions;

(E) Evidence of other treatment or rehabilitation related to criminal activity or potentially disqualifying conditions;

(F) Likelihood of repetition of criminal behavior or behaviors leading to potentially disqualifying conditions, including but not limited to patterns of criminal activity or behavior;

(G) Changes in circumstances subsequent to the criminal activity or disqualifying conditions including but not limited to:

(i) History of high school, college or other education related accomplishments;

(ii) Work history (employee or volunteer);

(iii) History regarding licensure, certification or training for licensure or certification; or

(iv) Written recommendations from current or past employers;

(H) Indication of the SI's cooperation, honesty or the making of a false statement during the criminal records check process, including acknowledgment and acceptance of responsibility of criminal activity and potentially disqualifying conditions.

(c) An agency shall consider the relevancy of the SI's criminal activity or potentially disqualifying conditions to the paid or volunteer position, or to the environment in which the SI will work, especially, but not exclusively:

(A) Access to medication;

(B) Access to clients' personal information;

(C) Access to vulnerable populations.

(5) An agency shall document the weighing test and place in the employee's file.

(6) A background check shall be performed by:

(a) The Department of Human Services Background Check Unit; or

(b) A vendor that:

(A) Is accredited by the National Association of Professional Background Screeners (NAPBS); or

(B) Meets the following criteria:

(i) Has been in business for at least two years;

(ii) Has a current business license and private investigator license, if required in the company's home state; and

(iii) Maintains an errors and omissions insurance policy in an amount not less than $1 million.

(7) An agency may use the Oregon State Police, Open Records Unit in order to fulfill the state records requirement for a criminal records check, however, an agency would still need to complete a nationwide check through a qualified vendor.

(8) The criminal records check must include the following:

(a) Name and address history trace;

(b) Verification that the SI's records have been correctly identified, via date of birth check and Social Security number trace;

(c) A local criminal records check, including city and county records for SI's places of residence for the last seven years;

(d) A nationwide multijurisdictional criminal database search, including state and federal records;

(e) A nationwide sex offender registry search;

(f) The name and contact information of the vendor who completed the background check;

(g) Arrest, warrant and conviction data, including but not limited to:

(A) Charge(s);

(B) Jurisdiction; and

(C) Date.

(h) Source(s) for data included in the report.

(9) An agency shall perform and document a query of an SI with the National Practitioner Data Bank (NPDB) and the List of Excluded Individuals and Entities (LEIE).

(10) All criminal records checks conducted under this rule shall be documented in writing and made part of the agency's personnel files.

(11) An agency that has a contract with the Department of Human Services (Department) or Oregon Health Authority for the provision of home health services on or after April 1, 2012 and who is subject to the Department's criminal records check rules does not have to comply with section (12) of this rule.

(12) For an SI working or volunteering for an agency on or after July 6, 2011, an agency shall have until July 1, 2012 to ensure that the agency is in compliance with section (3) of this rule.

(13) On or after April 1, 2012 an agency shall ensure that a criminal records check is performed on an SI every three years from the date of the SIs last criminal records check in accordance with these rules.

(14) Notwithstanding sections (12) and (13) of this rule, the Division and not the agency shall conduct a criminal records check on an owner of any agency who is subject to a criminal records check under subsection (1)(c) of this rule. The Division shall conduct a criminal records check:

(a) At the time of application for a person who applies for a license on or after April 1, 2012 and every three years thereafter.

(b) By April 1, 2013 for an agency that is licensed on or before April 1, 2012, and every three years thereafter.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.004 & 443.085
Hist.: PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0070
Acceptance of Patients

An agency shall accept patients for treatment on the basis of a reasonable expectation that the patient's needs can adequately be met by the agency in the patient's residence. The agency shall consider the following in relation to acceptance of its patients:

(1) Adequacy and suitability of the agency's staff and resources to provide needed services;

(2) Assessment of the patients' medical, nursing, and social needs as they relate to the benefits of home care;

(3) The services provided by the agency;

(4) Assurance that services can be effectively coordinated with care provided by other organizations and individuals;

(5) Degree of patient and family awareness of their rights and responsibilities;

(6) A plan to meet medical emergencies;

(7) Availability, ability, and willingness of others to participate in the care;

(8) Adequacy of physical facilities and equipment; and

(9) Attitudes of the patient and family.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.085
Hist.: HD 151, f. & ef. 12-30-77; HD 19-1987, f. 11-10-87, ef. 12-1-87; HD 20-1993, f. & cert. ef. 10-28-93; OHD 13-1998, f. & cert. ef. 11-6-98

333-027-0080
Patients' Rights

(1) Bill of Rights: An agency must provide each patient with a written notice of the patient's rights prior to furnishing care to the patient or during the initial evaluation visit prior to the initiation of treatment. This notice shall state that a patient of the agency has the following rights:

(a) The right to have personal property treated with respect;

(b) The right to voice grievances regarding treatment or care, a lack of respect for property by anyone furnishing services on behalf of the agency, or any other issue, without discrimination or reprisal for exercising such rights. The agency must investigate all complaints made by the patient or the patient's family or guardian regarding the above and must document the investigation and the resolution of the complaint;

(c) The right to be informed, in advance, about the care to be furnished, any changes in the care to be furnished, the disciplines that will furnish care, and the frequency of visits proposed to be furnished;

(d) The right to participate in the planning of care;

(e) The right to have clinical records confidentially maintained by the agency;

(f) The right to be advised, before care is initiated, of the extent that payment for the agency services may be expected from Medicare or other sources, and the extent that payment may be required from the patient. The agency must provide this information orally and in writing before care is initiated; and

(g) The right to be advised orally and in writing of any changes in the information provided in accordance with subsection (1)(f) as soon as possible, but no later than 30 working days from the date that the agency becomes aware of a change.

(2) Health Care Directives: An agency shall maintain written policies and procedures, applicable to any person 18 years of age or older, or to any adult as defined under ORS 127.505, who is receiving health care by, or through, the agency, that provide for:

(a) Delivery to the patient or the patient's legal representative of the following information and materials, in written form, without recommendation:

(A) Information on the rights of the individual under Oregon law to make health care decisions;

(B) Information on the policies of the agency with respect to the implementation of the rights of the individual under Oregon law to make health care decisions;

(C) A copy of the advance directive set forth in ORS 127.531 along with a disclaimer attached to each form in at least 16-point bold type stating "You do not have to fill out and sign this form"; and

(D) The name of a resource that can provide additional information concerning the forms for advance directives.

(b) Documentation placed prominently in the patient's record and reflecting whether the patient has executed an advance directive.

(c) Compliance by the agency with Oregon law relating to advance directives; and

(d) Education of agency personnel and the community on issues relating to advance directives.

(3) An agency shall provide the written information described in section (2) to the patient not later than 15 days after the initial provision of care by the agency, but in any event before discharge of the patient;

(4) An agency need not furnish a copy of an advance directive to a patient or the patient's legal representative if it has reason to believe that the patient has received a copy of an advance directive in the form set forth in ORS 127.531 within the preceding 12-month period or has previously executed an advance directive.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.085
Hist.: HD 151, f. & ef. 12-30-77; HD 19-1987, f. 11-10-87. ef. 12-1-87; OHD 13-1998, f. & cert. ef. 11-6-98; PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0090
Plan of Treatment

The primary agency is responsible for the patient's plan of treatment signed by the physician or nurse practitioner, including home health services provided to the patient through contractual arrangements with other organizations or individuals. A registered nurse must conduct an initial assessment visit to determine the immediate care and support needs of the patient. When rehabilitation therapy service (speech therapy, physical therapy or occupational therapy) is the only service ordered by the physician, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled professional.

(1) The agency shall ensure that the plan of treatment is developed in consultation with the agency personnel and established at the time of, or prior to, acceptance of the patient.

(2) The agency shall ensure that the plan of treatment is transmitted to the patient's physician or nurse practitioner for signature within 10 calendar days of admission to service.

(3) The plan of treatment shall cover the following:

(a) All pertinent diagnoses, mental status, types of services and equipment required;

(b) Frequency of visits;

(c) Prognosis;

(d) Rehabilitation potential;

(e) Functional limitations;

(f) Activities permitted;

(g) Nutritional requirements;

(h) Medications and treatments;

(i) Safety measures to protect against injury;

(j) Instructions for timely discharge or referral; and

(k) Any other appropriate items.

(4) If a patient is accepted under a plan of treatment that cannot be completed until after an evaluation visit, the physician or nurse practitioner shall be consulted to approve revisions to the original plan.

(5) Orders for therapy services shall include the specific procedures and modalities to be used and, as appropriate, the amount, frequency, and duration.

(6) The therapist and other agency personnel shall participate in developing the plan of treatment.

(7) The plan of treatment shall be signed by the physician or nurse practitioner and included in the patient's clinical record within the time period specified in the agency's policy but no longer than 30 calendar days after admission.

(8) The agency shall submit all plans of treatment to the primary physician or nurse practitioner and shall send copies to other physicians or nurse practitioners involved in the patient's care.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.075 & 443.085
Hist.: HD 151, f. & ef. 12-30-77; HD 20-1993, f. & cert. ef. 10-28-93; OHD 13-1998, f. & cert. ef. 11-6-98; OHD 9-2002, f. & cert. ef. 7-2-02; PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0100
Periodic Review of Plan of Treatment

An agency shall ensure that:

(1) The plan of treatment shall be reviewed by the attending physician or nurse practitioner and agency personnel as often as the patient's condition requires, but at least once every two months;

(2) Agency professional personnel promptly alert the physician or nurse practitioner to any changes that suggest a need to alter the plan of treatment;

(3) Information provided to the physician or nurse practitioner is documented in the clinical record; and

(4) The updated plan of treatment is included in the patient's clinical record within 30 calendar days of the revision.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.075 & 443.085

Hist.: HD 151, f. & ef. 12-30-77; HD 20-1993, f. & cert. ef. 10-28-93; OHD 13-1998, f. & cert. ef. 11-6-98; OHD 9-2002, f. & cert. ef. 7-2-02; PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0110
Conformance with Physician's or Nurse Practitioner's Orders

(1) Agency personnel shall administer drugs and treatments only as ordered by the patient's physician in accordance with 42 CFR 484.18 or by other providers as authorized by Oregon law.

(2) The nurse or therapist who receives a verbal order shall immediately record the order and transmit it to the physician or nurse practitioner within 72 hours.

(3) The physician's or nurse practitioner's countersignature shall be obtained within 30 calendar days of the verbal order.

(4) Agency professional personnel shall check all medicines that a patient may be taking to identify possible ineffective drug therapy, adverse reactions, significant side effects, drug allergies, and contraindicated medication.

(5) Agency professional personnel shall promptly report any problems to the patient's physician or nurse practitioner.

(6) Only medications and treatments that must be administered to the patient by agency personnel need to be on a written order form from the physician or nurse practitioner.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.075 & 443.085
Hist.: OHD 13-1998, f. & cert. ef. 11-6-98; OHD 9-2002, f. & cert. ef. 7-2-02; PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0120
Coordination of Patient Services

(1) All personnel furnishing services shall ensure that their efforts are coordinated effectively and support the objectives outlined in the patient's plan of care.

(2) The clinical record or minutes of case conferences shall reflect that effective communication and coordination of patient care occurs.

(3) A written summary report for each patient shall be sent to the attending physician or nurse practitioner at least every 62 days.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.085
Hist.: OHD 13-1998, f. & cert. ef. 11-6-98; OHD 9-2002, f. & cert. ef. 7-2-02; PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0130
Nursing Services

The agency shall provide skilled nursing service by or under the supervision of a registered nurse in accordance with agency policies and the plan of treatment. Such services shall comply with applicable laws. For the purposes of this rule, "critical and fluctuating" means a situation where the patient's clinical or behavioral state is of a serious nature, expected to rapidly change, and in need of continuous reassessment and evaluation.

(1) Registered Nurse's Duties: The registered nurse shall make the initial visit, regularly reevaluate the patient's nursing needs, initiate appropriate preventive and rehabilitative nursing procedures, provide those services requiring substantial specialized nursing skills, prepare clinical and progress notes, coordinate services, inform the physician or nurse practitioner and other personnel (including paid caregivers) of changes in the patient's condition and needs, counsel the patient, family or other caregivers (as applicable) in meeting nursing and related needs, participate in inservice programs, and supervise, teach, and assign care tasks to other nursing personnel. The registered nurse may delegate aspects of patient care to unlicensed individuals in accordance with OAR chapter 851, division 047.

(a) Supervision of the licensed practical nurse shall include:

(A) Initial evaluation of the patient to identify appropriate tasks to be performed by the licensed practical nurse. These tasks shall be documented in the patient's clinical record; and

(B) A supervisory visit every 60 days when the patient's condition is stable and predictable, and at least every two weeks when the patient's condition is critical and fluctuating. This visit shall be made either when the licensed practical nurse is present to observe and assist or when the licensed practical nurse is absent, to assess relationships and determine that goals are being met. Documentation of these activities shall be maintained in the patient's clinical record.

(b) Home Health Aide Supervision: The registered nurse is responsible for supervising for quality and appropriateness of care provided by the home health aide service. The registered nurse shall be readily available to the home health aide by telephone at all hours services are provided. Supervisory visits by the registered nurse or therapist shall be documented in the patient's clinical record.

(A) When skilled nursing services and home health aide services are being furnished to the patient, the registered nurse shall make a supervisory visit to the patient's residence at least every two weeks, either when the home health aide is present to observe and assist, or when the home health aide is absent to assess relationships and determine if goals are being met.

(B) If a patient is receiving only skilled therapy services and home health aide services, a skilled therapist may make the supervisory visits at least every two weeks, in lieu of a registered nurse. The therapist must convey information about the performance of the home health aide to the aide's registered nurse supervisor.

(C) When only home health aide services are being furnished to a patient, a registered nurse must make a supervisory visit to the patient's residence at least once every 60 days. Each supervisory visit must occur when the aide is furnishing patient care.

(2) Licensed Practical Nurse:

(a) Duties: The licensed practical nurse shall provide services in accordance with agency policies, prepare clinical and progress notes, assist the physician or nurse practitioner or registered nurse in performing specialized procedures, prepare equipment and materials for treatments, observe aseptic techniques as required, and assist the patient in learning designated self-care techniques.

(b) Supervision of Licensed Practical Nurse: A licensed practical nurse shall provide services only under the supervision of a registered nurse.

(3) Home Health Aide: When an agency provides or arranges for home health aide service, an aide shall be assigned if the plan of treatment, as described in OAR 333-027-0090, specifies that the patient needs personal care. Home health aide services shall be provided under the supervision of the registered nurse and in accordance with the registered nurse's assignment and agency policies.

(a) The duties of a home health aide shall include:

(A) Performance of simple procedures as assigned by the registered nurse;

(B) Personal care;

(C) Ambulation and exercise;

(D) Household services essential to health care at home;

(E) Assistance with medications that are ordinarily self-administered;

(F) Reporting changes in the patient's condition and needs; and

(G) Completing appropriate records.

(b) A home health aide must have the following qualifications:

(A) Oregon Certified Nursing Assistant (CNA) certification and inclusion on the Oregon State Board of Nursing Nurse Aide Registry.

(B) Prior to providing care to a patient, the home health aide must be evaluated by a registered nurse for competency in each of the following areas:

(i) Communication skills;

(ii) Observation of, reporting of, and documentation about the patient and care provided;

(iii) Maintenance of a clean, safe and healthy environment;

(iv) Basic infection control procedures;

(v) Basic nutrition and fluid intake, including food preparation techniques as appropriate;

(vi) Reading and recording temperature, pulse, and respiration;

(vii) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor;

(viii) Recognizing emergencies and knowledge of emergency procedures;

(ix) The physical, emotional, and developmental needs of, and ways to work with, the populations served by the agency, including the need for respect for the patient, the patient's privacy, and the patient's property;

(x) Appropriate and safe techniques in personal hygiene and grooming that include:

(I) Bed bath;

(II) Sponge, tub, or shower bath;

(III) Shampoo: sink, tub, or bed;

(IV) Nail and skin care;

(V) Oral hygiene; and

(VI) Toileting and elimination.

(xi) Safe transfer techniques and ambulation;

(xii) Normal range of motion and positioning; and

(xiii) Any other task the agency may choose to have the home health aide perform.

(c) Home health aide competency evaluation:

(A) An individual may furnish home health aide services on behalf of an agency only after that individual has successfully completed a competency evaluation program that meets the following requirements:

(i) The competency evaluation program must address each of the subjects listed in subparagraphs (3)(b)(B)(i) through (xiii) of this rule;

(ii) The subject areas listed at subparagraphs (3)(b)(B)(vi), (x), (xi), and (xii) of this rule must be evaluated through observation of the aide's performance of the tasks with a patient; and

(iii) All other subject areas listed in paragraph (3)(b)(B) of this rule may be evaluated through written examination, oral examination, or observation of the aide with a patient.

(B) A home health aide is not considered competent in any task for which the aide's performance is evaluated as unsatisfactory. The aide must not perform that task without direct supervision by a licensed nurse until the aide receives training in the tasks for which the aide's performance was evaluated as unsatisfactory and passes a subsequent evaluation with a satisfactory rating.

(C) A home health aide has not successfully passed a competency evaluation if the aide's performance is unsatisfactory in more than one of the areas delineated in paragraph (3)(b)(B) of this rule.

(D) The agency must maintain documentation that demonstrates that the home health aide has met competency evaluation requirements.

(d) Home Health Aide Orientation: The agency shall complete orientation of the home health aide to the agency's program and document the completion within two weeks of employment. This orientation must include information about:

(A) Policies and objectives of the agency;

(B) The duties of a home health aide;

(C) The functions of other agency personnel and how they relate to each other in caring for the patient;

(D) Other community agencies; and

(E) Ethics and confidentiality.

(e) Training on the Job: In addition to orientation, an agency shall provide the home health aide patient-specific, on-the-job instruction for carrying out procedures that are not transferable to another patient. Such training shall be in accordance with OAR chapter 851, division 061, and shall be documented in the patient's clinical record.

(f) Inservice Training: The agency shall arrange for and document at least 12 hours of inservice training annually. These training sessions shall pertain to the role and responsibilities of the home health aide.

(g) Home Health Aide Assignment: The agency shall provide teaching and supervision of the home health aide in accordance with OAR chapter 851, division 061. All assignments for patient care shall be written, prepared by a registered nurse, and updated on a monthly basis, or more often if the patient's condition requires. Special tasks of nursing care may be delegated by a registered nurse to a home health aide according to the provisions of OAR chapter 851, division 047.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.065 & 443.085
Hist.: OHD 13-1998, f. & cert. ef. 11-6-98; OHD 9-2002, f. & cert. ef. 7-2-02; PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0140
Therapy Services

(1) Physical Therapy Services: If an agency provides physical therapy services, either directly or under contract, these services shall be provided only by a physical therapist or by a physical therapist assistant. The physical therapist and the physical therapist assistant shall provide physical therapy services in accordance with applicable laws, rules, agency policies and the patient's plan of treatment. Services provided by a physical therapist assistant shall be supervised by a physical therapist.

(a) Duties of a physical therapist include: assisting a physician in evaluating levels of function, helping to develop and revise the plan of treatment, preparing clinical and progress notes, advising and consulting with the family and other agency personnel, participating in inservice programs, and providing services.

(b) Duties of the physical therapist assistant include: performing services that are planned, assigned, delegated, and supervised by the physical therapist; assisting in preparation of clinical notes and progress reports; participating in the education of the patient and family; and participating in inservice programs.

(c) Supervision of the physical therapist assistant shall include at a minimum:

(A) Initial evaluation of the patient by the physical therapist to identify appropriate tasks to be performed by the physical therapist assistant. These tasks shall be documented in each patient's clinical records; and

(B) A visit to the patient's residence by the physical therapist at least once a month when the patient's condition is no longer stable and predictable, or at 60-day intervals when the patient's condition is stable, either when the assistant is present to observe and assist or when the assistant is absent, to assess relationships and determine that goals are being met. Documentation of these visits by the physical therapist shall be maintained in the patient's clinical record.

(2) Occupational Therapy Services: If an agency provides occupational therapy services, either directly or under contract these services shall be provided only by an occupational therapist or by an occupational therapy assistant under the supervision of an occupational therapist. The occupational therapist and occupational therapy assistant shall provide occupational therapy services in accordance with applicable statutes, rules, agency policies and the patient's plan of treatment. The agency shall assure that services provided by an occupational therapy assistant shall be supervised by an occupational therapist.

(a) Duties of the occupational therapist include: assisting the physician in evaluating levels of function, helping to develop and revise the plan of treatment, preparing clinical and progress notes, advising and consulting with the family and other agency personnel, participating in inservice programs, and providing services.

(b) Duties of the occupational therapy assistant include: performing services planned, assigned, delegated, and supervised by the occupational therapist; assisting in the preparation of clinical notes and progress reports; participating in the education of the patient and family; and participating in inservice programs.

(c) Supervision of the occupational therapy assistant shall include at a minimum:

(A) Initial evaluation of the patient by the occupational therapist to identify appropriate tasks to be performed by the occupational therapy assistant. These tasks shall be documented in each patient's clinical record; and

(B) A visit to the patient's residence by the occupational therapist at least once a month when the patient's condition is no longer

stable and predictable, or at 60-day intervals when the patient's condition is stable, either when the assistant is present to observe and assist or when the assistant is absent, to assess relationships and determine that goals are being met. The occupational therapist shall document these visits in each patient's clinical record.

(3)(a) Speech Therapy Services: If an agency provides speech therapy services, either directly or under contract, these services shall be provided only by a speech pathologist. The speech pathologist shall provide speech therapy services in accordance with applicable statutes, rules, agency policies and the patient's plan of treatment.

(b) Duties of the speech pathologist include: assisting the physician in evaluating the patient's level of function; helping to develop and revise the plan of treatment; preparing clinical and progress notes; advising and consulting with the family and other agency personnel; participating in inservice programs; and providing services.

(4) Medical Social Services: If an agency provides medical social services, either directly or under contract these services shall be provided only by a social worker, or by a social work assistant. The social worker or the social work assistant shall provide social work services in accordance with applicable statutes, rules, agency policies and the patient's plan of treatment.

(a) Duties of the social worker include: assisting the physician, other team members, and the family in understanding the significant social and emotional factors related to health problems of the patient; participating in the development of the plan of treatment; preparing clinical and progress notes; working with the family; utilizing appropriate community resources; participating in discharge planning and inservice programs; and acting as a consultant to other agency personnel.

(b) Duties of the social work assistant include: performing services planned, assigned, delegated, and supervised by the qualified social worker, preparing clinical notes and progress reports; and participating in inservice programs.

(c) Supervision of the social work assistant shall include at a minimum:

(A) Initial evaluation of the patient by the social worker to identify appropriate tasks to be performed by the social work assistant. These tasks shall be documented in the individual patient's clinical records; and

(B) After the initial evaluation by the social worker and development of the plan of treatment, documented supervisory conferences with the social work assistant shall be held at least two times monthly to assess adherence to the goals and quality of relationships. In the event the patient's situation changes and requires a change in the treatment plan and goals, the social worker will make a joint visit with the social work assistant to revise the plan of treatment.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.065 & 443.085
Hist.: HD 151, f. & ef. 12-30-77; HD 19-1987, f. 11-10-87, ef. 12-1-87; HD 20-1993, f. & cert. ef. 10-28-93; Renumbered from 333-027-0055, OHD 13-1998, f. & cert. ef. 11-6-98; PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0150
Clinical Records

General Requirements for Clinical Records:

(1) An agency shall maintain, for each patient, a clinical record that covers the service(s) the agency provides directly, or through contract with another agency. All entries in the patient's clinical record must be dated and authenticated. Authentication of an entry requires the use of a unique identifier such as a signature, code thumbprint, voice print, or other means, that provides identification and the title of the individual responsible for the entry. Clinical notes shall be written the day services are rendered and shall be incorporated into the clinical record at least weekly. The agency shall maintain an approved list of standard abbreviations, signs and symbols for use in the clinical record.

(a) The record of each patient receiving home health services shall contain pertinent past and current findings. The findings shall include, but not be limited to, history and physical examination, and hospital discharge summary. The record shall contain other appropriate information such as: patient identifying information; name of physician; signed and dated clinical and progress notes; copies of summary reports that have been sent to the physician; and a discharge summary.

(b) The record shall contain the patient's plan of treatment.

(c) Clinical records shall contain all original or facsimile physician orders and agency caregiver documentation.

(2) Retention and Protection of Records:

(a) The administrator of the agency shall be responsible for proper preparation, adequate content, and preservation of the clinical records. The agency shall permit authorized personnel of the Division to review clinical records as necessary to determine compliance with these rules.

(b) An agency shall have written policies governing access to, and maintenance, retention, utilization, storage, and disposition of all clinical records.

(c) An agency shall complete all clinical records of discharged patients within 30 calendar days of the patient's discharge.

(d) Clinical records are the property of the agency.

(e) Upon a patient's request, the agency shall provide information from the patient's clinical record related to the patient's condition and the care provided.

(f) An agency shall ensure that original clinical records are readily retrievable. Clinical records may be retained on paper, microfilm, electronic, or other media.

(g) An agency shall keep all clinical records for a period of 10 years after the date of the patient's last discharge from the agency.

(h) An agency shall keep clinical records in a safe and secure environment that will protect them from damage and harm.

(i) If an agency changes ownership, the agency shall retain all clinical records in original or microfilmed form and it shall be the responsibility of the successor agency to protect and maintain these records.

(j) In the event of dissolution of an agency, the agency administrator shall notify the Division where the clinical records will be stored.

(k) The agency shall retain non-medical records according to the policy of the individual agency.

(l) An agency shall comply with ORS 192.518 through 192.529, which governs the use and disclosure of patient's protected health information.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.065 & 443.085
Hist.: OHD 13-1998, f. & cert. ef. 11-6-98; PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0160
Program Evaluation

An agency shall conduct an overall evaluation of its program at least annually. The Committee and the agency shall conduct the review. The evaluation shall consist of reviews of overall policies, administrative practices, and quality assurance activities. The evaluation shall assess the extent to which the agency's program is appropriate, adequate, effective, and efficient. The Committee shall provide a written report of the evaluation to the governing body of the agency. Evaluation reports shall be maintained in its administrative records. The agency shall take corrective action, if appropriate, on negative findings identified as a result of the program evaluation.

(1) Policy and Administrative Review: As part of the evaluation process, the agency shall review its policies and administrative practices to determine the extent to which they promote patient care that is appropriate, adequate, effective, and efficient.

(2) Quality assurance: The agency shall implement an ongoing quality assurance program designed to objectively and systematically monitor the quality and appropriateness of patient care. The agency shall perform this review at least quarterly. The agency's quality assurance program must include a review of clinical records.

(a) The quality assurance program shall consist of problem identification, implementation of a corrective action plan, and re-monitoring of identified problems.

(b) Quality assurance activities shall be performed by a multi-disciplinary team consisting of health professionals from each of the services the agency provides.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.085
Hist.: HD 151, f. & ef. 12-30-77; HD 19-1987, f. 11-10-87, ef. 12-1-87; HD 20-1993, f. & cert. ef. 10-28-93; Renumbered from 333-027-0065, OHD 13-1998, f. & cert. ef. 11-6-98

333-027-0170
Waivers

(1) Each agency must comply with ORS Chapter 443 and OAR chapter 333, division 027. However, an agency may request that the Division grant an exception to these rules for the use of alternative concepts, methods, procedures, techniques, equipment, facilities, personnel qualifications or the conducting of pilot projects or research. If an agency seeks an exception to the Division's rules, it must:

(a) Submit the request in writing to the Division;

(b) Identify the specific rule for which an exception is requested;

(c) Explain the special circumstances relied upon to justify the exception;

(d) List any alternatives that were considered and the reasons those alternatives were not selected;

(e) Demonstrate that the proposed exception is desirable to maintain or improve the health and safety of the patients and will not jeopardize patient health and safety; and

(f) State the proposed duration of the exception.

(2) After reviewing the written request, the Division may grant the exception. If the Division grants an exception, it shall issue its decision in writing.

(3) An agency may not implement any exception until it has received the Division's written approval of the exception.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.085
Hist.: HD 20-1993, f. & cert. ef. 10-28-93; Renumbered from 333-027-0067, OHD 13-1998, f. & cert. ef. 11-6-98; OHD 9-2002, f. & cert. ef. 7-2-02; PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0175
Violations

In addition to non-compliance with any law that governs a home health agency, it is a violation to:

(1) Refuse to cooperate with an investigation or survey, including but not limited to failure to permit Division staff access to the agency, its documents or records;

(2) Fail to implement an approved plan of correction;

(3) Refuse or fail to comply with an order issued by the Division;

(4) Refuse or fail to pay a civil penalty;

(5) Fail to comply with rules governing the storage of records following the closure of an agency;

(6) Fail to report suspected abuse of elderly persons as defined in ORS 124.050;

(7) Fail to return a license as provided in OAR 333-027-0033; or

(8) Operate without a license.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.045 & 443.085
Hist.: PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0180
Informal Enforcement

(1) If during an investigation or survey Division staff document violations of home health licensing rules or laws, the Division may issue a statement of deficiencies that cites the law alleged to have been violated and the facts supporting the allegation.

(2) A signed plan of correction must be mailed to the Division within 10 business days from the date the statement of deficiencies was received by the agency. A signed plan of correction will not be used by the Division as an admission of the violations alleged in the statement of deficiencies.

(3) An agency shall correct all deficiencies within 60 days from the date of the exit conference, unless an extension of time is requested from the Division. A request for such an extension shall be submitted in writing and must accompany the plan of correction.

(4) The Division shall determine if a written plan of correction is acceptable. If the plan of correction is not acceptable to the Division, the Division shall notify the agency owner in writing or by telephone:

(a) Identifying which provisions in the plan the Division finds unacceptable;

(b) Citing the reasons the Division finds them unacceptable; and

(c) Requesting that the plan of correction be modified and resubmitted no later than 10 working days from the date the letter of non-acceptance was received by the owner.

(5) If the agency does not come into compliance by the date of correction reflected on the plan of correction or 60 days from date of the exit conference, whichever is sooner, the Division may propose to deny, suspend, or revoke the agency license, or impose civil penalties.

Stat Auth.: ORS 443.085
Stats. Implemented: ORS 443.045 & 443.085
Hist.: PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0185
Formal Enforcement

(1) If during an investigation or survey Division staff document a substantial failure to comply with home health licensing laws or rules, or if an agency fails to pay a civil penalty imposed under ORS 443.045, the Division may issue a Notice of Proposed Suspension or Notice of Proposed Revocation in accordance with 183.411 through 183.470.

(2) The Division may issue a Notice of Imposition of Civil Penalty for violations of home health licensing laws.

(3) At any time the Division may issue a Notice of Emergency License Suspension under ORS 183.430(2).

(4) If the Division revokes an agency license, the order shall specify when, if ever, the agency may reapply for a license.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.045 & 443.085
Hist.: PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

333-027-0190
Civil Penalties

(1) An agency that violates home health licensing laws or rules, an administrative order, or settlement agreement is subject to the imposition of a civil penalty not to exceed $1,000 per violation and may not total more than $2,000.

(2) In determining the amount of a civil penalty, the Division shall consider whether:

(a) The Division made repeated attempts to obtain compliance;

(b) The licensee has a history of non-compliance with home health licensing laws and rules;

(c) The violation poses a serious risk to the public's health; and

(d) There are mitigating factors, such as a licensee's cooperation with an investigation or actions to come into compliance.

(3) The Division shall document its consideration of the factors in section (2) of this rule.

(4) Each day a violation continues is an additional violation.

(5) A civil penalty imposed under this rule shall comply with ORS 183.746.

Stat. Auth.: ORS 443.085
Stats. Implemented: ORS 443.045 & 443.085
Hist.: PH 7-2012, f. 3-30-12, cert. ef. 4-1-12

DIVISION 28

SCHOOL-BASED HEALTH PROGRAMS

School-Based Health Center Program

333-028-0200
Purpose

The school-based health center (SBHC) program supports communities in promoting the health and well-being of the school-age population through the evidence-based best practice within a public health framework. These rules (OAR 333-028-0200 through 333-028-0250) establish the procedure and criteria the Oregon Health Authority shall use to certify, suspend and decertify SBHCs. Certification of a SBHC by the SBHC state program is voluntary; an operating clinic is free to choose not to participate in certification and still operate. Only certified SBHCs are eligible for funding from Oregon Health Authority.

Stat. Auth.: ORS 413.223
Stats. Implemented: ORS 413.223, 413.225
Hist.: PH 15-2013, f.12-26-13, cert. ef. 1-1-14

333-028-0210
Definitions

(1) "Authority" means the Oregon Health Authority.

(2) "Certification year" means a one-year period beginning on July 1 and ending on June 30.

(3) "Electronic health record (EHR)" means an electronic record of an individual's health-related information that conforms to nationally recognized interoperability standards and that can be created, managed and consulted by authorized clinicians and staff across more than one health care provider.

(4) "Electronic medical record (EMR)" means a digital version of a paper chart that contains all of the patient's medical history from one practice. An EMR is mostly used by providers for diagnosis and treatment.

(5) "Program" means the Oregon Health Authority, Public Health Division, school-based health center program.

(6) "School-based health center" (SBHC) has the meaning given the term in ORS 413.225.

(7) "SBHC system" is one or more SBHCs that operate under the same sponsoring agency.

(8) "Sponsoring agency" is an entity that provides the following services for a SBHC or contracts with another entity to provide one or more of the following:

(a) Funding;
(b) Staffing;
(c) Medical oversight;
(d) Liability insurance; and
(e) Billing support.

Stat. Auth.: ORS 413.223
Stats. Implemented: ORS 413.223, 413.225
Hist.: PH 15-2013, f.12-26-13, cert. ef. 1-1-14

333-028-0220
Certification Requirements

In order to be certified as a SBHC, a SBHC must meet all requirements for certification in the following sections of the 2014 SBHC Standards for Certification Manual, incorporated by reference.

(1) Sponsoring agency, section B.1;
(2) Facility, section B.2;
(3) Hours of operation, section C.1;
(4) Staffing, section C.2;
(5) Eligibility for services, section C.3;
(6) Policies and procedures, section C.4;
(7) Laboratory/Diagnostic services, section D;
(8) Comprehensive Services, section E.1;
(9) Equipment, section E.2;
(10) Medication, section E.3;
(11) Data collection/reporting, section F; and
(12) Billing, section G.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 413.223
Stats. Implemented: ORS 413.223, 413.225
Hist.: PH 15-2013, f.12-26-13, cert. ef. 1-1-14; PH 9-2015(Temp), f. & cert. ef. 5-6-15 thru 11-1-15; PH 18-2015, f. 9-30-15, cert. ef. 10-1-15

333-028-0230
Application and Certification Process

(1) An individual with legal authority to act on behalf of the entity that administers a SBHC may apply for certification of a SBHC by submitting a SBHC Certification Application to the Authority via electronic mail to the program's electronic mail address posted on the program's website or by mail to the mailing address posted on the program's website, www.healthoregon.org/sbhc. Instructions and criteria for submitting a SBHC Certification Application is posted on the program's website.

(2) An individual may submit an application for more than one SBHC provided that each SBHC will be administered by the same entity and each SBHC individually meets the certification requirements.

(3) The program shall review the application within 30 days of receiving the application to determine whether it is complete.

(4) If the program determines that the application is not complete, it will be returned to the applicant for completion and resubmission.

(5) If the program determines that the application is complete it will be reviewed to determine if it meets certification requirements described in OAR 333-028-0210. If the program determines that on the face of the application and in reviewing any other applicable documents that the SBHC meets the certification requirements the program shall:

(a) Inform the applicant in writing that the application has been approved;

(b) Request the applicant complete the program's online Operational Profile forms prior to the on-site verification review; and

(c) Schedule an on-site verification review.

(6) If a SBHC does not meet certification requirements in their certification application, the Authority may choose one of the following actions:

(a) The program may deny SBHC certification if the SBHC does not meet the requirements of these rules. The program will provide the applicant with a clear description of reasons for denial based on the certification requirements in the denial letter. An applicant may request that the program reconsider the denial of SBHC certification. A request for reconsideration must be submitted in writing to the program within 90 days of the date of the denial letter and must include a detailed explanation of why the applicant believes the program's decision is in error along with any supporting documentation. The program shall inform the applicant in writing whether it has reconsidered its decision; or

(b) The program may approve the applicant's SBHC certification based on an agreed upon timeline for a corrective action plan for the non-compliant requirements. The site must submit a waiver to the program that includes an explanation of the non-compliant requirements, a plan for corrective action and date for meeting compliance.

(7) Once a SBHC is certified, the certification status is effective for the following certification year.

(8) A certified SBHC must renew its certification no later than October 1 each year via the program's online Operational Profile forms in order to remain certified.

(9) The program will notify SBHCs of their certification renewal status by November 1 each year.

Stat. Auth.: ORS 413.223
Stats. Implemented: ORS 413.223, 413.225
Hist.: PH 15-2013, f.12-26-13, cert. ef. 1-1-14

333-028-0240
Verification

(1) The program shall conduct one on-site verification review of each approved SBHC within one year of application approval to determine compliance with SBHC certification requirements.

(2) After the initial on-site verification review, the program shall conduct an on-site verification review every two years for a representative sample of certified SBHCs in each SBHC system.

(3) A SBHC will be notified, in writing, no less than 30 days before its scheduled verification review.

(4) A SBHC must permit program staff access to the site's place of business during the review.

(5) The verification review must include, but is not limited to:

(a) Review of documents, policies and procedures, and records;

(b) Review of electronic medical record systems, review of electronic health records systems, and review of practice management systems;

(c) Review of data reports from electronic systems or other patient registry and tracking systems;

(d) Interviews with practice management, clinical and administrative staff;

(e) On-site observation of practice staff with at a minimum two patients, with the consent of the patient; and

(f) On-site observation of patient environment and physical environment.

(6) Following a review, program staff may conduct an exit interview with SBHC representative(s). During the exit interview the program staff shall:

(a) Inform the SBHC representative(s) of the preliminary findings of the review; and

(b) Give the SBHC representatives(s) a reasonable opportunity to submit additional facts or other information to the program staff in response to the findings.

(7) Within two weeks of the on-site visit program staff must prepare and provide the SBHC with a written report of the findings from the on-site review.

(8) If no certification deficiencies are found during the review, the program shall issue written findings to the SBHC indicating no deficiencies were found.

(9) If certification deficiencies are found during the on-site review, the program may take action in compliance with OAR 333-028-0250.

(10) The program may conduct a review of a certified SBHC without prior notice of any or all selected certification requirements for compliance and perform a verification on-site review of a certified SBHC if the program is made aware of issues of compliance from any source.

(11) At any time, a SBHC may request an administrative review of compliance, which includes one on-site visit. The review will be considered a "no penalty" review with the exception of gross violation or negligence that may require site closure or temporary suspension of services.

Stat. Auth.: ORS 413.223
Stats. Implemented: ORS 413.223, 413.225
Hist.: PH 15-2013, f.12-26-13, cert. ef. 1-1-14

333-028-0250
Compliance

(1) A SBHC must notify the program within 20 days of any change that brings the SBHC out of compliance with the certification requirements. A SBHC must submit a waiver to the program that includes an explanation of the non-compliant requirement, a plan for corrective action and date for meeting compliance.

(2) The program will review the waiver request and inform the SBHC of approval or denial of the waiver within two weeks of submission.

(3) If the waiver is approved the SBHC must comply with certification requirements by the proposed date of compliance.

(4) If a waiver is denied; a SBHC does not come into compliance by the date of compliance stated on the waiver; or a SBHC is out of compliance with certification requirements and has not submitted a waiver, based on the program's discretion, the program may:

(a) Require the SBHC to complete an additional waiver with an updated plan for corrective action and updated date for meeting compliance; or

(b) Require the SBHC to complete a waiver to satisfy the requirements in section (1) of this rule; or

(c) Issue a written warning with a timeline for corrective action; or

(d) Issue a letter of non-compliance with the notification of a suspension or decertification status.

(5) A SBHC that had been decertified may be reinstated after reapplying for certification.

(6) A SBHC with its certification status suspended may have its suspension lifted once the program determines that compliance with certification requirements has been achieved satisfactorily.

(7) If there are updates to the current rules that require a SBHC to make any operational changes, the program will allow the SBHC until the beginning of the next certification year or a minimum of 90 days to come into compliance.

Stat. Auth.: ORS 413.223
Stats. Implemented: ORS 413.223, 413.225
Hist.: PH 15-2013, f.12-26-13, cert. ef. 1-1-14

333-028-0260
Funding Criteria for Certified SBHCs

(1) The program is required, under ORS 413.225 to provide funds for the expansion and continuation of certified school-based health centers.

(2) A SBHC that is certified by the program is eligible for funding by the program.

(3) Funding for a certified SBHC may be provided, but is not limited to being provided, to:

(a) A local public health authority, as that is defined in ORS 431.260;

(b) A sponsoring agency; or

(c) A coordinated care organization, or governmental entity or person that can demonstrate a significant interest and involvement in assisting and coordinating with SBHCs.

(4) Funding award amounts will be primarily based on the number of certified SBHCs in the county and legislatively approved budget. The program may take into consideration other factors such as the quality of the health care services, clients served, and population needs.

(5) Funding for certified SBHCs shall be awarded for up to two years. Fund awards are renewable based on the certification renewal process per OAR 333-028-0220.

(6) Funding for a certified SBHC may be suspended or discontinued at the program's discretion if a certified SBHC is out of compliance with certification requirements and the program has issued a suspension notice under OAR 333-028-0250(4).

(7) The program must discontinue funding of an SBHC that has been decertified.

Stat. Auth.: ORS 413.223
Stats. Implemented: ORS 413.223, 413.225
Hist.: PH 10-2014, f. & cert. ef. 4-1-14

333-028-0270
Funding Criteria for SBHC Planning Communities

(1) The program is required to direct funds to communities planning for certified school-based health centers and will do so through a competitive grant proposal process for one or two year planning grants.

(2) Any of the following entities may be eligible to apply for planning grant funds on behalf of their community:

(a) A local public health authority;

(b) A school or school district;

(c) A coordinated care organization as that is defined in ORS 414.025;

(d) Medical, dental or mental health organizations; or

(e) A governmental entity or person that can demonstrate a significant interest and involvement in establishing, assisting or coordinating with SBHCs.

(3) The program will specify in its published request for proposals which entities within a community are eligible for that specific grant award.

(4) Planning grant applicants will be evaluated on elements outlined in the request for proposal, which must include but is not limited to an evaluation of community need and readiness for a SBHC.

(5) The grant amount awarded shall be determined based on number of awarded applicants and legislatively approved budget.

(6) Funding for planning communities shall be awarded for up to two years.

Stat. Auth.: ORS 413.223
Stats. Implemented: ORS 413.223, 413.225
Hist.: PH 10-2014, f. & cert. ef. 4-1-14

333-028-0280
Funding Criteria for Incentive Funds

(1) The program shall award grant funding to communities with certified SBHCs through a competitive grant proposal process in order to incentivize:

(a) Increasing the number of SBHCs as state-recognized patient-centered primary care homes as that is defined in ORS 414.025;

(b) Improve coordination of care of patients served by coordinated care organizations and SBHCs; and

(c) Improve the effectiveness of the delivery of health services through SBHCs to children who qualify for medical assistance.

(2) Any entity or person described in OAR 333-028-0270(2) may apply for funding and the program will specify in its published request for proposals which entities within a community are eligible for that specific grant award.

(3) The program will evaluate applicants based on elements outlined in the request for proposals, which must include but is not limited to an evaluation of whether the person or entity has the qualifications to accomplish one or more of the activities described in subsections (1)(a) through (c) of this rule.

(4) Funding awards shall be determined based on number of awarded applicants and legislatively approved budget.

(5) Funding for the incentive grants shall be awarded for up to two years.

Stat. Auth.: ORS 413.223
Stats. Implemented: ORS 413.223, 413.225
Hist.: PH 10-2014, f. & cert. ef. 4-1-14

Certification for Local School Dental Sealant Programs

333-028-0300
Purpose

(1) The Oral Health Program supports communities in improving the oral health of the school-age population through evidence-based best practice within a public health framework. The Association of State and Territorial Dental Directors (ASTDD), Centers for Disease Control and Prevention (CDC), and the Community Preventive Services Task Force have all determined that school-based dental sealant programs are evidence-based best practices with strong evidence of effectiveness in preventing tooth decay among children.

(2) These rules (OAR 333-028-0300 through 333-028-0350) establish the procedure and criteria the Oregon Health Authority shall use to certify, train, suspend, decertify, and monitor and collect data from Local School Dental Sealant Programs. Certification of a Local School Dental Sealant Program by the State Oral Health Program is mandatory before dental sealants can be provided in a school setting.

Stat. Auth.: OL 2015, ch. 791
Stats. Implemented: OL 2015, ch. 791
Hist. : PH 2-2016, f. & cert. ef. 1-29-16

333-028-0310
Definitions

(1) "Authority" means the Oregon Health Authority.

(2) "Certification" means the Local School Dental Sealant Program has been authorized by the Oregon Health Authority to operate in an elementary or middle school setting. Certification by the Program is mandatory before dental sealants can be provided in a school setting.

(3) "Certification training" is a mandatory one-time training for Local School Dental Sealant Programs provided by the Program that must be taken before an application for certification is submitted. Training topics shall include:

(a) Research and evidence-based practices;
(b) Utilizing hygienists and dental assistants;
(c) Cultural competency and health literacy;
(d) Recruiting and working with schools;
(e) Providing services in a school setting;
(f) Equipment and supplies needed;
(g) Protocols for quality;
(h) Data collection and reporting; and
(i) Continuous quality improvement.

(4) "Certification year" means a one-year period beginning on August 1 and ending on July 31.

(5) "Clinical training" is an annual training provided by the Local School Dental Sealant Program or Program to update skills in determining the need for and appropriateness of dental sealants, and sealant application techniques.

(6) "Local School Dental Sealant Program" is an entity outside of the Oregon Health Authority where dental sealants are one of the services being provided in a school setting. Only Local School Dental Sealant Programs, and not individual dental hygienists, can be certified.

(7) "Program" means the Oregon Health Authority, Public Health Division, Oral Health Program.

(8) "Recertification" means the Local School Dental Sealant Program has been authorized by the Oregon Health Authority to operate in a school setting for the next certification year.

Stat. Auth.: OL 2015, ch. 791
Stats. Implemented: OL 2015, ch. 791
Hist. : PH 2-2016, f. & cert. ef. 1-29-16

333-028-0320
Certification Requirements

To be certified, a Local School Dental Sealant Program must meet all requirements for certification.

(1) A representative responsible for coordinating and implementing the Local School Dental Sealant Program must attend a one-time certification training provided by the Program. If the Local School Dental Sealant Program experiences personnel changes that impact the representative responsible for coordinating and implementing the Local School Dental Sealant Program, then a new representative must attend the one-time certification training before applying for recertification. Any templates or materials provided by the Program during the certification training that are modified or utilized by the Local School Dental Sealant Program must acknowledge the Program on such templates or materials.

(2) A Local School Dental Sealant Program must provide an annual clinical training to all providers rendering care within their scope of practice in a school setting. This requirement may be met by one of these methods:

(a) A Local School Dental Sealant Program develops and implements its own training.

(b) A Local School Dental Sealant Program sends their providers to an annual training provided by the Program.

(3) Before initially contacting any school to offer services, a Local School Dental Sealant Program must contact the Coordinated Care Organizations (CCOs) operating in the community. In consultation with the Program, the CCO will determine which Local School Dental Sealant Program is best able to provide services. A CCO must contact the Program before any decision is made. This collaboration will ensure access and minimize the duplication of services. Priorities should be given to the most cost-effective dental sealant delivery model that meets certification requirements. Existing relationships with schools and providers should be considered when multiple delivery models meet requirements. The Program will provide the CCOs with a list of school dental sealant

programs and the schools they serve from the Certification Application and Renewal Certification Application forms.

(4) A Local School Dental Sealant Program must ensure all Medicaid encounters are entered into the Medicaid system.

(5) A Local School Dental Sealant Program shall first target elementary and middle schools where 40 percent or greater of all students attending the school are eligible to receive assistance under the United States Department of Agriculture's National School Lunch Program.

(6) A Local School Dental Sealant Program must offer, at a minimum, screening and dental sealant services to students with parental/guardian permission regardless of insurance status, race, ethnicity or socio-economic status in these grade levels:

(a) Elementary school students in first and second grades or second and third grades; and

(b) Middle school students in sixth and seventh grades or seventh and eighth grades.

(7) A Local School Dental Sealant Program must develop and implement a plan to increase parental/guardian permission return rates.

(8) A Local School Dental Sealant Program must adhere to these standards for school dental sealant programs:

(a) Dental equipment must be used on school grounds during school hours;

(b) A medical history is required on the parent/guardian permission form;

(c) Use the four-handed technique to apply sealants in elementary schools;

(d) Use the two-handed technique using an Isolite or equivalent Program approved device or the four-handed technique to apply sealants in middle and high schools; and

(e) Apply resin-based sealants.

(9) A Local School Dental Sealant Program must comply with all scope of practice laws as determined by the Oregon Board of Dentistry.

(10) A Local School Dental Sealant Program must comply with Oregon Board of Dentistry oral health screening guidelines.

(11) A Local School Dental Sealant Program must comply with infection control guidelines established in OAR 818-012-0040.

(12) A Local School Dental Sealant Program must comply with the Health Insurance Portability and Accountability Act (HIPAA) and Federal Educational Rights and Privacy Act (FERPA) requirements.

(13) A Local School Dental Sealant Program must respect classroom time and limit demands on school staff. Services must be delivered efficiently to ensure a child's time out of the classroom is minimal.

(14) A Local School Dental Sealant Program must conduct retention checks at one year for quality assurance.

(15) A Local School Dental Sealant Program must submit a data report to the Program annually. The information required to be included in such data report will be defined by the Program. Aggregate-level data will be required for each school.

(16) A Local School Dental Sealant Program must include the certification logo provided by the Program on all parent/guardian permission forms and written communication to schools, or provide schools with a letter provided by the Program indicating the Local School Dental Sealant Program is certified.

Stat. Auth.: OL 2015, ch. 791
Stats. Implemented: OL 2015, ch. 791
Hist. : PH 2-2016, f. & cert. ef. 1-29-16

333-028-0330
Certification and Recertification Process

(1) Only an individual with legal authority to act on behalf of the Local School Dental Sealant Program can apply for initial certification by submitting a Certification Application to the Authority via electronic mail to the Program's electronic mail address posted on the Program's website or by mail to the mailing address posted on the Program's website, www.healthoregon.org/sealantcert. Instructions and criteria for submitting a Certification Application is posted on the Program's website.

(2) The Program shall review the application within 15 days of receiving the application to determine whether it is complete.

(3) If the Program determines the application is not complete, it will be returned to the applicant for completion and resubmission.

(4) If the Program determines the application is complete, it will be reviewed to determine if it meets certification requirements described in OAR 333-028-0320.

(5) If the Program determines the Local School Dental Sealant Program meets the certification requirements, the Program shall:

(a) Inform the applicant in writing that the application has been approved; and

(b) Schedule on-site verification reviews.

(6) If a Local School Dental Sealant Program does not meet certification requirements in their certification application, the Program shall choose one of the following two actions:

(a) Certification will be denied if the Local School Dental Sealant Program does not meet the requirements of these rules. The Program will provide the applicant with a clear description of reasons for denial based on the certification requirements in the denial letter. An applicant may request that the Program reconsider the denial of certification. A request for reconsideration must be submitted in writing to the Program within 30 days of the date of the denial letter and must include a detailed explanation of why the applicant believes the Program's decision is in error along with any supporting documentation. The Program shall inform the applicant in writing whether it has reconsidered its decision; or

(b) Provisional certification will be provided based on an agreed upon timeline for a corrective action plan for the non-compliant requirements. The Local School Dental Sealant Program must submit a waiver to the Program that includes an explanation of the non-compliant requirements, a plan for corrective action, and date for meeting compliance.

(7) Once a Local School Dental Sealant Program is certified, the certification status is effective for the certification year of August 1 – July 31. A Local School Dental Sealant Program must notify the Program and Coordinated Care Organizations (CCOs) operating in the community if it terminates services for a scheduled school during a certification year.

(8) A certified Local School Dental Sealant Program must renew its certification no later than July 15 each year via the Program's online Renewal Certification Application form in order to remain certified. A Local School Dental Sealant Program must submit the annual data report to the Program before applying for renewal certification.

(9) The Program will notify a Local School Dental Sealant Program of their certification renewal status by August 1 of each year.

(10) The Program will notify Coordinated Care Organizations (CCOs) operating in the community of the certification and recertification status of a Local School Dental Sealant Program.

Stat. Auth.: OL 2015, ch. 791
Stats. Implemented: OL 2015, ch. 791
Hist. : PH 2-2016, f. & cert. ef. 1-29-16

333-028-0340
Verification

(1) The Program shall conduct on-site verification review of each approved Local School Dental Sealant Program. A representative sample of schools being served by the certified program will be reviewed each certification year.

(2) The Program will work with a Local School Dental Sealant Program to schedule a verification review. A Local School Dental Sealant Program will have at least 20 days advance notice before a review will occur.

(3) A Local School Dental Sealant Program must coordinate with the Program to access the school and staff operating the sealant program on the verification review date.

(4) The verification review must include, but is not limited to:

(a) Review of documents, policies and procedures, and records;

(b) Review of techniques used while providing dental sealants;

(c) Review of infection control practices; and

(d) On-site observation of the client environment and physical set-up.

(5) Following a review, Program staff may conduct an exit interview with the Local School Dental Sealant Program representative(s). During the exit interview Program staff shall:

(a) Inform the Local School Dental Sealant Program representative(s) of the preliminary findings of the review; and

(b) Give the Local School Dental Sealant Program representative(s) 10 working days to submit additional facts or other information to the Program staff in response to the findings.

(6) Within four weeks of the on-site visit, Program staff must prepare and provide the Local School Dental Sealant Program with a written report of the findings from the on-site review.

(7) If no certification deficiencies are found during the review, the Program shall issue written findings to the Local School Dental Sealant Program indicating no deficiencies were found.

(8) If certification deficiencies are found during the on-site review, the Program may take action in compliance with OAR 333-028-0350.

(9) At any time, a Local School Dental Sealant Program may request an administrative review of compliance, which includes one on-site visit. The review will be considered a "no penalty" review with the exception of gross violation or negligence that may require temporary suspension of services.

Stat. Auth.: OL 2015, ch. 791
Stats. Implemented: OL 2015, ch. 791
Hist. : PH 2-2016, f. & cert. ef. 1-29-16

333-028-0350
Compliance

(1) A Local School Dental Sealant Program must notify the Program within 10 working days of any change that brings the Local School Dental Sealant Program out of compliance with the certification requirements. A Local School Dental Sealant Program must submit a waiver to the Program that includes:

(a) Explanation of the non-compliant requirement;

(b) Plan for corrective action; and

(c) Date for compliance.

(2) The Program will review the waiver request and inform the Local School Dental Sealant Program of approval or denial of the waiver within 10 working days of submission. Services may be provided until the Local School Dental Sealant Program has been notified of its waiver request.

(3) If the waiver is approved, the Local School Dental Sealant Program will be provided provisional certification and must comply with certification requirements by the proposed date of compliance.

(4) If a waiver is denied; a Local School Dental Sealant Program does not come into compliance by the date of compliance stated on the waiver; or a Local School Dental Sealant Program is out of compliance with certification requirements and has not submitted a waiver, the Program, in its discretion, shall:

(a) Require the Local School Dental Sealant Program to complete an additional waiver with an updated plan for corrective action and updated date for compliance;

(b) Require the Local School Dental Sealant Program to complete a waiver to satisfy the requirements in section (1) of this rule;

(c) Issue a written warning with a timeline for corrective action; or

(d) Issue a letter of non-compliance with the notification of a suspension or decertification status. The Program will notify the CCO operating in the community and Local School Dental Sealant Program schools that a Local School Dental Sealant Program has been suspended or decertified. Dental sealants may not be provided in the school until the Local School Dental Sealant Program is certified.

(5) A Local School Dental Sealant Program that had been decertified may be reinstated after reapplying for certification.

(6) A Local School Dental Sealant Program with suspended certification status may have its suspension lifted once the Program determines that compliance with certification requirements has been satisfactorily achieved. The Program will notify the Coordinated Care Organizations (CCOs) operating in the community and schools that the Local School Dental Sealant Program's suspension has been lifted and that dental sealants may now be provided in the school.

(7) If there are updates to the current rules that require a Local School Dental Sealant Program to make any operational changes, the Program will allow the Local School Dental Sealant Program until the beginning of the next certification year or a minimum of 90 days to come into compliance.

Stat. Auth.: OL 2015, ch. 791
Stats. Implemented: OL 2015, ch. 791
Hist. : PH 2-2016, f. & cert. ef. 1-29-16

DIVISION 29

TRAVELERS' ACCOMMODATION RULES

333-029-0005
Purpose

These rules adopted pursuant to the provisions of ORS 446.330, prescribe the requirements for the construction and operation of travelers' accommodations and hostels. They are for the purpose of protecting the health and welfare of persons using those facilities.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.315 & 446.310 - 446.375
Hist.: HD 1-1978, f. & ef. 1-4-78; HD 19-1983(Temp), f. & ef. 10-18-83; HD 12-1984, f. & ef. 6-20-84; HD 5-1985, f. & ef. 4-25-85

333-029-0010
Adoption by Reference

Outside standards, listings, and publications referred to in these rules are by reference made a part of this division.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 183.355
Hist.: HD 1-1978, f. & ef. 1-4-78; HD 5-1985, f. & ef. 4-25-85

333-029-0015
Definitions

As used in these rules unless otherwise required by context:

(1) "Administrator" means the Assistant Director for Oregon Health Authority, Public Health Division.

(2) "Approval or Approved" means approved in writing.

(3) "Division" means Health Services of the Oregon Health Authority, Public Health Division.

(4) "Dormitory" means a room containing beds, cots, or other sleeping places and occupied by unrelated or separate groups and/or other individuals. Every 100 square feet of usable floor space in a dormitory shall constitute a lodging unit.

(5) "Hostel" means any establishment having beds rented or kept for rent on a daily basis to travelers for a charge or fee paid or to be paid for rental or use of facilities and which are operated, managed or maintained under the sponsorship of a nonprofit organization which holds a valid exemption from federal income taxes under 26 USC Sec. 501.

(6) "Issuing Authority" means the Oregon Health Authority, Public Health Division, its delegate, or contract agent.

(7) "Lodging Unit" means one or more self-contained rooms for travelers' occupancy, including those for sleeping, sitting, or cooking purposes, and except where a travelers' accommodation is comprised of a single lodging unit, designated by a number, letter, or other means of identification.

(8) "Person" means individuals, corporations, associations, firms, partnerships, and joint stock companies as well as public entities of any character.

(9) "Tourist Facility" means any traveler's accommodation, hostel, picnic park, recreation park, and organizational camp.

(10) "Travelers' Accommodation" includes any establishment, which is not a hostel, having rooms, apartments or sleeping

facilities rented or kept for rent on a daily or weekly basis to travelers or transients for a charge or fee paid or to be paid for rental or use of facilities.

(11) "Unregulated Small Drinking Water System" means a facility licensed under the authority of these rules that is not regulated under OAR 333-061, Public Water Systems. These systems must comply with the requirements of OAR 333-029-0075.

(12) "Usable Floor Space" means all floor space in a lodging unit not occupied by closets, built-ins, toilet rooms, bathrooms, or shower rooms.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.310, 446.330
Hist.: HD 1-1978, f. & ef. 1-4-78; HD 19-1983(Temp), f. & ef. 10-18-83; HD 12-1984, f. & ef. 6-20-84; HD 5-1985, f. & ef. 4-25-85; PH 1-2005, f. & cert. ef. 1-14-05

333-029-0020
Licensure Required

No person shall operate, manage, or maintain any travelers' accommodation or hostel without first:

(1) Making application for a license;

(2) Paying the license application fee; and

(3) Securing a license from the issuing authority.

(4) All licenses issued under ORS 446.310 to 446.350 terminate and are renewable on December 31 of each year.

Stat. Auth.: ORS 446.315 & 446.321
Stats. Implemented: ORS 446.3320, 446.321 & 446.323
Hist.: HD 1-1978, f. & ef. 1-4-78; HD 19-1983(Temp), f. & ef. 10-18-83; HD 12-1984, f. & ef. 6-20-84; HD 5-1985, f. & ef. 4-25-85

333-029-0025
Plans Required

No person may construct, enlarge, or alter any travelers' accommodation or hostel without first:

(1) Submitting complete plans and specifications of the proposed construction, enlargement, or alteration to the issuing authority; and

(2) Securing plan approval from the issuing authority.

(3) Plan review is made by the Oregon Building Codes Division or by jurisdictions exempt under ORS 476.030. Written evidence of plan review, construction permit issuance, and a signed occupancy permit must be presented to the local public health authority before licensing.

(4) Whenever a food service facility, operating in conjunction with a travelers' accommodation so licensed under these rules, is constructed or extensively remodeled and whenever an existing structure is converted to use as a food service facility, properly prepared plans and specifications for such construction, remodeling or conversion must be submitted to the local public health authority for approval before construction. Plans must be submitted in accordance with Oregon Food Sanitation Rules OAR 333-150-0000 part 8-2.

Stat. Auth.: ORS 446.330 & 624.020
Stats. Implemented: ORS 446.310 - 446.350, 446.990 & 624.020
Hist.: HD 1-1978, f. & ef. 1-4-78; HD 19-1983(Temp), f. & ef. 10-18-83; HD 12-1984, f. & ef. 6-20-84; HD 5-1985, f. & ef. 4-25-85; PH 15-2009, f. & cert. ef. 12-23-09

333-029-0035
Supervision

The operator of a travelers' accommodation or hostel shall be available on the premises while it is open for use. In lieu thereof, there shall be posted on the premises the name and location of the operator or his representative who shall be responsible for the operation of the facility.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 1-1978, f. & ef. 1-4-78; HD 19-1983(Temp), f. & ef. 10-18-83; HD 12-1984, f. & ef. 6-20-84; HD 5-1985, f. & ef. 4-25-85

333-029-0040
General Sanitation

All buildings, other facilities, equipment, fixtures, furnishings and the premises of travelers' accommodations and hostels shall be kept clean, in good repair, and maintained so as to protect the health, safety, and well being of persons using those facilities.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 1-1978, f. & ef. 1-4-78; HD 19-1983(Temp), f. & ef. 10-18-83; HD 12-1984, f. & ef. 6-20-84; HD 5-1985, f. & ef. 4-25-85

333-029-0045
Air Volume, Heat, Light, and Ventilation for Hostels

(1) Each dormitory must:

(a) Have a ceiling height of not less than seven feet, six inches; and

(b) Have not less than 375 cubic feet of air volume and 50 square feet of usable floor area for each occupant.

NOTE: If any room used for sleeping purposes has a sloping ceiling, the prescribed ceiling height is required in only one-half the area thereof. Floor area where the ceiling is less than five feet from the finished floor to the finished ceiling may not be considered usable.

(2) Bed arrangements of dormitories must provide not less than 24 inches clear space between each bed, cot, or bunk. No dormitory may contain more than two tiers of beds. When two tiers are used, there must be at least:

(a) Three feet of clear vertical space between tiers of beds and between the top tier and ceiling;

(b) Thirty inches of horizontal space between beds;

(c) One foot of clear space between the floor of the dormitory and the underside of the first tier of beds. In lieu of such space, the first tier of bunks must have a continuous base that must be sealed to the floor; and

(d) A minimum aisle width with access to exits must be provided as follows:

(A) Thirty-six inch aisle width when serving a tributary occupant load of 30 or less persons;

(B) Forty-four inch aisle width when serving a tributary occupant load of more than 30 persons;

(C) If more than three beds are placed end to end in a row, there must be an approved aisleway at each end of the row in compliance with paragraph (A) or (B) of this subsection, whichever is appropriate to the occupant load.

(3) Every dormitory, shower, bath and toilet room used during periods requiring artificial heat must be provided with a safe and adequate source of heat by means of air exchange from other room(s) or by mechanical means capable of maintaining room temperature of not less than 68° F. at a level three feet above the floor during the time of occupancy.

(4) All sleeping rooms must be provided with natural light and ventilation by means of windows or skylights with an area of not less than one-tenth of the floor area of such rooms. The minimum area must be 10 square feet:

(a) Not less than one-half of the required window or skylight area may be openable to provide natural ventilation.

(b) In lieu of natural ventilation, a mechanical ventilation system must be provided. Such system must be capable of providing two air changes per hour and one-fifth of the air supply must be taken from the outside.

(c) In lieu of natural lighting, artificial lighting must be provided. Such lighting must be at least 10 foot candles in intensity three feet from the floor surface.

(5) All bathrooms, toilet rooms, laundry rooms, and similar rooms must be provided with natural light and ventilation by means of windows or skylights with an area equal to one-tenth of the floor area of such rooms. The minimum area must be three square feet:

(a) Not less that one-half of the required window or skylight area must be openable to provide natural ventilation. Openable windows must be screened.

(b) In lieu of natural ventilation, a mechanical ventilation system connected directly to the outside must be capable of providing five air changes per hour.

(c) In lieu of natural lighting, artificial lighting must be provided. Such lighting must be at least 10 foot candles in intensity three feet from the floor surface.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.310 - 446.350 & 446.990
Hist.: HD 1-1978, f. & ef. 1-4-78; HD 5-1985, f. & ef. 4-25-85; PH 15-2009, f. & cert. ef. 12-23-09

333-029-0050
Toilet, Lavatory, and Bath Facilities

(1) At least one toilet, lavatory, and bath must be provided for each five lodging units or fraction thereof where the individual lodging units are not provided such facilities. The required number of sanitary fixtures must be in accordance with the requirements of the Oregon Department of Consumer and Business Services, Building Codes Division.

(a) Multi-story accommodations constructed after July 1, 1970, must have toilet, lavatory, and bath facilities located on each floor. Toilets, lavatories and bath facilities must be maintained in a clean and sanitary condition.

(b) New toilet, lavatory and bath facilities, or facilities remodeled, enlarged or converted after the effective date of these rules must meet the requirements of the 2008 Oregon Plumbing Specialty Code and the 2007 Oregon Structural Specialty Code.

(2) The location and use of all public toilet and bath facilities must be clearly indicated by appropriate signs.

(3) Toilet, lavatory, and bath facilities for travelers' accommodations and hostels located in private homes must be separate from toilet and bath facilities utilized by the owner or operator of said travelers' accommodations and hostels.

(4) All lavatories, bathtubs, and showers must be provided with hot and cold water except where otherwise specifically exempted by the Division. Hot water must be at least 120° F.

(5) Toilet and bathrooms must:

(a) Have floors which are finished with a material that is smooth, easily cleanable, impervious to water, and coved to a height of four inches;

(b) Have shower compartments with walls which are impervious to water to a height of six feet above the floor. An effective water-tight joint between the wall and the floor must be maintained. (Wooden racks or duck boards over shower floors are prohibited);

(c) Have interior finishes which are smooth, easily cleanable, and impervious to water;

(d) Where rubber or impervious mats are used, have such mats clean and dry between usages;

(e) Have bathtub and shower stall floors that are finished with non-slip, impervious surfaces or provided with non-slip impervious bath mats; and

(f) Where glass bath or glass shower doors are used, have such doors made of safety glass.

(6) Non-water carried sewage disposal may not be used in lieu of water carried sewage disposal unless approved by the issuing authority and the Department of Environmental Quality according to OAR 340-071-0130.

(7) All plumbing installations must be in accordance with the requirements of the Oregon Department of Consumer and Business Services, Building Codes Division, 2008 Oregon Plumbing Specialty Code. New plumbing installations, or systems remodeled, enlarged or converted after the effective date of these rules must meet the requirements of the 2008 Oregon Plumbing Specialty Code.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.310 - 446.350 & 446.990
Hist.: HD 1-1978, f. & ef. 1-4-78; HD 19-1983(Temp), f. & ef. 10-18-83; HD 12-1984, f. & ef. 6-20-84; HD 5-1985, f. & ef. 4-25-85; PH 1-2005, f. & cert. ef. 1-14-05; PH 15-2009, f. & cert. ef. 12-23-09

333-029-0060
Solid Waste

(1) A minimum of one water-tight, non-absorbent and easily washable waste receptacle must be provided in each lodging unit. Such receptacle shall be kept clean and in good repair.

(2) Solid waste must be collected daily from rooms and areas used by guests.

(3) Solid waste must be disposed of in a manner which complies with the rules of the Department of Environmental Quality.

(4) Solid waste must be stored in individual garbage containers, bins, or storage vehicles.

(5) All such containers, bins, or vehicles must:

(a) Have tight fitting lids or covers; and

(b) Be durable, rust resistant, water-tight, rodent proof, readily washable, and kept in good repair.

(6) Solid waste must be collected at regular intervals. Such intervals may not exceed seven days. Collection frequency must be such so as not to create:

(a) Vector production and sustenance;

(b) Objectionable odors; or

(c) Any overflowing of solid waste or other unsanitary condition.

(7) Solid waste must be transported in a manner that complies with Department of Environmental Quality requirements.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.310 - 446.350 & 446.990
Hist.: HD 1-1978, f. & ef. 1-4-78; HD 5-1985, f. & ef. 4-25-85; PH 15-2009, f. & cert. ef. 12-23-09

333-029-0065
Vector Control

(1) Vector control measures shall be employed to prevent vector infestations in travelers' accommodations and hostels.

(2) Insect and rodent control measures to safeguard public health and to prevent nuisance to the public shall be applied. Developed areas, buildings, and structures shall be maintained free of accumulations of debris.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 1-1978, f. & ef. 1-4-78; HD 19-1983(Temp), f. & ef. 10-18-83; HD 12-1984, f. & ef. 6-20-84; HD 5-1985, f. & ef. 4-25-85

333-029-0070
Spa and Swimming Pools

Any spa or swimming pool located at or operated in connection with a travelers' accommodation or hostel must comply with the respective Oregon Public Health Division rules:

(1) For Public Spa Pools, OAR 333-062-0005 through 333-062-0185; and

(2) For Public Swimming Pools, OAR 333-060-0005 through 333-060-0515.

Stat. Auth.: ORS 448.035
Stats. Implemented: ORS 448.005 - 448.090
Hist.: HD 1-1978, f. & ef. 1-4-78; HD 19-1983(Temp), f. & ef. 10-18-83; HD 12-1984, f. & ef. 6-20-84; HD 5-1985, f. & ef. 4-25-85; PH 15-2009, f. & cert. ef. 12-23-09

333-029-0075
Water Supply Systems

(1) Definitions applicable to this rule:

(a) "Maximum Contaminant Level (MCL)" means the maximum allowable level of a contaminant in water for consumption delivered to the users of a system, except in the case of turbidity where the maximum allowable level is measured at the point of entry to the distribution system.

(b) "Quarterly Sampling" means a sample is taken and submitted according to the following schedule: 1st Quarter is from January 1 through March 31, 2nd Quarter is from April 1 through June 30, 3rd Quarter is from July 1 through September 30 and the 4th Quarter is from October 1 through December 31.

(2) Water supply systems serving travelers' accommodations and hostels shall comply with OAR for Public Water Systems, OAR 333-061-0005 through 333-061-0095, and must be:

(a) Regulated as a Public Drinking Water System under OAR 333-06; or

(b) Water systems serving travelers' accommodations and hostels that are not regulated under OAR 333-061 as a Public

Drinking Water System must meet the requirements in section (3) below.

(3) Unregulated Public Drinking Water Systems:

(a) Plan Review. All new facilities that are not regulated by OAR 333-061 must submit plans to the Authority for review prior to construction or major modification of system. Systems regulated prior to January 1, 2003 by OAR 333-061 are not required to re-submit plans.

(b) Surface Water Sources. New facilities with surface water sources not regulated under OAR 333-061 will not be licensable after January 1, 2005. Facilities existing prior to January 1, 2005 in compliance with OAR 333-061-0032 may continue to operate.

(c) Sampling frequency:

(A) For seasonal facilities, a coliform sample must be taken prior to operational period and each quarterly sampling period while open to public. A minimum of two samples will be required for coliform, regardless of length of operation.

(B) For year round facilities:

(i) Coliform: Monthly for surface water. Quarterly for populations under 1000 on ground water.

(ii) Inorganic Samples: One time sampling required for new facilities before beginning operation.

(d) MCL Violations. An item is not considered a violation until confirmed by second sample taken with 24 hours. Four repeat samples must be taken within 24 hours of the original positive sample for a sample result above the maximum contaminant level (MCL).

(A) Total coliform: Report positive total coliform samples to the Authority within 24 hours of being notified of the positive sample.

(B) Fecal coliform. Any positive fecal coliform sample must be reported to the Authority within 24 hours.

(i) Public notification for this potential acute health risk is required.

(ii) An alternative procedure approved by the Authority must be in place before serving public.

(C) Inorganic Samples. One time sampling is required for new facilities. Additional testing is not required for facilities that were previously regulated under OAR 333-061 and have tested prior to January 1, 2003. Inorganics include: antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, nitrate, nitrite, selenium and thallium.

(D) Nitrate: Sample must be submitted for testing annually

(i) Any samples exceeding the MCL for nitrate shall be reported to the Authority within at least 24 hours.

(ii) When a test on a sample is reported to exceed the MCL for nitrate, public notification is required. Bottled water must also be provided to public upon request.

(E) The Authority may require more frequent monitoring than specified or may require confirmation samples for positive and negative results. It is the responsibility of the operator to correct any problems and get a laboratory test result that is less than the maximum contaminant level.

(e) Sample collection methods.

(A) For the purpose of determining compliance with the MCL and the sampling requirements of these rules, sampling results may be considered only if they have been analyzed by a laboratory certified by the State Drinking Water Program.

(B) Samples submitted to laboratories for analysis shall be clearly identified with the name of the water system, facility license number, sampling date, time, sample location identifying the sample tap, the name of the person collecting the sample and whether it is a routine or a repeat sample.

(i) Routine: These are samples collected from established sampling locations within a water system at specified frequencies to satisfy monitoring requirements as prescribed in this rule. These samples are also used to calculate compliance with maximum contaminant levels for inorganics prescribed in OAR 333-061-0030 (Table 1);

(ii) Repeat: These are samples collected as a follow-up to a routine sample that has exceeded a maximum contaminant level.

(iii) Test results: Sample results must be submitted to the Local Public Health Authority by the 10th of the month following the sampling period.

(iv) The Authority may take additional samples to determine compliance with applicable requirements of these rules.

(f) Public Notice. All public notification must be posted conspicuously on site and must include:

(A) A description of the violation or situation of concern;

(B) Corrective actions taken to improve water quality;

(C) Any potential adverse health effects;

(D) The population at risk;

(E) The alternative measures in place to provide safe drinking water.

(4) All water distribution systems shall be designed, constructed, approved and maintained in compliance with the requirements of the Oregon Department of Consumer and Business Services, Building Codes Division. New water supply distribution systems, or systems remodeled, enlarged or converted after the effective date of these rules must meet the requirements of the 2000 Oregon Plumbing Specialty Code.

(5) Hot water heaters shall have installed an approved A.S.M.E. pressure relief valve which is accessible for inspection and testing.

(6) Where drinking fountains are provided, they shall be of an angle jet type with adequate water pressure at all times.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 446.330

Stats. Implemented: ORS 446.330

Hist.: HD 1-1978, f. & ef. 1-4-78; HD 19-1983(Temp), f. & ef. 10-18-83; HD 12-1984, f. & ef. 6-20-84; HD 5-1985, f. & ef. 4-25-85; PH 1-2005, f. & cert. ef. 1-14-05

333-029-0076
Temporary Water Quality Variance

The Division may grant a temporary variance from requirements of OAR 333-029-0075 by continuing or re-issuing previously issued certificates or licenses where:

(1) Failure to comply with such rule requirements is due to failure of a community, municipal or public utility water supply system to meet Division requirements;

(2) The Assistant Director is satisfied that necessary remedial action is ongoing or reasonably imminent in connection with such water supply system; and

(3) Continuance or re-issuance of the certificate or license is conditioned upon the carrying out of such remedial action and the provision of such other measures by the certificate or license holder which will in the judgment of the Assistant Director afford reasonable interim protection to the public health including, but not limited to, adequate warnings to public and personnel as to the safety of the water delivered to the premises from the distribution system and notice of measures to avoid use or consumption of such water or to render it safe for consumption; adequate warnings as to the need for supervision of children and others needing supervision against use of such water; provision of alternative potable water and adequate notification as to its availability; and measures to avoid the use and the availability of water on the premises.

Stat. Auth.: ORS 446.330

Stats. Implemented: ORS 446.330

Hist.: HD 5-1979(Temp), f. & ef. 6-19-79; HD 6-1979(Temp), f. & ef. 7-5-79; HD 10-1979(Temp), f. & ef. 8-21-79; HD 16-1979(Temp), f. & ef. 11-2-79; HD 17-1979(Temp), f. & ef. 12-20-79; HD 3-1980, f. & ef. 2-28-80; HD 19-1983(Temp), f. & ef. 10-18-83; HD 5-1985, f. & ef. 4-25-85

333-029-0080
Sewage Disposal

(1) Travelers' accommodations and hostels must provide an adequate and safe sewerage system.

(2) Sewage and waste water must be disposed of into a public sewerage system in a manner approved by the Department of Environmental Quality.

(3) All sewerage systems must be designed, constructed, approved and maintained in compliance with the minimum standards set forth in the 2008 Oregon Plumbing Specialty Code

and, where applicable, the additional statutes, rules and standards set forth by the Oregon Department of Environmental Quality.

(4) No untreated or partially-treated sewage, liquid waste, or septic tank effluent may be discharged directly or indirectly onto the surface of the ground or into the public waters.

[Publications: Publications referenced are available from the agency.]
Stat. Auth. ORS 446.330
Stats. Implemented: ORS 446.310 - 446.350 & 446.990
Hist.: HD 1-1978, f. & ef. 1-4-78; HD 19-1983(Temp), f. & ef. 10-18-83; HD 12-1984, f. & ef. 6-20-84; HD 5-1985, f. & ef. 4-25-85; PH 15-2009, f. & cert. ef. 12-23-09

333-029-0090
Bedding and Linen

(1) Conventional mattress covers or pads shall be used for protection of mattresses and shall be kept clean.

(2) All sheets, pillowcases, towels, and washcloths shall be freshly laundered before they are furnished to new guests or occupants of rental units.

(3) All clean linen shall be stored in a clean, dry place.

(4) All soiled laundry shall be handled and stored so as not to contaminate clean laundry.

(5) Containers for transporting or storing clean laundry shall be of impervious materials and shall be smooth and easily cleanable.

(6) All bedding for guest use shall be kept clean and in good repair.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 1-1978, f. & ef. 1-4-78; HD 19-1983(Temp), f. & ef. 10-18-83; HD 12-1984, f. & ef. 6-20-84; HD 5-1985, f. & ef. 4-25-85

333-029-0095
Fire Safety

(1) Portable fire extinguishers shall be provided in travelers' accommodations and hostels. Such fire extinguishers shall:

(a) Have a minimum rating of 2A:10B:C;

(b) Be located so as to require no more than 75 feet of travel distance to an extinguisher.

(2) Equivalent protection as outlined by NFPA No. 10 shall be accepted.

(3) Every gas water heater, and every other gas fired appliance except gas plates and gas ranges, installed or serviced for use in any rental units, shall be effectively vented as required by the State Fire Marshal.

(4) Liquefied petroleum gas storage tanks shall conform in construction, design, installation, and operation with the rules of the State Fire Marshal.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 1-1978, f. & ef. 1-4-78; HD 19-1983(Temp), f. & ef. 10-18-83; HD 12-1984, f. & ef. 6-20-84; HD 5-1985, f. & ef. 4-25-85

333-029-0100
Chemical and Physical Hazards

(1) Cleaning equipment and supplies, all insecticides, chemicals, paints, and other toxic substances shall be kept isolated from guests and stored so as to prevent contamination of clothing, toweling, and bedding materials. All applications of chemicals including, but not limited to, cleaners and disinfectants shall be in accordance with the manufacturers' recommendations.

(2) All toxic substances shall be clearly identified and accurately labeled as toxic.

(3) All stairways shall be provided with firmly attached handrails on both sides of the stairway.

(4) Stairways shall be well lighted with at least five foot candles of available light measured three feet from the stair tread.

(5) All boilers and pressure vessels shall be approved and maintained in accordance with the applicable state statutes and rules of the Department of Consumer and Business Services.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 1-1978, f. & ef. 1-4-78; HD 5-1985, f. & ef. 4-25-85

333-029-0105
Food Services

(1) Eating and drinking facilities, commissaries, mobile units and vending machine operated in conjunction with traveler's accommodations and hostels shall be operated in compliance with the Authority's Food Sanitation Rules OAR 333-150-0000.

(2) All multi-use drinking glasses and cups provided for guests shall be washed, rinsed and sanitized after being used according to OAR 333-150-0000 parts 4-6 and 4-7.

(3) Single service utensils shall be protected from contamination according to OAR 333-150-0000 section 4-904.11.

(4) Ice provided by traveler's accommodations and hostels shall comply with OAR 333-150-0000 sections 3-202.16 and 3-303.12.

Stat. Auth.: ORS 446.321
Stats. Implemented: ORS 446.330
Hist.: HD 1-1978, f. & ef. 1-4-78; HD 19-1983(Temp), f. & ef. 10-18-83; HD 12-1984, f. & ef. 6-20-84; HD 5-1985, f. & ef. 4-25-8; HD 27-1994, f. 10-27-94, cert. ef. 12-31-94; OHD 11-2002, f. & cert. ef. 8-7-02; PH 5-2004(Temp), f. & cert. ef. 2-13-04 thru 7-30-04; PH 15-2004, f. & cert. ef. 4-9-04

333-029-0110
Lodging Unit Kitchens

(1) Lodging unit kitchens shall have:

(a) A sink suitable for dishwashing with hot and cold water. Hot water shall be at not less than one hundred forty degrees (140º) F.;

(b) A refrigerator capable of maintaining a temperature of forty-five degrees (45º) F. or less.

(2) Utensil and equipment, if supplied, shall be easily cleanable, kept in good repair, and otherwise comply with OAR 333-150-0000 parts 4-1 and 4-2.

(3) Utensils supplied in lodging units shall be washed, rinsed, and sanitized after each occupancy according to OAR 333-150-0000 parts 4-6 and 4-7, or have a notice stating "For your convenience, dishes and utensils have been washed. If you would like to further sanitize these items, please contact the manager." The sanitizing agent shall be available in the office.

Stat. Auth.: ORS 446.321
Stats. Implemented: ORS 446.330
Hist.: HD 1-1978, f. & ef. 1-4-78; HD 19-1983(Temp), f. & ef. 10-18-83; HD 12-1984, f. & ef. 6-20-84; HD 5-1985, f. & ef. 4-25-85; HD 27-1994, f. 10-27-94, cert. ef. 12-31-94; OHD 11-2002, f. & cert. ef. 8-7-02; PH 5-2004(Temp), f. & cert. ef. 2-13-04 thru 7-30-04; PH 15-2004, f. & cert. ef. 4-9-04

333-029-0115
Fees

License fees are set by local county ordinance. Applicants for a Traveler's Accommodation or Hostel license will pay the license fee set by the LPHA for that county. If the state becomes the agency issuing the license, the applicant for a Traveler's Accommodation or Hostel license (OAR 333-029-0005 through 333-029-0110) must pay to the Oregon Public Health Division a fee of $60.

Stat. Auth.: ORS 446.321
Stats. Implemented: ORS 446.310 - 446.350 & 446.990
Hist.: HD 4-1980, f. & ef. 3-21-80; HD 19-1983(Temp), f. & ef. 10-18-83; HD 12-1984, f. & ef. 6-20-84; HD 5-1985, f. & ef. 4-25-85; HD 27-1994, f. 10-27-94, cert. ef. 12-31-94; PH 15-2009, f. & cert. ef. 12-23-09

333-029-0120
Variance

(1) The Division may grant a variance from the requirements of OAR 333-029-0005 through 333-029-0110 (except when in conflict with other Administrative Rules of the Division or other State Agencies) as follows:

(a) Where it is demonstrated to the satisfaction of the Division that strict compliance with the rule would be highly burdensome or impractical due to special conditions or cause;

(b) Where the public or private interest in the granting of the variance is found by the Division to clearly outweigh the interest of the application of uniform rules; and

(c) Where such alternative measures are provided which in the opinion of the Division will provide adequate health and safety protection.

(2) Such variance authority is not conferred upon any county notwithstanding delegated or contractual authority in the administration and enforcement of travelers' accommodation statutes and rules.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 13-1981(Temp), f. & ef. 7-31-81; HD 6-1982, f. & ef. 3-2-82; HD 5-1985, f. & ef. 4-25-85

333-029-0130
Civil Penalties

In accordance with ORS 446.348, the Assistant Director for Health will use the following schedule to impose civil penalties for violations of rules for travelers' accommodations and hostels:

(1) Violations of any requirement stated within any part of OAR 333-029-0075, 333-029-0076, 333-029-0080, 333-029-0095, and 333-029-0100 are Class I violations subject to a civil penalty in the amount of not less than $75 nor more than $1000 for each and every violation.

(2) Violations of any requirement stated within any part of OAR 333-029-0025, 333-029-0030, 333-029-0050, 333-029-0060, 333-029-0065, 333-029-0105, and 333-029-0110 are Class II violations subject to a civil penalty in the amount of not less than $50 nor more than $750 for each and every violation.

(3) Violations of any requirement stated within any part of OAR 333-029-0020, 333-029-0035, 333-029-0040, 333-029-0045, 333-029-0070, and 333-029-0090 are Class III violations subject to a civil penalty in the amount of not less than $25 nor more than $350 for each and every violation.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 5-1985, f. & ef. 4-25-85

DIVISION 30

ORGANIZATIONAL CAMP RULES

333-030-0005
Purpose

These rules prescribe the requirements for the construction, operation and use of organizational camps. They are for the purpose of protecting the health and welfare of persons using these camps. Various types of activities are found in organizational camps and the rules are designed to assure the protection of individuals consistent with those activities.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.310 - 446.350
Hist.: HD 25-1981, f. & ef. 11-25-81; PH 9-2007, f. & cert. ef. 7-13-07

333-030-0010
Adoption by Reference

Outside standards, listings and publications referred to in these rules are by reference made a part of these rules as if fully set forth.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.310 - 446.350
Hist.: HD 25-1981, f. & ef. 11-25-81; PH 9-2007, f. & cert. ef. 7-13-07

333-030-0015
Definitions

As used in these rules unless otherwise required by context:

(1) "Administrator" means the Public Health Director of the Oregon Health Authority or designee.

(2) "Ancillary Activity" means an individual or group using the camp facilities in a manner unrelated to the camp's mission or programs. An example might include a wedding party or a business group using a Boy Scout Camp for a reception or meeting. Such activities may require the camp to maintain a food service or traveler's accommodation license in addition to the organization camp license.

(3) "Approved" means approved in writing by the Oregon Health Authority, Public Health Division.

(4) "Aquatic Director" means a person over 18 years of age who is an employee or volunteer within the organizational camp and is a currently certified lifeguard, as defined by OAR 333-060-0015 (see "Program Director" and "Program Supervisor").

(5) "Cabin Cooking" means food preparation in a facility usually equipped with residential grade cooking and cooling equipment, and usually done by campers for themselves.

(6) "Camp" means an organizational camp as defined in section (26) of this rule.

(7) "Camp Commissary" means the central food storage and distribution facility when cabin or wilderness/primitive cooking are regularly practiced.

(8) "Camp Director" means the person on-site who has the overall responsibility for the programs and activities under the direction of the camp operator.

(9) "Camp Health Director" is an adult, 18 years of age or older, who is responsible for routine and emergency health care services at the camp (see "Program Director" and "Program Supervisor").

(10) "Camp Operator" means either the license holder or a contract or rental group the license holder has contracted with to use part or all of the camp facilities and, whichever has overall responsibility for the camp programs and activities.

(11) "Camp Staff" includes paid and unpaid staff and volunteer leaders working directly for the license holder or contract or rental group.

(12) "Contract groups" or "Rental groups" are organized groups that use the camp facilities under contracted arrangement with the license holder or camp owner.

(13) "Day Camp" means an organizational camp facility that campers attend for an established period of time, leaving at the end of the camping day that provides creative and recreational opportunities in the out-of-doors utilizing trained leadership and the resources of the natural surroundings to contribute to the camper's mental, physical and spiritual growth.

(14) "Delegated County" means a county delegated authority to administer the Organizational Camp Program under ORS 446.425. (See also "Local Public Health Authority").

(15) "Division" means the Public Health Division of the Oregon Health Authority.

(16) "Family Camp" means sessions operated or staffed by the license holder or contract group or rental group for parents and children as family groups. Parents and guardians are on-site and have frequent contact with and make decisions on behalf of their children.

(17) "Health Disclosure" means an up-to-date record of the camper's or staff's past and present health status.

(18) "Health Services" means the services provided to campers and staff including first aid, medication management, provision of prescribed medical treatment and health practices.

(19) "High Risk Program Facilities" means areas and equipment, developed by the license holder, that present a higher than normal opportunity for camper injuries. High Risk Program Facilities include but are not limited to rifle and archery ranges, ropes courses, climbing walls, trampolines, waterfront and swimming facilities, skiing and snowboarding.

(20) "Landlord" means a tourist facility owner holding a license issued under ORS 446.310 to 446.350.

(21) "License Holder" means the person to which the organizational camp license has been issued by the Division or local public health authority.

(22) "Lifeguard" means a currently certified lifeguard (with waterfront module where applicable), as determined by the Division.

(23) "Local Public Health Authority (LPHA)" has the meaning given that term in ORS 431.260.

(24) "Off-Site" means outside of the boundaries of the camp facility.

(25) "On-Site" means within the boundaries of the licensed camp facility.

(26) "Organizational Camp" has the meaning given that term in ORS 446.310.

(27) "Outdoor Youth Program" means a program that provides, in an outdoor living setting, treatment services to youth who are enrolled in the program because they have behavioral problems, mental health problems or problems with abuse of alcohol or drugs.

(28) "Permanent Sleeping Unit" means cabins, platform tents, huts and other shelters that are used for sleeping and remain stationary for more than six nights in an organizational camp.

(29) "Person" means individuals, corporations, associations, firms, partnerships and joint stock companies as well as public entities such as schools, colleges, public or private educational corporations.

(30) "Potentially Hazardous Food (Time/Temperature Control for Safety Food)" has the meaning given that term in OAR 333-150-0000 1-201.10(B).

(31) "Primitive Camping" means a type of camping, during which the campers use non-permanent sleeping structures such as tents, tarps and ground cloths.

(32) "Outdoor Cooking" means meals are prepared using primitive or outdoor cooking methods.

(33) "Program Assistants" means the staff required to operate a program area or activity, trained in their responsibilities and under the direct supervision of the program director or program supervisor.

(34) "Program Director" means an individual with appropriate training and experience in the program area or activity for which the individual has overall responsibility.

(35) "Program Supervisor" means an individual that supervises the operation of a program area or activity under the direction of a program director who has appropriate training and experience in the program area or activity he or she supervises.

(36) "Public Spa Pool" means any public swimming pool or wading pool designed primarily to direct water, or air-enriched water under pressure, onto the bather's body with the intent of producing a relaxing or therapeutic effect. A public spa pool includes, but is not limited to, spa pools owned or operated by organizational camps.

(37) "Public Swimming Pool" means an artificial structure, and its appurtenances, that contains water more than two feet deep that is used, or intended to be used, for swimming or recreational bathing and is for the use of any segment of the public. A public swimming pool includes, but is not limited to, swimming pools owned or operated by organizational camps.

(38) "Public Wading Pool" means an artificial structure, and its appurtenances, that contains water less than two feet deep that is expressly designated or used with the knowledge and consent of the owner or operator for wading or recreational bathing and is for the use of any segment of the public, whether limited to patrons of a companion facility or not. A public wading pool includes, but is not limited to, wading and spray pools owned or operated by an organizational camp.

(39) "Recreation Park" means any area designated by the person establishing, operating, managing or maintaining the same for picnicking or overnight camping by the general public or any segment of the public. Recreation park includes, but is not limited to, areas open to use free of charge or through payment of a tax or fee or by virtue of rental, lease, license, membership, association or common ownership and further includes, but is not limited to, those areas divided into two or more lots, parcels, units or other interests for purposes of such use.

(40) "Tenant" means a person or public body defined in ORS 174.109 that:

(a) Is not under the common ownership, management or control with the landlord;

(b) Rents or leases all or part of a tourist facility from a landlord for the purpose of operating an organizational camp, conference or other private gathering on one or more days during the term of the rental or lease; and

(c) For the term of the rental or lease enjoys exclusive occupancy of the rented or leased part of the tourist facility.

(41) "These Rules" means OAR 333-030-0005 through 333-030-0130.

(42) "Tourist Facility" means any travelers' accommodation, hostel, picnic park, recreation park and organizational camp.

(43) "Waterfront Activities" means those activities occurring in or on bodies of water other than a licensed public swimming, public wading or public spa pools.

(44) "Variance" means written permission from the Division for an organizational camp to be operated when it does not comply with all the applicable rules for Organizational Camps.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 445.310 - 446.350
Hist.: HD 25-1981, f. & ef. 11-25-81; HD 7-1996, f. & cert. ef. 12-10-96; PH 1-2005, f. & cert. ef. 1-14-05; PH 9-2007, f. & cert. ef. 7-13-07; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 11-2011, f. & cert. ef. 10-27-11; PH 2-2013, f. & cert. ef. 1-25-13; PH 15-2016, f. 5-4-16, cert. ef. 5-9-16

333-030-0020
Licensing Required

(1) No person shall establish, operate, manage or maintain an organizational camp without first securing a license from the Division or the local public health authority. Either the landlord or tenant may be issued a license for an organizational camp operated under contract, rental or leasehold arrangements. The license holder is responsible for compliance with these rules, with the exception of duties delegated to a tenant as specified in OAR 333-030-0023.

(2) All licenses issued under ORS 446.310 to 446.350 terminate and are renewable on December 31 of each year.

(3) Contract and rental groups may be required by the owner of the camp to obtain a license for the operating period.

(4) A contract or rental group that is the license holder is responsible for complying with these rules.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.322
Hist.: HD 25-1981, f. & ef. 11-25-81; HD 18-1983(Temp), f. & ef. 10-18-83; HD 11-1984, f. & ef. 6-20-84; HD 7-1996, f. & cert. ef. 12-10-96; PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13; PH 15-2016, f. 5-4-16, cert. ef. 5-9-16

333-030-0023
Delegation of Duties

(1) A landlord may enter into a contract to delegate specific duties to a tenant for the term of the rental or lease of all or part of an organizational camp. The duties that may be delegated to a tenant through contract are:

(a) OAR 333-030-0050(4) relating to bedding;

(b) OAR 333-030-0055(2)(e) relating to toilet tissue;

(c) OAR 333-030-0055(2)(f) relating to non-water-carried waste;

(d) OAR 333-030-0055(3)(a)(C) and (D) relating to soap and paper towels;

(e) OAR 333-030-0060(2) through (4) relating to laundry facilities;

(f) OAR 333-030-0065 relating to solid waste;

(g) OAR 333-030-0070(1), (2), (5) and (6) relating to insect and rodent control;

(h) OAR 333-030-0090(1) and (5) relating to sewage collection and disposal;

(i) OAR 333-030-0095(2) through (6) relating to food service;

(j) OAR 333-030-0100(3) relating to an emergency plan;

(k) OAR 333-030-0103 relating to camp administration;

(l) OAR 333-030-0105 relating to health services;

(m) OAR 333-030-0110(1)(b) and (c), (3) and (4) relating to programs and facilities;

(n) OAR 333-030-0115 relating to transportation;

(o) OAR 333-030-0120(3)(b), (5) and (6)(e) relating to fire safety; and

(p) OAR 333-030-0125 relating to chemical and physical hazards.

(2) The landlord is responsible for compliance with duties specified in section (1) of this rule relating to cleanliness of the facility prior to contracting duties to a tenant. The tenant is responsible for compliance with delegated duties relating to facility cleanliness for the term of the contract.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.310 - 446.350
Hist.: PH 15-2016, f. 5-4-16, cert. ef. 5-9-16

333-030-0025
Application

(1) An application for a license, accompanied by the required fee, must be made upon forms provided by the Division or local public health authority at least 30 days prior to opening an organizational camp.

(2) Thirty days prior to any change of license holder, the Division or local public health authority must be notified of the change and an application for a new license, accompanied by the required fee, must be submitted by the new owner or operator.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.323
Hist.: HD 25-1981, f. & ef. 11-25-81; HD 18-1983(Temp), f. & ef. 10-18-83; HD 11-1984, f. & ef. 6-20-84; HD 7-1996, f. & cert. ef. 12-10-96; PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13

333-030-0030
Required Fees

The fee for an original license or the annual renewal of a license must be specified in county ordinance by the delegated local public health authority, or as specified by statute.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.321
Hist.: HD 25-1981, f. & ef. 11-25-81; HD 18-1983(Temp), f. & ef. 10-18-83; HD 11-1984, f. & ef. 6-20-84; HD 27-1994, f. 10-27-94, cert. ef. 12-31-94; PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13

333-030-0035
Renewal of License

(1) Application for renewal licenses must be submitted on the forms supplied by the Division or local public health authority and must be accompanied by the required fee.

(2) Renewal licenses may be issued upon determination of substantial compliance with ORS Chapter 446 and these rules.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 25-1981, f. & ef. 11-25-81; HD 18-1983(Temp), f. & ef. 10-18-83; HD 11-1984, f. & ef. 6-20-84; HD 7-1996, f. & cert. ef. 12-10-96; PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13

333-030-0040
Plans

(1) No person shall construct, enlarge or alter any organizational camp or convert the use of an existing structure to an organizational camp without first securing appropriate permits. A copy of a building plan approval or building permits issued by the building department having jurisdiction must accompany the plot plan.

(2) When proposing to make improvements to an organizational camp a plot plan showing the general layout of the organizational camp must be submitted to the local public health authority. The location for each of the following must be clearly shown and identified:

(a) Property lines;

(b) Proposed and existing construction;

(c) Building floor plans that include the location of plumbing fixtures;

(d) The number, size, type and location of all permanent structures and facilities;

(e) Location of all proposed and existing water supply and sewage disposal systems;

(f) Location of water and sewer lines;

(g) Estimated total number of campers and staff to be using the facilities at any given time; and

(h) Location of storage, collection and disposal facilities of solid waste.

(3) Whenever a food service facility at an organizational camp is constructed or extensively remodeled and whenever an existing structure at an organizational camp is converted to use as a food service facility, properly prepared plans and specifications for such construction, remodeling or conversion must be submitted to the local public health authority for approval before construction. Plans must be submitted in accordance with Oregon Food Sanitation Rules OAR 333-150-0000 part 8-2.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 25-1981, f. & ef. 11-25-81; HD 18-1983(Temp), f. & ef. 10-18-83; HD 11-1984, f. & ef.6-20-84; HD 7-1996, f. & cert. ef. 12-10-96; PH 1-2005, f. & cert. ef. 1-14-05; PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13

333-030-0050
Sleeping Space

(1) Each permanent sleeping unit must have:

(a) For fire safety, at least 30 inches (760 mm) of walking space between beds or sleeping bags placed on the floor.

(b) At least 30 inches (760 mm) separation between the heads of sleepers must be provided for communicable disease prevention. In lieu of such separation, partitions or physical barriers are acceptable.

(c) At least 30 inches (760 mm) vertical separation between tiers of beds or between the top tier and the ceiling.

(d) Where two tiers of beds are provided, there must be at least 10 inches (254 mm) of space between the floor of the sleeping units and the underside of the first tier of beds. In lieu of such spacing, the first tier of bunks must have a continuous base, which must be sealed to the floor.

(e) Upper bunk beds must have a guardrail on each side of the bed, except a guardrail need not be provided on the side of a bed securely attached to a wall. The guardrails must create no spaces wider than 3.5 inches (89 mm) to prevent an entrapment or choking hazard, and must extend at least 5 inches (127 mm) above the top of the mattress. Guardrails are not necessary for campers 15 years or older.

(2) Permanent sleeping units must be provided with cross ventilation or must comply with the ventilation requirements of the Oregon Department of Consumer and Business Services (DCBS), Building Codes Division.

(3) Sleeping units and furnishings must be kept clean and in good repair.

(4) Bedding:

(a) Pillowslips, sheets, towels and washcloths, when provided by the camp operator, must be washed at least once per week and before being assigned to a different camper or staff member.

(b) Blankets, spreads, mattresses and pillows must be kept clean and free of insect infestation. Mattresses must be covered with a non-absorbent cover or other approved protection and must be maintained clean and in good repair.

(c) If sheets are not provided by the camp operator, the cover, pad, or mattress must be cleaned for each incoming camper or staff member, and more often if necessary.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 25-1981, f. & ef. 11-25-81; HD 7-1996, f. & cert. ef. 12-10-96; PH 1-2005, f. & cert. ef. 1-14-05; PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13

333-030-0055
Bathing, Handwashing and Toilet Facilities

(1) Facilities for toileting, bathing and handwashing must:

(a) Be illuminated for cleaning;

(b) Be ventilated by mechanical or natural means;

(c) Have floors that are smooth, impervious and easily cleanable;

(d) Have an effective water-tight union where a floor and wall join;

(e) Have smooth, easily cleanable and impervious wall surfaces; and

(f) Be kept clean, sanitary, free of mold and mildew, and in good repair.

(2) Plumbed and unplumbed toilet facilities in all organizational camps must meet the following requirements:

(a) There must be one toilet (plumbed or unplumbed) for every 15 campers or fraction thereof except in day camps in which one toilet for every 50 campers or fraction thereof is required.

(b) Separate toilet rooms for each gender, or locking unisex toilet rooms, must be provided when both genders are to be accommodated simultaneously;

(c) Urinals may be substituted for no more than one-third the required toilets for males;

(d) Toilets or urinals must not be located in sleeping rooms;

(e) Toilet tissue must be provided at each privy or toilet at all times the camp is in operation; and

(f) Unplumbed toilet facilities must comply with OAR 340-071-0320 and the Nonwater-Carried Waste Disposal Facilities, Materials, and Construction requirements of the Department of Environmental Quality (DEQ), OAR 340-073-0065 through 0075 and the DCBS Building Specialty Codes.

(3) Bathing and handwashing facilities in all organizational camps must meet the following requirements:

(a) A minimum of one handwashing sink must be provided for every 30 campers. A handwash set-up must be conveniently provided wherever a toilet facility is located. Where permanently plumbed handwash sinks cannot be provided, hand sanitizer or a water container may be used provided it allows a stream of water without needing to be held open and waste water must be collected in a container and disposed of properly or must flow into an approved waste water drain system. Each handwash set-up must:

(A) Be located in close proximity to privies, toilets or urinals;

(B) Be supplied with a change of clean water for each use;

(C) Be supplied with soap; and

(D) Be provided with single use towels, or if an individual sleeping room has a dedicated toilet room, personal towels may be used.

(b) In any camp where participants are present for four or more nights, there must be one bathing facility (shower or bathtub) provided for every 20 campers or fraction thereof. Bathing facilities must:

(A) Be supplied with a change of clean warm water for each use:

(i) By having a tempering valve capable of providing a water temperature not to exceed 110 degrees Fahrenheit (43 degrees Celsius); or

(ii) In lieu of a tempering valve, a mixing faucet with a hot water supply providing a water temperature of not to exceed 110 degrees Fahrenheit (43 degrees Celsius) may be provided along with a cold water supply.

(B) Separate bathing facilities must be provided for each gender, or locking unisex bathing facilities must be provided when both genders are to be accommodated simultaneously;

(C) Shower walls, ceilings and partitions must be impervious to water;

(D) Bathtub and shower floor areas must be finished with slip-resistant, impervious and easily cleanable surfaces;

(E) Shower floors must be sloped to effectively drain all waste water;

(F) Wooden racks over shower floors are prohibited; and

(G) Where glass bath or glass shower doors are used, such doors must be made of safety glass.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 25-1981, f. & ef. 11-25-81; HD 7-1996, f. & cert. ef. 12-10-96; PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13

333-030-0060
Laundry Facilities

(1) Laundry facilities, when provided, must be located in areas separate from sleeping units, food preparation areas and perishable food storage areas.

(2) Laundry facilities must be kept clean and well maintained.

(3) All clean linen must be stored in clean storage rooms or cupboards.

(4) Soiled linen and clothing must be stored in an area separate from food preparation and perishable food storage areas prior to laundering.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 25-1981, f. & ef. 11-25-81; HD 7-1996, f. & cert. ef. 12-10-96; PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13

333-030-0065
Solid Waste

(1) Solid waste must be disposed of in a manner, which complies with the applicable rules of the Department of Environmental Quality, OAR chapter 340, divisions 93, 94, 95 and 96.

(2) Solid waste must be stored in individual garbage containers, storage bins or storage vehicles. All such containers, bins or vehicles must:

(a) Have tight-fitting lids, covers or closable tops;

(b) Be durable, rust-resistant watertight, rodent proof and readily washable; and

(c) During times of food preparation and service, waste containers in food preparation and service areas may be uncovered.

(3) The premises of each organizational camp must be kept orderly and free of litter and refuse.

(4) All solid waste must be collected for disposal or recycling at regular intervals so as not to create:

(a) Vector harborage and sustenance;

(b) Objectionable odors; or

(c) Any overflowing of solid waste or other unsanitary conditions.

(5) Solid waste containing putrescible waste must be collected for disposal at regular intervals not to exceed seven days.

(6) Solid waste must be transported in a manner that complies with the rules of the Department of Environmental Quality OAR 340-093-0220 (Transportation).

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.340
Hist.: HD 25-1981, f. & ef. 11-25-81; HD 7-1996, f. & cert. ef. 12-10-96; PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13

333-030-0070
Insect and Rodent Control

(1) The grounds, buildings and structures used or intended for human habitation must be kept clean and maintained to prevent harborage and infestation of insects, rodents and vermin.

(2) The camp health director, or other person knowledgeable in pest identification, must check the sleeping areas and other harborages for bedbugs whenever there are complaints or possible bites.

(3) A license holder may not begin treatment for insects, rodents and vermin without first consulting with a currently certified pest management professional (PMP). A license holder may contract with a certified PMP for pest management services.

(4) During the season when flies, mosquitoes and other insects are prevalent, all openings into the outer air of permanent kitchens and dining room must be effectively screened, unless other effective means are provided to prevent the entrance of insects or rodents. Where screens are used, there must be not less than 16 meshes per lineal inch, and all screen doors must be equipped with a self-closing device.

(5) For insecticide and rodenticide extermination methods, only pesticides registered with the Environmental Protection Agency and the state Department of Agriculture can be used. Pesticides must be applied in accordance with the directions on the labels and must be handled and stored as to avoid health hazards.

(6) Poisons, chemicals, rodenticides, insecticides, pesticides, herbicides and other toxic materials must be properly labeled, or in the original containers, and stored in locked areas not accessible to campers separate from all food service, food storage and food preparation areas, sleeping areas and linens. Except that insecticides, rodenticides and cleaning and sanitizing materials necessary for maintaining the food service facility may be present in the food

service facility, but must be stored separately from cleaning and sanitizing materials. Both must be stored in cabinets or compartments used for no other purpose and must not be stored above or intermingled with food, food equipment and dishes or utensils. Detergents and sanitizers may be conveniently stored at warewashing facilities.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 25-1981, f. & ef. 11-25-81; HD 7-1996, f. & cert. ef. 12-10-96; PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13

333-030-0075
Recreational Vehicles

Organizational camps that provide accommodations for recreational vehicles as defined in ORS 446.003 must comply with the Division's rules for the Construction, Operation and Maintenance of Recreation Parks, OAR 333-031-0002 through 333-031-0020, and 333-031-0059 through 333-031-0075 and must comply with the DCBS Building Codes Division's rules for the Recreational Parks and Organizational Camps, OAR 918-650-0000 through 918-650-0080. The licensure requirement of ORS 446.320 for a recreation park does not have to be met unless the park is used by individuals not participating in, or working for the organizational camp program.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 25-1981, f. & ef. 11-24-81; HD 7-1996, f. & cert. ef. 12-10-96; PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13

333-030-0080
Water Quality, Source and Distribution

(1) Definitions applicable to this rule:

(a) "Maximum Contaminant Level (MCL)" means the maximum allowable level of a contaminant in water for consumption delivered to the users of a system, except in the case of turbidity where the maximum allowable level is measured at the point of entry to the distribution system.

(b) "Quarterly Sampling" means a sample is taken and submitted according to the following schedule:

(A) 1st Quarter is from January 1 through March 31;

(B) 2nd Quarter is from April 1 through June 30;

(C) 3rd Quarter is from July 1 through September 30; and the

(D) 4th Quarter is from October 1 through December 31.

(2) Water supply systems serving travelers' accommodations and hostels must comply with Oregon Administrative Rules for Public Water Systems, OAR 333-061-0005 through 333-061-0095, and must be:

(a) Regulated as a Public Drinking Water System under OAR 333-061; or

(b) Water systems serving travelers' accommodations and hostels that are not regulated under OAR 333-061 as a Public Drinking Water System must meet the requirements in section (3) of this rule.

(3) Unregulated Public Drinking Water Systems:

(a) Plan Review. All new facilities that are not regulated by OAR 333-061 must submit plans to the Division for review prior to construction or major modification of system. Systems regulated prior to January 1, 2003 by OAR 333-061 are not required to resubmit plans.

(b) Surface Water Sources. New facilities with surface water sources not regulated under OAR 333-061 will not be licensable after January 1, 2005. Facilities existing prior to January 1, 2005 in compliance with OAR 333-061-0032 may continue to operate.

(c) Sampling frequency:

(A) For seasonal facilities, a coliform sample must be taken prior to the camp's operational period and each quarterly sampling period while open to public. A minimum of two samples will be required for coliform, regardless of length of operation.

(B) For year round facilities:

(i) Coliform: Monthly for surface water. Quarterly for populations under 1000 using ground water.

(ii) Inorganic Samples. One time sampling required for new facilities before beginning operation.

(d) MCL Violations. An item is not considered a violation until confirmed by second sample taken within 24 hours. Four repeat samples must be taken within 24 hours of the original sample for a sample result above the maximum contaminant level (MCL).

(A) Total Coliform. Any positive total coliform samples must be reported to the Division or Local Public Health Authority within 24 hours of being notified of the positive sample.

(B) Fecal Coliform. Any positive fecal coliform sample must be reported to the Division or Local Public Health Authority within 24 hours of being notified of the positive sample.

(i) Public notification for this potential acute health risk is required.

(ii) An alternative procedure approved by the Division must be in place before serving the public.

(C) Inorganic Samples. One time sampling is required for new facilities. Additional testing is not required for facilities that were previously regulated under OAR 333-061 and have tested prior to January 1, 2003. Inorganics include: antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, nitrate, nitrite, selenium and thallium.

(D) Nitrate. A sample must be submitted for testing annually.

(i) Any samples exceeding the MCL for nitrate must be reported to the Division within 24 hours.

(ii) When a test on a sample is reported to exceed the MCL for nitrate, public notification is required. Bottled water must be provided to public upon request.

(E) The Division may require more frequent monitoring than specified or may require confirmation samples for positive and negative results. It is the responsibility of the operator to correct any problems and get a laboratory test result that is less than the maximum contaminant level.

(e) Sample collection methods.

(A) For the purpose of determining compliance with the MCL and the sampling requirements of these rules, sampling results may be considered only if they have been analyzed by a laboratory certified by the State Drinking Water Program.

(B) Samples submitted to laboratories for analysis must be clearly identified with the name of the water system, facility license number, sampling date, time, sample location identifying the sample tap, the name of the person collecting the sample and whether it is a routine or a repeat sample.

(i) Routine. These are samples collected from established sampling locations within a water system at specified frequencies to satisfy monitoring requirements as prescribed in this rule. These samples are used to calculate compliance with maximum contaminant levels for inorganics prescribed in OAR 333-061-0030 (Table 1);

(ii) Repeat. These are samples collected as a follow-up to a routine sample that has exceeded a maximum contaminant level.

(iii) Test results. Sample results must be submitted to the Local Public Health Authority by the 10th of the month following the sampling period.

(iv) The Division may take additional samples to determine compliance with applicable requirements of these rules.

(f) Public Notice. Public Notice must be posted conspicuously on-site and must include:

(A) A description of the violation or situation of concern;

(B) Corrective actions taken to improve water quality;

(C) Any potential adverse health effects;

(D) The population at risk; and

(E) The alternative measures in place to provide safe drinking water.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 25-1981, f. & ef. 11-25-81; HD 7-1996, f. & cert. ef. 12-10-96; PH 1-2005, f. & cert. ef. 1-14-05; PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13

333-030-0085
Building Plumbing

All building plumbing must comply with the applicable requirements of the Oregon Department of Consumer and Business Services, Building Codes Division. New water supply distribution systems, or systems remodeled, enlarged or converted after the effective date of these rules must meet the requirements of the 2008 Oregon Plumbing Specialty Code.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 25-1981, f. & ef. 11-25-81; HD 7-1996, f. & cert. ef. 12-10-96; PH 1-2005, f. & cert. ef. 1-14-05; PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13

333-030-0090
Sewage Collection and Disposal

(1) No untreated or partially treated sewage, liquid waste or septic tank effluent shall be discharged directly or indirectly onto the surface of the ground or into the public waters.

(2) All sewage and waste water plumbing must be designed, constructed and maintained in compliance with the minimum standards set forth in the 2011 Oregon State Plumbing Specialty Code.

(3) Sewage and waste water must be disposed of into an area-wide sewerage system or in a manner approved by the Department of Environmental Quality in accordance with the rules for On-Site Sewage Disposal, OAR 340-071-0100 through 340-071-0600.

(4) Any construction, alteration or repair of an on-site sewage disposal system or any part thereof must comply with the rules of the Department of Environmental Quality, OAR chapter 340, division 71.

(5) If non-water carried waste disposal facilities are provided, such facilities must comply with the rules of the Department of Environmental Quality, OAR 340-071-0330.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.340
Hist.: HD 25-1981, f. & ef. 11-25-81; HD 7-1996, f. & cert. ef. 12-10-96; PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13

333-030-0095
Food Service

(1) FOOD SANITATION RULES. Eating and drinking facilities, commissaries, mobile units and vending machines operated in conjunction with organizational camps must be constructed, operated and maintained in compliance with the Division's Food Sanitation Rules, OAR 333-150-0000 with the following exceptions:

(a) Areas for food storage, preparation and service that are restricted to individual or single-family use;

(b) A food service facility must have toilet and handwashing facilities for use by the kitchen staff and food handlers. Public toilet and handwashing facilities associated with the food service facility are not required for the participants of the camp;

(c) Food service facilities operated for participants of the camp shall not be graded as "Complied" or "Failed to Comply", or given a numerical score; and

(d) Due to the unique nature of some of the food service preparation conditions encountered in primitive cooking and other types of non-dining hall food service found in camps, the Division, or local public health authority in consultation with the Division, may implement alternate requirements to the Division's Food Sanitation Rules, OAR 333-150-0000, as long as the food safety intent of the original rule is preserved.

(2) EMPLOYEE TRAINING. The camp must have trained food preparation staff if the organizational camp prepares food in camp food service facilities.

(a) For camp programs longer than three consecutive nights the camp must:

(A) Provide a food manager, currently certified by one of the Division-approved food manager certifying agencies or organizations, who supervises the food preparation activities; or

(B) Assure that all food preparation staff have a current Oregon food handler certification.

(b) Camp contract or rental groups operating for three nights or more in length must have at least one individual involved with food preparation activities that has, at a minimum, an Oregon food handler certification.

(3) CAMP COMMISSARIES:

(a) A camp commissary must have staff trained as required in section (2) of this rule.

(b) The food service equipment and utensils must be washed, rinsed, sanitized and air-dried between uses. The camp commissary must have a minimum three-compartment sink or commercial mechanical warewashing machine approved by the Division. The sinks or dishwashing equipment must be large enough to immerse the largest dish or utensil to properly wash, rinse and sanitize dishes and utensils (see OAR 333-150-0000 for details).

(c) To the extent possible, the food distributed from the camp commissary to the remote cooking location should be in a form so that handling is minimized (i.e. pre-formed meat patties, pre-prepared salads, etc.).

(4) OUTDOOR COOKING. A camp engaging in wilderness and outdoor cooking must ensure that group leaders are knowledgeable about and practice food service in accordance with the following health and safety guidelines:

(a) A camp should minimize or avoid the serving of high risk (potentially hazardous) foods.

(b) Leftover time and temperature controlled for safety (TCS) foods that have been prepared for service may not be re-served.

(c) Campers and staff doing the food preparation must wash their hands frequently to remove dirt and prevent cross-contamination of foods (see OAR 333-150-0000 2-301.11 through 2-301.16).

(d) The license holder must assure an adequate supply of safe drinking water or provide equipment, methods and procedures for purifying drinking water. Whenever possible, drinking water should be obtained from an approved water system. If that is not possible:

(A) Water must be purified by boiling for one minute followed by the addition of three to four drops of liquid chlorine per quart of water and allowing 30 minutes contact before drinking; or

(B) Water must be purified using a micro-filter filtration system to remove microorganisms and viruses and two drops of liquid chlorine per quart of water must be added to finish treatment, with 30 minutes of contact time allowed before drinking.

(5) CABIN COOKING. A camp engaging in cabin cooking must ensure that group leaders are knowledgeable about and practice food service in accordance with the following health and safety guidelines:

(a) Leftover TCS foods that have been prepared for service may not be re-served.

(b) Campers and staff doing the food preparation must wash their hands frequently to remove dirt and prevent cross-contamination of foods.

(c) The license holder must assure an adequate supply of safe drinking water. Drinking water must be obtained from an approved water system.

(6) DAY CAMP FOOD SERVICE. Full-service meal service must comply with OAR 333-150-0000 and sections (1) and (2) of this rule. Food service limited to beverages, snacks and sack lunches must comply with OAR 333-150-0000 and the additional guidelines below:

(a) Sack lunches must be stored in coolers and refrigerators maintaining a temperature of 41 degrees Fahrenheit or lower, or the attendees' parents or guardians must be advised to only include non-perishable foods in the sack lunch.

(b) Foods or beverages, once served and if opened, may not be collected and re-served.

(c) Persons handling foods must properly wash their hands before handling foods. Where unprotected foods are handled, bare hand contact must be minimized.

Stat. Auth.: ORS 446
Stats. Implemented: ORS 446.330
Hist.: HD 25-1981, f. & ef. 11-25-81; HD 27-1994, f. 10-27-94, cert. ef. 12-31-94; HD 7-1996, f. & cert. ef. 12-10-96; OHD 11-2002, f. & cert. ef. 8-7-02; PH 5-2004(Temp), f. & cert. ef. 2-13-04 thru 7-30-04; PH 15-2004, f. & cert. ef. 4-9-04; PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13

333-030-0100
Emergency Procedures

(1) Each organizational camp must retain on-site a written emergency plan outlining procedures to be followed in each of the following situations:

(a) Natural disasters and other emergencies;

(b) Lost camper or lost swimmer, if applicable;

(c) Fires;

(d) Transportation emergencies;

(e) Severe illnesses, injuries or communicable diseases;

(f) Stranger in camp; and

(g) Transition of supervision and release of campers to a designated responsible party.

(2) The emergency plan must contain at least evacuation procedures, procedures for communication with emergency medical services and facilities and the nearest fire station, and procedures for the control of vehicular traffic through the camp.

(3) The camp operator of an organizational camp must:

(a) Designate individuals to be responsible for carrying out the emergency plan;

(b) Instruct all employees and volunteers in the emergency plan and their duties in the event of an emergency situation; and

(c) Retain written documentation that all employees are aware of their responsibilities under the emergency plan and their duties therein.

(4) The following emergency information must be posted conspicuously, near the phone or alternative communication system used by the camp for off-site emergency communication, accessible during all hours of operation and maintained in all organizational camps:

(a) When telephones are provided, the license holder must post by each telephone:

(A) The current telephone numbers for contacting hospitals, poison control, police, ambulances and fire departments in the immediate area;

(B) The telephone number of the organizational camp office; and

(C) The locations of the nearest medical facility and the organizational camp including highway number, street number, rural route and box number or other data (i.e. global positioning system (GPS) coordinates, life flight landing zone locations, etc.) to aid in assuring prompt emergency response.

(b) When an alternative communication system is provided, the license holder must post by each communication location:

(A) The current procedure to contact hospitals, poison control, police, ambulances and fire departments in the immediate area;

(B) The telephone number of the organizational camp office or alternate contact information; and

(C) The locations of the nearest medical facility and the organizational camp including highway number, street number, rural route and box number or other data (i.e. GPS coordinates, life flight landing zone locations, etc.) to aid in assuring prompt emergency response.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.310 – 446.350
Hist.: HD 25-1981, f. & ef. 11-25-81; HD 7-1996, f. & cert. ef. 12-10-96; PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13; PH 15-2016, f. 5-4-16, cert. ef. 5-9-16

333-030-0103
Camp Administration

(1) REGISTER RECORD. A record of all campers and staff attending camp must be kept by the license holder for a period of at least three years from the date attended.

(a) The record must include their name, address, phone number and dates of attendance.

(b) If the camp is contracted or rented out to a group, the license holder may inform the group in writing that they are required to do the following:

(A) Maintain a record of campers; and

(B) The license holder must keep a record of the group with contact information.

(2) VISITOR TRACKING. The camp operator must have a system to track visitors.

(3) CAMPER LOG. The camp operator must have a log of campers and staff under the age of 18 that leave or arrive at camp during the camp session. The record must include the identity of the person taking responsibility for the camper or staff person.

(4) CAMP IDENTIFIED. When the camp is being used by a contract or rental group that is not the license holder, the license holder must inform the group that they are required to include information identifying the license holder in promotional and informational materials distributed to attendees of the contract program.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13

333-030-0105
Health Services

(1) All camp operators must have health and first aid services available whenever the camp is operating.

(2) A camp director or license holder must ensure that residential camps with 100 or more campers and staff on-site at any one time has on-site at least one automatic external defibrillator (AED) with pediatric and adult capability meeting the local emergency medical services' protocol. The camp director or license holder must comply with the following:

(a) Each AED must have documented maintenance inspections and service records, including the battery and electrodes according to the guidelines set forth by the manufacturer.

(b) The AED must be stored in a central location where the AED is accessible to camp users and can be quickly retrieved.

(c) Signage must be provided that indicates the location of the AED.

(d) A policy must be developed for the use of the AED, including the need to contact 911 as soon as possible. This policy should be made available to camp staff and must be posted with the AED.

(3) The license holder or camp operator must report to the Division and local public health authority any unusual illness outbreaks or fatality that occurs at the camp. If possible, these incidents should be reported within 24 hours of occurrence.

Note: A reporting form is available from the Division, in this rule's appendices depending on the source, or at: http://www.oregon.gov/DHS/ph/pl/docs/campaccident.pdf.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 25-1981, f. & ef. 11-25-81; HD 7-1996, f. & cert. ef. 12-10-96; PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13

333-030-0110
Special Programs and Facilities

(1) HIGH RISK PROGRAM FACILITIES:

(a) A license holder is responsible for maintenance of a permanent high-risk program facility.

(b) The camp operator must ensure that the program director for each activity has training or experience in the high-risk program areas.

(c) Written procedures for the high risk activity must be communicated by the program supervisor to necessary camp staff and participants. Safety procedures must include:

(A) Eligibility requirements for participation;

(B) Camper/staff supervision ratios;

(C) Safety regulations;

(D) Emergency procedures;

(E) Safety and protective equipment and usage; and

(F) Activity area design or safety features, if applicable.

(2) AQUATIC FACILITIES:

(a) Public swimming pools and wading pools in organizational camps must comply with OAR chapter 333, division 60 (Public Swimming Pools).

(b) Public spa pools in organizational camps must comply with OAR chapter 333, division 62 (Public Spa Pools).

(3) AQUATIC PROGRAMS. The aquatic programs must be under the direction of an aquatic director or supervisor.

(4) WATERFRONT ACTIVITIES:

(a) An aquatic director must supervise any waterfront activity serving a total of 10 or more persons;

(b) There must be at least one lifeguard for each 25 persons in or on the water. An overall ratio of one observer or lifeguard for every 10 persons in or on the water must be maintained;

(c) Waterfront activities serving less than 10 persons in or on the water may operate with only the supervision of a lifeguard;

(d) If waterfront activities take place at more than one location, a lifeguard must be present at each location. Lifesaving, first aid, and safety equipment must be present at each location. Such equipment must be suitable for the users and conditions under which the equipment is expected to be used; and

(e) All watercraft must be equipped with a U.S. Coast Guard approved personal flotation device (PFD) in good, serviceable condition and of appropriate size for each person on board whenever the watercraft is in use.

(f) Subsections (4)(a) through (d) of this rule do not apply to groups comprised of only adults.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.310 – 446.350
Hist.: HD 25-1981, f. & ef. 11-25-81; HD 7-1996, f. & cert. ef. 12-10-96; PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13; PH 15-2016, f. 5-4-16, cert. ef. 5-9-16

333-030-0115
Transportation

(1) EMERGENCY TRANSPORTATION. All camp operators must provide transportation for use in emergency situations. When emergency transportation does not include an on-site vehicle in good running condition, a specific written plan for emergency transportation must be maintained at the camp.

(2) NON-EMERGENCY TRANSPORTATION. Campers must only be transported in areas of vehicles designed for passengers. Drivers must have a current driver's license with proper endorsement for the vehicle being operated and must be a minimum of 18 years of age.

(3) Slow-moving vehicles used for activities that do not exceed five miles-per-hour are allowed to transport campers.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 25-1981, f. & ef. 11-25-81; HD 7-1996, f. & cert. ef. 12-10-96; PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13

333-030-0120
Fire Safety

(1) The camp licensee that is the camp owner must comply with the 2014 Oregon Fire Code.

(2) WRITTEN NOTIFICATION:

(a) At least once per year, written notification must be provided to the fire department or fire authority serving the camp, concerning the camp's operation period and including a copy of the camp's emergency plan. Any suggestions from the fire department or fire authority should be considered for addition to the emergency plan.

(b) For camps located outside of an established fire district, the camp must have an agreement or contract with a fire protection agency agreeing to provide fire protection services.

(3) EMERGENCY PLAN:

(a) The camp license holder must have a written plan for dealing with fire emergencies. The plan must ensure camper security, notifying emergency fire-fighting resources, and staff duties and responsibilities.

(b) The fire emergency plan must be communicated to campers prior to overnight occupancy.

(4) STAFF TRAINING:

(a) Staff employed by the landlord must be instructed and periodically drilled on the use of the emergency equipment and procedures to follow for notifying emergency personnel.

(b) The camp operator for contract and rental groups must be provided with and oriented to the fire emergency plan.

(5) NON-PERMANENT SLEEPING AREAS. A camp must have firefighting equipment available near sleeping areas that are non-permanent in nature, having no electricity, water, or wood stoves. Such non-permanent sleeping areas are areas using tents, provided camping spaces, and other temporary structures, including open-air structures.

(6) PERMANENT BUILDINGS. Permanent buildings within the organizational camp that are accessible to entry by the campers must meet the requirements of the 2014 Oregon Fire Code..

(a) Buildings with an occupancy of more than 10 persons must be provided with at least two separate and independent means of emergency exit, located as far apart as possible but in no case closer than 50 percent of the longest diagonal dimension of the building.

(b) Where wood burning stoves or other combustible fuel heating devices are used in sleeping quarters, a carbon monoxide detector that is listed by a nationally recognized testing organization as meeting the Underwriter's Laboratories, Inc., UL 2034 or UL 2075 standards for carbon monoxide alarms must be provided, properly located, and maintained in compliance with OAR 837-047-0100 through 837-047-0170.

(c) Smoke detectors in good working order must be provided, properly located, and maintained in compliance with OAR 837-045-0040 through 837-045-0065 in all buildings used for sleeping by camp participants or staff. Smoke detectors must be listed by a nationally recognized testing organization as meeting the Underwriter's Laboratories, Inc., UL 217 or UL 265 standards for smoke detectors and alarms.

(d) Fire extinguishers must be provided and located as required by the 2014 Oregon Fire Code.

(e) Fire escape plans and routes must be communicated to campers prior to overnight occupancy.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.310 – 446.350
Hist.: HD 25-1981, f. & ef. 11-25-81; HD 7-1996, f. & cert. ef. 12-10-96; PH 1-2005, f. & cert. ef. 1-14-05; PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13; PH 15-2016, f. 5-4-16, cert. ef. 5-9-16

333-030-0125
Chemical and Physical Hazards

(1) Cleaning equipment and supplies, all insecticides, chemicals, paints, flammable liquids, and other toxic substances that bear the warning "keep out of reach of children" must be stored isolated from campers and stored so as to prevent contamination of clothing, toweling, bedding materials and food supplies. All applications of chemicals including, but not limited to, cleaners and disinfectants must be in accordance with the manufacturer's recommendations and by appropriately trained personnel.

(2) All toxic substances must be clearly labeled or stored in the original container. When not in use, all toxic materials must be stored according to the applicable requirements specified below:

(a) In a locked storage area or unit;

(b) As required by OAR 333-030-0070(6); or

(c) As required by OAR 333-150-0000, Food Sanitation Rules, for food preparation areas.

(3) Organizational camps must be a safe environment and must minimize or eliminate safety hazards including, but not limited to, debris, open excavations, abandoned wells, unused refrigerators or freezers with latchable doors. The licensee that is the camp owner must take measures to limit unsupervised access to natural hazards such as cliffs or bodies of water. All buildings and equipment must be kept in good repair.

(4) Gasoline and other flammable and combustible liquids must be clearly labeled, stored and dispensed in accordance with OAR 837-020-0025 through 837-020-0085 and the 2010 Oregon Fire Code.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 25-1981, f. & ef. 11-25-81; HD 7-1996, f. & cert. ef. 12-10-96; PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13

333-030-0130
Variance

(1) A license applicant or licensee may apply to the Division in writing for a variance from a requirement in OAR 333-030-0015 through 333-030-0125. In order to qualify for a variance an applicant or licensee must demonstrate, to the satisfaction of the Division, that:

(a) Strict compliance with the rule would be highly burdensome or impractical due to special conditions or cause;

(b) The public or private interest in granting the variance clearly outweighs the interest of the application of uniform rules; and

(c) Alternative measures, if applicable, provide adequate public health and safety protection for camp participants.

(2) A variance may only be granted by the Division and not by a LPHA.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 25-1981, f. & ef. 11-25-81; PH 9-2007, f. & cert. ef. 7-13-07; PH 2-2013, f. & cert. ef. 1-25-13

DIVISION 31

OPERATION AND MAINTENANCE OF RECREATION PARKS

333-031-0001
Adoption by Reference

Outside standards, listings and publications referred to in these rules are by reference made a part of these rules.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 183.355
Hist.: HD 7-1985(Temp), f. & ef. 4-30-85; HD 27-1985, f. & ef. 10-28-85

333-031-0002
Definitions

As used in these rules 333-031-0002 to 333-031-0085, unless otherwise required by context:

(1) "Administrator" means the Assistant Director for the Public Health Division.

(2) "Approval or Approved" means approved in writing.

(3) "Camping Space" means an area of ground within a recreation park intended for the accommodation of a recreational vehicle, camping vehicle, tent vehicle, tent or other individual camping unit on a temporary basis.

(4) "Camping Vehicle" means either a vacation trailer or a self-propelled vehicle or structure equipped with wheels for highway use and which is intended for human occupancy and is being used for vacation and recreational purposes, but not for residential purposes, and is equipped with plumbing, sink or toilet.

(5) "Campground" provides facilities and space for tents, tent vehicles, camping vehicles, or recreational vehicles.

(6) "Division" means Oregon Health Authority, Public Health Division.

(7) "Hostel" means an establishment having beds rented or kept for rent on a daily or weekly basis to travelers for a charge or fee paid or to be paid for rental or use of facilities and which are operated, managed or maintained under the sponsorship of a nonprofit organization which holds a valid exemption from federal income taxes under 26 USC Sec. 501.

(8) "Organizational Camp" includes any area designated by the person establishing, operating, managing or maintaining the same for recreational use by groups or organizations which include but are not limited to youth camps, scout camps, summer camps, day camps, nature camps, survival camps, athletic camps, camps which are operated and maintained under the guidance, supervision or auspices of religious, public and private educational systems and community service organizations. Organizational camps are distinguished from recreation parks by the existence of organized group activities comprising the majority of activities by all participants rather than individual and family recreation.

(9) "Overnight Camping" means the activity of using a camping space for overnight accommodation.

(10) "Permanently affixed thereto" as used in these rules includes but is not limited to affixation as evidenced by: permanent water, sewer, and electrical connections; wheels removed; permanent foundations; or towing assembly removed.

(11) "Picnic Park" means any recreation park which is for day use only and provides no recreation vehicle or overnight camping spaces.

(12) "Recreation Park" means any area designated by the person establishing, operating, managing or maintaining the same for picnicking or overnight camping by the general public or any segment of the public. "Recreation park" includes but is not limited to area open to use free of charge or through payment of a tax or fee or by virtue of rental, lease, license, membership, association or common ownership and further includes, but is not limited to those areas divided into two or more lots, parcels, units or other interests for purposes of such use. "Recreation park" excludes sites that have units for human occupancy permanently affixed thereto but includes an area that has camping spaces available to be moved onto for transitory use.

(13) "Recreational Vehicle" means a camping vehicle.

(14) "Tent Vehicle" is any camping vehicle intended for overnight occupancy but not equipped with plumbing, sink, or toilet.

(15) "Tourist Facility" means any travelers' accommodation, hostel, picnic park, recreation park and organizational camp.

(16) "Travelers' Accommodation" includes any establishment, which is not a hostel, having rooms, apartments or sleeping facilities rented or kept for rent on a daily or weekly basis to travelers or transients for a charge or fee paid or to be paid for rental or use of facilities.

(17) "Unregulated Small Drinking Water System" means a facility licensed under the authority of these rules that is not regulated under OAR 333-061, Public Water Systems. These systems must comply with the requirements of OAR 333-031-0004.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HB 129, f. 12-3-59; HB 231, f. 12-22-69; HD 7-1985(Temp), f. & ef. 4-30-85; HD 27-1985, f. & ef. 10-28-85; HD 18-1987(Temp), f. & ef. 10-22-87; HD 7-1988, f. & cert. ef. 4-18-88; PH 1-2005, f. & cert. ef. 1-14-05

General Rules Applicable to All Establishments

333-031-0003
Purpose

These rules adopted pursuant to the provisions of ORS 446.330 prescribe the requirements for the construction and operation of recreation parks. They are for the purpose of protecting the health and welfare of persons using these facilities.

Stat. Auth.: ORS 446.0315
Stats. Implemented:ORS 446.310 - 446.350, 446.435 & 446.990
Hist.: HB 231, f. 12-22-69; HD 7-1985(Temp), f. & ef. 4-30-85; HD 27-1985, f. & ef. 10-28-85

333-031-0004
Water Supply

(1) Definitions applicable to this rule:

(a) "Maximum Contaminant Level (MCL)" means the maximum allowable level of a contaminant in water for consumption delivered to the users of a system, except in the case of turbidity where the maximum allowable level is measured at the point of entry to the distribution system.

(b) "Quarterly Sampling" means a sample is taken and submitted according to the following schedule: 1st Quarter is from January 1 through March 31, 2nd Quarter is from April 1 through June 30, 3rd Quarter is from July 1 through September 30 and the 4th Quarter is from October 1 through December 31.

(2) Water supply systems serving travelers' accommodations and hostels shall comply with OARs for Public Water Systems, OAR 333-061-0005 through 333-061-0095, and must be:

(a) Regulated as a Public Drinking Water System under OAR 333-061; or

(b) Water systems serving travelers' accommodations and hostels that are not regulated under OAR 333-061 as a Public Drinking Water System must meet the requirements in section (3) below.

(3) Unregulated Public Drinking Water Systems:

(a) Plan Review. All new facilities that are not regulated by OAR 333-061 must submit plans to the Authority for review prior to construction or major modification of system. Systems regulated prior to January 1, 2003 by OAR 333-061 are not required to re-submit plans.

(b) Surface Water Sources. New facilities with surface water sources not regulated under OAR 333-061 will not be licensable after January 1, 2005. Facilities existing prior to January 1, 2005 in compliance with OAR 333-061-0032 may continue to operate.

(c) Sampling frequency:

(A) For seasonal facilities, a coliform sample must be taken prior to operational period and each quarterly sampling period while open to public. A minimum of two samples will be required for coliform, regardless of length of operation.

(B) For year round facilities:

(i) Coliform: Monthly for surface water. Quarterly for populations under 1000 on ground water.

(ii) Inorganic Samples: One time sampling required for new facilities before beginning operation.

(d) MCL Violations. An item is not considered a violation until confirmed by second sample taken within 24 hours. Four repeat samples must be taken within 24 hours of the original positive sample for a sample result above the maximum contaminant level (MCL).

(A) Total coliform: Report positive total coliform samples to the Authority within 24 hours of being notified of the positive sample.

(B) Fecal coliform. Any positive fecal coliform sample must be reported to the Authority within 24 hours.

(i) Public notification for this potential acute health risk is required.

(ii) An alternative procedure approved by the Authority must be in place before serving public.

(C) Inorganic Samples. One time sampling is required for new facilities. Additional testing is not required for facilities that were previously regulated under OAR 333-061 and have tested prior to January 1, 2003. Inorganics include: antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, nitrate, nitrite, selenium and thallium.

(D) Nitrate: Sample must be submitted for testing annually

(i) Any samples exceeding the MCL for nitrate shall be reported to the Authority within at least 24 hours.

(ii) When a test on a sample is reported to exceed the MCL for nitrate, public notification is required. Bottled water must also be provided to public upon request.

(E) The Authority may require more frequent monitoring than specified or may require confirmation samples for positive and negative results. It is the responsibility of the operator to correct any problems and get a laboratory test result that is less than the maximum contaminant level.

(e) Sample collection methods.

(A) For the purpose of determining compliance with the MCL and the sampling requirements of these rules, sampling results may be considered only if they have been analyzed by a laboratory certified by the State Drinking Water Program.

(B) Samples submitted to laboratories for analysis shall be clearly identified with the name of the water system, facility license number, sampling date, time, sample location identifying the sample tap, the name of the person collecting the sample and whether it is a routine or a repeat sample.

(i) Routine: These are samples collected from established sampling locations within a water system at specified frequencies to satisfy monitoring requirements as prescribed in this rule. These samples are also used to calculate compliance with maximum contaminant levels for inorganics prescribed in OAR 333-061-0030(Table 1);

(ii) Repeat: These are samples collected as a follow-up to a routine sample that has exceeded a maximum contaminant level.

(iii) Test results: Sample results must be submitted to the Local Public Health Authority by the 10th of the month following the sampling period.

(iv) The Authority may take additional samples to determine compliance with applicable requirements of these rules.

(f) Public Notice. All public notification must be posted conspicuously on site and must include:

(A) A description of the violation or situation of concern;

(B) Corrective actions taken to improve water quality;

(C) Any potential adverse health effects;

(D) The population at risk;

(E) The alternative measures in place to provide safe drinking water.

(4) The water distribution system shall be designed, constructed, approved and maintained in compliance with the requirements of the Oregon Department of Consumer and Business Services, Building Codes Division. New water supply distribution systems, or systems remodeled, enlarged or converted after the effective date of these rules must meet the requirements of the **2000 Oregon Plumbing Specialty Code.**

(5) No owner or operator of an establishment covered by these regulations shall supply common drinking cups or vessels.

(6) Where drinking fountains are provided, they shall be of an approved angle jet type with adequate water pressure at all times.

[Publications: Publications & Tables referenced are available from the agency.]

Stat. Auth.: ORS 446.330

Stats. Implemented: ORS 446.330

Hist.: HB 129, f. 12-3-59; HB 231, f. 12-22-69; HD 7-1985(Temp), f. & ef. 4-30-85; HD 27-1985, f. & ef. 10-28-85; PH 1-2005, f. & cert. ef. 1-14-05

333-031-0005

Temporary Water Quality Variance

The Division may grant a temporary variance from requirements of OAR 333-031-0004 by continuing or re-issuing previously issued certificates or licenses where:

(1) Failure to comply with such rule requirements is due to failure of a community, municipal or public utility water supply system to meet Division requirements;

(2) The Assistant Director is satisfied that necessary remedial action is ongoing or reasonably imminent in connection with such water supply system; and

(3) Continuance or re-issuance of the certificate or license is conditioned upon the carrying out of such remedial action and the provision of such other measures by the certificate or license holder which will in the judgment of the Assistant Director afford reasonable interim protection to the public health including, but not limited to, adequate warnings to public and personnel as to the safety of the water delivered to the premises from the distribution system and notice of measures to avoid use or consumption of such water or to render it safe for consumption; adequate warnings as to the need for supervision of children and others needing supervision against use of such water; provision of alternative potable water a n d adequate notification as to its availability; and measures to avoid the use and the availability of water on the premises.

Stat. Auth.: ORS 446.330

Stats. Implemented: ORS 446.330

Hist.: HD 5-1979(Temp), f. & ef. 6-19-79; HD 6-1979(Temp), f. & ef. 7-5-79; HD 10-1979(Temp), f. & ef. 8-21-79; HD 16-1979(Temp), f. & ef. 11-2-79; HD 17-1979(Temp), f. & ef. 12-20-79; HD 3-1980, f. & ef. 2-28-80

333-031-0006

Sewage and Liquid Waste Disposal

(1) Sewage and waste water shall be disposed of into a public sewerage system or in a manner approved by the Department of Environmental Quality, OAR 340-071-0100 to 340-071-0600.

(2) All sewage collection systems when provided shall be designed, constructed, approved and maintained in compliance with the requirements of the Oregon Department of Consumer and

Business Services, Building Codes Division, and, where applicable, the additional statutes, rules and standards set forth by the Department of Environmental Quality. New sewage collection systems and recreational vehicle waste disposal stations, or systems remodeled, enlarged or converted after the effective date of these rules must meet the requirements of the **2000 Oregon Plumbing Specialty Code**.

(3) No liquid wastes shall be discharged onto the ground or allowed to accumulate on the ground surface.

(4) In lieu of individual sewer connections, at least one kitchen waste water disposal facility shall be provided for the recreation park. A kitchen waste water disposal facility shall:

(a) Discharge into a public sewerage system.

(b) If such a system is not available then liquid wastes shall be disposed of in a manner approved by the Department of Environmental Quality, OAR 340-071-0100 through 340-071-0600.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HB 129, f. 12-3-59; HB 231, f. 12-22-69; HD 7-1985(Temp), f. & ef. 4-30-85; HD 27-1985, f. & ef. 10-28-85; PH 1-2005, f. & cert. ef. 1-14-05

333-031-0007
Solid Waste

(1) Solid waste shall be disposed of in a manner which complies with the rules of the Department of Environmental Quality, OAR 340-061-0040, 340-061-0045, 340-061-0050 and 340-061-0060, governing solid waste;

(2) Solid waste shall be stored in individual garbage containers, storage bins or storage vehicles. All such containers, bins or vehicles shall:

(a) Have tight-fitting lids, covers or closable tops;

(b) Be durable, rust-resistant, watertight, rodent-proof and readily washable.

(3) The premises of each recreation park shall be kept orderly and free of litter and refuse.

(4) All solid waste shall be collected for disposal at regular intervals so as not to create:

(a) Vector production and sustenance;

(b) Objectionable odors;

(c) Any overflowing of solid waste or other unsanitary conditions.

(5) Solid waste containing putrescible waste shall be collected for disposal at regular intervals not to exceed seven days.

(6) Solid waste shall be transported in a manner which complies with the rules of the Department of Environmental Quality, OAR 340-061-0075(1) and (2).

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 7-1985(Temp), f. & ef. 4-30-85; HD 27-1985, f. & ef. 10-28-85

333-031-0008
Insect and Rodent Control

(1) Insect and rodent control measures to safeguard public health and to prevent nuisance to the public shall be applied. Developed areas, buildings, and structures shall be maintained free of accumulations of debris.

(2) All floors not constructed of solid concrete or other effective rodent-proof and moisture-proof foundation material shall be built so that the minimum clearance between the bottom of floor joists or bottom of floors without joists and the ground beneath shall be 18 inches and so that the minimum clearance under girders shall be 12 inches. The space underneath shall be kept free from obstructions. This rule shall be applied to structures in recreation parks built after January 25, 1970.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HB 129, f. 12-3-59; HB 231, f. 12-22-69

333-031-0010
Fire Protection and the Elimination of Accident Factors

(1) Electrical installations shall comply with the requirements of the Oregon Department of Consumer and Business Services, Building Codes Division. New electrical installations or systems remodeled, enlarged or converted after the effective date of these rules must meet the requirements of the **2002 Oregon Electrical Specialty Code**.

(2) Local building ordinances shall be complied with.

(3) Every gas water heater, and every other gas fired appliance except gas plates and gas ranges, installed or serviced for use in any rental unit, shall be effectively vented as required by the State Fire Marshal.

(4) Liquefied petroleum gas storage tanks shall conform in construction, design, installation, and operation with the rules of the State Fire Marshal.

(5) All boilers and pressure vessels shall be approved and maintained in accordance with the applicable state statutes and rules of the Department of Commerce.

(6) An approved ASME pressure relief valve shall be installed on all hot water tanks.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HB 129, f. 12-3-59; HB 231, f. 12-22-69; HD 7-1985(Temp), f. & ef. 4-30-85; HD 27-1985, f. & ef. 10-28-85; PH 1-2005, f. & cert. ef. 1-14-05

333-031-0012
Bath and Toilet Room

(1) Toilet, handwashing and bathing facilities shall be maintained to meet the following requirements:

(a) Illumination and ventilation shall be provided in accordance with the requirements of the Oregon Department of Consumer and Business Services, Building Codes Division. New Toilet, handwashing, and bathing facilities, or facilities remodeled, enlarged or converted after the effective date of these rules must meet the requirements of the **2004 Oregon Structural Specialty Code** and the **2004 Oregon Mechanical Specialty Code**;

(b) Floors and walls shall be smooth, impervious to water and easily cleanable;

(c) Shower walls, ceilings and/or partitions shall be impervious to water. Where a wall and a floor join, an effective, watertight union shall be maintained;

(d) Bathtub and shower floor areas shall be finished with nonslip, impervious, easily cleaned surfaces and sloped to effectively drain all waste water. Wooden racks or duck boards over shower floors are prohibited;

(e) Where glass bath or shower doors are used, such doors shall be made of safety glass.

(2) All plumbing installations must be designed, constructed, approved and maintained in compliance with the requirements of the Oregon Department of Consumer and Business Services, Building Codes Division. New water supply distribution systems, or systems remodeled, enlarged or converted after the effective date of these rules must meet the requirements of the **2000 Oregon Plumbing Specialty Code**.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 446
Stats. Implemented: ORS 446
Hist.: HB 129, f. 12-3-59; HB 231, f. 12-22-69; HD 7-1985(Temp), f. & ef. 4-30-85; HD 27-1985, f. & ef. 10-28-85; PH 1-2005, f. & cert. ef. 1-14-05

333-031-0014
Maintenance Generally

All floors, interior walls, and ceilings of buildings containing living, sleeping, and eating areas, bath, toilet, and laundry areas and kitchen areas shall be of easily cleanable materials, except as otherwise required by the preceding OAR 333-031-0012, and shall be kept in good repair. Building exteriors shall be of such materials and be so constructed and protected as to prevent entrance or penetration by moisture and weather. However, this shall not preclude the construction of picnic or cooking shelters without walls.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HB 129, f. 12-3-59; HB 231, f. 12-22-69; HD 27-1985, f. & ef. 10-28-85

333-031-0018

Supplemental Services and Swimming Pools

(1) Eating and drinking establishments, commissaries, mobile units, and vending machines operated in conjunction with recreation parks shall be operated in compliance with the Authority's Food Sanitation Rules, OAR 333-150-0000 (1/2002).

(2) All swimming pools, spa pools and wading pools located at or operated in a recreation park shall comply with the respective Rules of the Authority:

(a) Public Swimming Pools and Wading Pools OAR 333-060-0005 through 333-060-0225; and

(b) Public Spa Pools OAR 333-062-0005 through 333-062-0185.

(3) Ice provided by recreation parks shall comply with OAR 333-150-0000 sections 3-202.16 and 3-303.12.

Stat. Auth.: ORS 446.330

Stats. Implemented: ORS 446.330

Hist.: HB 129, f. 12-3-59; HB 231, f. 12-22-69; HD 7-1985(Temp), f. & ef. 4-30-85; HD 27-1985, f. & ef. 10-28-85; HD 27-1994, f. 10-27-94, cert. ef. 12-31-94; PH 1-2005, f. & cert. ef. 1-14-05

333-031-0020

Supervision

(1) The management shall maintain buildings, grounds, rental units, spaces, and furnishings in good repair and appearance and in clean condition.

(2) Either the owner, an operator, a resident manager, a night clerk, or other such supervisor shall be available on the premises while it is open for use. In lieu thereof, there shall be posted on the premises the name and location of a representative who will be responsible for the operation of the establishment.

Stat. Auth.: ORS 446.330

Stats. Implemented: ORS 446.330

Hist.: HB 129, f. 12-3-59; HB 231, f. 12-22-69

333-031-0059

Plans

(1) Prior to construction, enlargement or alteration of any recreation park or picnic park, plan approval and permits shall be obtained from the Department of Consumer and Business Services, Building Codes Division.

(2) A copy of the approved plans shall be submitted to the Division.

Stat. Auth.: ORS 446.330

Stats. Implemented: ORS 446.330

Hist.: HB 231, f. 12-22-69; HD 7-1985(Temp), f. & ef. 4-30-85; HD 27-1985, f. & ef. 10-28-85; HD 9-1986, f. & ef. 6-12-86

333-031-0060

All Recreation Parksites

Condition of soil, groundwater level, drainage, and topography shall be considered in the design of the park and in the selection of the type and location of water supply and sewage disposal systems so that a health hazard is not created.

Stat. Auth.: ORS 466.330

Stats. Implemented: ORS 446.330, 446.340 & 446.345

Hist.: HB 231, f. 12-22-69

333-031-0061

Establishing Compliance with Statewide Planning Goals and Compatibility with Acknowledged Comprehensive Plans and Land Use Regulations Prior to Approval of Construction, Enlargement, or Alteration Plans for Recreation Parks and Organizational Camps

(1) No approval of construction, enlargement, or alteration plans will be given unless the applicant for approval submits to the Division a written determination supported by written findings as required in ORS 215.416(6) or 227.173(2) from the unit of local government having comprehensive planning authority over the proposed construction, enlargement, or alteration site, that the proposed project is compatible with the Land Conservation and Development Commission acknowledged comprehensive plan, as defined in OAR 660-031-0010(1), or where there is no acknowledged local comprehensive plan, or in those instances described in OAR 660-031-0020(3), that the proposed project is in compliance with the Land Conservation and Development Commission's statewide planning goals under ORS Chapter 197. Findings for an activity or use addressed by the acknowledged comprehensive plan in accordance with OAR 660-031-0020, may simply reference the specific plan policies, criteria, or standards which were relied upon in rendering the decision and state why the decision is justified based on the plan polices, criteria or standards. The determination shall be on a form supplied by the Division accompanied by attachments as necessary.

(2) Where more than one unit of local government as comprehensive planning authority over the site of the proposed construction, enlargement or alteration, written determinations statements from each of these jurisdictions (e.g., city, county and regional planning jurisdictions) must be submitted to the Division.

(3) "Acknowledged Comprehensive Plan" as used in this rule has the meaning given in OAR 660-031-0010(1).

Stat. Auth.: ORS 197.013 & 446.315

Stats. Implemented: ORS 446.315

Hist.: HD 5-1983(Temp), f. & ef. 5-17-83; HD 14-1983, f. & ef. 9-21-83; HD 21-1984, f. & ef. 10-23-84

333-031-0062

Special Rules for Overnight Campgrounds

Camping Spaces:

(1) Each camping space shall be identified by letter, number or name;

(2) Each camping space shall be large enough to accommodate the parked camping vehicle, tent vehicle or tent as the case may be and to maintain at least ten feet separation from any other camping vehicle or tent, ten feet from any building, ten feet from any awning or carport on an adjacent space, ten feet from a boundary line abutting upon a public street or highway, and five feet from any property line;

(3) Only one camping vehicle, tent vehicle or tent shall be located within a designated camping space and shall be maintained ten feet from any other such vehicle or tent. However, more than one such vehicle or tent may locate on a space and each vehicle or tent may be less than ten feet apart if:

(a) The owner of each vehicle or tent consents to such an arrangement;

(b) The park water and sewage disposal systems are not jeopardized by the additional camping load.

(4) No owner or operator shall require or encourage the location of more than one camping vehicle, tent vehicle, or tent on any space;

(5) Camping vehicles, tent vehicles, and tents shall not obstruct any public or private roadway or walkway. Each space shall have access to a park driveway or road.

Stat. Auth.: ORS 446.330

Stats. Implemented: ORS 446.330

Hist.: HB 231, f. 12-22-69; HD 7-1985(Temp), f. & ef. 4-30-85; HD 27-1985, f. & ef. 10-28-85; HD 17-1986(Temp), f. & ef. 10-24-86; HD 2-1987, f. & ef. 1-21-87

333-031-0064
Special Rules for Picnic Parks

All vehicular traffic shall remain on roadways or parking areas.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HB 129, f. 12-3-59; HB 231, f. 12-22-69; HD 27-1985, f. & ef. 10-28-85

333-031-0066
All Toilets

(1)(a) Toilets shall be provided in all recreation parks in the following ratios: Number of picnic spaces, camping spaces or car parking spaces — Number of Toilets: [Table not included. See ED. NOTE.]

(b) The location of toilets shall be indicated by appropriate signs.

(2) If flush toilets are provided, the building containing them shall be constructed in accordance with OAR 333-031-0012 and the requirements of the Oregon Department of Consumer and Business Services, Building Codes Division. New flush toilet facilities, or facilities remodeled, enlarged or converted after the effective date of these rules must meet the requirements of the 2000 Oregon Plumbing Specialty Code.

(3) If pit privies or chemical toilets are provided, they shall be constructed, located, and maintained in accordance with the requirements of the Department of Environmental Quality OAR 340-071-0100 through 340-071-0600.

[ED. NOTE: Tables referenced are available from the agency.]
Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HB 231, f. 12-22-69; HD 7-1985(Temp), f. & ef. 4-30-85; HD 27-1985, f. & ef. 10-28-85; PH 1-2005, f. & cert. ef. 1-14-05

333-031-0068
Picnic Tables and Firepits

(1) Picnic table tops shall have a smooth, weather resistant finish.

(2) Fireplaces, fire pits, or cooking facilities shall be of cleanable construction and designed to permit easy removal of ash and other wastes.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HB 231, f. 12-22-69; HD 7-1985(Temp), f. & ef. 4-30-85; HD 27-1985, f. & ef. 10-28-85

333-031-0070
Rallies and Caravans

(1) Any temporary facilities for accommodating a camping vehicle rally or other groups of camping vehicles assembled for the purpose of traveling together may be exempted by the Administrator from the requirements of these rules for toilets and spacing if the Administrator finds the public health will not be endangered. The period of operation shall be designated by the Administrator.

(2) Prior to using any recreation park, camping vehicle rally groups shall obtain permission from the park owner or operator.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HB 231, f. 12-22-69; HD 7-1985(Temp), f. & ef. 4-30-85; HD 27-1985, f. & ef. 10-28-85

333-031-0072
Special Conditions

The Administrator may exempt any requirements of the rules for toilets, waste water disposals and spacing, to meet special short-term campground needs either arising annually during hunting season or other similar special situations if he finds that public health will not be endangered.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HB 231, f. 12-22-69; HD 7-1985(Temp), f. & ef. 4-30-85; HD 27-1985, f. & ef. 10-28-85

333-031-0074
Rules for Recreation Park Patrons

(1) Patrons shall dispose of all sewage and waste water in the facilities provided by the park owner or operator. No sewage or waste water shall be discharged onto the ground or allowed to accumulate on the ground surface.

(2) Patrons shall dispose of their solid waste in the containers provided for this purpose.

(3) Only one camping vehicle, tent vehicle or tent is permitted in a camping space and a distance of at least ten feet must be maintained from any other such vehicle or tent. However, more than one such vehicle or tent may occupy a camping space and a spacing of less than ten feet is permitted provided the owner of each vehicle and the park owner or operator agree.

(4) No person shall permit his camping vehicle, tent vehicle, or tent to obstruct any public or private roadway or walkway. All vehicular traffic within picnic areas shall remain on the roadways or parking areas.

(5) Camping vehicle rally groups or other groups of camping vehicle owners assembled for the purpose of traveling together must obtain permission from the park owner or operator before entering any recreation park.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330 & 446.346
Hist.: HB 231, f. 12-22-69; HD 17-1986(Temp), f. & ef. 10-24-86; HD 2-1987, f. & ef. 1-21-87

333-031-0075
Fees

(1) Every applicant for a Recreation Park license shall pay to the Public Health Division a fee of $60 plus $2 for each space from 1–50, $1.50 for each recreation park space from 51–100, $1 for each space above 100.

(2) Every applicant for a Picnic Park license shall pay to the Public Health Division a fee of $60.

(3) All licenses issued under ORS 446.310 to 446.350 terminate and are renewable on December 31 of each year.

Stat. Auth.: ORS 446.321
Stats. Implemented: ORS 446.320
Hist.: HD 4-1980, f. & ef. 3-21-80; HD 18-1983(Temp), f. & ef. 10-18-83; HD 11-1984, f. & ef. 6-20-84; HD 27-1994, f. 10-27-94, cert. ef. 12-31-94

333-031-0085
Variance

(1) The Division may grant a variance from the requirements of OAR 333-031-0002 through 333-031-0075 as follows:

(a) Where it is demonstrated to the satisfaction of the Division that strict compliance with the rule would be highly burdensome or impractical due to special conditions or cause;

(b) Where the public or private interest in the granting of the variance is found by the Division to clearly outweigh the interest of the application of uniform rules; and

(c) Where such alternative measures are provided which in the opinion of the Division will provide adequate health and safety protection.

(2) Such variance authority is not conferred upon any county notwithstanding delegated or contractual authority in the administration and enforcement of travelers' accommodation and recreation park statutes and rules.

Stat. Auth.: ORS 446.330
Stats. Implemented: ORS 446.330
Hist.: HD 13-1981(Temp), f. & ef. 7-31-81; HD 5-1982, f. & ef. 3-1-82

333-031-0090
Civil Penalties

In accordance with ORS 446.348, the Assistant Director for Health will use the following schedule to impose civil penalties for violations of rules for recreation parks and picnic parks:

(1) Violations of any requirements stated in any part of OAR 333-031-0004, 333-031-0005, 333-031-0006 and 333-031-0110 are Class I violations subject to a civil penalty in the amount of not less than $75 nor more than $1,000 for each and every violation.

(2) Violations of any requirements stated in any part of OAR 333-031-0007, 333-031-0008, 333-031-0012, 333-031-0018, 333-

031-0059, and 333-031-0066 are Class II violations subject to a civil penalty in the amount of not less than $50 nor more than $750 for each and every violation.

(3) Violations of any of the requirements stated in any part of OAR 333-031-0014, 333-031-0020, 333-031-0060, 333-031-0062, 333-031-0064 and 333-031-0068 are Class III violations subject to a civil penalty in the amount of not less than $25 nor more than $350 for each and every violation.

Stat. Auth.: ORS 446.348
Stats. Implemented: ORS 446.347 & 446.348
Hist.: HD 9-1986, f. & ef. 6-12-86

DIVISION 35

HOSPICE PROGRAM LICENSURE

333-035-0045
Purpose

These rules establish the authority of the Oregon Health Authority, Public Health Division to license hospice programs in order to ensure the health and safety of individuals who are experiencing the last phases of life.

Stat. Auth.: ORS 443.860
Stats. Implemented: ORS 443.860
Hist.: PH 19-2010, f. 8-30-10, cert. ef. 9-1-10

333-035-0050
Definitions

As used in OAR chapter 333, division 35, the following definitions apply:

(1) "Accreditation" means a designation by an accrediting organization that a hospice program has met standards that have been developed to indicate a quality program.

(2) "Administrator" means a person responsible for the administrative functions and operation of the hospice program.

(3) "CMS" means Centers for Medicare and Medicaid Services.

(4) "Certification" means a state agency's official recommendations and findings to CMS regarding a hospice program's compliance with federal CMS regulations.

(5) "Conditions of Participation" mean the applicable federal regulations that hospice programs are required to comply with in order to participate in the federal Medicare and Medicaid programs.

(6) "Division" means the Oregon Health Authority, Public Health Division.

(7) "Hospice aide" has the same meaning as nurse's aide.

(8) "Hospice program" means a coordinated program of home and inpatient care, available 24 hours a day, that utilizes an interdisciplinary team of personnel trained to provide palliative and supportive services to a patient-family unit experiencing a life threatening disease with a limited medical prognosis. A hospice program is an institution for purposes of ORS 146.100.

(9) "Hospice services" means items and services provided to a patient-family unit by a hospice program or by other individuals or community agencies under a consulting or contractual arrangement with a hospice program. Hospice services include home care, inpatient care for acute pain and symptom management or respite, and bereavement services provided to meet the physical, psychosocial, emotional, spiritual and other special needs of a patient-family unit during the final stages of illness, dying and the bereavement period.

(10) "Interdisciplinary team" means a group of individuals working together in a coordinated manner to provide hospice care. An interdisciplinary team includes, but is not limited to, the patient-family unit, the patient's attending physician or clinician and one or more of the following hospice program personnel:

(a) Physician;
(b) Nurse practitioner;
(c) Nurse;
(d) Nurse's aide;
(e) Occupational therapist;
(f) Physical therapist;
(g) Trained lay volunteer;
(h) Clergy or spiritual counselor; or
(i) Credentialed mental health professional such as psychiatrist, psychologist, psychiatric nurse or social worker.

(11) "Medicare Certification Number" means the unique identification number, also referred to as the Medicare Provider Number, assigned to a qualifying hospice program by CMS.

(12) "Nurse's Aide" means a person certified as a nursing assistant under ORS 678.442 who has received special hospice training in accordance with CMS Conditions of Participation.

(13) "Patient-family unit" includes an individual who has a life threatening disease with a limited prognosis and all others sharing housing, common ancestry or a common personal commitment with the individual.

(14) "Person" includes individuals, organizations and groups of organizations.

(15) "Survey" means an inspection of an applicant for a hospice program license or a hospice program to determine the extent to which the applicant or hospice program is in compliance with state hospice program statutes, these rules and CMS Conditions of Participation.

Stat. Auth.: ORS 443.860
Stats Implemented: ORS 443.850
Hist.: PH 19-2010, f. 8-30-10, cert. ef. 9-1-10

333-035-0055
Licensing and Fees

(1) A person may not establish, conduct or maintain a hospice program providing hospice services, or hold itself out to the public as a hospice program, without obtaining a license from the Division.

(2) A person may apply to operate a hospice program by submitting a complete application on a form prescribed by the Division, accompanied by a fee of $750. An application that is incomplete or that is not accompanied by the correct fee will be returned to the person applying.

(3) In order for a license application to be considered complete, it shall include, but is not limited to:

(a) Business name;
(b) Medicare Certification Number (Medicare Provider Number)(if applicable);
(c) Primary and multiple locations (if any);
(d) Tax status;
(e) Ownership category (e.g. corporation, partnership, sole proprietorship);
(f) Physical and mailing addresses;
(g) Owner information;
(h) Descriptions of services;
(i) Staffing levels; and
(j) Average daily census.

(4) The Division shall conduct an initial survey prior to licensure.

(5) In lieu of an initial survey required under section (4) of this rule, the Division may accept a CMS certification or a survey conducted within the previous three years by an accrediting organization approved by the Division.

(6) A hospice program licensed in Washington, Idaho or California must be licensed in Oregon in order to provide care in Oregon within a 60 mile radius of the parent agency in the other state. A hospice program licensed in these other states shall pay the required fee and the Division:

(a) Shall conduct a licensing survey; or
(b) May accept a CMS certification or a survey conducted within the previous three years by an accrediting organization approved by the Division.

(7) The Division may waive the mileage guideline in section (6) of this rule if the parent hospice program proposes to provide hospice services to an underserved area of the state and adequately demonstrates the ability to manage and control the services.

(8) The Division shall issue a license to an applicant that has the necessary qualifications, meets all requirements established by

the Division, meets the CMS Conditions of Participation for hospice programs found in 42 CFR Part 418, and has paid the fee.

(9) A license issued under this section is valid for one year and is not transferable.

(10) A licensee may apply for renewal of a license by completing a renewal application on a form prescribed by the Division and submission of a $750 renewal fee. The Division shall renew a license if the licensee is in compliance with ORS 443.850 through 443.869, these rules, and CMS Conditions of Participation, 42 CFR Part 418.

(11) The Division may permit a hospice program providing care at multiple locations, to operate under one license for all locations, if:

(a) All locations are operating under the same Medicare Certification Number;

(b) The multiple location provides the same full range of care and services that is required by the hospice program issued the Medicare Certification Number; and

(c) The locations are located within a 60 mile radius of the parent hospice program applying for licensure.

(12) The Division may waive the mileage guideline in subsection (11)(c) of this rule if the parent hospice program proposes to provide hospice services to an underserved area of the state and adequately demonstrates the ability to manage and control the services.

(13) An applicant or licensee may be required by CMS to obtain a survey by a CMS deemed accrediting organization in addition to any survey conducted by the Division under section (4) of this rule or OAR 333-035-0075.

Stat. Auth.: ORS 443.860
Stats. Implemented: ORS 443.860
Hist.: PH 19-2010, f. 8-30-10, cert. ef. 9-1-10

333-035-0060
Criminal Background Checks

(1) Except as provided in section (7) of this rule, a hospice program must obtain a criminal background check for the following prior to employment, entering into a contract, or permitting a volunteer to have direct patient contact and every three years thereafter:

(a) Hospice program employees;

(b) Individuals who contract with the hospice program and who have direct patient contact or access to patient records; and

(c) Volunteers who have direct patient contact or access to patient records.

(2) A hospice program must have written policies and procedures for conducting criminal background checks in accordance with section (1) of this rule including a description of criminal convictions that disqualifies an individual from being employed, contracted with or working as a volunteer.

(3) If the criminal background check or other information obtained by a hospice program indicates an employee, contractor or volunteer has been convicted of a crime against a person or property that reasonably raises questions about the ability of that individual to safely provide services or care, the hospice program shall notify the individual in writing that they have been found unfit to be employed, contracted with or to be a volunteer.

(4) If an individual has been found unfit in accordance with section (3) of this rule, the hospice program shall provide that individual with information on how to appeal to the source of the criminal background check if the individual believes the records are in error.

(5) A hospice program shall keep the information obtained from criminal background checks confidential and use it solely to determine an individual's eligibility to be employed, contracted with or to be a volunteer.

(6) A hospice program shall require the individuals described in subsection (1)(a) through (c) of this rule to report within 10 days:

(a) Any criminal conviction;

(b) Any arrest, indictment, or charge for a sexual offense or property crime; and

(c) Any disciplinary action taken by a health professional regulatory board or agency.

(7) An individual licensed by a health professional regulatory board as defined in ORS 676.160 is not subject to the criminal background checks described in section (1) of this rule.

(8) A hospice program shall have policies and procedures that ensure the entities it contracts with have conducted criminal background checks for individuals that will have direct contact with the hospice program's patients or access to hospice program patient records.

Stat. Auth.: ORS 443.860
Stats. Implemented: ORS 443.860
Hist.: PH 19-2010, f. 8-30-10, cert. ef. 9-1-10

333-035-0065
Complaints

(1) Any person may make a complaint verbally or in writing to the Division regarding an allegation as to the care or services provided by a hospice program or violations of any hospice program laws or regulations.

(2) The identity of a person making a complaint will be kept confidential.

(3) An investigation will be carried out as soon as practicable after the receipt of a complaint in accordance with OAR 333-035-0070.

(4) If the complaint involves an allegation of criminal conduct or an allegation that is within the jurisdiction of another local, state, or federal agency, the Division will refer the matter to that agency.

Stat. Auth.: ORS 443.860
Stats. Implemented: ORS 443.860
Hist.: PH 19-2010, f. 8-30-10, cert. ef. 9-1-10

333-035-0070
Investigations

(1) As soon as practicable after receiving a complaint, taking into consideration the nature of the complaint, Division staff may begin an investigation.

(2) A hospice program shall permit Division staff access to any location from which it is operating its program or providing services during an investigation.

(3) An investigation may include but is not limited to:

(a) Interviews of the complainant, patients of the hospice program, patient family members, witnesses, hospice program management and staff;

(b) On-site observations of patients and staff performance; and

(c) Review of documents and records.

(4) Except as otherwise specified in 42 CFR § 401, Subpart B, the Division shall draft an investigation report and may make publicly available a copy of that report that does not contain any information that could lead to the identification of the complainant, a patient, or any other information that is confidential under state law.

Stat. Auth.: ORS 443.860
Stats. Implemented: ORS 443.860
Hist.: PH 19-2010, f. 8-30-10, cert. ef. 9-1-10

333-035-0075
Surveys

(1) The Division shall, in addition to any investigations conducted under OAR 333-035-0070, conduct at least one survey of each hospice program every three years and at such other times as the Division deems necessary.

(2) In lieu of a survey required under section (1) of this rule, the Division may:

(a) Accept certification by a federal agency; or

(b) Accept a survey performed by an accrediting organization approved by the Division under OAR 333-035-0100, and conducted within the last three years.

(3) A hospice program shall permit Division staff access to any location from which it is operating its program or providing services during a survey.

(4) A survey may include but is not limited to:

(a) Interviews of patients, patient family members, hospice program management and staff;

(b) On-site observations of patients and staff performance;

(c) Review of documents and records; and

(d) Patient audits.

(5) A hospice program shall make all requested documents and records available to the surveyor for review and copying.

(6) Following a survey, Division staff may conduct an exit conference with the hospice program administrator or his or her designee. During the exit conference Division staff shall:

(a) Inform the hospice program representative of the preliminary findings of the inspection; and

(b) Give the person a reasonable opportunity to submit additional facts or other information to the surveyor in response to those findings.

(7) Following the survey, Division staff shall prepare and provide the hospice program administrator or his or her designee specific and timely written notice of the findings.

(8) If the findings result in a referral to another regulatory agency, Division staff shall submit the applicable information to that referral agency for its review and determination of appropriate action.

(9) If no deficiencies are found during a survey, the Division shall issue written findings to the hospice program administrator indicating that fact.

(10) If the surveyor's written notice of findings indicates that the agency was in compliance with hospice program licensing laws and no deficiencies were cited, the agency administrator or administrator's designee shall sign the written notice and return it to the Division.

(11) If deficiencies are found, the Division shall take informal or formal enforcement action in compliance with OAR 333-035-0085 or 333-035-0090.

Stat. Auth.: ORS 443.860
Stats. Implemented: ORS 443.860
Hist.: PH 19-2010, f. 8-30-10, cert. ef. 9-1-10

333-035-0080
Violations

In addition to non-compliance with any hospice program licensing law or CMS Conditions of Participation, it is a violation to:

(1) Refuse to cooperate with an investigation or survey, including but not limited to failure to permit Division staff access to the hospice program, its documents or records;

(2) Fail to implement an approved plan of correction;

(3) Fail to comply with all applicable laws, lawful ordinances and rules relating to safety from fire;

(4) Refuse or fail to comply with an order issued by the Division;

(5) Refuse or fail to pay a civil penalty;

(6) Fail to comply with rules governing the storage of records following the closure of a hospice program; or

(7) Fail to obtain a license.

Stat. Auth.: ORS 443.860
Stats. Implemented: ORS 443.860
Hist.: PH 19-2010, f. 8-30-10, cert. ef. 9-1-10

333-035-0085
Informal Enforcement

(1) If during an investigation or survey Division staff document violations of hospice program licensing laws or conditions of participation, the Division may issue a statement of deficiencies that cites the law alleged to have been violated and the facts supporting the allegation.

(2) A signed plan of correction must be received by the Division within 10 business days from the date the statement of deficiencies was mailed to the hospice program. A signed plan of correction will not be used by the Division as an admission of the violations alleged in the statement of deficiencies.

(3) A hospice program shall correct all deficiencies within 45 days from the date of the exit conference, unless an extension of time is requested from the Division. A request for such an extension shall be submitted in writing and must accompany the plan of correction.

(4) The Division shall determine if a written plan of correction is acceptable. If the plan of correction is not acceptable to the Division, the Division shall notify the hospice program administrator in writing and request that the plan of correction be modified and resubmitted no later than 10 working days from the date the letter of non-acceptance was mailed to the administrator.

(5) If the hospice program does not come into compliance by the date of correction reflected on the plan of correction or 45 days from date of the exit conference, whichever is sooner, the Division may propose to deny, suspend, or revoke the hospice program license, or impose civil penalties.

Stat. Auth.: ORS 443.860
Stats. Implemented: ORS 443.860
Hist.: PH 19-2010, f. 8-30-10, cert. ef. 9-1-10

333-035-0090
Formal Enforcement

(1) If during an investigation or survey Division staff document a substantial failure to comply with hospice program licensing laws or conditions of participation, or if a hospice program fails to pay a civil penalty imposed under ORS 443.869, the Division may issue a Notice of Proposed Suspension or Notice of Proposed Revocation in accordance with ORS 183.411 through 183.470.

(2) The Division may issue a Notice of Imposition of Civil Penalty for violations of hospice program licensing laws.

(3) At any time the Division may issue a Notice of Emergency License Suspension under ORS 183.430(2).

(4) If the Division revokes a hospice program license, the order shall specify when, if ever, the hospice program may reapply for a license.

Stat. Auth.: ORS 443.860
Stats. Implemented: ORS 443.860
Hist.: PH 19-2010, f. 8-30-10, cert. ef. 9-1-10

333-035-0095
Civil Penalties

(1) In addition to any other liability or penalty provided by law, the Division may impose a civil penalty of $1,000 per day, up to $10,000 in any 30-day period, for any of the following:

(a) Violation of any of the terms or conditions of a license issued under these rules;

(b) Violation of any of these rules or an order issued by the Division to a hospice program licensed under these rules;

(c) Violation of any final order of the director that pertains specifically to a hospice program owned or operated by the person incurring the penalty; or

(d) Violation of ORS 443.860 or of rules adopted under ORS 443.860.

(2) In determining the amount of a civil penalty the Division shall consider whether:

(a) The Division made repeated attempts to obtain compliance;

(b) There is a history of noncompliance with hospice program licensing laws;

(c) The violation poses a serious risk to the public's health;

(d) The person or licensee gained financially from the noncompliance; and

(e) There are mitigating factors, such as a person or licensee's cooperation with an investigation or actions to come into compliance.

(3) The Division shall document its consideration of the factors in section (2) of this rule.

(4) Each day a violation continues is an additional violation.

(5) Civil penalties under this section shall be imposed in the manner provided by ORS 183.745.

Stat. Auth.: ORS 443.860
Stats. Implemented: ORS 443.869
Hist.: PH 19-2010, f. 8-30-10, cert. ef. 9-1-10

333-035-0100
Approval of Accrediting Organizations

(1) An accrediting organization must request approval by the Division to accredit hospice programs in Oregon.

(2) An accrediting organization shall request approval in writing and shall provide, at a minimum:

(a) Evidence that it is recognized as a deemed accrediting organization by CMS; or

(b) Documentation of program policies and procedures that the accreditation meets standards and conditions established for hospice programs by CMS;

(c) Accreditation history; and

(d) References from a minimum of two hospice programs currently receiving services from the organization.

(3) If the Division finds that an accrediting organization's qualifications are equal to or exceed state licensing requirements in Oregon, the Division will enter into an agreement with the accrediting organization permitting it to accredit hospice programs in Oregon.

(4) CMS will not accept accreditation by an organization that is not a deemed organization by CMS, for purposes of CMS certification.

Stat. Auth.: ORS 443.860
Stats. Implemented: ORS 443.860
Hist.: PH 19-2010, f. 8-30-10, cert. ef. 9-1-10

333-035-0105
Applicability of Rules

(1) A hospice program already in operation on September 1, 2010 shall apply to the Division for a license and pay the applicable fee by October 1, 2010.

(2) The Division shall allow a hospice program already in operation on September 1, 2010, three months from its date of application before an on-site inspection is conducted, in order to allow a hospice program to come into compliance with these rules.

(3) A hospice program already in operation on September 1, 2010 shall conduct criminal background checks in accordance with OAR 333-035-0060 prior to September 1, 2012.

Stat. Auth: ORS 443.860
Stats. Implemented: ORS 443.860
Hist.: PH 19-2010, f. 8-30-10, cert. ef. 9-1-10

DIVISION 39

REGULATIONS GOVERNING HEALTH AND SAFETY AT OUTDOOR MASS GATHERINGS

333-039-0005
Purpose

These rules govern health and safety at outdoor mass gatherings pursuant to ORS 433.735 through 433.770. Organizers of such gatherings must apply for a permit to the county governing body of the county in which an outdoor mass gathering is to take place. Applications for permits must be accompanied by sufficiently detailed plans, specifications, and reports from which it can be determined by the county governing body and other reviewing public officials and agencies that there is or will be compliance with these rules.

Stat. Auth.: ORS 433.740 & 433.760
Stats. Implemented: ORS 433.740
Hist.: HD 2, f. 9-15-71, ef. 10-1-71; HD 18-1985(Temp), f. & ef. 9-26-85; HD 32-1985, f. & ef. 12-9-85

333-039-0010
Definitions

As used in these rules unless the context requires otherwise:

(1) "Division" means Oregon Health Authority, Public Health Division.

(2) "Outdoor Mass Gathering" means an actual or reasonably anticipated assembly of more than 3,000 persons which continues or can reasonably be expected to continue for more than 24 consecutive hours but less than 120 hours within any three month period and which is held primarily in open spaces and not in any permanent structure.

(3) "Organizer" includes any person who holds, stages, or sponsors an outdoor mass gathering and the owner, lessee, or possessor of the real property upon which the outdoor mass gathering is to take place.

(4) "Oregon Physician" means a person licensed by the Oregon State Board of Medical Examiners or any other physician authorized to practice medicine and surgery in any part of Oregon.

(5) "Nurse" means a licensed professional nurse.

(6) "Ambulance" means any privately or publicly owned motor vehicle, aircraft or marine craft that is regularly provided or offered to be provided for the emergency transportation of persons suffering from illness, injury, or disability and which is equipped, staffed and licensed in accordance with OAR 333-028-0000 to 333-028-0065.

(7) "Temporary Structure" includes tents, trailers, chemical toilet facilities and other structures customarily erected or sited for temporary use.

Stat. Auth.: ORS 433.740 & 433.760
Stats. Implemented: ORS 433.740
Hist.: HD 2, f. 9-15-71, ef. 10-1-71; HD 18-1985(Temp), f. & ef. 9-26-85; HD 32-1985, f. & ef. 12-9-85

333-039-0015
Water Supply

(1) Required Amounts:

(a) A minimum of 12 gallons per person per day shall be available for the anticipated assembly;

(b) Storage facilities equal to one day's total water usage shall be provided, unless a greater or lesser amount, with a minimum of five gallons per person per day, is determined by the Division as sufficient or necessary, based on the availability and quantity of the reserve water supply and the required water demands for toilets, food vendors, camping areas and other facilities;

(c) A Division approved well or water system may be used as a source of water, or in addition to Division approved outside sources, to meet all requirements;

(d) An amount of water equal to one day's total usage shall be kept in reserve at all times.

(2) Bacteriological and Chemical Requirements:

(a) All water provided shall give a negative result for the presence of coliform bacteria when subjected to standard laboratory test procedures for detecting the presence of coliform bacteria and shall be from sources and in containers approved by the Division;

(b) Water provided shall not contain the following substances in excess of amounts listed. The organizer shall provide a laboratory analysis report as evidence of this: Substance Concentration in mg/1:

(A) Arsenic — 0.1;
(B) Cadmium — 1.0;
(C) Chloride — 250.0;
(D) Copper — 1.0;
(E) Cyanide — 0.01;
(F) Fluoride — 1.7;
(G) Iron — 0.3;
(H) Lead — 0.05;
(I) Selenium — 0.01;
(J) Nitrate (NO3) — 45.0;
(K) Total Dissolved Solids — 500.0;
(L) Zinc — 5.0.

(3) Construction, Maintenance, and Design:

(a) All parts of the water supply system shall be constructed of non-toxic materials;

(b) All water distribution lines and fittings shall be constructed of galvanized wrought iron, galvanized steel, copper, or NSF approved plastic pipe. All plastic pipe and fittings must bear the NSF seal;

(c) Pressure tanks and storage tanks shall be constructed of non-toxic materials. Tanks which have previously been used to contain toxic substances shall not be used;

(d) Prior to placing the water supply system into use, all portions of the system including storage tanks and distribution system shall be disinfected by adding a chlorine solution of not less than 50 mg/1 and retaining the mixture within all portions of the system

for at least 24 hours. Following disinfection, the system is to be thoroughly flushed of the chlorine solution;

(e) Hydrants equipped with self-closing faucets shall be provided at a ratio of not less than one for every 250 persons or fraction thereof anticipated;

(f) Each faucet shall be mounted on a minimum 36 inch riser. The riser is to be securely fastened to a supporting structure equal in strength to a four inch by four inch timber which is securely anchored in the ground;

(g) Each faucet and riser shall be accompanied by a seepage pit located directly beneath the faucet which shall have a minimum inside diameter of 12 inches and a minimum depth of three feet and shall be backfilled with clean coarse rock;

(h) All water distribution lines shall be installed at a minimum depth of 12 inches in the soil and shall be covered;

(i) If camping and activity areas are separately designated, 60 percent of the total required faucets shall be located within the area designated for camping, and 40 percent of the total required faucets shall be located in the area designated for activities;

(j) A minimum of one faucet shall be located not more than 25 lineal feet from each food service facility and a minimum of one faucet shall be located not more than 25 lineal feet from any emergency medical facility;

(k) Garden hoses, flexible hoses, pipes, or similar devices shall not be connected to any faucet or any other portion of the water supply system for personal convenience or any other reason;

(l) A minimum pressure of 20 pounds per square inch shall be maintained at all times and at all points within the water distribution system.

Stat. Auth.: ORS 433.760
Stats. Implemented: ORS 433.735 - 433.770
Hist.: HD 2, f. 9-15-71, ef. 10-1-71; PH 12-2005(Temp), f. & cert. ef. 7-21-05 thru 1-13-06; PH 15-2005(Temp), f. & cert. ef. 9-22-05 thru 1-13-06; Administrative correction 1-19-06; PH 8-2007, f. & cert. ef. 6-20-07

333-039-0020
Drainage

(1) The site selected for the outdoor mass gathering shall have good natural drainage. Areas which are swampy, or areas known to be susceptible to flash flooding are not acceptable.

(2) Roads at the outdoor mass gathering site shall be provided with culverts, tiles, and ditching wherever needed to protect such roads from erosion due to precipitation.

Stat. Auth.: ORS 433.763
Stats. Implemented: ORS 433.763
Hist.: HD 2, f. 9-15-71, ef. 10-1-71

333-039-0025
Sewerage Facilities

(1) Non-Water Carried Sewage Facilities:

(a) The construction and maintenance of earth pit privies shall comply with the following requirements:

(A) They shall be located at least 50 feet from a well, spring, or other source of domestic water supply, and at least 50 feet from any stream, river or lake, and at least ten feet from any property line;

(B) The pit shall have a minimum capacity of 50 cubic feet, and shall be at least five feet deep and shall be lined with lumber, concrete, steel, or other equivalently substantial material to prevent caving. The pit shall be covered by a building of substantial construction located on either a concrete or wood sill to make it as fly-tight and rodent-proof as possible from the outside. The floor and riser shall be built water impervious and fly-tight of wood, concrete, ceramic, stainless steel, or other equivalently substantial material;

(C) The seat opening shall be equipped with a self-closing lid hinged and so constructed that when closed it will exclude flies from the pit. Vents connected to the pit shall be covered with 16 mesh copper, aluminum, or plastic wire screen and shall have a total effective cross section of at least 50 square inches. The building shall be equipped with a tight fitting, self-closing door and shall be weather-proof;

(D) The contents of the pit shall not be permitted to overflow onto the surface of the ground or be exposed to flies or rodents;

(E) A minimum of one-half pound of chlorinated lime shall be deposited in each pit once every 24 hours;

(F) At the conclusion of the outdoor mass gathering, the contents of the pit shall be covered by backfilling with at least a two foot depth of earth.

(b) In areas where high water tables are encountered, concrete vault privies, pail privies, chemical toilets or incinerator toilets shall be used in place of earth pit privies for disposal of human excreta. All vaults and receptacles of such privies shall be water-tight and constructed of reinforced concrete, plastic, fiberglass or metal:

(A) The contents of vault privies, pail privies, and chemical toilets shall be removed by a registered sewage cesspool operator in accordance with state and local laws, ordinances, and regulations;

(B) Chemical toilets shall be serviced daily with respect to sanitation, removal of contents, and recharging of chemical solution;

(C) All earth pit privies, privies with water-tight receptacles, chemical toilets, and incinerator toilets shall be maintained in a sanitary condition at all times.

(2) Water Carried Sewage Disposal Facilities: If water carried subsurface sewage disposal facilities are provided, they shall be governed by OAR 333-041-0001 through 333-041-0040, and by this reference are incorporated herein and made a part hereof.

(3) Number and Location of Toilets and Privies:

(a) Seven privies or toilets or any combination thereof shall be provided for each 800 persons or fraction thereof anticipated;

(b) If camping and planned activity areas are separately designated, sixty percent of the total required toilets or privies shall be located within the designated camping area and forty percent of the total required toilets or privies shall be located in the designated planned activity area. If areas are not designated, location and spacing of toilets and privies shall be in accordance with anticipated crowd clustering or grouping, or spaced uniformly throughout the entire mass gathering site;

(c) All chemical toilets, if provided, shall be located so as to be easily and readily serviced by servicing vehicles.

(4) Liquid Wastes not Containing Human Excreta:

(a) Facilities shall be provided for the disposal of all liquid wastes not containing human excreta such as, but not limited to, kitchen or cooking waste water, grease, dishwater, wash water, and bath water. These facilities shall be specifically identified by means of a sign which states "**Waste Water Disposal**";

(b) Such facilities shall consist of a seepage pit having a minimum depth of three feet and a lateral area of not less than 32 square feet. The pit shall be backfilled with clean, coarse rock and be protected by a one-fourth inch screen which is removable and will effectively trap food particles and prevent other wastes from entering the backfilled rock;

(c) All food particles and other waste material shall be removed from the facilities at least once every 24 hours or at more frequent intervals if necessary to prevent fly and insect attraction;

(d) Such facilities shall be located or spaced so as to uniformly serve the participants of the outdoor mass gathering;

(e) One facility shall be provided for each 3,000 persons or fraction thereof anticipated;

(f) At least one facility shall be located not more than 50 lineal feet from each food service facility.

Stat. Auth.: ORS 433.760
Stats. Implemented: ORS 433.760
Hist.: HD 2, f. 9-15-71, ef. 10-1-71

333-039-0030
Refuse Storage and Disposal

(1) All refuse and solid waste shall be stored in fly-tight containers constructed of impervious material.

(2) Containers for refuse and solid waste storage shall be provided at a minimum ratio of one 30 gallon container for each 16 persons or fraction thereof anticipated or one cubic yard of container capacity for each 125 persons or fraction thereof anticipated.

(3) All refuse and solid waste shall be removed from storage containers at least once every 24 hours and transported and

disposed of in a manner which is authorized and complies with state and local laws, ordinances and regulations.

Stat. Auth.: ORS 433.760
Stats. Implemented: ORS 433.760
Hist.: HD 2, f. 9-15-71, ef. 10-1-71

333-039-0035
Food and Sanitary Food Service

(1) Food service facilities, if supplied, shall be located in clean surroundings and shall be maintained in a clean and sanitary condition.

(2) Food service facilities, if supplied, shall be so constructed and arranged that food, drink, utensils, and equipment will not be exposed to rodents, insects, dust, dirt, or other contamination. If flies are present, screening shall be required.

(3) The water supply for food service facilities shall be adequate in amount to serve the requirements of the facility and shall be safe for human consumption. Storage tanks or containers, when used, shall be of smooth, easily cleanable material, and shall be cleaned and sanitized each time they are refilled. Water shall not be dipped from a receptacle for drinking or culinary purposes.

(4) Toilet or privy facilities which comply with these rules shall be available within the immediate area for use by the food service facility personnel.

(5) Hand washing facilities shall be made available for the food service facility personnel. In lieu of a handwashing sink, there shall be provided a pan with soap and water for washing of hands, and a pan of water containing a bactericidal solution of 50 mg/1 of available chlorine or its equivalent for rinsing of hands. Sanitary paper towels shall be provided. The use of a common-type towel is prohibited. Utensil washing vats shall not be used for handwashing.

(6)(a) All multi-use utensils and all display cases or windows, counters, shelves, tables, refrigeration equipment, sinks, and other equipment used in connection with the operation of a food service facility shall be constructed as to be easily cleaned and shall be kept in good repair;

(b) Utensils containing or plated with cadmium or lead shall not be used, provided, however, that solder containing lead may be used for jointing;

(c) Food containers with seams which are not sealed flush with the surface shall not be re-used. Single service containers and utensils shall not be re-used.

(7)(a) Single service paper plates, cups, and plastic or wood knives, forks, and spoons are recommended but not required. If multiple use dishes, utensils, or equipment are used, they must be subjected to one of the following methods of bactericidal treatment after cleaning and washing:

(A) Immersion for at least two minutes in clean, hot water at a temperature of at least 170°F If hot water is used, a dependable thermometer shall be available at all times and shall be used. The pouring of scalding water over washed utensils is not acceptable as a satisfactory bactericidal treatment;

(B) Immersion for at least two minutes in a lukewarm chlorine bath. This bath shall be made up at a strength of at least 100 mg/1 of available chlorine. The bath shall not be used after its strength has been reduced to 50 mg/1;

(C) Immersion for at least two minutes in an approved quaternary ammonium bath containing at least 25 mg/1 as determined by a suitable field test.

(b) In machine dishwashing, the hot water rinse shall be at least 170°F and shall be for a minimum of ten seconds;

(c) In hand dishwashing, a three compartment sink shall be required. The first compartment shall be used for washing with a soap or detergent solution. The second compartment shall be used for clear water rinse, and the third compartment shall be used for the bactericidal solution and sanitizing bath.

(8) If ice cream or frozen desserts are dipped and served at the food service facility, all scoops and dippers shall be kept in running water dipper wells.

(9)(a) All refuse and solid waste shall be stored or collected in tightly covered, water impervious containers until removed from the food service facility. Such containers when emptied shall be washed to prevent them from attracting flies and rodents;

(b) All dishwater and liquid wastes not containing human excreta shall be disposed of in accordance with OAR 333-039-0025(4)(a) to (f) of these rules.

(10)(a) All readily perishable food shall be kept at or below 45°F except when being prepared or actually served. Readily perishable foods shall be stored in shallow containers under refrigeration until cooled below 45°F. When such foods have been cooled below 45°F, they may be stored in deep containers. Food shall not be served which has been stored, handled, or otherwise cared for in a manner not in compliance with these rules;

(b) A dependable indicating thermometer shall be provided in each refrigerator;

(c) All ice shall be stored and handled in such a way as to prevent contamination. Ice scoops or tongs shall be used to place ice in glasses or cups. Ice shall be obtained only at sources which are licensed under ORS Chapter 624 or 627.

(11) All food products, raw, cooked, canned, or otherwise, shall be wholesome and free of spoilage during storage, preparation, and serving. All milk and milk products shall come from a source which is licensed and approved by the Oregon State Department of Agriculture. Home canned or home processed foods shall not be stored, prepared, or served by the food service facility.

(12) Pre-cooked foods or meats must be kept at or below 45°F at all times and subjected to continuously applied heat which will sustain the internal temperature of the food item to not less than 140°F until such time as it is served.

(13) Bottled soda or fruit drinks may be cooled in tanks with water and ice provided the tanks contain not less than 50 mg/1 available chlorine. The tops of the containers shall not be submerged. Milk and milk products shall be kept at or below 45°F in dry refrigeration.

(14) Canned soda or fruit drinks may be cooled in tanks of ice and water provided that the water contains not less than 50 mg/1 available chlorine.

(15) All persons within the food service facility shall wear clean outer garments and shall keep their hands clean at all times while engaged in preparing or serving food and drink, or washing and storing utensils and equipment.

(16) All persons while within a food service facility shall refrain from any personal action or conduct which would directly or indirectly harm the quality or wholesomeness of the food.

(17) No live animals or fowl shall be permitted within the confines of any food service facility.

Stat. Auth.: ORS 433.760
Stats. Implemented: ORS 433.760
Hist.: HD 2, f. 9-15-71, ef. 10-1-71

333-039-0040
Emergency Medical Facilities

(1) There shall be present at the outdoor mass gathering site for emergency medical services, physicians and nurses in the following ratios:

(a) Daylight Hours — At least one Oregon physician plus sufficient other physicians (licensed to practice medicine and surgery in any of the 50 states of the United States) to provide a ratio of one for each 10,000 persons attending or fraction thereof and one nurse for each 7,500 persons attending or fraction thereof;

(b) Nighttime Hours — (1 a.m. to 7 a.m.) — At least one Oregon physician plus sufficient other physicians (licensed to practice medicine and surgery in any of the 50 states of the United States) to provide a ratio of one for each 20,000 persons attending or fraction thereof and one nurse for each 15,000 persons attending or fraction thereof.

(2) Facilities shall be provided in which physicians can provide patient care and treatment. The facility shall be enclosed, protected from the elements, and shall have chairs, examining tables with stirrups, and locked cabinets for equipment and medicine. All necessary medicine and instruments for conducting minor surgery and examinations shall be available.

(3) Lighting within the emergency medical facilities shall be provided and shall be not less than 200 foot candles in areas where treatment and minor surgery are conducted.

(4) Attending physicians shall keep accurate records of patients and treatment, and shall notify the local health officer of all cases involving a communicable disease.

(5) Temporary holding facilities shall be provided for the sick and injured while awaiting transport to a hospital. The facility shall be enclosed, protected from the elements, and shall be furnished with one cot or bed for each 1,000 persons anticipated or fraction thereof.

(6) Communication, either telephone or radio-telephone, shall be provided to summon aid or notify the nearest hospital, law enforcement, or fire protection agency, as required.

(7) Ambulances shall be provided at the outdoor mass gathering for emergency evacuation of sick and injured persons at a ratio of one ambulance for each 10,000 persons anticipated or fraction thereof.

Stat. Auth.: ORS 433.760
Stats. Implemented: ORS 433.760
Hist.: HD 2, f. 9-15-71, ef. 10-1-71; HD 18-1985(Temp), f. & ef. 9-26-85; HD 32-1985, f. & ef. 12-9-85

333-039-0045
Fire Protection

(1) Each camping space shall be a minimum of 1,000 square feet or large enough to accommodate a parked camping vehicle, tent vehicle or tent, as the case may be, and to maintain at least 15 feet separation from any other camping vehicle, tent vehicle or tent, building, structure, or property line.

(2) The organizer shall secure a written statement from the local fire protection agency having jurisdiction that fire protection complies with state and local laws, ordinances, and regulations, and is satisfactory with respect to anticipated crowds and location of the outdoor mass gathering.

Stat. Auth.: ORS 433.760
Stats. Implemented: ORS 433.760
Hist.: HD 2, f. 9-15-71, ef. 10-1-71

333-039-0050
Security Personnel

(1) The organizer shall maintain an accurate count of persons attending the outdoor mass gathering and shall provide adequate security arrangements to limit further admissions to the outdoor mass gathering when the anticipated number of persons have been admitted.

(2) The organizer shall secure a written statement from the chief law enforcement officer of the county in which the outdoor mass gathering is to take place that arrangements for security and the orderly flow of traffic to and from the outdoor mass gathering complies with state and local laws, ordinances, and regulations, and is satisfactory with respect to anticipated crowds and location of the outdoor mass gathering.

Stat. Auth.: ORS 433.760
Stats. Implemented: ORS 433.760
Hist.: HD 2, f. 9-15-71, ef. 10-1-71

333-039-0055
Traffic

(1) The organizer shall provide easily accessible roads of all-weather construction at the outdoor mass gathering site.

(2) All roads shall be graded so as to be self-draining and shall be maintained in such condition that emergency and other required vehicles can move upon them unencumbered and can carry out their functions at all times.

(3) An ungraveled dirt road shall not be considered as being an all-weather road.

(4) No road or portion of any road constructed shall exceed a maximum grade of 12 percent.

(5) The organizer shall acquire approval from the local agency having jurisdiction for fire safety that the minimum width of all roads complies with state and local laws, ordinances, and regulations, and is satisfactory with respect to anticipated crowds and locations of the outdoor mass gatherings.

(6) The organizer shall provide and designate a suitable area at the outdoor mass gathering for parking of motor vehicles:

(a) The total area provided for motor vehicle parking shall be based on the following ratio: 300 square feet for every four persons anticipated;

(b) Each motor vehicle parking space shall have a minimum width of ten feet and a minimum length of twenty feet and shall be clearly marked with lime;

(c) The motor vehicle parking spaces shall be arranged to eliminate blockage of parked vehicles and allow vehicles free access to exits at all times.

Stat. Auth.: ORS 433.760
Stats. Implemented: ORS 433.735 - 433.770
Hist.: HD 2, f. 9-15-71, ef. 10-1-71; PH 8-2007, f. & cert. ef. 6-20-07

DIVISION 40

DECONTAMINATION OF ILLEGAL DRUG MANUFACTURING SITES

333-040-0010
Purpose and Scope

(1) **Purpose**: The purpose of these rules is to implement ORS 453.855–453.912 and Oregon Laws 1999, Chapter 861 and provide a means whereby property found to be unfit fit for use due to chemical contamination that may result from illegal drug manufacturing can be evaluated, decontaminated and returned to use.

(2) **Scope**: These rules apply to any property as defined in ORS 453.858 and Oregon Laws 1999, Chapter 861 and also includes the following: criteria used by agencies when determining property unfit for use; maintenance of listing of unfit for use properties; property owner responsibilities; assessment, decontamination, sampling and testing procedures; requirements for demolition and disposal of property contents; disclosure requirements for property sale or transfer; qualifications for decontamination and sampling personnel; licensing requirements for decontamination contractors; requirements for inspections and consultations by the Public Health Division; Public Health Division fees and reciprocity requirements; and contractor penalties.

Stat. Auth.: ORS 453.864
Stats. Implemented: ORS 453.855 - 453.912
Hist.: HD 20-1990, f. 6-29-90, cert. ef. 7-1-90 (and corrected 7-13-90); OHD 2-1998, f. & cert. ef. 2-13-98; OHD 1-2000, f. & cert. ef. 1-24-00

333-040-0020
Definitions

(1) "**Agent of the Owner**" — means a current employee of the owner of record who was in the employ of that owner at the time the property was determined to be an illegal drug manufacturing site; or is a current employee of any new owner and who was an employee of that owner at the time the property was sold or transferred to that owner prior to decontamination.

(2) "**Certificate of Fitness**" — means a certificate issued for a particular property by the Public Health Division indicating that the property is fit for use.

(3) "**Contractor**" — means a contractor licensed by the Public Health Division under these rules to perform assessment and decontamination activities at illegal drug manufacturing sites.

(4) "**Decontamination**" **and** "**Contamination Reduction**" — mean reduction in levels of known contaminants to the lowest practical level, as determined by the Public Health Division, using currently available methods and processes.

(5) "**Division**" — means Oregon Health Authority, Public Health Division.

(6) "**Full disclosure**" — means written notice to a prospective buyer or recipient of any illegal drug manufacturing site as set forth in OAR 333-040-0100.

(7) "**Owner**" — means:

(a) For real property, the owner of record as disclosed by the records of the recorder in the county where the property is located; or,

(b) For personal property for which a certificate of title or ownership has been issued, the person shown as owner on such certificate.

(8) "**Reasonable grounds**" — includes, but is not limited to, the presence of chemicals, substances, apparatus and chemical residues commonly associated with an illegal drug manufacturing site.

(9) "**Unfit for Use**" — means a determination made by an agency as listed in ORS 453.876 that a property is an illegal drug manufacturing site and may be contaminated with hazardous chemicals or substances.

(10) "**Unfit for Use listing**" — means a listing of properties in Oregon that have been determined to be illegal drug manufacturing sites, and that have not been issued a Certificate of Fitness. The list is maintained by the Department of Consumer and Business Services-Building Codes Division, pursuant to ORS 453.879.

(11) "**Use**" — means occupancy or entry for any reason including, but not limited to, entry for such things as cleaning, remodeling, repairs, or demolition, except as allowed in ORS 453.873, 453.876, 453.885 and Oregon Laws 1999, Chapter 861.

Stat. Auth.: ORS 453.864
Stats. Implemented: ORS 453.855 - 453.912
Hist.: HD 20-1990, f. 6-29-90, cert. ef. 7-1-90 (and corrected 7-13-90); OHD 2-1998, f. & cert. ef. 2-13-98; OHD 1-2000, f. & cert. ef. 1-24-00

333-040-0050
Determination of Unfitness for Use

(1) The determination that a property is unfit for use applies to any property that is known to have been used as an illegal drug manufacturing site, or for which there are reasonable grounds to believe that the property has been used as an illegal drug manufacturing site.

(2) Any owner of a property that was an illegal drug manufacturing site prior to August 3, 1989 may obtain a Certificate of Fitness by following all the procedures and meeting all the criteria of these rules.

(3) An agency determining property unfit for use shall proceed as follows:

(a) Notify the owner or agent of the affected property by personal service or by certified mail sent within 3 working days of the determination. Proof of such mailing shall be considered service. Proof of actual delivery is not required. Where the owner of record or the title or certificate holder is not listed in public records or cannot be reasonably notified, service of notice on the registered agent or other designated agent is sufficient;

(b) Mail a copy of the notice to the owner/agent as required in subsection (3)(a) of this rule to the Division. The Division shall notify the State Building Codes Division, the Department of Motor Vehicles, the State Marine Board and/or other affected agencies; and

(c) Post a standard warning notice provided by the Division at all entrances to the contaminated property at the time of the determination. Such notice(s) shall be displayed continuously until a Certificate of Fitness has been issued by the Division.

(4) The notice required in subsection (3)(a) of this rule shall include all of the specific information in the sample notice available from the Division, but need not be identical in form. This notice shall also include a statement that the owner may obtain a hearing by making a written request to the agency making the determination within 30 days.

Stat. Auth.: ORS 453.864
Stats. Implemented: ORS 453.855 - 453.912
Hist.: HD 20-1990, f. 6-29-90, cert. ef. 7-1-90 (and corrected 7-13-90); OHD 2-1998, f. & cert. ef. 2-13-98; OHD 1-2000, f. & cert. ef. 1-24-00

333-040-0060
Unfit for Use Listing by State Department of Consumer and Business Services, Building Codes Division

(1) The Director of the State Department of Consumer and Business Services shall place the property on an official unfit for use listing after it receives a copy of a notice of determination that a property is unfit for use from the Division, or any owner of record. The State Department of Consumer and Business Services — Building Codes Division shall update and distribute the list according to their rules.

(2) To remove a property from the unfit for use list, the owner must provide the Division written proof that:

(a) The determination that the property is unfit for use has been reversed by the agency that made the initial determination; or

(b) The determination by the agency that made the initial determination has been reversed by a court of law; or

(c) A Certificate of Fitness has been issued for the property.

Stat. Auth.: ORS 453.864
Stats. Implemented: ORS 453.855 - 453.912
Hist.: HD 20-1990, f. 6-29-90, cert. ef. 7-1-90 (and corrected 7-13-90); OHD 2-1998, f. & cert. ef. 2-13-98; OHD 1-2000, f. & cert. ef. 1-24-00

333-040-0065
Procedures for Owners of Unfit for Use Properties

(1) The owner of property determined to be unfit for use shall:

(a) Prevent by reasonable means the entry, occupancy or any use whatsoever by anyone of the property in question until the property has been issued a Certificate of Fitness or until the determination that the property is unfit for use has been reversed in writing by the determining agency or by a court of law; except that qualified contractors and regulatory agencies and their authorized agents may enter such properties for purposes of evaluation, sampling, and/or decontamination; and owners or agents of the owner may enter such properties for the purposes of decontamination when approved by the Division as set forth in section (2) of this rule; and

(b) Retain a contractor to supervise the decontamination efforts, including: performing a site assessment; supervising site sampling by an independent third party as required in OAR 333-040-0130(1); submitting a work plan for Division approval; and decontaminating the property or supervising the decontamination of the property. An owner or an agent of the owner may perform the decontamination when the requirements of this subsection and the criteria of section (2) or (3) of this rule are met.

(2) The Division may approve the performance of the decontamination work by the owner or an agent of the owner in accordance with subsection (1)(b) of this rule if all of the following criteria are met:

(a) Methamphetamine was the only drug manufactured at the site; and

(b) The method of manufacturing was the ephedrine-red phosphorus or ephedrine-sodium/lithium metal method; and

(c) The manufacturing occurred after 1994; and

(d) No visual or apparent evidence of manufacturing-related contamination, filth and debris, or biohazards are present; and

(e) No manufacturing-related fire occurred.

(3) When a contractor is proposing a demolition as a method of decontamination as set forth in section (2) of this rule, the Division may waive subsections (2)(a) through (2)(e) if:

(a) Methamphetamine was the only drug manufactured; and

(b) The owner or agent of the owner is prohibited from entering the structure(s) to be demolished.

(4) The Division may disallow the owner or agent of the owner from performing the decontamination work when there is evidence of removal of contents or any other form of decontamination not approved by the Division.

(5) An owner must do one of the following before unfit for use property can be used: provide evidence that the unfit for use property designation has been reversed on appeal; provide evidence that the property has been assessed as set forth in OAR 333-040-0070(1)(a), found not to be contaminated, and a Certificate of Fitness issued; or provide evidence that the property has been decontaminated and a Certificate of Fitness issued.

Stat. Auth.: ORS 453.864
Stats. Implemented: ORS 453.855 - 453.912
Hist.: OHD 2-1998, f. & cert. ef. 2-13-98; OHD 1-2000, f. & cert. ef. 1-24-00

333-040-0070
Procedures for Assessment, Decontamination, Sampling and Testing

(1) A contractor who has been retained to assess a property shall submit all information, proposals and the appropriate fee to the Division on the form supplied by the Division.

(a) The contractor shall assess the site and characterize the extent of contamination by, but not limited to, the following:

(A) Securing any documentation available from the Division, the determining agency, other appropriate state agencies or other sources regarding the nature and extent of the illegal drug activity and evidence of such activity;

(B) Evaluating the property site to determine the nature and extent of observable damage and contamination;

(C) Providing a written site assessment with an accompanying sampling and analysis plan. The contractor shall submit the assessment and sampling plan, along with the appropriate fee listed in OAR 333-040-0180(4), to the Division for approval prior to commencement of the decontamination work;

(D) Supervising qualified, third-party sampling personnel, as set forth in OAR 333-040-0135, in the collection of site samples;

(E) Arranging for the qualified scientific testing of air, surfaces, and articles and materials on or taken from the site;

(F) Providing a brief written description of the contaminated site and buildings, and a scale drawing of the property including the location and type of all site structures; floor plans drawn to reasonable scale of all affected buildings; location of any surface waters, wells, and/or septic tanks; location of any damage, observable contamination, chemical storage, dump sites, burn piles, or drug lab operations;

(G) Supplying photographs of the site and the interior and exterior of any buildings, vehicles, boats or other potentially contaminated structures or areas. These photographs must show any damage, observable contamination or identified dump sites that may be present;

(H) Providing a list of the sample locations, methods, and laboratory tests to be performed prior to decontamination of the property, and a list of the articles and materials that may need removal from the site during the decontamination process; and

(I) Supplying the name of the company retained to collect the samples, name(s) of the analytical laboratory(ies) performing the analyses on the samples, and the name and qualifications of the sample collector.

(b) The contractor shall submit the assessment along with all tests, findings and conclusions, the name of the owner, mailing and street address, legal description of the property, clear directions for locating the property, and a completed application for a Certificate of Fitness along with the applicable fee to the Division if no contamination is found. If the findings are acceptable to the Division, the Division shall issue a Certificate of Fitness.

(2) If contamination is found, the contractor shall proceed as follows to decontaminate the property, or to supervise the owner or agent of the owner in the decontamination:

(a) Prepare and submit to the Division a written work plan for decontamination along with the applicable fee. The work plan, at a minimum, shall include:

(A) Complete identifying information such as street address, mailing address, owner of record, legal description, and clear directions for locating the property;

(B) A drawing of the contaminated property including floor plans of all affected buildings drawn to reasonable scale showing the location of damage and contamination, chemical storage, and the location of all sampling points used in the initial evaluation;

(C) A summary of the information obtained from the determining agency and/or other sources and a discussion of its relevance to the contamination;

(D) A summary of all tests performed, test results and a discussion of the significance of the test, along with a copy of the laboratory test results;

(E) Specific procedures for decontamination detailing any and all materials or articles to be removed, all procedures to be employed to remove contaminants, any proposed processes to cover or encapsulate contaminants, and any other proposed procedures for decontamination and disposal of contaminated materials;

(F) A complete listing of proposed post-decontamination laboratory tests of the property and the name(s) of the laboratory(ies) doing the testing;

(G) A listing of all personnel who will participate in the on-site decontamination and qualifications of each;

(H) Certification that all workers, except as set forth in OAR 333-040-0065(2), are qualified and trained under applicable OSHA rules, per 29 CFR 1910.120(e) and 437-002-0100(18)(b) through (o), and will use appropriate protective clothing and equipment whenever on the property;

(I) All results of the site assessment; and

(J) Documentation that the site to be decontaminated meets the criteria established in OAR 333-040-0065(2) or (3) when proposing an owner decontamination.

(b) After securing written approval from the Division for the work plan or amended work plan, the contractor shall complete the decontamination work, or supervise the completion of the work, in accordance with the approved work plan;

(c) The contractor shall arrange for, and supervise as necessary as set forth in OAR 333-040-0130(1), all follow-up sampling as specified in the approved work plan;

(d) The contractor shall submit to the Division written and photographic documentation showing that the decontamination has been completed in accordance with the approved work plan, along with all follow-up test results required by the approved work plan, and a completed affidavit on a form supplied by the Division attesting to compliance with the approved work plan; and

(e) If in the course of decontamination, factors are discovered requiring modifications to the work plan, such modifications may be made only upon prior written approval from the Division. The contractor shall provide the Division with written confirmation that the modified work as approved was performed.

(3) The contractor shall insure that all samples collected from the site, including the taking of air, surface and bulk samples prior to and after decontamination of the property are performed by independent, qualified personnel using industry-recognized standards and protocols. The contractor shall insure that the sampling personnel utilize the Division's Drug Lab Field and Sampling Guidelines.

(a) The contractor shall insure that all laboratory tests on the samples collected from the site are performed by a laboratory following standard laboratory practices. The laboratory shall:

(A) Be currently certified or approved under appropriate state, federal, or professional programs;

(B) Use standard methods and procedures when available;

(C) Have implemented a quality assurance program, including use of quality control measures, that is acceptable to the Division; and

(D) Have a US Drug Enforcement Administration registration on file with the Division if analyzing for controlled substances.

(b) The contractor shall insure that the following components of the site sampling and laboratory testing are integrated into the work plan:

(A) The materials, equipment and techniques used, or to be used, for sampling at each location;

(B) All control samples taken, or to be taken, including the location, materials, techniques and results;

(C) The exact location within the property where each test sample was or will be collected. Samples collected after decontamination shall be collected immediately adjacent to the location initially tested, and shall be sampled by identical methods in order to accurately reflect the effectiveness of the decontamination work; and

(D) The amount of area, volume of material or air taken, or to be taken, for each test sample: air sample test results are reported in ppm; liquid and solid sample test are reported in ppm, or in weight/weight; and surface sample test results are reported as total weight of contaminant per appropriate unit of area.

(c) All site assessment reports and test results shall be retained by the contractor for a period of not less than one calendar year from the date of certification of the site.

Stat. Auth.: ORS 453.864

Stats. Implemented: ORS 453.855 - 453.912
Hist.: HD 20-1990, f. 6-29-90, cert. ef. 7-1-90 (and corrected 7-13-90); OHD 2-1998, f. & cert. ef. 2-13-98; OHD 1-2000, f. & cert. ef. 1-24-00

333-040-0080
Compliance with Regulations and Disposing of Contents of Unfit for Use Properties

A contractor must conduct any abatement activities in compliance with applicable state and federal regulations. Permits may be required for such activities. The contractor shall provide written documentation to the Division of proper disposal of all materials removed from unfit for use properties.

Stat. Auth.: ORS 453.864
Stats. Implemented: ORS 453.855 - 453.912
Hist.: HD 20-1990, f. 6-29-90, cert. ef. 7-1-90 (and corrected 7-13-90); OHD 2-1998, f. & cert. ef. 2-13-98; OHD 1-2000, f. & cert. ef. 1-24-00

333-040-0090
Destruction of Unfit for Use Property

Property found to be unfit for use may be demolished all or in part in order to remove the contamination. A contractor shall comply with all state and local requirements, including any permits, for protecting health and the environment in any Division-approved demolition, and shall remove or contain all hazards resulting from the illegal drug manufacturing. A contractor shall submit a written work plan to the Division and receive written approval from the Division prior to the demolition. Where required, permits for demolition shall also be obtained from the Building Codes Division, city or county building authority before demolition begins.

Stat. Auth.: ORS 453.864
Stats. Implemented: ORS 453.855 - 453.912
Hist.: HD 20-1990, f. 6-29-90, cert. ef. 7-1-90 (and corrected 7-13-90); HD 2-1991, f. & cert. ef. 2-28-91; OHD 2-1998, f. & cert. ef. 2-13-98; OHD 1-2000, f. & cert. ef. 1-24-00

333-040-0100
Disclosure for Sale or Transfer of Illegal Drug Manufacturing Sites

(1) An owner of unfit for use property may transfer or sell the property before a Certificate of Fitness is issued if the owner provides full written disclosure to the buyer or transferee. The owner shall attach the disclosure statement to the earnest money receipt, if any, or otherwise attach the disclosure statement to the sale or transfer document for each transaction, and shall, at a minimum, include each of the following:

(a) A verbatim statement as follows: "The property in this transaction has been determined to be an illegal drug manufacturing site and cannot be rented, leased, entered or used for any reason without first being issued a Certificate of Fitness by the Public Health Division." The statement shall be in 10-point, bold type or equivalent;

(b) A brief description of the property including street address and legal description;

(c) A brief description of the kind and location of all drug manufacturing activities on the property if known;

(d) The name and address of the owner of record, the name and address of the buyer/recipient, and the date of the transfer;

(e) The name of the agency that determined the property was unfit for use;

(f) The address and telephone number of the agency that made the above determination; and

(g) A photocopy of the written notice of determination as issued by the determining agency listed in ORS 453.876.

(2) The owner shall provide a copy of the disclosure statement for each transaction to the Building Codes Division and the Public Health Division within 10 days of the closing of the sale or transfer.

Stat. Auth.: ORS 453.864
Stats. Implemented: ORS 453.855 - 453.912
Hist.: HD 20-1990, f. 6-29-90, cert. ef. 7-1-90 (and corrected 7-13-90); OHD 2-1998, f. & cert. ef. 2-13-98; Administrative correction 7-8-98; OHD 1-2000, f. & cert. ef. 1-24-00

333-040-0110
Qualifications, Training and Licensing of Contractors and Employees

(1) No person or entity shall advertise to undertake, or perform the work necessary to assess or decontaminate properties found to be unfit for use, without first complying with these rules and securing a license to do so pursuant to ORS 453.885(2), 453.888 and Oregon Laws 1999, Chapter 861, section 3, except as set forth in section (2) of this rule or in OAR 333-040-0065(2) and (3).

(2) Before applying for a decontamination contractor license, a contractor must be registered, bonded and insured as a general contractor with the Construction Contractor's Board. Companies and persons providing only sample collection, transportation and testing services for drug laboratory decontamination contractors are not required to be licensed pursuant to these rules; however, a contractor shall supervise anyone providing sample collection as set forth in OAR 333-040-0130(1), and anyone providing sample collection services shall comply with the hazardous materials training required in section (5) of this rule and the qualification and training requirements of 333-040-0135. Laboratories providing sample analysis shall comply with 333-040-0070(3)(a).

(3) The contractor shall provide documentation to the Division that its supervisory personnel seeking training and certification as a drug laboratory decontamination supervisor have successfully completed at least 40 hours of hazardous materials training satisfying the requirements of OAR 437-002-0100(18) and 29 CFR 1910.120(e). The contractor shall insure that only persons so qualifying are admitted for training, examination or on-site work as an illegal drug manufacturing site decontamination supervisor.

(4) Applicants shall demonstrate that all employees who will perform work on illegal drug manufacturing sites have completed a Division-sponsored specialized training course and have successfully passed the course examination with a score of seventy percent or greater.

(5) The contractor shall insure that its employees and agents who have on-site duties or who handle contaminated materials, chemicals or contaminated equipment, shall be trained as required by OAR 437-002-0100(18) and 29 CFR 1910.120(e) before engaging in assessment, testing or decontaminating illegal drug manufacturing sites. Refresher training as required by said rules and regulations shall be kept current.

(6) The contractor's supervisory employees performing on-site drug site decontamination activities shall successfully complete the initial training course required in section (4) of this rule and shall successfully complete refresher training specified by the Division every other year to renew their certification. The Division may also require more frequent training updates.

(7) The contractor's non-supervisory employees who have on-site exposure to properties found unfit for use shall receive specialized drug site decontamination training before having any on-site exposure, and must attend refresher training at least every other year to renew their certification. The contractor shall supply the Division with documentation of such training for each employee who enters an illegal drug manufacturing site. Training referred to in sections (6) and (7) of this rule is required in addition to the training required by State and Federal OSHA regulations referred to in section (5) of this rule.

(8) All contractors and all employees of any contractor shall carry identification provided by the Division attesting to their training credentials and level of training whenever performing duties at an illegal drug manufacturing site.

Stat. Auth.: ORS 453.864
Stats. Implemented: ORS 453.855 - 453.912
Hist.: HD 20-1990, f. 6-29-90, cert. ef. 7-1-90 (and corrected 7-13-90); OHD 2-1998, f. & cert. ef. 2-13-98; OHD 1-2000, f. & cert. ef. 1-24-00

333-040-0120
Contractor Listing

The Division shall maintain a complete listing of Drug Laboratory Decontamination Contractors and shall provide copies of the list as follows:

(1) To the Director of the Department of Consumer and Business Services who shall supply the list and updates to local building code enforcement agencies;

(2) To the Administrator of each county health department in the state;

(3) Upon request, to any property owner, prospective buyer, licensee or other interested person.

Stat. Auth.: ORS 453.864
Stats. Implemented: ORS 453.855 - 453.912
Hist.: HD 20-1990, f. 6-29-90, cert. ef. 7-1-90 (and corrected 7-13-90); OHD 2-1998, f. & cert. ef. 2-13-98; OHD 1-2000, f. & cert. ef. 1-24-00

333-040-0130
On-Site Supervision

(1) The contractor shall insure that at all times during site assessment and sampling activities on illegal drug manufacturing sites, a qualified supervisor employed by the contractor shall be on site and responsible for the activities performed. The Division may also require the presence of such a supervisor on these sites during decontamination activities. Supervisors shall at all times while on site carry identification provided by the Division attesting to their training and credentials.

(2) An applicant for a decontamination license must demonstrate that it has one or more qualified supervisors on staff.

(3) A contractor may not perform any illegal drug manufacturing site activities unless the contractor has at least one certified supervisor.

Stat. Auth.: ORS 453.864
Stats. Implemented: ORS 453.855 - 453.912
Hist.: HD 20-1990, f. 6-29-90, cert. ef. 7-1-90 (and corrected 7-13-90); HD 15-1993(Temp), f. & cert. ef. 10-14-93; HD 12-1994, f. & cert. ef. 4-22-94; OHD 2-1998, f. & cert. ef. 2-13-98; OHD 1-2000, f. & cert. ef. 1-24-00

333-040-0135
Qualifications and Training of Sampling Personnel

Persons collecting site samples shall have the following minimum qualifications:

(1) Have completed hazardous materials training, as set forth in OAR 333-040-0110(5); and

(2) Be a certified Industrial Hygienist (CIH); or

(3) Have a Bachelor of Science Degree in Health and Safety, Industrial Hygiene, Environmental Sciences, or Basic Sciences, and six months experience working with or for a professional environmental or industrial hygiene firm, Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Department of Environmental Quality (DEQ), or for an environmental laboratory certified under a state, federal, or professional program; or

(4) Have an Associate Degree in Hazardous Materials Management or Environmental Evaluations/Chemistry, and one year experience working under the direct supervision of personnel identified in section (2) or (3) of this rule. Persons who have been collecting samples at drug lab sites consistently since prior to January 1, 2000, are exempt from the requirements in sections (2), (3), and (4) of this rule.

Stat. Auth.: ORS 453.864
Stats. Implemented: ORS 453.855 - 453.912
Hist.: OHD 2-1998, f. & cert. ef. 2-13-98; OHD 1-2000, f. & cert. ef. 1-24-00; PH 15-2003(Temp), f. & cert. ef. 10-27-03 thru 4-16-04; PH 14-2004, f. & cert. ef. 4-9-04

333-040-0140
Entry and Inspection

Properties determined to be unfit for use may be entered and inspected as set forth in ORS 453.873 and Oregon Laws 1999, Chapter 861. Law enforcement officials may accompany such entries for safety or security purposes. The owner, manager, tenant, or occupant of such property shall allow access to all parts of such property for these purposes and for quality control evaluations pursuant to OAR 333-040-0150 from the date of the finding that the property is unfit for use and up to six months after a Certificate of Fitness has been issued.

Stat. Auth.: ORS 453.864
Stats. Implemented: ORS 453.855 - 453.912
Hist.: HD 20-1990, f. 6-29-90, cert. ef. 7-1-90 (and corrected 7-13-90); OHD 1-2000, f. & cert. ef. 1-24-00

333-040-0150
Quality Control Checks

(1) The Division or designated agents may inspect, evaluate and perform tests upon any property for which a Certificate of Fitness has been requested or issued. The inspection, evaluation and tests shall determine whether the approved work plan was followed, whether post-cleaning tests submitted meet the requirements of OAR 333-040-0070(3), and whether the property has been decontaminated adequately. The contractor shall be subject to license revocation, suspension, civil penalties or other penalties as set forth in ORS 453.990 if inadequate decontamination is found.

(2) The Division may monitor the work of any contractor at any illegal drug manufacturing site.

Stat. Auth.: ORS 453.864
Stats. Implemented: ORS 453.855 - 453.912
Hist.: HD 20-1990, f. 6-29-90, cert. ef. 7-1-90 (and corrected 7-13-90); OHD 1-2000, f. & cert. ef. 1-24-00

333-040-0170
Advice and Consultation

Between the dates of scheduled training for contractors as set forth in ORS 453.888, the Division shall be available to consult with contractors, as well as those planning to become contractors, on information pertinent to illegal drug manufacturing sites, including but not limited to chemicals found at such sites and their toxicity, new or revised decontamination procedures, personal protective equipment and applicable federal regulations and state rules.

Stat. Auth.: ORS 453.864
Stats. Implemented: ORS 453.855 - 453.912
Hist.: HD 20-1990, f. 6-29-90, cert. ef. 7-1-90 (and corrected 7-13-90); HD 2-1991, f. & cert. ef. 2-28-91; OHD 1-2000, f. & cert. ef. 1-24-00

333-040-0180
Licenses and Fees

(1) For applicants applying for an initial license, the following fees are payable to the Division:

(a) Drug Site Decontamination Contractors initial training course:

(A) Course Registration and Processing fee: $150.00;

(B) Initial Examination fee (each time taken): $100.00;

(C) Refresher Course fee: $100.00.

(b) Initial License Application fee: $1,000.00 (if made on or before July 1, of even-numbered calendar years) If initial application is made before July 1, of any odd-numbered year: $500.00.

(2) Renewal of License:

(a) Renewal fee (must be made on or before July 1 of even-numbered years): $1,000.00. Licenses expire on June 30 of each even-numbered year and must be renewed on or before July 1 of each even-numbered year.

(b) Penalty for late renewal (if made after July 15): $100.00.

(3) Reciprocity fees:

(a) License Application fee: $1,000.00 (if made on or before July 1 of even-numbered calendar years). If application is made before July 1 of any odd-numbered year: $500.00;

(b) Contractor License Review fee: $200.00;

(c) Worker or Supervisor Certification Review fee: $100.00.

(4) Decontamination fees:

(a) Site Assessment Review fee: $300.00;

(b) Work Plan Review fee — for each real property including all property associated thereto: $900.00. Work Plan Review fee — for vehicles, trailers, and boats not associated with real property: $100.00;

(c) Project Completion Review and Certificate of Fitness fee (for each property): $200.00;

(d) Issuance of additional copies of Certificate of Fitness: $5.00.

(5) No portion of any of the above fees is refundable unless the fee was submitted in error and the application is withdrawn by

written request of the applicant within 10 working days of submission.

Stat. Auth.: ORS 453.864 & 453.894
Stats. Implemented: ORS 453.855 - 453.995
Hist.: HD 20-1990, f. 6-29-90, cert. ef. 7-1-90 (and corrected 7-13-90); OHD 2-1998, f. & cert. ef. 2-13-98; OHD 1-2000, f. & cert. ef. 1-24-00; OHD 5-2000, f. & cert. ef. 5-4-00

333-040-0190
Reciprocity

(1) The Division may provide reciprocal licensure for contractors licensed in another state, and reciprocal certification for supervisors and workers trained and certified in another state if standards and training are substantially equivalent to these rules. Applications for a decontamination contractor license or worker/supervisor certification are subject to review and approval by the Division. Applicants for reciprocity shall submit to the Division:

(a) A completed application on a form provided by the Division;

(b) Documentation of specialized training for drug manufacturing site decontamination;

(c) Evidence of successful completion of training as set forth in OAR 437-002-0100(18) and 29 CFR 1910.120(e);

(d) Evidence of registration, bonding, and insurance with the Oregon Construction Contractor's Board; and

(e) A fee as set forth in OAR 333-040-0180.

(2) After reviewing the application, the Division may issue the applicant a certificate/license or require:

(a) Additional information;

(b) A refresher course; or

(c) A Division-administered examination.

Stat. Auth.: ORS 453.864
Stats. Implemented: ORS 453.855 - 453.912
Hist.: HD 20-1990, f. 6-29-90, cert. ef. 7-1-90 (and corrected 7-13-90); OHD 1-2000, f. & cert. ef. 1-24-00

333-040-0230
Denial, Suspension, Revocation of License and Civil Penalties

(1) An applicant for an initial license as a Drug Laboratory Decontamination Contractor will be denied if the applicant fails to meet any of the qualifications or requirements of these rules.

(2) The Division may deny, suspend or revoke the license of any contractor pursuant to ORS 453.888, 183.310 to 183.550 and Oregon Laws 1999, Chapter 849.

(3) Denials, suspensions and revocations of licenses are contested cases subject to ORS 183 and Oregon Laws 1999, Chapter 849 and the model procedural rules of the Attorney General.

Stat. Auth.: ORS 453.864
Stats. Implemented: ORS 453.855 - 453.912 & 453.912
Hist.: OHD 2-1998, f. & cert. ef. 2-13-98; OHD 1-2000, f. & cert. ef. 1-24-00

DIVISION 47

STATE SUPPLIED VACCINE ACCOUNTABILITY

333-047-0010
Definitions Used in the Vaccine Accountability Rules

(1) All definitions of ORS 433.090 and 433.235 apply to these rules.

(2) In addition to the definitions of ORS 433.090 and 433.235, the following definitions apply:

(a) "Authority" means the Oregon Health Authority.

(b) "Certify" means to attest, in writing, on a form prescribed by Oregon Health Authority that at least two employees, owners or partners have completed required vaccine-related trainings as provided or approved by Oregon Health Authority.

(c) "Entity" means a health clinic or provider, pharmacy or pharmacist who receives state-supplied vaccine.

(d) "Oregon Immunization Program" means Oregon Health Authority, Public Health Division, Immunization Program.

(e) "Public Health Division" means the Oregon Health Authority, Public Health Division.

(f) "Receives vaccines" means an entity is supplied with vaccines by the Oregon Immunization Program, including vaccines acquired with federal and state funds, including the Vaccines for Children Program (VFC), the Section 317 Vaccine Program, state Special Project vaccine, and state Billable Project vaccine.

(g) "State supplied vaccine" means vaccine provided by the federal government or the Oregon Immunization Program.

(h) "State-supplied Vaccine User Vaccine Accountability Reporting Requirements and Timelines" means the schedule of reporting timelines found in the Vaccine User Accountability Reporting Table of OAR 333-047-0050.

Stat. Auth.: ORS 433.103
Stats. Implemented: ORS 433.103
Hist.: PH 14-2011, f. 12-28-11, cert. ef. 1-1-12

333-047-0030
Training

(1) Any entity receiving state supplied vaccine shall require that at least two currently employed staff persons, owners or partners complete immunization related training at least once every two years as follows:

(a) Clinical administration of vaccines; and

(b) Storage, handling and inventory management of vaccines.

(2) An entity shall provide Authority staff with written documentation that it has met the requirements of section (1) of this rule or that it is exempt from training upon request or at every official Vaccines for Children site visit.

(3) An entity receiving state-supplied vaccine is responsible for retaining documentation that at least two currently employed staff persons, owners, or partners have completed the required clinical administration and vaccine management training course at least once every two years.

(4) The Authority will make available to entities no-cost internet based training available in on-demand format.

(5) Web-based training will include an official certification receipt for staff meeting competence standards.

(6) The Authority will exempt an entity from the training requirement in section (1) of this rule if an entity demonstrates to the satisfaction of the Authority that it, or that a licensing board with jurisdiction over some employees of the entity, requires training that is substantially similar to the training available from the Authority. An entity may submit a request for an exemption on a form prescribed by the Authority.

(7) The training requirements required by section (1) of this rule are effective January 1, 2013.

Stat. Auth.: ORS 433.103
Stats. Implemented: ORS 433.103
Hist.: PH 14-2011, f. 12-28-11, cert. ef. 1-1-12

333-047-0040
Accounting for Vaccine

Any entity receiving state supplied vaccine shall account for vaccines through data submission and inventory management via the Authority's Immunization Registry, as outlined in OAR 333-049-0010 through 333-049-0050. (See the Vaccine User Accountability Reporting Table, OAR 333-047-0050).

[ED. NOTE: Tables referenced are available from the agency.]
Stat. Auth.: ORS 433.103
Stats. Implemented: ORS 433.103
Hist.: PH 14-2011, f. 12-28-11, cert. ef. 1-1-12

333-047-0050
Timeline for Reporting

An entity receiving state supplied vaccine shall submit vaccine accounting information required under OAR 333-047-0040 according to the schedule set out in the Vaccine User Accountability Reporting Table.

[ED. NOTE: Tables referenced are available from the agency.]
Stat. Auth.: ORS 433.103
Stats. Implemented: ORS 433.103
Hist.: PH 14-2011, f. 12-28-11, cert. ef. 1-1-12

DIVISION 48

VACCINE EDUCATION AND PRIORITIZATION PLAN

333-048-0010
Definitions

As used in OAR 333-048-0010 through 333-048-0030:

(1) "Division" means the Public Health Division of the Oregon Health Authority.

(2) "Local Public Health Authority" means the district or county Board of Health, Public Health Officer, Public Health Administrator or health department having jurisdiction within the area.

(3) "Sponsor" means any medical practice, clinic, hospital, local health department, health system, long-term-care facility, home-care agency, occupational health program, pharmacy, or other entity that sponsors the direct provision of vaccination services in Oregon.

(4) "High Risk" means broad categories of people defined by the Advisory Committee on Immunization Practices or the State Public Health Officer as being at increased risk of severe disease or complications from a vaccine-preventable disease for which the State Health Officer has declared a vaccine shortage pursuant to OAR 333-048-0020. Risk categories may be further broken down into prioritized sub-categories.

(5) "Low Risk" means broad categories of people defined by the Advisory Committee on Immunization Practices or the State Public Health Officer as being unlikely to experience severe disease or complications from a vaccine-preventable disease for which the State Health Officer has declared a vaccine shortage pursuant to OAR 333-048-0020. Risk categories may be further broken down into prioritized sub-categories.

(6) "Provider" means any health care practitioner, or other person, who can administer vaccine directly to a patient.

(7) "Vaccine" means any vaccine, any immune product or chemo prophylactic medication.

(8) "Plan" means an Oregon Vaccine Education and Prioritization Plan.

(9) "CD Summary" means the Oregon CD Summary, an Oregon Health Authority publication sent to providers statewide.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 433.040
Stats. Implemented: ORS 433.040
Hist.: OHD 27-2001, f. & cert. ef. 12-4-01; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 11-2011, f. & cert. ef. 10-27-11

333-048-0020
Plan Development

(1) When the State Public Health Officer declares a vaccine shortage emergency, the Division will adopt a Vaccine Education and Prioritization Plan specific for that vaccine shortage.

(2) The plan will include, but is not limited to:

(a) A timeline that lists when specific vaccine administration activities can be initiated by providers and/or sponsors;

(b) The risk categories, or sub-categories, that will be covered with the vaccine that is available based on categories developed and/or adopted by the Division;

(c) The role of the local public health authorities in assuring that services are available to those in the designated risk categories.

(3) The plan will be published and distributed to providers within forty-five days of a declared vaccine shortage emergency.

(4) In situations where a vaccine shortage changes after the finalized plan has been distributed, the prioritized risk categories can be redefined by publishing a written supplement to the plan.

(5) In cases of a vaccine shortage emergency as determined by the State Public Health Officer, the local public health authority may facilitate the voluntary sharing of vaccine in their community or delegate that responsibility to a community partner. State-supplied vaccine will be shared only within guidelines provided by the Division.

(6) The Vaccine Education and Prioritization Plan will remain in effect until notification is made by the State Public Health Officer, or unless specified in the plan.

Stat. Auth.: ORS 433.040
Stats. Implemented: ORS 433.040
Hist.: OHD 27-2001, f. & cert. ef. 12-4-01

333-048-0030
Penalties

(1) Penalties will not be levied unless the State Public Health Officer declares a vaccine shortage.

(2) If a complaint is made to the Division about a provider and/or sponsor not acting in accordance with the timeline of activities and the targeting of risk categories as specified in a Vaccine Education and Prioritization Plan:

(a) An investigation will be initiated by the Division within five working days;

(b) If the Division determines that a person has knowingly violated the timeline of activities and the targeting of risk categories as specified in the Vaccine Education and Prioritization Plan, such violation shall be documented in the Health Service records and the provider and/or sponsor notified of the determination. If the violation is a repeat violation, a civil penalty shall be levied as set forth in the OAR 333-048-0030(2)(c);

(c) If the Division determines that a provider and/or sponsor has committed a repeat violation of the timeline of activities and targeting of risk categories as specified in the Vaccine Education and Prioritization Plan, a fine of no more than $500 per incident shall be levied against the provider and/or sponsor; and

(d) If the Division determines that a provider has committed repeat violations as set forth in the OAR 333-048-0030(2)(c), then the Division will report the provider to the appropriate licensing authorities in addition to any civil penalties assessed by the Division.

Stat. Auth.: ORS 433.040
Stats. Implemented: ORS 433.040
Hist.: OHD 27-2001, f. & cert. ef. 12-4-01

DIVISION 49

IMMUNIZATION REGISTRY

333-049-0010
Definitions

(1) All definitions of ORS 433.090 and 433.235 apply to these rules.

(2) In addition to the definitions of ORS 433.090 and 433.235, the following definitions apply:

(a) "Authorized user" has the meaning as defined in ORS 433.090(1).

(b) "Client" has the meaning as defined in ORS 433.090(3).

(c) "Exempt" means the special status of information on certain clients that will limit its disclosure.

(d) "Manager" means the manager of the statewide immunization registry or his/her designee.

(e) "Oregon Immunization Program" means the Oregon Health Authority, Public Health Division, Immunization Program.

(f) "Public Health Division" means the Oregon Health Authority, Public Health Division.

(g) "State Public Health Division Timelines" means the schedule of reporting timelines shown in the Vaccine User Accountability Reporting Table (OAR 333-047-0050), detailing data elements required and when each element must be included for submission.

(h) "State supplied vaccine" means vaccine provided by the federal government or the Oregon Immunization Program.

Stat. Auth.: ORS 433.100
Stats. Implemented: ORS 433.100
Hist.: HD 6-1996(Temp), f. & cert. ef. 11-26-96; HD 4-1997, f. & cert. ef. 2-24-97; OHD 13-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0100; PH 6-2008, f. & cert. ef. 3-17-08; PH 14-2011, f. 12-28-11, cert. ef. 1-1-12

333-049-0020
Purpose and Intent

(1) The purpose of these rules is to implement ORS 433.090 et seq., which:

(a) Authorizes the Public Health Division to develop a registry for all children and adults born or living in Oregon; and

(b) Requires the Public Health Division to adopt rules to develop and implement the registry, including a process by which a parent or guardian can control the transfer of information from the immunization record when such control is necessary to protect the health or safety of the family.

(2) In order to increase appropriate immunizations among preschool age children, it is the intent that, as soon as practical, all children born in the state will be automatically enrolled in the registry using information derived from birth certificates, and that all children from birth through 35 months of age, who are not enrolled from birth certificates, will receive priority for enrollment in the registry.

Stat. Auth.: ORS 433.100
Stats. Implemented: ORS 433.092
Hist.: HD 6-1996(Temp), f. & cert. ef. 11-26-96; HD 4-1997, f. & cert. ef. 2-24-97, f. & cert. ef. 7-12-01; OHD 13-2001, Renumbered from 333-019-0105; PH 6-2008, f. & cert. ef. 3-17-08

333-049-0030
Enrollment

(1) All children born in the state shall be enrolled in the registry.

(2) All children who live with a parent or guardian in the state for any period of time, and who receive an immunization, may be enrolled in the registry.

(3) Any person who receives an immunization in the state may be enrolled in the registry.

(4) The enrollment of clients in the registry shall be in a manner and on such forms as prescribed by the Manager.

(5) Nothing in these rules require the consent of a parent, guardian or client prior to enrollment in the registry.

(6) For the purposes of enrolling children in the registry, the Manager may identify children born in the state from any birth record or abstract.

Stat. Auth.: ORS 433.094, 433.100 & 432.119
Stats. Implemented: ORS 433.094 & 433.100
Hist.: HD 6-1996(Temp), f. & cert. ef. 11-26-96; HD 4-1997, f. & cert. ef. 2-24-97; OHD 13-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0110; PH 6-2008, f. & cert. ef. 3-17-08

333-049-0040
Collection and Release of Information

(1) The manager may collect information for a client's immunization record from any authorized user. Such information to be collected shall be determined by the manager and provided to the registry on forms or in a format provided by the manager.

(2) The manager may collect information for a client's tracking and recall record from any authorized user. Information to be collected includes such information necessary to send reminder cards to, place telephone calls to, or personally contact the client or the parent or the guardian of a client. Such information shall be determined by the manager and provided to the tracking and recall system on forms or in a format provided by the manager.

(3) The manager may receive information from other registries and may share information with other such registries, provided that the manager makes a determination that other registries have confidentiality protection at least equivalent to those under ORS 433.090 through 433.102 and these rules. The manager shall prescribe the information that may be shared and the forms for sharing information to and from other registries.

(4) The manager may request information to determine the name of any person and information on contacting the person or such person's parent or guardian in order to notify them about the existence of the registry. The manager may seek information on persons in the state who have not enrolled in the registry through contacting other state agencies, and other appropriate organizations that have access to such information.

(5) The manager may release and publish information in the registry in an aggregate form that does not identify a client.

Stat. Auth.: ORS 433.096, 433.094 & 432.119
Stats. Implemented: ORS 433.096 & 433.094
Hist.: HD 6-1996(Temp), f. & cert. ef. 11-26-96; HD 4-1997, f. & cert. ef. 2-24-97; OHD 13-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0115; PH 6-2008, f. & cert. ef. 3-17-08; PH 14-2011, f. 12-28-11, cert. ef. 1-1-12

333-049-0050
Reporting to the Immunization Registry

(1) Any provider who participates in the registry and who administers immunizations identified by the manager shall report such immunization to the registry within 14 calendar days of such immunization.

(2) Any pharmacist who immunizes must report all immunizations administered to the registry.

(3) Reports shall be submitted to the registry in a manner and on such forms as required by the manager. Such forms shall be provided by the manager.

(4) Any authorized user may report immunizations, and other such information, permitted under ORS 433.090(3) and (5), as prescribed by the manager, to the registry without the consent of the client or the parent or guardian of the client. Reporting this information without the consent mentioned above shall not subject a person to liability or civil action.

(5) Any authorized user who administers state-supplied vaccine must report in a manner prescribed by the Authority the following data elements for all administered doses to the Statewide Immunization Registry in accordance with Public Health Division timelines in the Vaccine User Accountability Reporting Table (OAR 333-047-0050):

(a) The name, address, phone number, gender, and date of birth of a client;

(b) The date of administration of the vaccine;

(c) The CPT, CVX, or NDC code of the vaccine administered;

(d) The dose-level vaccine eligibility code;

(e) The organizational identifier of the administering or reporting clinic or site;

(f) The lot number of the vaccine;

(g) The dose amount and manufacturer of the vaccine, when available; and

(h) Other data elements as specified by the Public Health Division.

(6) Any authorized user who administers state-supplied vaccine shall utilize, in accordance with OAR 333-047-0050:

(a) The ordering module for ordering state-supplied vaccines; and

(b) The inventory module for tracking public or public and private vaccine supply.

[ED. NOTE: Tables referenced are available from the agency.]
Stat. Auth.: ORS 433.096, 433.103, 689.645
Stats. Implemented: ORS 433.096, 433.103, 689.645
Hist.: HD 6-1996(Temp), f. & cert. ef. 11-26-96; HD 4-1997, f. & cert. ef. 2-24-97; OHD 13-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0120; PH 6-2008, f. & cert. ef. 3-17-08; PH 24-2010, f. & cert. ef. 9-30-10; PH 14-2011, f. 12-28-11, cert. ef. 1-1-12

333-049-0060
Access to Immunization Records

(1) Clients, parents and guardians:

(a) Clients and parents or guardians of children less than 18 years of age may request a copy of their, or their child's, immunization record by submitting a request for the record, as prescribed by the Manager.

(b) The Manager may provide a maximum of four (4) copies of any client's immunization record without charge, within one calendar year, pursuant to the request from a client, parent or guardian. Additional copies of the immunization record may be provided based on a fee established by the Manager that is reasonably calculated to reimburse the registry for the actual cost in making such records available.

(2) Other authorized users: All other authorized users shall access such records in a manner prescribed by the Manager.

Stat. Auth.: ORS 433.094 & 433.096
Stats. Implemented: ORS 433.094 & 433.096
Hist.: HD 6-1996(Temp), f. & cert. ef. 11-26-96; HD 4-1997, f. & cert. ef. 2-24-97; OHD 13-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0125; PH 6-2008, f. & cert. ef. 3-17-08

333-049-0065
Fees

For the purpose of implementing ORS 433.090 through 433.104 fees may be charged in accordance with this rule:

(1) Fees may be charged to authorized users including, but not limited to, the following: health plans, health provider associations, private or non-profit institutions, other state registries, federal health agencies or their contractors.

(2) Fees shall not be charged to the following users: individual health care providers and clinics, Oregon schools, Oregon children's facilities, Oregon hospitals or Oregon Health Authority, Division of Medical Assistance Programs.

(3) Fees may be waived at the discretion of the ALERT Manager or Oregon Health Authority Immunization Program Manager in accordance with Immunization Policy.

(4) Unless waived, or exempt under subsection (2) of this rule, a fee of $10 per client shall be charged to each authorized user for each client specific immunization data request.

(5) A request for client specific data shall be responded to only when made by an authorized user for information about a client under its care or by a public health entity for clients within its jurisdiction. Requests from persons other than authorized users or from authorized users for data beyond that of a specific patient(s) under its care or within the public health entity's jurisdiction will be considered on a case by case basis in the interests of public health practice and may be responded to only with aggregate/de-identified data.

Stat. Auth.: ORS 433.100
Stats. Implemented: ORS 433.100
Hist.: PH 6-2005, f. & cert. ef. 4-13-05; PH 6-2008, f. & cert. ef. 3-17-08; PH 14-2011, f. 12-28-11, cert. ef. 1-1-12

333-049-0070
Limitations on Access to Information in the Immunization Registry and Tracking and Recall System

(1) An authorized user may only access information in the Registry or Tracking and Recall System as follows:

(a) An authorized user may access information on a client who is presently under that authorized user's care, or enrolled in the authorized user's children's facility, school, post-secondary educational institution, program or health plan, except as otherwise provided by law.

(b) An authorized user that is a state or local public health authority may, in addition to accessing information described in subsection (1)(a) of this rule, access information on an individual within a public health entity's jurisdiction for:

(A) Assessment, evaluation, surveillance and outreach related to immunization promotion and vaccine-preventable disease prevention; and

(B) The Pregnancy Risk Assessment Monitoring System (PRAMS).

(2) The manager may monitor and audit all access to a client's record contained in the registry.

(3) The manager may require any person who has accessed a client's record to provide evidence that such client was under the care of the person or enrolled in the person's post-secondary educational institution, school, children's facility, program or health plan at the time the client's record was accessed.

(4) The Public Health Division may report violations of these rules by any authorized user who has accessed a client's record to the appropriate licensing or regulatory authority.

Stat. Auth.: ORS 433.098
Stats. Implemented: ORS 433.098
Hist.: HD 6-1996(Temp), f. & cert. ef. 11-26-96; HD 4-1997, f. & cert. ef. 2-24-97; OHD 13-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0130; PH 6-2008, f. & cert. ef. 3-17-08; PH 14-2011, f. 12-28-11, cert. ef. 1-1-12

333-049-0080
Limitations on the Transfer of Information from the Immunization Registry

(1) A parent or guardian may request a limitation on the transfer of information pertaining to a child enrolled in a registry when such child has a disease or condition that precludes administration of some or all immunizations. No information on such children will be disclosed in response to inquiries to the registry.

(a) Any parent or guardian of a child who has a disease or condition that may preclude administration of some or all immunizations may request a limitation on the child's information that may be transferred from the registry by providing a written request to the Manager.

(b) Upon verification of the information in the request, the Manager shall cause the registry to flag the client's record and to limit transfer of the information on the client. The Manager shall also notify the parent or guardian of such action.

(2) Safety. A parent or guardian may request a limitation on the transfer of information pertaining to a child enrolled in a registry when a third party could use the information in the record to locate the child, or other family members who reside with the child, and who the parent or guardian reasonably believes presents a risk of harm to the child or other family members.

(a) Any parent or guardian of a client may request a limitation on the transfer of child's information by providing a written request to the Manager when the parent or guardian reasonably believes there is a risk of harm to the child, or other family members, where such person could be located through information from the registry, and the child or other family members may be harmed if located.

(b) The request for limitation must also include a statement and evidence that supports the request. Such evidence may include any evidence accepted under ORS 192.445(2)(b)(A)–(E).

(c) Upon receipt of acceptable evidence to support the request, the Manager shall cause the registry to flag the child's record and to limit transfer of the information on the child. The Manager shall also notify the parent or guardian of such action.

(3) Upon receipt of any request under this section, the Manager may cause the registry to flag the child's record for a period of 30 days until the request can be approved.

(4) After approval of a request under this section, such request will remain in effect until the Manager receives a written request from the parent or guardian to remove the flag from the child's record.

Stat. Auth.: ORS 433.100
Stats. Implemented: ORS 433.100
Hist.: HD 6-1996(Temp), f. & cert. ef. 11-26-96; HD 4-1997, f. & cert. ef. 2-24-97; OHD 13-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0135; PH 6-2008, f. & cert. ef. 3-17-08

333-049-0090
Notification of Needed Immunizations, Hearing Screening, or Lead Screening

(1) The manager, authorized user, or public health entity may contact or provide notice to clients or parents and guardians of clients less than 18 years of age when the tracking and recall system indicates that a client has missed:

(a) A scheduled immunization;

(b) Lead screening; or

(c) Hearing screening for clients zero through 12 years of age.

(2) The manager, authorized user, or public health entity may also notify the client's provider of last record of the client's needed immunizations, hearing screening, or lead screening. Notification shall be in such form as prescribed by the manager.

Stat. Auth.: ORS 433.096
Stats. Implemented: ORS 433.096
Hist.: HD 6-1996(Temp), f. & cert. ef. 11-26-96; HD 4-1997, f. & cert. ef. 2-24-97; OHD 13-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0140; PH 6-2008, f. & cert. ef. 3-17-08; PH 14-2011, f. 12-28-11, cert. ef. 1-1-12

333-049-0100
Confidentiality

(1) Personal identifying information from the registry shall only be disclosed to authorized users.

(2) An authorized user shall not disclose information from the registry except to another authorized user.

(3) Any request for the limitations on the transfer of information from the immunization record or the immunization tracking and recall record shall be confidential.

(4) All providers with access to the registry shall provide to the Director an agreement signed by such providers or their authorized agent. The agreement shall be in a form prescribed by the Director, and may include provisions to maintain the confidentiality of the information in the registry, and to only access information on clients under the care of such persons.

Stat. Auth.: ORS 433.098
Stats. Implemented: ORS 433.098
Hist.: HD 6-1996(Temp), f. & cert. ef. 11-26-96; HD 4-1997, f. & cert. ef. 2-24-97; OHD 13-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0145

333-049-0120
Deletion of Information in the Registry and Tracking and Recall System

A client who is 18 years of age or older may request to have their record sealed or removed from the registry. The election of whether to seal the record or remove the record is at the sole discretion of the client.

(1) Process. A client requesting sealing or removal of their registry record must submit a form approved by the Manager for that purpose. The client may elect to have their record sealed or removed from the registry. If the client does not elect either option then their record will be removed from the registry.

(2) The request for sealing or removal of a client's record must also include a legible photocopy of one piece of photo identification. Acceptable identification includes any of the following: a valid state-issued driver's license or identification card; a passport; or a U.S. military identification card.

(3) If a client elects to have their registry record sealed, the information will remain in the registry but will not be released to authorized users. In the case of a declared public health emergency, the Manager may release the information to public health officials for the sole purpose of responding to the declared emergency. A client may request that their record be unsealed by submitting the form approved by the Manager along with a photocopy of an approved document that verifies the client's identity. A record that is removed from the registry cannot be recovered.

(4) When an immunization record is removed from the registry, certain pieces of demographic information, including a client's name and date of birth, must be kept on file in order to keep the immunization record from being repopulated.

Stat. Auth.: ORS 433.098
Stats. Implemented: ORS 433.098
Hist.: HD 6-1996(Temp), f. & cert. ef. 11-26-96; HD 4-1997, f. & cert. ef. 2-24-97; OHD 13-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0155; PH 6-2008, f. & cert. ef. 3-17-08

333-049-0130
Security

(1) All authorized users shall abide by such security policies and procedures to safeguard information in the registry deemed necessary by the Director. Such policies and procedures may include, but are not limited to, confidentiality agreements, the use of computer passwords, and user identification numbers. The Director shall provide copies of the policies and procedures to all authorized users who participate in either or both the immunization registry or tracking and recall system.

(2) The Director shall develop security standards to safeguard the information in the registry. The standards will address, but not be limited to, the collection, transfer, storage, and processing of information in the registry and tracking and recall system.

(3) The Director shall review the security policies, procedures, and standards at least once each year and shall revise such policies, procedures, and standards as necessary.

Stat. Auth.: ORS 433.098
Stats. Implemented: ORS 433.098
Hist.: HD 6-1996(Temp), f. & cert. ef. 11-26-96; HD 4-1997, f. & cert. ef. 2-24-97; OHD 13-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0160

DIVISION 50

SCHOOL IMMUNIZATION RULES

333-050-0010
Definitions Used in the Immunization Rules

As used in OAR 333-050-0010 through 333-050-0140:

(1) "Certificate of Immunization Status" means a form provided or approved by the Public Health Division on which to enter the child's immunization record.

(2) "Complete" means a category assigned to any child whose record indicates that the child is fully immunized or has immunity documentation as specified by OAR 333-050-0050(2) or (6).

(3) "Contraindication" means either a child or a household member's physical condition or disease that renders a particular vaccine improper or undesirable in accordance with the current recommendations of the Advisory Committee on Immunization Practices, Department of Health and Human Services, Centers for Disease Control and Prevention, and the American Academy of Pediatrics.

(4) "County Immunization Status Report" means a report submitted by the local health department (or school or facility if there is no local health department) to the Public Health Division to report annually the number of children as specified, in the area served, and the number susceptible to the vaccine preventable diseases covered by these rules.

(5) "Evidence of Immunization" means an appropriately signed and dated statement indicating the month, day and year each dose of each vaccine was received.

(6) "Exclude" or "Exclusion" means not being allowed to attend a school or facility pursuant to an Exclusion Order from the local health department based on non-compliance with the requirements of ORS 433.267(1), and these rules.

(7) "Exclusion Order for Incomplete Immunization or Insufficient Information" means a form provided or approved by the Public Health Division for local health department and Public Health Division use in excluding a child who, based on the child's record, is in non-compliance with the vaccine requirements of OAR 333-050-0050(2) or who has insufficient information on his or her record to determine whether the child is in compliance. Forms submitted for approval must contain the substantive content of the Public Health Division form.

(8) "Exclusion Order for No Record" means a form provided or approved by the Public Health Division for local health department, Public Health Division and school or facility use in excluding a child with no record. Forms submitted for approval must contain the substantive content of the Public Health Division form.

(9) "Exempted Children's Facilities" are those that:

(a) Are primarily for supervised training in a specific subject, including, but not limited to, dancing, drama, or music;

(b) Are primarily an incident of group athletic or social activities sponsored by or under the supervision of an organized club or hobby group;

(c) Are operated at a facility where children may only attend on a limited basis not exceeding four different days per year; or

(d) Are operated on an occasional basis by a person, sponsor, or organization not ordinarily engaged in providing child care.

(10) "Exemption" means either a documented medical or non-medical exemption.

(11) "Health Care Practitioner" means a practitioner of the healing arts who has within the scope of the practitioner's license, the authority to order immunizations, to include: M.D., D.O., N.D., nurse practitioners, and physician assistants, or a registered nurse working under the direction of an M.D., D.O., N.D. or nurse practitioner.

(12) "Immunity Documentation" means a written statement signed by a physician or an authorized representative of the local health department that the child should be exempted from receiving specified immunizations due to a disease history based on a health care practitioner's diagnosis or the results of an immune titer.

(13) "Incomplete" means a category assigned to any child whose record indicates, on or before the date the Primary Review Summary form is due at the local health department, that the child:

(a) Is not fully immunized as required in OAR 333-050-0050(2); and

(b) Does not have a completed exemption or immunity documentation for a vaccine for which the child is not fully immunized.

(14) "Insufficient" means a category assigned to any child whose record does not have enough information to make a proper determination about the child's immunization status, including unsigned records, vaccine dates before day of birth, dates out of sequence, and missing doses in the middle of a vaccine series. This category does not apply to signed but undated records.

(15) "Local Health Department" means the District or County Board of Health, Public Health Officer, Public Health Administrator or local public health agency having jurisdiction within the area.

(16) "Main Office" means a central administrative location at the school or children's facility where immunization rates are made available to parents.

(17) "Medical Exemption" means a document signed by a physician or an authorized representative of the local health department stating that the child should be exempted from receiving specified immunizations based on a medical diagnosis resulting from a specific medical contraindication.

(18) "New Enterer" means a child who meets one of the following criteria:

(a) Infants or preschoolers attending an Oregon facility;

(b) Infants or preschoolers attending a drop-in facility on five or more different days within one year;

(c) Children initially attending a school at the entry level (prekindergarten, kindergarten or the first grade, whichever is the entry level);

(d) Children from a home-school setting initially attending a school or facility at any grade (preschool through 12th grade); or

(e) Children initially attending a school or facility after entering the United States from a foreign country at any grade (preschool through 12th grade).

(19) "Non-Compliance" means failure to comply with any requirement of ORS 433.267(1) or these rules.

(20) "Nonmedical Exemption" means a document, on a form prescribed by the Public Health Division, signed by the parent stating that the parent is declining one or more immunizations on behalf of the child, and including documentation of completion of the vaccine educational module or a signature from a health care practitioner verifying discussion of risks and benefits of immunization.

(21) "Post-Secondary Education Institution" means:

(a) A state institution of higher education under the jurisdiction of the State Board of Higher Education;

(b) A community college operated under ORS Chapter 341;

(c) A school or division of Oregon Health and Science University; or

(d) An Oregon-based, generally accredited, private institution of higher education, where:

(A) Oregon-based, generally accredited includes any post-secondary institution described in OAR 583-030-0005(2) or classified as exempt under ORS 348.604; and

(B) Private institution refers to any non-public post-secondary education institution.

(22) "Primary Review Summary" means a form provided or approved by the Public Health Division to schools and facilities for enclosure with records forwarded to the local health department for secondary review and follow up. Forms submitted for approval must contain the substantive content of the Public Health Division form.

(23) "Primary Review Table" means a document provided by the Public Health Division for the judgment of compliance or non-compliance with the required immunizations.

(24) "Public Health Division" means the Oregon Health Authority, Public Health Division.

(25) "Record" means a statement relating to compliance with the requirements of ORS 433.267(1)(a) through (c) and these rules.

(26) "Restrictable Disease" means a communicable disease for which the local health department or administrator has the authority to exclude a child as described in OAR 333-019-0010 through 333-019-0014.

(27) "School Year" means an academic year as adopted by the school or school district (usually September through June).

(28) "Susceptible" means being at risk of contracting one of the diseases covered by these rules, by virtue of being in one or more of the following categories:

(a) Not being complete on the immunizations required by these rules;

(b) Possessing a medical exemption from any of the vaccines required by these rules due to a specific medical diagnosis based on a specific medical contraindication; or

(c) Possessing a nonmedical exemption for any of the vaccines required by these rules.

(29) "These Rules" means OAR 333-050-0010 through 333-050-0140.

(30) "Transferring Child" means a child moving from:

(a) One facility to another facility, only when records are requested in advance of attendance from a previous facility;

(b) One school in this state to another school in this state when the move is not the result of a normal progression of grade level; or

(c) A school in another state to a school in this state.

(31) "Up-to-Date" means not complete, currently on schedule and not subject to exclusion, based on the immunization schedule for spacing doses, as prescribed in OAR 333-050-0120.

(32) "Vaccine Educational Module" means a resource approved by the Public Health Division to fulfill the requirement of receiving information about the risks and benefits of immunization in order to claim a nonmedical exemption.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 433.004 & 433.273

Stats. Implemented: ORS 433.001, 433.004, 433.006 & 433.235 - 433.284

Hist.: HD 21-1981, f. & ef. 10-21-81; HD 17-1982, f. & ef. 8-13-82; HD 12-1983, f. & ef. 8-1-83; HD 22-1983, f. & ef. 11-1-83; HD 15-1986, f. & ef. 7-15-86; HD 8-1987, f. & ef. 7-15-87; HD 6-1991, f. & cert. ef. 5-15-91; HD 9-1992, f. & cert. ef. 8-14-92; HD 29-1994, f. & cert. ef. 12-2-94; HD 16-1997, f. & cert. ef. 12-3-97; OHD 14-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0021; OHD 26-2001, f. & cert. ef. 12-4-01; OHD 21-2002, f. & cert. ef. 12-13-02; PH 35-2004(Temp), f. & cert. ef. 11-10-04 thru 5-6-05; PH 2-2005, f. & cert. ef. 2-3-05; PH 1-2006, f. & cert. ef. 1-27-06; PH 12-2007, f. & cert .ef. 9-27-07; PH 6-2008, f. & cert. ef. 3-17-08; PH 24-2010, f. & cert. ef. 9-30-10; PH 3-2014, f. 1-30-14, cert. ef. 3-1-14; PH 13-2015(Temp), f. & cert. ef. 8-24-15 thru 2-19-16; PH 1-2016, f. & cert. ef. 1-20-16

333-050-0020
Purpose and Intent

(1) The purpose of these rules is to implement ORS 433.235 through 433.284, which require evidence of immunization, a medical or nonmedical exemption, or immunity documentation for each child as a condition of attendance in any school or facility, and which require exclusion from school or facility attendance until such requirements are met.

(2) The intent of the school and facility immunization statutes and these rules is to require that:

(a) A new enterer provide a signed and dated Certificate of Immunization Status form documenting evidence of immunization, documentation of medical or nonmedical exemption, or immunity documentation.

(b) A transferring child provide evidence of immunization, immunity documentation or an exemption:

(A) Within 30 days of initial attendance if records will be requested from a school in the United States;

(B) Prior to initial attendance, as specified in OAR 333-050-0020(2)(a), if records will not be requested from a school in the United States;

(C) Prior to initial attendance, as specified in OAR 333-050-0020(2)(a), if the child is transferring from one facility to another;

(c) A child currently attending not be allowed to continue in attendance without complete or up-to-date evidence of immunization, immunity documentation, or an exemption.

(3) All children's facilities are required to comply with these rules, including but not limited to certified child care centers, certified family child care homes, child care centers exempt from certification, Head Start programs, preschools and Early Intervention/Early Childhood Special Education child care programs.

(4) The only exception is for family child care homes, either registered or exempt from registration, providing child care, six weeks of age to kindergarten entry, in a residential or nonresidential setting. These programs are exempt from all requirements except an up-to-date Certificate of Immunization Status form on each child in attendance.

(5) All schools are required to comply with these rules, including but not limited to public schools, private schools, charter schools, and alternative education programs. Any program that provides educational instruction designed to lead to a high school diploma or transfer into a regular high school program must also comply with these rules.

(6) Nothing prohibits a school, children's facility, or post-secondary educational institution from adopting additional or more stringent requirements than the statutes or rules as long as:

(a) Medical and nonmedical exemptions and immunity documentation are included;

(b) The requirements are in compliance with the recommendations of the Advisory Committee on Immunization Practices, Department of Health and Human Services, Centers for Disease Control and Prevention; and

(c) Public schools are required to allow transferring students at least 30 days to provide an immunization record.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 433.004 & 433.273

Stats. Implemented: ORS 433.001, 433.004, 433.006 & 433.235 - 433.284

Hist.: HD 21-1981, f. & ef. 10-21-81; HD 17-1982, f. & ef. 8-13-82; HD 12-1983, f. & ef. 8-1-83; HD 22-1983, f. & ef. 11-1-83; HD 8-1987, f. & ef. 7-15-87; HD 6-1991, f. & cert. ef. 5-15-91; HD 9-1992, f. & cert. ef. 8-14-92; HD 29-1994, f. & cert. ef. 12-2-94; HD 16-1997, f. & cert. ef. 12-3-97; OHD 14-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0025; OHD 26-2001, f. & cert. ef. 12-4-01; OHD 21-2002, f. & cert. ef. 12-13-02; PH 35-2004(Temp), f. & cert. ef. 11-10-04 thru 5-6-05; PH 2-2005, f. & cert. ef. 2-3-05; PH 1-2006, f. & cert. ef. 1-27-06; PH 12-2007, f. & cert .ef. 9-27-07; PH 1-2008(Temp), f. & cert. ef. 1-8-08 thru 6-30-08; PH 6-2008, f. & cert. ef. 3-17-08; PH 16-2008(Temp), f. & cert. ef. 10-27-08 thru 4-20-09; Administrative correction 5-20-09; PH 13-2009(Temp), f. 12-17-09, cert. ef. 12-21-09 thru 6-18-10; Administrative correction 7-27-10; PH 24-2010, f. & cert. ef. 9-30-10; PH 3-2014, f. 1-30-14, cert. ef. 3-1-14

333-050-0030
Visitors, Part-Time Students, and Residents

(1) Any child visiting or attending a school or facility on five or more different days in a given school year or residing on the premises of a school or facility regardless of whether the child attends classes or receives child care, at any age or grade through grade 12, shall be subject to the requirements of either a new enterer or transferring child as appropriate. Such residents and visitors for the purposes of these rules are in attendance.

(2) Home-schooled, private, or special education students or students in other non-traditional educational settings are subject to these rules if they:

(a) Meet with an instructor in a school building for any amount of time on a regular or irregular basis, but at least five times per school year; or

(b) Participate in sports or other activities through a school-sponsored program at least five times per school year.

(3) Students in residential, correctional, or treatment programs that receive educational instruction are subject to these rules.

(4) For facilities providing drop-in child care, a child may attend on up to four different days without a Certificate of Immunization Status on file. Before allowing attendance on the fifth visit, a Certificate of Immunization Status must be provided showing at least one dose of each required vaccine or an appropriately signed exemption.

Stat. Auth.: 433.004 & 433.273

Stats. Implemented: ORS 433.001, 433.004, 433.006 & 433.235 - 433.284

Hist.: HD 8-1987, f. & ef. 7-15-87; HD 6-1991, f. & cert. ef. 5-15-91; HD 9-1992, f. & cert. ef. 8-14-92; OHD 14-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0026; OHD 26-2001, f. & cert. ef. 12-4-01; OHD 21-2002, f. & cert. ef. 12-13-02; PH 35-2004(Temp), f. & cert. ef. 11-10-04 thru 5-6-05; PH 2-2005, f. & cert. ef. 2-3-05; PH 12-2007, f. & cert .ef. 9-27-07; PH 6-2008, f. & cert. ef. 3-17-08; PH 24-2010, f. & cert. ef. 9-30-10

333-050-0040
Statements (Records) Required

(1) The statement initially documenting evidence of immunization, immunity or exemption under ORS 433.267(1)(a) through (c) must be on a Certificate of Immunization Status form or a form approved by the Public Health Division and include one or more of the following:

(a) Evidence of immunization signed by the parent, health care practitioner or an authorized representative of the local health department;

(b) A written statement of medical exemption signed by a physician or authorized representative of the local health department and approved by an authorized representative of the local health department;

(c) A written statement of immunity documentation approved by an authorized representative of the local health department;

(d) A written statement of nonmedical exemption signed by the parent, including documentation of completion of a vaccine educational module approved by the Public Health Division or signature of a health care practitioner verifying that the risks and benefits of immunizations have been discussed with the parent; or

(e) A written statement of disease history (immunity documentation) for varicella signed by a parent, physician or authorized representative of the local health department.

(2) If age appropriate, required for the child's grade level, and the child has not claimed an exemption or immunity documentation, a minimum of one dose each of the following vaccines must be received for new enterers prior to attendance: Polio, Measles, Mumps, Rubella, Hepatitis B, Hepatitis A, Varicella, Haemophilus influenzae Type b vaccine and Diphtheria/Tetanus/Pertussis containing vaccine. (See Primary Review Table); [Table not included. See ED. NOTE.]

(3) Evidence of immunization shall include the month, day and year of each dose of each vaccine received and must be appropriately signed and dated to indicate verification by the signer.

(a) If evidence of immunization includes the month and year, but the day of the dose is not provided, the administrator shall attempt to get the day of immunization from the parent, the ALERT Immunization Information System or another source. If no day is obtainable, the administrator may use the last day of the month to assess the immunization status for the child.

(b) Pre-signed Certificate of Immunization Status forms without vaccine dates are not allowed.

(c) If a Certificate of Immunization Status form is signed but not dated, the person who receives the form at the school or facility may date the form with the date it was received.

(4) The school or facility may choose to complete or update a Certificate of Immunization Status form, by transcribing dates from, attaching and referencing on the form, one or more of the following records listed in subsections (a) through (f) of this section.

(a) A health care practitioner documented immunization record;

(b) An unsigned record on health care practitioner or clinic letterhead;

(c) An unsigned record printout from the statewide immunization information system, ALERT IIS. ALERT IIS records may be placed in the student's file without transcription onto a Certificate of Immunization Status as long as the printout represents a complete or up-to-date immunization history. If the ALERT IIS record is an update to the Certificate of Immunization Status, it may be attached to the original certificate without transcription;

(d) An unsigned record printout from a computer system approved by the Public Health Division as specified in OAR 333-050-0060(5). Record printouts for Public Health Division-approved computer systems may be placed in the student's file without transcription onto a Certificate of Immunization Status as long as the

printout represents a complete or up-to-date immunization history, and includes a history of chickenpox disease if present;

(e) A written statement signed and dated by the parent; or

(f) A statement electronically mailed by the parent.

(5) The Certificate of Immunization Status form must be signed and dated by the person transcribing the information.

(6) When a transferring student enters an Oregon school, the receiving school will attempt to obtain immunization records from the previous school. If immunization records are not immediately available, the receiving school may, according to school policy, allow the student to enroll conditionally. If immunization records are not received, the school will include the student on the Primary Review Summary report.

(7) If the student transfers to a new school district, except when the move is due to the normal progression of grade levels, such as to a junior high or senior high from a feeder school, the receiving school shall ensure that the transferred records are on a signed Certificate of Immunization Status form or another Public Health Division-approved form. The original transferred records that are not on an approved form shall be attached to a Certificate of Immunization Status form and the form shall be marked with a reference to the attached records, signed, and dated by the person transcribing the information on the form.

(8) The records relating to the immunization status of children in schools shall be transferred to the receiving schools pursuant to ORS 326.575(2) within 30 days.

(9) When a new enterer is admitted in error to a school or facility without an immunization history, immunity documentation or appropriately signed exemption, the school or facility may contact the local health department to request that an Exclusion Order for No Record be issued, or include the student on the Primary Review Summary report.

(10) When a child is determined by the facility, school or school district to be homeless and does not have a completed Certificate of Immunization Status on file with the school, the student will be allowed to enroll conditionally.

(a) If immunization records are not received the school will include the student on the Primary Review Summary report or contact the local health department to request that an Exclusion Order for No Record be issued with an exclusion date of not less than 30 days after initial attendance.

(b) School staff shall make every effort to help the family compile an immunization record for the student, including requesting a record from a previous school, ALERT IIS or a previous medical provider.

(11) Where a child attends both a facility and a school, the school is responsible for reporting and for enforcing these rules in accordance with the school and facility vaccine requirements. However, because of the need for outbreak control when school is not in session, the facility administrator will be responsible for requesting that the parent also provide an up-to-date Certificate of Immunization Status to the facility. If the parent does not comply, the facility administrator shall inform the parent that in the event of a case of vaccine preventable disease the child may be excluded until it is determined that the child is not susceptible or the local health authority has determined that the risk of exposure within the school or facility has passed.

(12) Evidence of nonmedical exemption must include documentation that the parent has completed a vaccine educational module approved by the Public Health Division or signature from a health care practitioner verifying that risks and benefits of immunization have been discussed with the parent. Information provided must be consistent with information published by the Centers for Disease Control and Prevention, including epidemiology, the prevention of disease through use of vaccination, and the safety and efficacy of vaccines.

(a) The Public Health Division will make available to parents a no-cost internet based vaccine educational module.

(A) Criteria for the vaccine educational module must include:

(i) Information consistent with information published by the Centers for Disease Control and Prevention;

(ii) Information about the benefits and risks of each vaccine for which a parent is claiming a nonmedical exemption;

(iii) Information about the epidemiology, prevention of disease through use of vaccination, and the safety and efficacy of vaccines; and

(B) A person who wishes to have a vaccine educational module approved by the Oregon Health Authority shall submit the module to the medical director of the Public Health Division, Immunization Program. For approval, the vaccine educational module must contain the substantive content of the internet based vaccine educational module made available by the Public Health Division. The medical director must review the module to determine if it meets the criteria in these rules including the requirement that a vaccine educational module present information that is consistent with information published by the Centers for Disease Control and Prevention. Approval or disapproval shall be made in writing. If the module is disapproved the medical director must explain the reasons for disapproval.

(C) An official certification receipt to provide documentation of completion of the vaccine educational module must be in a form approved by the Public Health Division, Immunization Program.

(b) A health care practitioner may discuss with the parent the risks and benefits of immunization and provide documentation for the parent to claim a nonmedical exemption.

(A) The information provided by the health care practitioner must contain the substantive content of Internet based vaccine educational module made available by the Public Health Division. The content may be adjusted to meet individual parents' concerns.

(B) The health care practitioner will provide documentation to parents on a form prescribed by the Public Health Division that the practitioner has provided vaccine information to the parent.

(c) Parents claiming a nonmedical exemption must provide documentation of completion of a vaccine educational module or a signed document from a health care practitioner to the administrator.

(d) The administrator must keep a copy of the documentation of nonmedical exemption with the child's Certificate of Immunization Status.

(13) The evidence of nonmedical exemption from a health care practitioner or the viewing of the educational module must:

(a) Have occurred within 12 months of the parent signing of the nonmedical exemption; and

(b) Specify the vaccines about which information about the benefits and risks has been provided and for which a nonmedical exemption may be claimed for the child.

(14) When a child reaches the age of medical consent in Oregon, 15 years of age, the child may sign his or her own Certificate of Immunization Status and complete the process for obtaining a nonmedical exemption.

Stat. Auth.: ORS 433.004 & 433.273

Stats. Implemented: ORS 433.001, 433.004, 433.006 & 433.235 - 433.284

Hist.: HD 21-1981, f. & ef. 10-21-81; HD 17-1982, f. & ef. 8-13-82; HD 12-1983, f. & ef. 8-1-83; HD 15-1986, f. & ef. 7-15-86; HD 8-1987, f. & ef. 7-15-87; HD 6-1991, f. & cert. ef. 5-15-91; HD 9-1992, f. & cert. ef. 8-14-92; HD 16-1997, f. & cert. ef. 12-3-97; OHD 14-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0030; OHD 26-2001, f. & cert. ef. 12-4-01; OHD 21-2002, f. & cert. ef. 12-13-02; PH 35-2004(Temp), f. & cert. ef. 11-10-04 thru 5-6-05; PH 2-2005, f. & cert. ef. 2-3-05; PH 1-2006, f. & cert. ef. 1-27-06; PH 12-2007, f. & cert .ef. 9-27-07; PH 6-2008, f. & cert. ef. 3-17-08; PH 24-2010, f. & cert. ef. 9-30-10; PH 3-2014, f. 1-30-14, cert. ef. 3-1-14; PH 13-2015(Temp), f. & cert. ef. 8-24-15 thru 2-19-16; PH 1-2016, f. & cert. ef. 1-20-16

333-050-0050
Immunization Requirements

(1) For purposes of this section, immunization against the following diseases means receipt of any vaccine licensed by the United States Food and Drug Administration (or the foreign equivalent) for the prevention of that disease.

(2) For purposes of ORS 433.267(1), immunizations are required as follows (see Primary Review Table to determine the number of required doses for a child's age or grade):

(a) Diphtheria/Tetanus/Pertussis containing vaccine (DTaP) — Five doses must be received unless:

(A) The fourth dose was given at, within four days prior to or after the fourth birthday, in which case the child is complete with four doses; or

(B) The third dose of Diphtheria/Tetanus containing vaccine was received at, within four days prior to or after the seventh birthday, in which case the child is complete with three doses.

(b) Polio — Four doses must be received unless:

(A) The third dose was given at, within four days prior to or after the fourth birthday, in which case the child is complete with three doses of polio vaccine; or

(B) The student is 18 years of age or older. Polio vaccination at or after the 18th birthday is not required.

(c) Measles — Two doses must be received at or after 12 months of age. Vaccine doses given four days or fewer before 12 months of age are acceptable. The second dose must be received at least 24 days after first dose.

(d) Rubella — One dose must be received at or after 12 months of age. Vaccine doses given four days or fewer before 12 months of age are acceptable.

(e) Mumps — One dose must be received at or after 12 months of age. Vaccine doses given four days or fewer before 12 months of age are acceptable.

(f) Haemophilus influenzae Type b (Hib) — Up to four doses depending on the child's current age and when previous doses were administered.

(g) Hepatitis B — Up to three doses must be received. If the first dose was received at or after 11 years of age and the second dose is received at least four months after dose one, the child is complete with two doses. Vaccine doses given four days or fewer before the 11th birthday are acceptable.

(h) Varicella — Up to two doses must be received, depending on the child's age when the first dose was administered. The first dose must be received at or after 12 months of age. Vaccine doses given four days or fewer before 12 months of age are acceptable. Second dose, if required, must be received at least 24 days after first dose.

(i) Hepatitis A — Two doses must be received at or after 12 months of age. Vaccine doses given four days or fewer before 12 months of age are acceptable. Beginning school year 2008–2009, the requirement for Hepatitis A vaccine will be phased in by grade. (See Primary Review Table.) [Table not included. See ED. NOTE.]

(j) Tetanus/Diphtheria/Pertussis booster (Tdap) — One dose must be received at or after seven years of age, unless the last Diphtheria/Tetanus containing vaccine was given less than five years ago.

(3) Interrupted series: If there is a lapse of time between doses longer than that recommended by the standard described in OAR 333-050-0120, the schedule should not be restarted. Immunization may resume with the next dose in the series.

(4) A child shall not be excluded from school for failing to receive a required vaccine if the State Health Officer has determined that there is a vaccine shortage and that is the reason the child has not received the vaccine. Any vaccine that has been waived due to a vaccine shortage will be required at the next review cycle, once the shortage has been lifted. The Public Health Division shall notify local health departments, schools and facilities of any shortages that affect their procedures under these rules.

(5) The local public health officer, after consultation with the Public Health Division, may allow a child to attend a school or facility without meeting the minimum immunization requirements in case of temporary local vaccine shortage.

(a) The local health department shall provide a letter signed by the local health officer to the parent of the affected student detailing which vaccines the student is being exempted from. The letter must state that the student will receive an Exclusion Order if the student's record is not updated with the missing doses prior to the next exclusion cycle.

(b) A copy of the letter must be attached to the student's Certificate of Immunization Status on file at the school or facility.

(c) A photocopied form letter signed by the local health officer may be used by the local health department when the shortage is expected to affect more than one child.

(d) If the vaccine is still unavailable at the next exclusion cycle, the local health department, with the agreement of the Public Health Division, will not issue Exclusion Orders for the unavailable vaccine.

(6) The following immunity documentation satisfies the immunization requirements for the specified vaccines:

(a) Immunity documentation for Measles, Mumps or Rubella vaccination due to a disease history may be certified by a physician or an authorized representative of the local health department for a child who has immunity based on a health care practitioner's diagnosis;

(b) Immunity documentation for Measles, Mumps or Rubella vaccination due to a documented immune titer may be certified by a physician or an authorized representative of the local health department;

(c) Immunity documentation for Hib vaccination may be certified by a physician or authorized representative of the local health department for a child who experienced invasive Haemophilus influenzae Type b disease at 24 months of age or older;

(d) Immunity documentation for Varicella vaccine may be signed by the parent for history of varicella. The date of the disease is not required. This immunity documentation will be automatically authorized by the local health department.

(e) Immunity documentation for Varicella based on laboratory confirmation of immunity may be certified by a physician or authorized representative of the local health department;

(f) Immunity documentation for Hepatitis B vaccination based on laboratory confirmation of immunity or confirmation of carrier status may be certified by a physician or authorized representative of the local health department; and

(g) Immunity documentation for Hepatitis A vaccination based on laboratory confirmation of immunity may be certified by a physician or authorized representative of the local health department.

(7) Children possessing the following medical exemptions are susceptible to the diseases for which they are exempt from vaccination:

(a) Exemption for Measles, Mumps, Rubella or Varicella vaccination may be certified by a physician or an authorized representative of the local health department for a post-pubertal female when she is currently pregnant or there is a significant risk of her becoming pregnant within one month; and

(b) Exemption for one or more immunizations shall be established by a diagnosis based on a specific medical contraindication certified in a letter from the physician or an authorized representative of the local health department. The vaccines, medical diagnosis, practitioner's name, address and phone number must be documented and attached to the record.

(8) Exemptions and immunity documentation submitted to the school or facility must be in English.

(9) A child may attend a school or facility under ORS 433.267(1) if the child is up-to-date and remains up-to-date and in compliance with immunization schedules for spacing between doses presented in OAR 333-050-0120.

(10) If evidence is presented to the local health department that an Exclusion Order was issued in error because a vaccine was given within the four-day grace period recommended by the Advisory Committee on Immunization Practices as published in the General Recommendations on Immunization, the local health department shall rescind the Exclusion Order. The local health department shall notify the child's school or facility when an Exclusion Order is rescinded.

(11) In situations where a child's vaccine history presents an unusual problem not covered by these rules, the local health department may use its judgment to make a final determination of the child's immunization status.

(12) A nonmedical exemption from immunization requirement is allowed for one or more of the vaccines. Parents claiming a non-

medical exemption must select which vaccines a child is being exempted from by checking the appropriate boxes on the Certificate of Immunization Status and submit the Certificate of Immunization status and the documentation specified in OAR 333-050-0040(12)(a)(C) or 333-050-0040(12)(b)(B) to the school or facility.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 433.004 & 433.273

Stats. Implemented: ORS 433.001, 433.004, 433.006 & 433.235 - 433.284

Hist.: HD 21-1981, f. & ef. 10-21-81; HD 17-1982, f. & ef. 8-13-82; HD 12-1983, f. & ef. 8-1-83; HD 8-1987, f. & ef. 7-15-87; HD 6-1991, f. & cert. ef. 5-15-91; HD 10-1991, f. & cert. ef. 7-23-91; HD 9-1992, f. & cert. ef. 8-14-92; HD 16-1997, f. & cert. ef. 12-3-97; OHD 12-2000, f. & cert. ef. 12-26-00; OHD 14-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0035; OHD 26-2001, f. & cert. ef. 12-4-01; OHD 21-2002, f. & cert. ef. 12-13-02; PH 35-2004(Temp), f. & cert. ef. 11-10-04 thru 5-6-05; PH 2-2005, f. & cert. ef. 2-3-05; PH 1-2006, f. & cert. ef. 1-27-06; PH 12-2007, f. & cert .ef. 9-27-07; PH 1-2008(Temp), f. & cert. ef. 1-8-08 thru 6-30-08; PH 6-2008, f. & cert. ef. 3-17-08; PH 16-2008(Temp), f. & cert. ef. 10-27-08 thru 4-20-09; Administrative correction 5-20-09; PH 13-2009(Temp), f. 12-17-09, cert. ef. 12-21-09 thru 6-18-10; Administrative correction 7-27-10; PH 24-2010, f. & cert. ef. 9-30-10; PH 3-2014, f. 1-30-14, cert. ef. 3-1-14; PH 13-2015(Temp), f. & cert. ef. 8-24-15 thru 2-19-16; PH 1-2016, f. & cert. ef. 1-20-16

333-050-0060
Primary Review of Records

(1) At least annually the administrator will conduct a primary review of each child's record to determine the appropriate category of each child. This review shall be completed no later than 35 calendar days prior to the third Wednesday in February unless otherwise approved in writing first by the local health department and then by the Public Health Division.

(2) The administrator shall categorize all children as follows:

(a) "Complete or Up-to-Date";

(b) "Nonmedical Exemption": This category applies to any child whose incomplete immunizations are covered by a nonmedical exemption;

(c) "Permanent Medical Exemption": This category applies to any child who is susceptible as evidenced by a medical exemption statement on file as specified by OAR 333-050-0050(6), whose medical exemption statement has been reviewed by the local health department and has been determined to be based on a contraindication that is permanent;

(d) "Temporary Medical Exemption": This category applies to any child who is susceptible as evidenced by a medical exemption statement on file as specified by OAR 333-050-0050(7), whose medical exemption statement has not been reviewed by the local health department, or whose medical exemption is not permanent;

(e) "Incomplete/Insufficient";

(f) "No Record": This category applies to any child with no record on file at the school or facility. This category also applies to any child with a nonmedical exemption signed on or after August 1, 2008 with no vaccines selected for nonmedical exemption and with no vaccine dates;

(g) "Children not to be counted": School age children also attending a facility should be counted by the school. Children enrolled in a school but physically attending another school should be counted by the school they physically attend. Children attending a preschool or Head Start program and another facility should be counted by the preschool or Head Start program. Children physically attending more than one child care facility or school should be counted by the facility or school where they attend the most hours.

(3) Thirty-five calendar days prior to the third Wednesday in February, unless otherwise approved in writing first by the local health department and then by the Public Health Division, the administrator shall provide to the local health department for secondary review:

(a) Organized alphabetically within category, copies of records or a computer printout of the records for all children with incomplete immunizations or insufficient information;

(b) Copies of records of children with a medical exemption, except those records that have been certified by the local health department as having a permanent medical exemption or immunity documentation and are otherwise complete with no further review required.

(c) A completed Primary Review Summary form that includes an alphabetical list for each category and includes children with no record. The form must include each child's name, current grade level, parent names and current mailing address. A computer-generated list from a system currently approved by the Public Health Division may be submitted in lieu of the Primary Review Summary form.

(4) The administrator shall review the completed Primary Review Summary form for mathematical accuracy and correct any errors before forwarding the completed Primary Review Summary form to the local health department.

(5) All copies of records provided to the local health department for secondary review must contain at least the following: The child's name, date of birth, and evidence of immunization or exemption. A copy of the records or a computer printout of the records must be used in place of the original record.

(a) Computer printouts and the results from computer-generated immunization assessments (computer outputs) must have the prior approval of the Public Health Division. To receive approval to be used for the primary review report in January, computer printouts and computer outputs must be received by the Public Health Division no later than the last working day of November in the year prior to the year in which the primary review reports are due.

(b) The Public Health Division will review computer printouts and computer outputs for essential data elements, the sequence of data elements, and specific test results as calculated by the computerized system.

(c) Provisional approval will be given to a computer tracking system after correct assessment has been confirmed for test data and essential data elements in required reports. Computer tracking systems with provisional approval will be reviewed after use during the annual review and exclusion cycle. Final approval will be given after any programming errors identified during the cycle have been corrected by the tracking system and additional reports have been approved by the Public Health Division.

(d) The Public Health Division also reserves the right to withdraw computer system approval.

(e) When ORS 433.235 through 433.284 or these rules are amended, computer systems must be updated within 120 calendar days. The Public Health Division will then allow 60 calendar days for review, needed changes and final approval. Computer outputs that are not in compliance will not be authorized for use during the annual review and exclusion cycle.

(6) Additional review cycles for incomplete or insufficient records with specific time-frames are allowable if:

(a) Mutually agreed upon by the affected local health department and school or facility.

(b) Additional exclusion cycles may be required at the direction of the local health department or the Public Health Division. Exclusion dates shall be no less than 14 calendar days from the date that the Exclusion Orders are mailed.

(7) It is the responsibility of the administrator to see that primary review of immunization records is accomplished according to these rules. All or part of the actual review may be delegated by mutual agreement of parties affected to a third party subject to this requirement.

Hist.: HD 21-1981, f. & ef. 10-21-81; HD 17-1982, f. & ef. 8-13-82; HD 12-1983, f. & ef. 8-1-83; HD 8-1987, f. & ef. 7-15-87; HD 6-1991, f. & cert. ef. 5-15-91; HD 9-1992, f. & cert. ef. 8-14-92; HD 16-1997, f. & cert. ef. 12-3-97; OHD 14-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0040; OHD 26-2001, f. & cert. ef. 12-4-01; OHD 21-2002, f. & cert. ef. 12-13-02; PH 35-2004(Temp), f. & cert. ef. 11-10-04 thru 5-6-05; PH 2-2005, f. & cert. ef. 2-3-05; PH 1-2006, f. & cert. ef. 1-27-06; PH 12-2007, f. & cert .ef. 9-27-07; PH 6-2008, f. & cert. ef. 3-17-08; PH 24-2010, f. & cert. ef. 9-30-10; PH 3-2014, f. 1-30-14, cert. ef. 3-1-14

333-050-0070
Secondary Review of Records

(1) The local health department shall conduct a secondary review of those records received from the administrator. The

review shall begin 35 calendar days prior to the third Wednesday in February, unless otherwise approved by the Public Health Division.

(2) In conducting secondary review of the records, the local health department shall review the Primary Review Summary for mathematical accuracy. Any errors should be corrected by contacting the affected school or facility. The local health department shall review each child's record that was received for appropriate medical or nonmedical exemptions and then use the Primary Review Table to determine each child's current immunization status for each of the required vaccines.

(3) The local health department shall indicate on the Primary Review Summary form those children whose records are judged to be:

(a) Complete/Up-to-date; or

(b) Medically exempt, and whether temporary or permanent.

(4) The local health department shall indicate on the Primary Review Summary form the specific vaccines that the exclusion order will need to be issued for children whose records are judged to be:

(a) Incomplete/Insufficient; or

(b) No record.

(5) In the event that any of the above records are original documents, the local health department shall return such records to the administrator.

(6) The local health department shall submit an updated copy of the Primary Review Summary form to the administrator.

(7) The local health department shall initiate exclusion procedures for those children whose records are judged to have insufficient information or incomplete immunizations, or who have no record, in accordance with OAR 333-050-0080.

(8) Additional secondary review cycles with specific time frames are allowable for incomplete or insufficient records as mutually agreed upon in writing by the affected local health department and school or facility. Exclusion dates shall be no less than 14 calendar days from the date that the Exclusion Orders were mailed.

(9) It is the responsibility of the local health department to see that secondary review of immunization records is accomplished according to these rules. All or part of the actual review may be delegated by mutual agreement of parties affected to a third party subject to this requirement.

[ED. NOTE: Tables referenced are available from the agency]

Stat. Auth.: ORS 433.004 & 433.273

Stats. Implemented: ORS 433.001, 433.004, 433.006 & 433.235 - 433.284

Hist.: HD 21-1981, f. & ef. 10-21-81; HD 23-1981, f. & ef. 11-17-81; HD 17-1982, f. & ef. 8-13-82; HD 12-1983, f. & ef. 8-1-83; HD 22-1983, f. & ef. 11-1-83; HD 8-1987, f. & ef. 7-15-87; HD 6-1991, f. & cert. ef. 5-15-91; HD 9-1992, f. & cert. ef. 8-14-92; HD 16-1997, f. & cert. ef. 12-3-97; OHD 14-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0045; OHD 26-2001, f. & cert. ef. 12-4-01; PH 12-2007, f. & cert .ef. 9-27-07; PH 6-2008, f. & cert. ef. 3-17-08; PH 24-2010, f. & cert. ef. 9-30-10; PH 3-2014, f. 1-30-14, cert. ef. 3-1-14

333-050-0080
Exclusion

(1) The date of exclusion shall be the third Wednesday in February.

(a) If additional exclusion cycles are conducted, the exclusion dates shall be set at no less than 14 calendar days from the date that the Exclusion Orders are mailed.

(b) Exclusion occurs when records have not been received or updated by the starting time of the school or facility on the specified exclusion day.

(2) The local health department shall use an Exclusion Order for Incomplete Immunization or Insufficient Information or an Exclusion Order for No Record depending upon the reason the child is found to be in non-compliance with ORS 433.267(1) and these rules:

(a) At least 14 days before the exclusion day, the local health department shall mail by first class mail an appropriately completed and signed order of exclusion to the parent of each child determined to be out of compliance with these rules.

(b) If a student is listed by the school as the "person responsible," the Exclusion Order will be sent to the student.

(c) In the event that the local health department has knowledge that the address of the parent provided on the Primary Review Summary form is incorrect, the local health department shall use all reasonable means to notify the parent, including inquiries to the school or facility administrator, to establish the appropriate mailing address and sending home from the school a copy of the Exclusion Order with the child.

(d) For all orders issued, one copy of the Exclusion Order shall be sent to the administrator and the local health department shall retain one copy. The local health department shall also retain copies of the records of children to be excluded until notification from the school or facility that such children are in compliance, or for one year.

(3) On the specified date of exclusion, the administrator shall exclude from school or facility attendance all children so ordered by the local health department until the requirements specified by the local health department are verified by the administrator in accordance with section (9) of this rule.

(4) The local health department shall maintain copies of immunization records of children excluded and shall maintain contact with administrators regarding the status of such children.

(5) If children whose records are not updated on the specified exclusion day arrive at their school or facility, the administrator shall make every effort to contact their parent by phone. The administrator shall place excluded children in a space away from the other children until their parent arrives to pick them up or until they are returned home by regular school district transportation.

(6) If the excluded children do not meet the requirements specified by the local health department in accordance with section (9) of this rule and do not return to school within four school days, it is the responsibility of the public school administrator, as proper authority, to notify the attendance supervisor of the unexcused absence. The attendance supervisor is required to proceed as required in ORS 339.080 and 339.090.

(7) Children who have been issued an Exclusion Order are not entitled to begin or continue in attendance in any school or facility in Oregon while the Exclusion Order is still in effect. Administrators who receive or are otherwise made aware of the records of a child from another school or facility containing an Exclusion Order that has not been cancelled shall notify the parent and immediately exclude the child until the requirements specified on the Exclusion Order are met and verified by the administrator.

(8) Students in treatment facilities or court-mandated residential correctional facilities, including but not limited to Oregon Youth Authority closed custody sites, are not subject to exclusion. The administrator of such treatment or residential correctional facilities must comply with all other provisions of these rules, including submission of the required reports as specified by these rules. The administrator must ensure that students have complete or up-to-date immunization records, a medical or nonmedical exemption or immunity documentation for all vaccines required for the student's grade.

(9) Compliance:

(a) For children excluded for insufficient information or incomplete immunizations, compliance will be achieved by submitting to the administrator one of the statements allowed in OAR 333-050-0040(1);

(b) For children excluded for no record, compliance will be achieved by submitting to the administrator evidence of immunizations that includes at least one dose of each vaccine required for that grade or age, a medical or nonmedical exemption or immunity documentation.

(c) When the administrator verifies that the required information has been provided or that an appropriate immunity documentation or medical or nonmedical exemption has been provided, the child shall be in compliance with ORS 433.267(1) and these rules and qualified for school or facility attendance.

(10) Twelve calendar days after the mandatory exclusion date, the administrator shall ensure that:

(a) The Primary Review Summary form returned from the local health department is updated by appropriately marking the

current status of each child as specified (including children listed as having no record);

(b) The mathematics on the Primary Review Summary form are accurate including the number of children in the full school or children's facility, kindergarten and seventh grade with:

(A) The specified number of doses of each vaccine or all the doses required for the child's grade;

(B) Nonmedical exemptions for each vaccine;

(C) Nonmedical exemptions from each source, whether documentation from a health care practitioner or vaccine educational module;

(D) Nonmedical exemptions;

(E) Medical exemptions; and

(F) No record.

(c) A copy of the revised Primary Review Summary form is submitted to the local health department on that day. The administrator shall maintain a file copy of the updated Primary Review Summary form.

(11) The local health department shall review the updated Primary Review Summary form for mathematical accuracy. Any errors should be corrected by contacting the affected school or facility.

Stat. Auth.: ORS 433.004 & 433.273

Stats. Implemented: ORS 433.001, 433.004, 433.006 & 433.235 - 433.284

Hist.: HD 21-1981, f. & ef. 10-21-81; HD 23-1981, f. & ef. 11-17-81; HD 17-1982, f. & ef. 8-13-82; HD 12-1983, f. & ef. 8-1-83; HD 22-1983, f. & ef. 11-1-83; HD 8-1987, f. & ef. 7-15-87; HD 6-1991, f. & cert. ef. 5-15-91; HD 9-1992, f. & cert. ef. 8-14-92; HD 16-1997, f. & cert. ef. 12-3-97; OHD 14-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0050; OHD 26-2001, f. & cert. ef. 12-4-01; OHD 21-2002, f. & cert. ef. 12-13-02; PH 35-2004(Temp), f. & cert. ef. 11-10-04 thru 5-6-05; PH 2-2005, f. & cert. ef. 2-3-05; PH 1-2006, f. & cert. ef. 1-27-06; PH 12-2007, f. & cert .ef. 9-27-07; PH 6-2008, f. & cert. ef. 3-17-08; PH 24-2010, f. & cert. ef. 9-30-10; PH 3-2014, f. 1-30-14, cert. ef. 3-1-14; PH 13-2015(Temp), f. & cert. ef. 8-24-15 thru 2-19-16; PH 1-2016, f. & cert. ef. 1-20-16

333-050-0090
Review of Exclusion Orders

(1) If a parent believes an Exclusion Order is in error, the parent shall contact the local health department and request that the local health department review and re-check the information to determine the accuracy of the Exclusion Order.

(2) A local health department shall review and re-check a child's immunization records upon receipt of a request by a parent.

(3) If the Exclusion Order is found by the local health department to be in error, or if compliance is achieved pursuant to OAR 333-050-0080(9), the Exclusion Order shall be rescinded.

Stat. Auth.: ORS 433.004 & 433.273

Stats. Implemented: ORS 433.001, 433.004, 433.006 & 433.235 - 433.284

Hist.: HD 2-1982, f. & ef. 2-4-82; HD 17-1982, f. & ef. 8-13-82; HD 12-1983, f. & ef. 8-1-83; HD 6-1991, f. & cert. ef. 5-15-91; HD 9-1992, f. & cert. ef. 8-14-92; HD 16-1997, f. & cert. ef. 12-3-97; OHD 14-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0051; OHD 21-2002, f. & cert. ef. 12-13-02; PH 35-2004(Temp), f. & cert. ef. 11-10-04 thru 5-6-05; PH 2-2005, f. & cert. ef. 2-3-05; PH 1-2006, f. & cert. ef. 1-27-06; PH 12-2007, f. & cert .ef. 9-27-07; PH 6-2008, f. & cert. ef. 3-17-08; PH 24-2010, f. & cert. ef. 9-30-10

333-050-0095
School/Facility Compliance

(1) In the event that a school or facility fails to comply with these rules, the local health department shall make a verbal, documented contact with the non-compliant school or facility that covers:

(a) The specific requirements of the state's immunization law and rules; and

(b) Establishes a four-working-day time frame for the school or facility administrator to comply.

(2) If the school or facility still fails to comply, the local health department shall notify the Public Health Division of the name and address of the school or facility.

(3) The local health department shall send to the Public Health Division, via mail, electronic mail or facsimile, documentation of contacts made with the non-compliant school or facility.

(4) Within five working days of notification by the local health department, the Public Health Division shall send a certified letter to the non-compliant school or facility that:

(a) Notifies the school or facility that it is out of compliance and how it is out of compliance with the immunization law and rules;

(b) Establishes seven calendar days to comply before the matter is referred to the Attorney General's office; and

(c) Notifies the school or facility that a civil penalty may be imposed if the school or facility does not comply within seven calendar days.

(5) The Public Health Division shall send copies of the letter to the Child Care Division of the Employment Department, the Department of Education and/or the school district superintendent as appropriate.

(6) The Public Health Division shall notify the local health department of the new due date for compliance.

(7) If the school or facility does not comply by the new due date, the local health department shall notify the Public Health Division.

(8) The Public Health Division may impose a civil penalty on a school or facility that does not comply with the immunization law or rules after a notification of non-compliance. Civil penalties will be imposed as follows:

(a) One day late in complying: $100;

(b) Two days late in complying: $200;

(c) Three days late in complying: $300;

(d) Four days late in complying: $400;

(e) Five days or more late in complying: $500 per day until there is compliance.

(9) A notice of imposition of civil penalties shall comply with ORS 183.745.

(10) The Public Health Division shall forward all documentation of contacts to the Attorney General's office for action if the school or facility does not comply by the new date.

Stat. Auth.: ORS 431.262, 433.004, 433.273

Stats. Implemented: ORS 431.262, 433.001, 433.004, 433.006 & 433.235 - 433.284

Hist.: OHD 26-2001, f. & cert. ef. 12-4-01; PH 12-2007, f. & cert .ef. 9-27-07; PH 6-2008, f. & cert. ef. 3-17-08; PH 24-2010, f. & cert. ef. 9-30-10; PH 13-2015(Temp), f. & cert. ef. 8-24-15 thru 2-19-16; PH 1-2016, f. & cert. ef. 1-20-16

333-050-0100
Follow Up

(1) In the event that the local health department receives records that are original documents from a school or facility, the local health department shall return such records to the administrator.

(2) The administrator shall be responsible for updating records each time the parents, health care practitioner, or an authorized representative of the local health department provides evidence of immunization or exemption for each child.

(3) Information on disease restrictions for schools and facilities can be found in OAR 333-019-0010 and 333-019-0014. When there is a case of restrictable disease, the parent of a susceptible child must be notified verbally or in writing by the local health department, school or children's facility administrator or designee when the child is to be excluded and for how long the exclusion will occur.

(4) The administrator shall maintain a system to track and report susceptible persons. The local health department may request that the list of persons susceptible to a disease be sorted by classroom, grade, or school. The administrator will provide the list within one calendar day of the local health department's request in order to facilitate appropriate disease control measures.

(5) The local health department or the Public Health Division may conduct school or facility record validation surveys to ensure compliance with ORS 433.235 through 433.280 and these rules.

(6) The local health department may issue Exclusion Orders as needed for compliance with these rules during the validation survey process.

(7) The Public Health Division may issue Exclusion Orders when the Public Health Division is the recognized Public Health Authority in the county.

Stat. Auth.: ORS 433.004 & 433.273
Stats. Implemented: ORS 433.001, 433.004, 433.006 & 433.235 - 433.284
Hist.: HD 21-1981, f. & ef. 10-21-81; HD 17-1982, f. & ef. 8-13-82; HD 12-1983, f. & ef. 8-1-83; HD 6-1991, f. & cert. ef. 5-15-91; HD 9-1992, f. & cert. ef. 8-14-92; OHD 14-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0055; OHD 26-2001, f. & cert. ef. 12-4-01; OHD 21-2002, f. & cert. ef. 12-13-02; PH 35-2004(Temp), f. & cert. ef. 11-10-04 thru 5-6-05; PH 2-2005, f. & cert. ef. 2-3-05; PH 1-2006, f. & cert. ef. 1-27-06; PH 12-2007, f. & cert .ef. 9-27-07; PH 6-2008, f. & cert. ef. 3-17-08; PH 3-2014, f. 1-30-14, cert. ef. 3-1-14; PH 13-2015(Temp), f. & cert. ef. 8-24-15 thru 2-19-16; PH 1-2016, f. & cert. ef. 1-20-16

333-050-0110
Annual Reporting Requirements

(1) The local health department shall submit a County Immunization Status Report to the Public Health Division annually no later than 23 calendar days after the third Wednesday in February.

(2) On or before the last day of April, the Public Health Division shall publicize a summary of the immunization status of children in schools, children's facilities, kindergarten and seventh grade attending schools and facilities for each local public health jurisdiction.

(3) On or before May 15, the local health department shall make available immunization rates to each school and children's facility in the area served by the local health department, by disease, of children in the local area:

(a) Compiled from school reports for kindergarten through 12th grade combined; and

(b) Calculated from ALERT IIS for children 19 months up to kindergarten age.

(4) The local health department may request assistance from the Oregon Health Authority in calculating the rates described in section (3) of this rule.

(5) The administrator of the school or children's facility must make available a summary of the immunization status, for the school or children's facility and local area, by 30 days after the first day of school and by 30 days after the third Wednesday in February.

(a) The summary of immunization status for the school or children's facility must include:

(A) The percentage of children with all the doses required for each child's age or grade, by vaccine, for the school or children's facility and for the local area;

(B) The percentage of children with nonmedical exemptions by vaccine for the school or children's facility;

(C) The percentage of children with no record for the school or children's facility;

(D) The percentage of children with medical exemptions for one or more vaccine for the school or children's facility;

(E) The number of children for whom documentation of immunization status is required at the school or children's facility;

(F) The number of enrolled children for whom documentation of immunization status is not required at the school or children's facility;

(G) The number of children 18 months of age and younger in attendance at the school or children's facility who are not required to have completed the full series of vaccines required before kindergarten because of their age.

(b) Rates must be made available:

(A) In the main office;

(B) On the school or children's facility website, if available. Rates may be posted on a social media website, such as Facebook, if this is the primary website for the school or children's facility. Public school rates must also be made available on the district website. If individual school webpages are linked to a district website, a central district webpage containing the required information for each school may be used to comply with this requirement; and

(C) By sending to a parent of each child for whom documentation of immunization status is required at the school or children's facility, in electronic or paper format, in a clear and easy to understand manner.

(c) Children's facilities shall make rates available based on the school calendar in the local area.

(d) Rates may include immunization data collected in the previous school year.

(6) Schools and children's facilities for which immunization records are required for fewer than 10 children in attendance 18 months of age up to kindergarten are exempt from the requirements of OAR 333-050-0110(5) for these children. These sites must still comply with the reporting requirements specified in OAR 333-050-0060 and 333-050-0080.

(7) Schools and children's facilities for which immunization records for a vaccine are required for fewer than 10 students in attendance in kindergarten grade and older are exempt from the requirements of OAR 333-050-0110(5) for that vaccine for these students. These sites must still comply with the reporting requirements specified in OAR 333-050-0060 and 333-050-0080.

Stat. Auth.: ORS 433.004 & 433.273
Stats. Implemented: ORS 433.001, 433.004, 433.006 & 433.235 - 433.284
Hist.: HD 21-1981, f. & ef. 10-21-81; HD 23-1981, f. & ef. 11-17-81; HD 17-1982, f. & ef. 8-13-82; HD 12-1983, f. & ef. 8-1-83; HD 8-1987, f. & ef. 7-15-87; HD 6-1991, f. & cert. ef. 5-15-91; HD 16-1997, f. & cert. ef. 12-3-97; OHD 14-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0060; OHD 26-2001, f. & cert. ef. 12-4-01; PH 12-2007, f. & cert .ef. 9-27-07; PH 6-2008, f. & cert. ef. 3-17-08; PH 24-2010, f. & cert. ef. 9-30-10; PH 3-2014, f. 1-30-14, cert. ef. 3-1-14; PH 13-2015(Temp), f. & cert. ef. 8-24-15 thru 2-19-16; PH 1-2016, f. & cert. ef. 1-20-16

333-050-0120
Immunizations Schedules for Spacing of Doses

See Primary Review Table for the judgment of compliance or non-compliance with the required immunizations.

[ED. NOTE: Tables referenced are available from the agency.]
Stat. Auth.: ORS 433.004 & 433.273
Stats. Implemented: ORS 433.001, 433.004, 433.006 & 433.235 - 433.284
Hist.: HD 21-1981, f. & ef. 10-21-81; HD 17-1982, f. & ef. 8-13-82; HD 22-1983, f. & ef. 11-1-83; HD 15-1986, f. & ef. 7-15-86; HD 4-1990(Temp), f. & cert. ef. 1-11-90; HD 10-1991, f. & cert. ef. 7-23-91; HD 12-1991(Temp), f. 8-26-91, cert. ef. 9-3-91; HD 16-1997, f. & cert. ef. 12-3-97; OHD 8-1998, f. & cert. ef 9-10-98; OHD 12-2000, f. & cert. ef. 12-26-00; OHD 14-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0070; PH 12-2007, f. & cert .ef. 9-27-07; PH 1-2008(Temp). f. & cert. ef. 1-8-08 thru 6-30-08; PH 6-2008, f. & cert. ef. 3-17-08; PH 16-2008(Temp), f. & cert. ef. 10-27-08 thru 4-20-09; Administrative correction 5-20-09; PH 13-2009(Temp), f. 12-17-09, cert. ef. 12-21-09 thru 6-18-10; Administrative correction 7-27-10; PH 24-2010, f. & cert. ef. 9-30-10; PH 3-2014, f. 1-30-14, cert. ef. 3-1-14

333-050-0130
Second Dose Measles in Post Secondary Educational Institution

(1) Each post-secondary education institution, except a community college and a private, proprietary vocational school, shall require that each entering full-time student born on or after January 1, 1957, has two doses of measles vaccine prior to the student's second quarter or semester of enrollment on an Oregon campus, using procedures developed by the institution.

(2) For students subject to section (1) of this rule who are attending the institution pursuant to a non-immigrant visa, documentation of measles vaccination must be provided prior to the student attending classes. If the student's first dose of measles vaccine was received less than 30 days prior to attendance, the student has until the beginning of the second term or semester to provide documentation of the second dose.

(3) The following records may be accepted as adequate proof of two doses of measles vaccine:

(a) Written documentation by student, health care practitioner, or an authorized representative of the local health department of the month, day and year of each dose, within four days prior to, on or after the first birthday, with a minimum of 24 days between the first and second dose;

(b) For students born prior to 1984, no available date for the first dose but written documentation by student, health care practitioner, or an authorized representative of the local health department of the month, day and year of the second dose in or after December, 1989;

(c) An unsigned record printout from the statewide immunization information system, ALERT IIS; or

(d) An unsigned record printout from a computer system approved by the Public Health Division as specified in OAR 333-050-0060(5).

(4) Each post-secondary education institution under the jurisdiction of the law shall include a medical and nonmedical exemption and immunity documentation. Signing for a nonmedical exemption requires documentation of a signature of a health care practitioner that the practitioner has reviewed with the student the risks and benefits of immunization or a certificate verifying that the student has completed a vaccine educational module approved by the Public Health Division.

(5) Each post-secondary educational institution under the jurisdiction of the law shall develop procedures to implement and maintain this requirement.

(6) The Public Health Division may conduct validation surveys to ensure compliance.

(7) A student shall not be excluded from a post-secondary institution for failing to receive a required vaccine if the State Health Officer has determined that there is a vaccine shortage and that is the reason the student has not received the vaccine. Any vaccine that has been waived due to a vaccine shortage will be required at the next term or semester, once the shortage has been lifted.

(8) The local public health officer, after consultation with the Public Health Division, may allow a student to attend an educational institution without meeting the minimum immunization requirements in case of temporary local vaccine shortage.

(a) The local health department shall provide a letter signed by the local health officer to the affected student stating that the vaccine requirement is being postponed. The letter must give guidance to the post-secondary institution about when vaccine is expected to be available.

(b) A photocopied form letter signed by the local health officer may be used by the local health department when the shortage is expected to affect more than one student.

Stat. Auth.: ORS 433.004, 433.273 & 433.282

Stats. Implemented: ORS 433.001, 433.004, 433.006 & 433.235 - 433.284

Hist.: HD 9-1992, f. & cert. ef. 8-14-92; OHD 14-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0080; OHD 21-2002, f. & cert. ef. 12-13-02; PH 35-2004(Temp), f. & cert. ef. 11-10-04 thru 5-6-05; PH 2-2005, f. & cert. ef. 2-3-05; PH 1-2006, f. & cert. ef. 1-27-06; PH 12-2007, f. & cert .ef. 9-27-07; PH 6-2008, f. & cert. ef. 3-17-08; PH 24-2010, f. & cert. ef. 9-30-10; PH 3-2014, f. 1-30-14, cert. ef. 3-1-14

333-050-0140
Second Dose Measles in Community Colleges

(1) Each community college shall require that students involved in clinical experiences in allied health programs, practicum experiences in education and child care programs and membership on intercollegiate sports teams have two doses of measles vaccine prior to each student's participation. The requirement shall apply only to those students born on or after January 1, 1957, using procedures developed by the institutions.

(2) The following records may be accepted as adequate proof of two doses of measles vaccine:

(a) Written documentation by student, health care practitioner, or an authorized representative of the local health department of the month, day and year of each dose, within four days prior to, on or after the first birthday, with a minimum of 24 days between first dose and second dose;

(b) For students born prior to 1984, no available date for the first dose but written documentation by student, health care practitioner, or an authorized representative of the local health department of the month, day and year of the second dose in or after December, 1989;

(c) An unsigned record printout from the statewide immunization information system, ALERT IIS; or

(d) An unsigned record printout from a computer system approved by the Public Health Division as specified in OAR 333-050-0060(5).

(3) Each community college under the jurisdiction of the law shall include a medical and nonmedical exemption and immunity documentation. Signing for a nonmedical exemption requires documentation of a signature of a health care practitioner that the practitioner has reviewed with the student the risks and benefits of immunization or a certificate verifying that the student has completed a vaccine educational module approved by the Public Health Division.

(4) Each community college shall develop procedures to implement and maintain this requirement.

(5) The Public Health Division may conduct validation surveys to ensure compliance.

(6) A student shall not be excluded from a community college for failing to receive a required vaccine if the State Health Officer has determined that there is a vaccine shortage and that is the reason the student has not received the vaccine. Any vaccine that has been waived due to a vaccine shortage will be required at the next term or semester, once the shortage has been lifted.

(7) The local public health officer, after consultation with the Public Health Division, may allow a student to attend an educational institution without meeting the minimum immunization requirements in case of temporary local vaccine shortage.

(a) The local health department shall provide a letter signed by the local health officer to the affected student stating that the vaccine requirement is being postponed. The letter must give guidance to the community college about when vaccine is expected to be available.

(b) A photocopied form letter signed by the local health officer may be used by the local health department when the shortage is expected to affect more than one student.

Stat. Auth.: ORS 433.004, 433.273 & 433.283

Stats. Implemented: ORS 433.001, 433.004, 433.006 & 433.235 - 433.284

Hist.: HD 9-1992, f. & cert. ef. 8-14-92; OHD 14-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0090; OHD 21-2002, f. & cert. ef. 12-13-02; PH 35-2004(Temp), f. & cert. ef. 11-10-04 thru 5-6-05; PH 2-2005, f. & cert. ef. 2-3-05; PH 12-2007, f. & cert .ef. 9-27-07; PH 6-2008, f. & cert. ef. 3-17-08; PH 24-2010, f. & cert. ef. 9-30-10; PH 3-2014, f. 1-30-14, cert. ef. 3-1-14

DIVISION 52

WIC FARM DIRECT NUTRITION PROGRAM

333-052-0030
Program Overview

(1) The purpose of the Oregon Farm Direct Nutrition Program (Oregon FDNP or FDNP) is to:

(a) Provide locally grown, fresh, nutritious, unprepared fruits, vegetables, and cut culinary herbs to women, infants, and children, who participate in the special supplemental nutrition program for women, infants, and children (WIC) and to low income seniors; and

(b) Expand the awareness and use of farmers' markets and farm stands where consumers can buy directly from the farmer.

(2) The Oregon FDNP is administered by Oregon Health Authority (Authority) in partnership with the Oregon Department of Agriculture.

Stat. Auth.: ORS 413.500

Stats. Implemented: ORS 413.500

Hist.: PH 10-2006, f. & cert. ef. 6-5-06; PH 7-2008, f. & cert. ef. 4-3-08; PH 8-2012(Temp), f. & cert. ef. 6-11-12 thru 12-7-12; PH 15-2012, f. & cert. ef. 12-20-12

333-052-0040
Definitions

(1) "Adequate Participant Access" means there are authorized farmers sufficient for participant need.

(2) "Agreement" means a written legal document binding the market or farmer and the Authority to designated terms and conditions.

(3) "AAA" means Area Agency on Aging.

(4) "ADRC" means Aging and Disability Resource Connection.

(5) "APD" means Department of Human Services, Aging and People with Disabilities.

(6) "Authority" means the Oregon Health Authority.

(7) "Authorized" or "authorization" means an eligible farmer or farmers' market has met the selection criteria and signed an agreement with the Authority allowing participation in FDNP, and is not currently disqualified.

(8) "Check" means a negotiable financial instrument by which FDNP benefits are provided to participants.

(9) "CMP" means a civil money penalty, which is a monetary penalty imposed against the farmer for noncompliance of FDNP rules.

(10) "Disqualification" means the act of terminating the agreement of an authorized farmers' market, or farmer from the FDNP for noncompliance with program requirements.

(11) "Eligible foods" means fresh, nutritious, unprepared, locally grown fruits and vegetables and culinary herbs for human consumption. Eligible foods may not be processed or prepared beyond their natural state except for usual harvesting and cleaning processes. For example, checks cannot be used for honey, maple syrup, cider, nuts, seeds, plants, eggs, meat, cheese and seafood.

(12) "Farm Direct Nutrition Program" or "FDNP" means the Oregon Farm Direct Nutrition Program (Oregon FDNP), which is composed of the collective Senior Farm Direct Nutrition Program and WIC Farm Direct Nutrition Program, regulated by the United States Department of Agriculture, Food and Nutrition Services and administered by the State of Oregon.

(13) "Farmer" means an individual who owns, leases, rents or sharecrops land to grow, cultivate or harvest crops on that land.

(14) "Farmers' Market" means a group of farmers who assemble over the course of a year at a defined location for the purpose of selling their produce directly to consumers.

(15) "Farm Stand" means a location at which a farmer sells produce directly to consumers.

(16) "FDNP Participant" or "participant" means a senior participant or a WIC participant receiving FDNP benefits.

(17) "Locally grown" means grown in the state of Oregon or in the following counties of a contiguous state: California — Del Norte, Modoc, Siskiyou; Idaho — Adams, Canyon, Idaho, Owyhee, Payette, Washington; Nevada — Humboldt, Washoe; Washington — Asotin, Benton, Clark, Columbia, Cowlitz, Garfield, Klickitat, Pacific, Skamania, Wahkiakum, Walla Walla.

(18) "Local WIC agency" means the agency or clinic where a WIC participant receives WIC services and benefits.

(19) "Market" means a farmers' market that has a signed agreement with the Authority to participate in the FDNP.

(20) "Market Coordinator" means an individual designated by the farmers' market manager (or market board members) responsible for overseeing the market's participation in the FDNP.

(21) "Market Season" means the time period in which FDNP checks may be transacted as determined by the Authority.

(22) "Senior Farm Direct Nutrition Program (SFDNP)" means the Senior Farmers' Market Nutrition Program funded by USDA that provides senior participants with checks that can be used to buy eligible foods from an authorized farmer.

(23) "Senior Participant" means an individual who meets all the eligibility components of the program and who receives FDNP checks.

(24) "SNAP" means the Supplemental Nutrition Assistance Program of the Food and Nutrition Services of the United States Department of Agriculture.

(25) "Trafficking" means the buying or exchanging of FDNP checks for cash, drugs, firearms or alcohol.

(26) "USDA" means the United States Department of Agriculture.

(27) "Validating" means stamping the FDNP check in the designated box with the farmer identification number using the stamp provided by the Authority or a replacement stamp purchased by the farmer.

(28) "Violation" means an activity that is prohibited by OAR 333-052-0030 through 333-052-0090 and classified in OAR 333-052-0080 through 333-052-0130.

(29) "WIC" or "WIC program" means the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) authorized by Section 17 of the Federal Child Nutrition Act of 1966, as amended, 42 U.S.C.§1786.

(30) "WIC Farm Direct Nutrition Program (WIC FDNP)" means the Farmers' Market Nutrition Program funded by USDA that provides WIC participants with checks that can be used to buy eligible foods from an authorized farmer.

(31) "WIC participant" means any pregnant, breastfeeding, or postpartum woman, infant, or child who meets all of the eligibility components of the WIC FDNP and receives WIC FDNP checks.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 10-2006, f. & cert. ef. 6-5-06; PH 7-2008, f. & cert. ef. 4-3-08; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 11-2011, f. & cert. ef. 10-27-11; PH 8-2012(Temp), f. & cert. ef. 6-11-12 thru 12-7-12; PH 15-2012, f. & cert. ef. 12-20-12; PH 4-2014, f. & cert. ef. 1-30-14; PH 24-2015, f. 12-8-15, cert. ef. 1-1-16

333-052-0043
Senior Participant Eligibility and Benefits

(1) An individual is eligible for the Senior Farm Direct Nutrition Program (SFDNP) if the individual meets all of the following eligibility criteria on April 1 of the calendar year in which benefits are sought:

(a) Has income less than 138 percent of the Federal Poverty Level;

(b) Receives Medicaid or SNAP benefits;

(c) Is homeless or resides in their own home or rental property; and

(d) Is age 62 years or older.

(2) SFDNP benefits are limited and benefits will be distributed in an equitable manner but may not be distributed to all individuals who are eligible.

(3) The Authority shall inform eligible seniors each year of the available benefits and how the benefits will be distributed.

(4) SFDNP benefits are valid from June 1 through October 31 of the year in which benefits were issued.

(5) Lost or stolen SFDNP benefits will not be replaced.

(6) An individual who does not receive a benefit in any given year due to lack of sufficient funding to provide SFDNP benefits to all eligible seniors is not entitled to hearing rights.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 15-2012, f. & cert. ef. 12-20-12; PH 4-2014, f. & cert. ef. 1-30-14; PH 24-2015, f. 12-8-15, cert. ef. 1-1-16

333-052-0044
WIC Participant Eligibility and Benefits

(1) A WIC participant is eligible to receive WIC Farm Direct Nutrition Program (WIC FDNP) benefits if the participant meets all of the following eligibility criteria on the date of FDNP benefit issuance:

(a) Is currently receiving benefits under the WIC Program; and

(b) Belongs to any of the following WIC categories:

(A) A pregnant woman;

(B) A breastfeeding woman less than one year after delivery;

(C) A non-lactating post-partum woman less than six months after delivery;

(D) A child through the end of the month he or she turns five years of age; or

(E) An infant four months of age or older.

(2) WIC FDNP benefits are limited and benefits will be distributed in an equitable manner within participating local agencies but may not be distributed to all individuals who are eligible.

(3) The Authority will determine a standard benefit package per eligible individual and per family each year.

(4) WIC FDNP benefits will only be issued to the participant/caretaker in a face-to-face contact at the local agency

where WIC benefits are received, and the participant/caretaker must receive a FDNP orientation when receiving checks for the first time in the current year.

(5) WIC FDNP benefits are valid from June 1 through October 31 of the year in which benefits were issued.

(6) Lost or stolen WIC FDNP benefits will not be replaced.

(7) Individuals who are denied WIC FDNP benefits may appeal the denial, but shall not receive WIC FDNP benefits while awaiting the decision.

(8) WIC participants whose WIC FDNP benefits are terminated may appeal the termination of benefits and shall continue to receive WIC FDNP benefits until the hearing official reaches a decision or the expiration of the current FDNP season, whichever occurs first.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 15-2012, f. & cert. ef. 12-20-12; PH 4-2014, f. & cert. ef. 1-30-14

333-052-0050
Eligible Foods

(1) FDNP checks may be used to purchase only eligible foods.

(2) Ineligible items include, but are not limited to:

(a) Baked goods, cheeses, cider, crafts, dairy products, dried fruits, dried herbs, dried vegetables, eggs, flowers, fruit juices, honey, jams, jellies, meats, nuts, plants of any kind, potted herbs, seafood, seeds, and syrups.

(b) Fresh fruits, vegetables, and cut culinary herbs that are not locally grown.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 10-2006, f. & cert. ef. 6-5-06; PH 7-2008, f. & cert. ef. 4-3-08; PH 15-2012, f. & cert. ef. 12-20-12

333-052-0060
Farmer Participation

(1) Only authorized farmers may accept FDNP checks from participants in exchange for eligible foods. Authorized farmers may not accept checks from unauthorized farmers.

(2) In order to be eligible for participation in the FDNP, a farmer applicant must:

(a) Own, lease, rent or sharecrop land to grow, cultivate, or harvest fruits, vegetables and cut herbs in Oregon or a bordering county in a contiguous state to sell fresh at a farmers' market or farm stand;

(b) Complete the farmer application and return it to the Oregon Department of Agriculture to verify eligibility; and

(c) Agree to follow the terms and conditions of the farmer agreement.

(3) Applications will be used to determine authorization for FDNP.

(4) The Authority and the FDNP are not required to authorize all applicants.

(5) Any individual who purchases all the produce they plan to sell is considered a distributor and is not allowed to participate in the FDNP.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 10-2006, f. & cert. ef. 6-5-06; PH 7-2008, f. & cert. ef. 4-3-08; PH 15-2012, f. & cert. ef. 12-20-12

333-052-0065
Farmer Agreements

(1) A farmer application/agreement must be signed by a representative who has legal authority to obligate the farmer.

(2) The farmer agreement must include a requirement that the farmer comply with OAR 333-052-0030 to 333-052-0130, as applicable to farmers.

(3) The farmer application/agreement will be valid for no more than three years.

(4) Neither the Authority nor the farmer is obligated to renew the agreement.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 10-2006, f. & cert. ef. 6-5-06; PH 7-2008, f. & cert. ef. 4-3-08; PH 15-2012, f. & cert. ef. 12-20-12

333-052-0070
Farmers' Market Participation

(1) In order to be eligible for participation in the FDNP a farmers' market applicant must:

(a) Designate an individual to be the FDNP market coordinator who will be on-site during operating hours;

(b) Have a minimum of five FDNP-eligible farmers participating in the market each year;

(c) Operate on a consistent basis over the course of the season; and

(d) Agree to comply with all terms and conditions specified in the FDNP agreement.

(2) The Authority and the FDNP are not required to authorize all applicants.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 10-2006, f. & cert. ef. 6-5-06; PH 7-2008, f. & cert. ef. 4-3-08; PH 15-2012, f. & cert. ef. 12-20-12

333-052-0075
Farmers' Market Agreements

(1) A farmers' market application/agreement must be signed by a representative who has legal authority to obligate the market.

(2) The application/agreement must include a requirement that the market:

(a) Comply with OAR 333-052-0030 to 333-052-0130, as applicable to markets;

(b) Furnish the necessary personnel and services to conduct market activities; and

(c) Do all things necessary for or incidental to the performance of the work set forth in the application/agreement.

(3) The market application/agreement will be valid for one market season.

(4) Neither the Authority nor the market has an obligation to renew an agreement.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 10-2006, f. & cert. ef. 6-5-06; PH 7-2008, f. & cert. ef. 4-3-08

333-052-0080
Farmer Participation Requirements, Violations and Sanctions

(1) An authorized farmer must:

(a) Comply with FDNP requirements contained in 7 CFR 248 and 7 CFR 249 and the terms and conditions of the farmer application/agreement;

(b) Accept training on FDNP requirements and ensure that all individuals working in the farmer's stall(s) at the farmers' market(s) or farm stand(s) are trained;

(c) Accept FDNP checks:

(A) For eligible foods only; and

(B) Within the valid dates of the program.

(d) Prominently display the official FDNP sign provided by the Authority on each day of operation when at authorized farmers' markets or authorized farm stands;

(e) Provide FDNP clients with the full amount of product for the value of each FDNP check;

(f) Cooperate with staff from the Authority, the Oregon Department of Agriculture, or their designees in monitoring for compliance with program requirements and provide information that the Authority or the Oregon Department of Agriculture may require;

(g) Comply with all state or federal laws regarding non-discrimination, and applicable USDA instructions to ensure that no individual will, on the grounds of race, color, national origin, age, sex or handicap, be excluded from participation, be denied benefits, or be otherwise subjected to discrimination, under the FDNP;

(h) Ensure that FDNP shoppers receive equitable treatment, including the availability of produce that is of the same quality and no greater price than sold to other shoppers;

(i) Assure that all FDNP checks are stamped with the farmer's Authority-assigned identification number and properly endorsed before cashing or depositing at the farmer's financial institution;

(j) Deposit or cash FDNP checks at the authorized farmer's financial institution by the date determined by the Authority;

(k) Reimburse the Authority for FDNP checks that are improperly transacted;

(l) Respond to requests, implement corrective action, and comply with the terms in final orders as directed by the Authority;

(m) Not provide credit in exchange for FDNP checks;

(n) Not charge sales tax on FDNP check purchases;

(o) Not seek restitution from FDNP participants for a check not paid by the Authority;

(p) Not give cash back for purchases that amount to less than the value of a check (providing change);

(q) Not use FDNP checks for any purpose other than deposit or cash at their financial institution; and

(r) Not accept FDNP checks from unauthorized farmers.

(2) A farmer is in violation of the FDNP if the farmer:

(a) Fails to:

(A) Comply with FDNP rules and the terms and conditions of the farmer application/agreement;

(B) Accept training on FDNP requirements and ensure that all individuals working in the farmer's stall(s) at the farmers' market(s) or farm stand(s) are trained;

(C) Prominently display the official FDNP sign provided by the Authority on each day of operation when at authorized farmers' markets or authorized farm stands;

(D) Provide FDNP clients with the full amount of product for the value of each FDNP check;

(E) Comply with all state or federal laws regarding non-discrimination, and applicable USDA instructions to ensure that no individual will, on the grounds of race, color, national origin, age, sex or handicap, be excluded from participation, be denied benefits, or be otherwise subjected to discrimination, under the FDNP;

(F) Ensure that FDNP shoppers receive equitable treatment, including the availability of produce that is of the same quality and no greater price than sold to other shoppers;

(G) Assure that all FDNP checks are stamped with the farmer's Authority-assigned identification number and properly endorsed before cashing or depositing at the farmer's financial institution;

(H) Deposit or cash FDNP checks at the authorized farmer's financial institution by the date determined by the Authority;

(I) Reimburse the Authority for FDNP checks that are improperly transacted;

(J) Cooperate with staff from the Authority, the Oregon Department of Agriculture, or their designees in monitoring for compliance with program requirements and provide information that the Authority or the Oregon Department of Agriculture may require;

(K) Respond to requests, implement corrective action, or comply with the terms in final orders as directed by the Authority.

(b) Accepts FDNP checks:

(A) For ineligible foods;

(B) For invalid dates; or

(C) From an unauthorized farmer.

(c) Provides credit in exchange for FDNP checks;

(d) Charges sales tax on FDNP check purchases;

(e) Seeks restitution from FDNP participants for a check not paid by the Authority;

(f) Gives cash back for purchases that amount to less than the value of a check (providing change);

(g) Uses FDNP checks for any purpose other than deposit or cash at their financial institution.

(3) Farmer sanctions:

(a) The Authority may issue a notification of non-compliance to an authorized farmer for an initial incident of:

(A) Accepting FDNP checks for ineligible foods;

(B) Failing to prominently display the official sign provided by the Authority, each market day when at authorized farmers' markets or authorized farm stands;

(C) Failing to provide FDNP clients with the full amount of product for the value of each FDNP check;

(D) Failing to ensure that FDNP shoppers receive equitable treatment, including the availability of produce that is of the same quality and no greater price than sold to other shoppers;

(E) Failing to reimburse the Authority for FDNP checks that are improperly transacted;

(F) Charging sales tax on FDNP check purchases;

(G) Seeking restitution from FDNP participants for checks not paid by the Authority;

(H) Giving cash back for purchases less than the value of the checks (providing change);

(I) Accepting FDNP checks from an unauthorized farmer;

(J) Failing to respond to requests, implement corrective action, or comply with the terms in final orders as directed by the Authority;

(K) Using FDNP checks for any purpose other than deposit or cash at the authorized farmer's financial institution; and

(L) Failing to cooperate with staff from the Authority, the Oregon Department of Agriculture, or their designees in monitoring for compliance with program requirements and failing to provide information that the Authority or the Oregon Department of Agriculture may require.

(b) The Authority may disqualify a farmer for four season months, which may cross from the year during which the violation occurred into the following year for an initial incident of providing credit in exchange for FDNP checks.

(c) The Authority may disqualify a farmer for four season months, which may cross from the year during which the violation occurred into the following year, for second or subsequent incidents of:

(A) Accepting FDNP checks for ineligible foods;

(B) Failing to prominently display the official sign provided by the Authority, each market day when at authorized farmers' markets or authorized farm stands;

(C) Failing to provide FDNP clients with the full amount of product for the value of each FDNP check;

(D) Failing to ensure that FDNP shoppers receive equitable treatment, including the availability of produce that is of the same quality and no greater price than sold to other shoppers;

(E) Charging sales tax on FDNP check purchases;

(F) Seeking restitution from FDNP participants for checks not paid by the Authority;

(G) Using FDNP checks for any purpose other than deposit or cash at the authorized farmer's financial institution;

(H) Charging FDNP participants higher prices than other customers;

(I) Giving cash back for purchases less than the value of the checks (providing change);

(J) Accepting FDNP checks from an unauthorized farmer; and

(K) Failing to respond to requests, implement corrective action, or comply with the terms in final orders as directed by the Authority.

(d) The Authority may not authorize farmers to accept FDNP checks the season following second or subsequent incidents of:

(A) Failing to reimburse the Authority for FDNP checks that are improperly transacted; or

(B) Failing to cooperate with staff from the Authority or the Oregon Department of Agriculture, or their designees in monitoring for compliance with program requirements and failing to provide information required to be submitted by the Authority or the Oregon Department of Agriculture.

(e) The Authority may immediately disqualify a farmer from the FDNP program for the remainder of the current season and the entire following season for an initial incident of:

(A) Trafficking in FDNP checks (exchanging checks for cash, controlled substances, tobacco products, firearms or alcohol) in any amount; or

(B) A USDA substantiated violation of laws regarding non-discrimination, and applicable USDA instructions.

(f) FDNP checks that are not stamped with the farmer's Authority-assigned identification number will be returned to the farmer without payment;

(g) FDNP checks redeemed outside the dates determined by the Authority will not be reimbursed; and

(h) FDNP checks redeemed by a farmer who has not been authorized will not be reimbursed.

(4) Farmers who do not comply with FDNP requirements are subject to sanctions, including civil money penalties, in addition to, or in lieu of, disqualification.

(a) Prior to disqualifying a farmer, the Authority may determine if disqualification of the farmer would result in inadequate participant access. If the Authority determines that disqualification of the farmer would result in inadequate participant access, the Authority may impose a CMP in lieu of disqualification in the amount of 5 percent of the farmer's previous season FDNP sales or $250, whichever is greater.

(b) The Authority must give written notice to a farmer of an action proposed to be taken against a farmer, not less than 15 days before the effective date of the action. The notice must state what action is being taken, the effective date of the action, and the procedure for requesting a hearing.

(c) A farmer that has been disqualified from the FDNP may reapply at the end of the disqualification period.

(d) The Authority may accept a farmer's voluntary withdrawal from the program as an alternative to disqualification. If a farmer chooses to withdraw in lieu of disqualification, the farmer may not apply for participation until the following year.

(e) The Authority will not reimburse farmers who have been disqualified or have withdrawn in lieu of disqualification.

(f) Civil money penalties must be paid to the Authority within the time period specified in the Notice.

(5) A farmer who commits fraud or abuse of the FDNP is subject to prosecution under applicable federal, state or local laws.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 10-2006, f. & cert. ef. 6-5-06; PH 7-2008, f. & cert. ef. 4-3-08; PH 15-2012, f. & cert. ef. 12-20-12; PH 24-2015, f. 12-8-15, cert. ef. 1-1-16

333-052-0090
Market Participation Requirements, Violations and Sanctions

(1) An authorized market must:

(a) Comply with FDNP requirements contained in 7 CFR 248 and 7 CFR 249, FDNP rules, and the terms and conditions of the market application/agreement;

(b) Ensure that an authorized farmer is present at the market during all market hours of operation;

(c) Accept training on FDNP procedures and provide such training to market staff including volunteers and eligible farmers on behalf of the Authority;

(d) Cooperate in the Authority investigations of authorized farmers who:

(A) Redeem checks for ineligible foods;

(B) Charge FDNP customers higher prices than other customers;

(C) Accept checks outside the Authority determined market season;

(D) Give change for food purchased with FDNP checks (providing change);

(E) May not meet the definitions of "eligible farmer;" and

(F) Abuse any other program procedures.

(e) Comply with all state or federal laws regarding non-discrimination, and applicable USDA instructions to ensure that no individual will, on the grounds of race, color, national origin, age, sex or handicap, be excluded from participation, be denied benefits, or be otherwise subjected to discrimination, under the FDNP;

(f) Cooperate with staff from the Authority or the Oregon Department of Agriculture, or their designees in monitoring for compliance with program requirements and provide information required to be submitted by the Authority or the Oregon Department of Agriculture may require; and

(g) Respond to requests, implement corrective action, and comply with the terms in final orders as directed by the Authority.

(2) A market is in violation of the FDNP rules if the market fails to:

(a) Ensure that an authorized farmer is present at the market during all market hours of operation;

(b) Accept training on FDNP procedures and provide such training to market staff including volunteers and eligible farmers on behalf of the Authority;

(c) Cooperate in the Authority investigations of authorized farmers;

(d) Comply with all state or federal laws regarding non-discrimination, and applicable USDA instructions to ensure that no individual will, on the grounds of race, color, national origin, age, sex or handicap, be excluded from participation, be denied benefits, or be otherwise subjected to discrimination, under the FDNP;

(e) Cooperate with staff from the Authority or the Oregon Department of Agriculture, or their designees in monitoring for compliance with program requirements and provide information that the Authority or the Oregon Department of Agriculture may require;

(f) Notify the Authority when and if the market ceases operation prior to the end of the authorization period;

(g) Be accountable for the actions of market staff, including volunteers, in the provision of foods and related activities; and

(h) Respond to requests, implement corrective action, and comply with the terms in final orders as directed by the Authority.

(3) Market sanctions:

(a) The Authority may issue a notice of non-compliance to an authorized market for an initial incident of failing to:

(A) Ensure that an authorized farmer is present at the market during all market hours of operations;

(B) Accept training on FDNP procedures and provide such training to market staff including volunteers and eligible farmers on behalf of the Authority;

(C) Cooperate in the Authority investigations of authorized farmers;

(D) Cooperate with staff from the Authority, the Oregon Department of Agriculture, or their designees in monitoring for compliance with program requirements and provide information that the Authority or the Oregon Department of Agriculture may require; and

(E) Respond to requests, implement corrective action, and comply with the terms in final orders as directed by the Authority.

(b) A market may not be authorized the following year if, within the current season, there is a second or subsequent occurrence of failing to:

(A) Ensure that an authorized farmer is present at the market during all market hours of operations;

(B) Accept training on FDNP procedures and provide such training to market staff including volunteers and eligible farmers on behalf of the Authority;

(C) Cooperate in the Authority investigations of authorized farmers;

(D) Cooperate with staff from the Authority, the Oregon Department of Agriculture, or their designees in monitoring for compliance with program requirements and failing to provide information required to be submitted by the Authority or the Oregon Department of Agriculture; and

(E) Respond to requests, implement corrective action, and comply with the terms in final orders as directed by the Authority.

(c) The Authority may immediately disqualify a market from the FDNP program for the remainder of the current season and the entire following season for an initial incident of a USDA substantiated violation of laws regarding non-discrimination, and applicable USDA instructions.

(4) Markets who do not comply with FDNP requirements are subject to sanctions.

(a) The Authority must give written notice to a market of an action proposed to be taken against a market, not less than 15 days before the effective date of the action. The notice must state what action is being taken, the effective date of the action, and the procedure for requesting a hearing;

(b) A market that has been disqualified from the FDNP may reapply at the end of the disqualification period; and

(c) The Authority may accept a market's voluntary withdrawal from the program as an alternative to disqualification. If a market chooses to withdraw in lieu of disqualification, the market may not apply for participation until the following year.

(5) A market that commits fraud or abuse of the FDNP is subject to prosecution under applicable federal, state or local laws.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 10-2006, f. & cert. ef. 6-5-06; PH 7-2008, f. & cert. ef. 4-3-08; PH 15-2012, f. & cert. ef. 12-20-12

333-052-0100
Oregon Health Authority Responsibilities

The Authority must:

(1) Administer the Oregon Farm Direct Nutrition Program in accordance with 7 CFR 248 (Farmers' Market Nutrition Program) and 7 CFR 249 (Senior Farmers' Market Nutrition Program);

(2) Distribute or facilitate distribution of FDNP checks to participants;

(3) Assure payment to farmers for properly redeemed FDNP checks;

(4) Assure that training is provided to new market managers and farmers who are new to the FDNP;

(5) Assure that "Oregon Farm Direct Nutrition Checks Welcome Here" signs are provided to all authorized farmers; and

(6) Monitor authorized farmers and markets for compliance with FDNP rules and agreements, and if necessary, impose sanctions.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 10-2006, f. & cert. ef. 6-5-06; PH 7-2008, f. & cert. ef. 4-3-08; PH 8-2012(Temp), f. & cert. ef. 6-11-12 thru 12-7-12; PH 15-2012, f. & cert. ef. 12-20-12

333-052-0110
Monitoring

(1) The Authority must monitor farmers and markets for compliance with applicable laws and rules, including on-site investigation of randomly selected farmers and markets.

(2) The Authority may conduct covert compliance buys of FDNP authorized farmers for compliance with the Authority rules and regulations.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 10-2006, f. & cert. ef. 6-5-06; PH 7-2008, f. & cert. ef. 4-3-08

333-052-0120
Complaints

(1) Anyone wishing to file a complaint against a FDNP participant, an authorized farmer, an authorized market, or the FDNP may do so in the following manner:

(a) Send a written comment to the WIC Compliance Coordinator at PO Box 14450, Portland, Oregon, 97293; or

(b) Call the state WIC office at 971-673-0040.

(2) A local WIC clinic, APD office, ADRC, AAA office or market manager may file a complaint on behalf of an individual who does not want to file a complaint independently.

(3) When the Authority receives a complaint alleging discrimination on the basis of race, color, national origin, age, sex or disability the Authority must automatically forward the complaint to USDA for investigation.

(4) Individuals alleging discrimination on the basis of race, color, national origin, age, sex or disability may also write directly to USDA, Director, Office of Adjudication and Compliance, 1400 Independence Avenue SW, Washington, D.C. 20250-9410 or call (800) 795-3272 (voice) or (202) 720-6382 (TTY).

(5) The Authority may refer complaints regarding farmers or markets to the Oregon Department of Agriculture for investigation.

(6) The identity of any individual filing a complaint will be kept confidential except to the extent necessary to conduct any investigation, hearing or judicial proceeding regarding the complaint.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 10-2006, f. & cert. ef. 6-5-06; PH 7-2008, f. & cert. ef. 4-3-08; PH 15-2012, f. & cert. ef. 12-20-12; PH 4-2014, f. & cert. ef. 1-30-14; PH 24-2015, f. 12-8-15, cert. ef. 1-1-16

333-052-0130
Appeals

(1) Markets and farmers are entitled to a hearing as provided by the Administrative Procedures Act (ORS Chapter 183) for a denial of participation, imposition of a sanction, or disqualification.

(2) Markets and farmers may not be entitled to a hearing under the Administrative Procedures Act to challenge:

(a) The validity or appropriateness of the Authority's selection criteria for farmer or market participation;

(b) The validity or appropriateness of the Authority's participant access determinations;

(c) The duration or expiration of a farmer or market agreement; or

(d) An Authority decision regarding a check payment or claims.

(3) The Authority may, at its discretion, permit the market or farmer to continue participating in the program pending the outcome of an administrative hearing. The farmer may be required to repay funds for FDNP checks redeemed during the pendency of the hearing, depending on the hearing outcome.

(4) A request for a hearing must be in writing and must be received within 30 days from the date of the notice describing the proposed action.

(5) The request for hearing must include:

(a) The name and address of the farmer or market requesting the hearing;

(b) The name and address of the attorney representing the farmer or market, if any;

(c) The decision made or action taken by the Authority against the farmer or market;

(d) The reason the farmer or market disagrees with the decision or action;

(e) Any special needs or requirements, such as, an interpreter or other special accommodations; and

(f) An attached copy of the notice from the Authority.

(6) If a hearing is requested under subsection (1) of this rule, a final written decision must be made within 60 days from the date the request for a hearing was received by the WIC Operations Manager. The time for issuing a decision may be extended upon agreement by the parties.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 10-2006, f. & cert. ef. 6-5-06; PH 7-2008, f. & cert. ef. 4-3-08; PH 15-2012, f. & cert. ef. 12-20-12

DIVISION 53

SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS AND CHILDREN (WIC) PARTICIPANT ADMINISTRATION

333-053-0000
Suspension of WIC Program

(1) Notwithstanding any other rules in this division, all WIC program benefits are suspended if there is a government or WIC program closure or if the government does not provide WIC funding. A suspension shall remain in effect until such time as funding is approved or as soon as the closure ends and only to the extent benefit issuance to participants is approved by the federal government.

(2) Notice of suspensions shall be made by the Oregon Health Authority by posting a notice on the WIC program website and by

notifying participants in writing. Notice of suspensions shall include the suspension effective date. As soon as funding is restored or as soon as the closure has ended, the Authority shall notify participants of the date that a suspension is lifted.

(3) Benefits may not be issued to participants and participants shall not redeem WIC food instruments they have already received during a suspension.

(4) Participants who disagree with a suspension are not entitled to continuing benefits or a contested case hearing but may challenge a suspension through a rule challenge under ORS 183.335 or 183.400.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 5-2014, f. & cert. ef. 1-30-14

333-053-0030
Description of the WIC Program

(1) The WIC program is a federally funded program established in 1972 by an amendment to the Child Nutrition Act of 1966. The purpose of the WIC program is to serve as an adjunct to health care by providing: nutrition education and counseling; nutritious supplemental foods; health screening and referral services to pregnant and breastfeeding women, infants and children in certain high-risk categories.

(2) Federal regulations governing the WIC program, 7 CFR § 246, require adoption and implementation of standards and procedures to guide the state's administration of the WIC program. These regulations also define the rights and responsibilities of participants.

(3) The Oregon Health Authority administers the WIC program in the State of Oregon.

(4) Any participant who receives benefits from the WIC program shall comply with these rules. Failure to comply with these rules shall result in sanctions.

(5) WIC program participation may include participation in the Oregon Farm Direct Nutrition Program (FDNP).

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 17-2008, f. & cert. ef. 11-5-08; PH 10-2013, f. 11-6-13, cert. ef. 12-1-13

333-053-0040
Definitions

(1) "Adjunctively income eligible" means an applicant or participant who is eligible for WIC because they are:

(a) Certified and fully eligible to receive benefits for the:

(A) Food Distribution Program on Indian Reservations (FDPIR);

(B) Supplemental Nutrition Assistance Program (SNAP);

(C) Medicaid/Oregon Health Plan (OHP); or

(D) Temporary Assistance for Needy Families (TANF); or

(b) A member of a household with:

(A) A SNAP recipient;

(B) A pregnant woman or infant currently on Medicaid/OHP;

(C) A TANF recipient; or

(D) A FDPIR recipient.

(2) "Appeal" means review of an agency decision by a neutral third party.

(3) "Applicant" means any pregnant woman, post-partum woman, infant or child who is applying to receive WIC program benefits, and a breastfed infant of an applicant breastfeeding woman. Applicants include individuals who are currently participating in the program but are re-applying because their certification period is about to expire.

(4) "Authority" means the Oregon Health Authority.

(5) "Authorized food" means any supplemental foods approved by the Oregon WIC program and listed on the WIC Authorized Food List or food instrument.

(6) "Authorized shopper" means:

(a) The participant or any person designated by a participant who has been documented as such to act on the participant's behalf; and

(b) In the case of an infant or child, the caretaker or the caretaker's designee; or

(c) Any representative of the Authority posing as a participant or participant designee as authorized by the Authority.

(7) "Cardholder" means the person authorized by the WIC program to use the eWIC card to purchase WIC food benefits at WIC-authorized vendors.

(8) "Cash Value Benefit" or "CVB" means a fixed-dollar benefit on a check, voucher, electronic benefit transfer (EBT) card or other document which is used by an authorized shopper to obtain WIC authorized fruits and vegetables.

(9) "Certification" means the implementation of criteria and procedures to assess and document each applicant's eligibility for participation in the WIC program.

(10) "CFR" means Code of Federal Regulations.

(11) "Claim" means a demand for repayment for intentional misuse of WIC or FDNP benefits.

(12) "CSFP" means the Commodity Supplemental Food Program.

(13) "Disqualification" means termination of participation in the WIC program and cessation of WIC benefits due to a participant violation for a specific amount of time.

(14) "Dual participation" means simultaneous participation in more than one WIC program (more than one state or more than one local agency within Oregon) or participation in the WIC program and in the CSFP at the same time.

(15) "Electronic benefit account" or "EBA" means an account established for a WIC household administered by Oregon's eWIC banking contractor and where food benefits for all participants in the household are aggregated into that single account.

(16) "eWIC card" means the electronic benefit transfer (EBT) card used by cardholders to purchase WIC authorized foods or formulas from their electronic benefit account (EBA).

(17) "Fair hearing" means a proceeding before an administrative law judge to review actions proposed by the Authority.

(18) "Farm Direct Nutrition Program" or "FDNP" means the Farmers' Market Nutrition Program administered by the United States Department of Agriculture (USDA), Food and Nutrition Services and implemented by the State of Oregon, Oregon Health Authority.

(19) "First cardholder" means the required cardholder for an electronic benefit account. The first cardholder is either the woman participant or the parent or caretaker from the same household as the infant or child participant therefore sharing the same address.

(20) "Food instrument" means a WIC program voucher, check, coupon, electronic benefit transfer (EBT) card, or other document which is used to obtain authorized foods.

(21) "Hearing request" or "request for a hearing" means any clear expression by an individual, or the individual's parent, caretaker or representative, that he or she desires an opportunity to present his or her case to a higher authority.

(22) "Local agency" means:

(a) A public or private non-profit health or human services agency that provides health services, either directly or through contract with the Authority to provide services, in accordance with 7 CFR § 246.5;

(b) An Indian Health Service unit in contract with the Authority to provide services;

(c) An Indian tribe, band or group recognized by the Department of the Interior that operates a health clinic or is provided health services by an Indian Health Service unit; or

(d) An intertribal council or group that is an authorized representative of Indian tribes, bands or groups recognized by the Department of the Interior that operates a health clinic or is provided health services by an Indian Health Service unit.

(23) "Notice of Non-compliance" means a letter notifying participants, parents or caretakers of an infant or child participant when they commit a program violation. This notice is an explanation of the violation and a warning about repercussions of subsequent violations.

(24) "Participant" means any pregnant woman, breastfeeding woman, post-partum non-lactating woman, infant or child who has been certified to receive benefits from the WIC program.

(25) "Participant's caretaker" means a person who has significant responsibility for providing food to the infant or child. The caretaker is usually part of the family unit, for example the parent or legal guardian of the infant or child.

(26) "Restitution" means reimbursement to the Authority of the cash value of WIC program benefits received by a participant as a result of a violation.

(27) "Sanction" means a penalty imposed by the state WIC program because of a violation.

(28) "Second cardholder" means an individual authorized on a WIC electronic benefit account who has been issued their own eWIC card with the permission of the first cardholder.

(29) "Service area" means a local program or subdivision of a local agency that encompasses a specific geographic area.

(30) "Termination" means a participant's file is closed and WIC program benefits cease for any reason including, but not limited to, lack of eligibility, no longer breastfeeding, or transferring out of state, and participant violations.

(31) "Trafficking" means the buying or selling of a WIC food instrument for cash.

(32) "Violation" means any intentional action of a participant, parent or caretaker of an infant or child participant, or any eWIC cardholder, including actions listed in OAR 333-053-0080, that violates federal or state statutes, regulations, policies or procedures governing the WIC program.

(33) "WIC program" or "WIC" means the Special Supplemental Nutrition Program for Women, Infants and Children authorized by Section 17 of the Federal Child Nutrition Act of 1966, as amended, 42 U.S.C. § 1786.

(34) "WIC program benefits" mean benefits a participant receives that includes but are not limited to food, formula, and breast pumps.

Stat. Auth.: ORS 413.500

Stats. Implemented: ORS 413.500

Hist.: PH 17-2008, f. & cert. ef. 11-5-08; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 11-2011, f. & cert. ef. 10-27-11; PH 10-2013, f. 11-6-13, cert. ef. 12-1-13; PH 26-2015, f. 12-8-15, cert. ef. 1-1-16

333-053-0050
Participant Eligibility

(1) In order to be eligible for the WIC program, at the time of application an applicant must:

(a) Be a pregnant woman, a breastfeeding woman less than one year after delivery, a non-lactating, post-partum woman less than six months after delivery, or a child through the end of the month he or she turns five years of age;

(b) Reside within the jurisdiction of the State of Oregon or within the Indian State jurisdiction;

(c) Meet the state's income eligibility criteria at the time of application; and

(d) Be at nutritional risk as defined by the Authority.

(2) In order to establish eligibility, a state or local agency shall require proof of residency, identity, and income and may require verification of pregnancy.

(3) Participants may only be enrolled in one local agency or clinic within a local agency in Oregon at a time.

(4) Participants may be enrolled in only one state WIC program at a time. If a participant moves to a new state they are no longer eligible to receive Oregon WIC program benefits.

(5) A participant may be terminated from the WIC program because they are no longer eligible.

(6) A participant may be disqualified from the WIC program for violations of program rules.

(7) A participant may voluntarily withdraw from participating in the WIC program at any time.

(8) A participant is eligible to receive FDNP benefits if the individual meets all of the following eligibility criteria on the date of FDNP benefit issuance:

(a) Is currently receiving benefits under the WIC program; and

(b) Belongs to any eligible WIC category described in subsection (1)(a) of this rule; and

(c) Is four months of age or older.

(9) A participant will be informed of and required to verify that he or she understands the rights and responsibilities of WIC participation at the time of their eligibility certification.

Stat. Auth.: ORS 413.500

Stats. Implemented: ORS 413.500

Hist.: PH 17-2008, f. & cert. ef. 11-5-08; PH 10-2013, f. 11-6-13, cert. ef. 12-1-13; PH 26-2015, f. 12-8-15, cert. ef. 1-1-16

333-053-0060
Participant Information

(1) Applicants shall provide accurate information as part of the certification process.

(2) State or local WIC staff may verify any of the information provided by the applicant, participant, or participant's caretaker.

(3) The WIC program may share information about applicants and participants with other public health programs and Oregon Head Start programs. This information will only be used to access other health services and assess the effectiveness of those services.

(4) Information concerning eligibility shall be shared with another WIC clinic or local agency if the participant moves from one service area to another or to a different state.

(5) Applicants, participants and the participant's caretakers will be given the opportunity to register to vote at the local agency, and they may decline to provide this information. Receipt of WIC program benefits will not be affected by answers to voter registration questions.

Stat. Auth.: ORS 413.500

Stats. Implemented: ORS 413.500

Hist.: PH 17-2008, f. & cert. ef. 11-5-08; PH 10-2013, f. 11-6-13, cert. ef. 12-1-13

333-053-0075
eWIC Cards

(1) At the time of certification, a first cardholder will be identified and issued a eWIC card for the family.

(a) If a family requires more than one authorized shopper, a second eWIC card for use by the family's second cardholder will be issued.

(b) Each family will have no more than two activated eWIC cards at a time.

(c) No more than one activated eWIC card can be assigned to a cardholder at a time.

(2) The Authority may issue replacement eWIC cards at its discretion.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 10-2013, f. 11-6-13, cert. ef. 12-1-13

333-053-0080
Participant Violations

(1) During each certification visit, participants shall be informed of their rights and responsibilities, program rules and the sanctions issued should they intentionally violate a program rule.

(2) Whenever the Authority assesses a claim of misappropriated WIC program benefits of $100 or more resulting from a participant violation, assesses a claim for dual participation, or assesses a second or subsequent claim of any amount resulting from a participant violation, the Authority shall disqualify the participant for one year.

(3) A participant shall be issued a Notice of Non-compliance for the first instance; a six month disqualification from the program and issued a claim for the second instance; and a one year disqualification from the program and issued a claim for the third and any subsequent instance of the following violations:

(a) Simultaneously using his or her own WIC benefits and acting as a store cashier for the transaction if employed by or owns store;

(b) Destruction of vendor or farmer property during a WIC transaction;

(c) Verbal abuse of store, farmer, or farm stand employees or owners during a WIC or FDNP transaction;

(d) Verbal abuse of state or local agency staff;

(e) Destruction of state or local agency property;

(f) Altering a food instrument;

(g) Returning foods purchased with a food instrument to a WIC vendor in exchange for money or different food unless they are receiving the identical item in exchange;

(h) Using or attempting to use a food instrument reported lost or stolen; or

(i) Redeeming a food instrument for unauthorized foods or formula.

(4) A participant shall be issued a Notice of Non-compliance and issued a claim for the first instance; and disqualified from the program for one year and issued a claim for the second and any subsequent instance of misrepresenting eligibility information to gain WIC or FDNP benefits.

(5) A participant shall be disqualified from the program for six months for the first instance and disqualified from the program for one year for the second or any subsequent instance of the following violations:

(a) Assaulting or using physical force, actual or threatened, against store, farmer, or farm stand employees or owners during a WIC or FDNP transaction; or

(b) Assaulting or using physical force, actual or threatened, against state or local agency staff.

(6) A participant shall be disqualified from the program for one year and issued a claim for the first and any subsequent instance of the following violations:

(a) Collusion with local agency staff to improperly obtain WIC program or FDNP benefits;

(b) Collusion with store staff to use a food instrument for the purchase of anything other than specifically indicated WIC program benefits;

(c) Theft of a food instrument;

(d) Buying, attempting to buy, exchanging, attempting to exchange, selling, or attempting to sell food or formula purchased with a food instrument for cash, credit, merchandise, favors, or other non-food items;

(e) Trafficking or attempting to traffic a food instrument; or

(f) Collusion with store staff to accept the return of food or formula purchased with a food instrument for cash, credit, merchandise, favors, or other non-food items.

(7) The Authority may decide not to impose a disqualification if, within 30 days of the date the letter was mailed demanding repayment, full restitution is made or a repayment schedule is agreed upon. In the case of a violation committed by the parent or caretaker of an infant or child participant, or by a participant under the age of 18, the Authority may approve the designation of a proxy in order to continue program benefits to these participants.

(8) Participants may reapply for benefits at any time after the disqualification period is over.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 17-2008, f. & cert. ef. 11-5-08; PH 10-2013, f. 11-6-13, cert. ef. 12-1-13; PH 26-2015, f. 12-8-15, cert. ef. 1-1-16

333-053-0100
Participant Claims

(1) If the Authority determines that WIC program benefits have been obtained, sold, given away, traded, or otherwise disposed of improperly as the result of a participant violation, the Authority shall establish a claim against the participant for the full value of such benefits.

(2) For all participant claims, the Authority shall issue a written notification demanding repayment.

(3) If the full restitution is not made or a repayment schedule is not agreed on within 30 days of the date the letter was mailed, the Authority shall take additional collection actions until restitution is made or a repayment schedule is agreed on, unless the Authority determines that further collection actions would not be cost-effective to pursue.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 17-2008, f. & cert. ef. 11-5-08; PH 10-2013, f. 11-6-13, cert. ef. 12-1-13

333-053-0110
Administrative Review

(1) The Authority shall provide a participant with a fair hearing in accordance with the provision of ORS Chapter 183 and 7 CFR 246.9 for the following:

(a) Denial of participation;

(b) Disqualification; or

(c) A claim against the individual for repayment of the cash value of improperly obtained or disposed of WIC program benefits.

(2) The Authority shall notify the participant in writing of the right to a fair hearing, of the method by which a hearing may be requested, and that any positions or arguments on behalf of the individual may be presented personally or by a representative such as a relative, friend, legal counsel or other spokesperson.

(3) The Authority shall not limit or interfere with the participant's freedom to request a hearing.

(4) Participants must request a fair hearing within 60 days from the date the Authority notifies the applicant or participant of an adverse action.

(5) The Authority shall not deny or dismiss the request for a fair hearing unless:

(a) The request is not received within 60 days;

(b) The request is withdrawn in writing by the participant or participant's representative;

(c) The participant or the participant's representative fails, without good cause, to appear at the scheduled hearing; or

(d) The participant has been denied participation by a previous hearing and cannot provide evidence that the circumstances relevant to program eligibility have changed in such a way as to justify a hearing.

(6) Participants may continue receiving WIC benefits pending a hearing outcome or their certification period expires, whichever comes first.

(7) Applicants who are denied benefits at initial certification, participants whose certification periods have expired, and participants who become categorically ineligible during a certification

period may request an administrative hearing to appeal the denial or termination of WIC program benefits, however they shall not receive WIC program benefits while awaiting the hearing or its outcome.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 17-2008, f. & cert. ef. 11-5-08; PH 10-2013, f. 11-6-13, cert. ef. 12-1-13

DIVISION 54

SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS AND CHILDREN (WIC)

333-054-0000
Description of WIC Program

(1) The WIC Program is a federally funded program established in 1972 by an amendment to the Child Nutrition Act of 1966. The purpose of the WIC Program is to serve as an adjunct to health care by providing: nutrition education and counseling; nutritious supplemental foods; and health screening and referral services to pregnant and breast-feeding women, infants, and children in certain high-risk categories.

(2) Federal regulations governing the WIC Program, 7 CFR § Part 246, require adoption and implementation of standards and procedures to guide the state's administration of the WIC Program. These regulations also define the rights and responsibilities of vendors and farmers.

(3) The WIC Program in the State of Oregon is administered by the Oregon Health Authority (Authority).

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: HD 7-1993, f. & cert. ef. 6-11-93; OHD 17-2001, f. 8-02-01, cert. ef. 8-15-01; OHD 22-2002, f. & cert. ef. 12-24-02; PH 19-2003(Temp), f. & cert. ef. 11-14-03 thru 5-12-04; PH 22-2003, f. 12-31-03, cert. ef. 1-5-04; PH 30-2006, f. & cert. ef. 12-27-06; PH 11-2013, f. 11-6-13, cert. ef. 12-1-13

333-054-0010
Definitions

(1) "A50" means an authorized vendor or applicant that derives, or is expected to derive, more than 50 percent of its total annual food sales from WIC food sales. The total food sales do not include alcohol, tobacco, lottery or any other non-food item.

(2) "Abbreviated administrative review" means a hearing that is held at the request of a vendor that has been issued an application denial, civil money penalty, civil penalty, or sanction by the Authority. Abbreviated reviews are facilitated by the Authority staff other than the staff person that imposed the sanction. A facilitated discussion is held in order to resolve the imposition of a sanction.

(3) "Adequate participant access" means there are authorized vendors sufficient for participant need using Authority criteria in OAR 333-054-0060.

(4) "Annual Food Sales" means sales of all Supplemental Nutrition Assistance Program (SNAP) eligible foods intended for home preparation and consumption including meat, fish, and poultry; bread and cereal products; dairy products; and fruits and vegetables. Food items such as condiments and spices, coffee, tea, cocoa, and carbonated and non-carbonated drinks may be included in food sales when offered for sale along with foods in the categories identified above. Food sales do not include sales of any items that cannot be purchased with SNAP benefits, such as hot foods or food that will be eaten in the store.

(5) "Applicant" means any person, or person with an interest in the business, making a written request for authorization to participate in the WIC Program, including vendors and farmers that reapply for authorization.

(6) "Authority" means the Oregon Health Authority.

(7) "Authorization" means the process by which the Authority assesses, selects, and enters into agreements with stores and farmers that apply or subsequently reapply to be vendors or authorized farmers.

(8) "Authorized food" means any supplemental foods approved by the Oregon WIC Program and listed on the WIC Authorized Food List or food instrument.

(9) "Authorized shopper" means the participant or any person designated by a participant who has been documented as such to act on the participant's behalf and, in the case of an infant or child, the caretaker or the caretaker's designee. This includes any representative posing as a participant or participant designee as authorized by the Authority.

(10) "CFR" means Code of Federal Regulations.

(11) "CMP" means civil money penalty.

(12) "Cash Value Benefit" or "CVB" means a fixed-dollar benefit on a check, voucher, electronic benefit transfer (EBT) card or other document which is used by an authorized shopper to obtain WIC authorized fruits and vegetables.

(13) "Compliance buy" means a single covert, on-site visit in which an Authority authorized representative poses as an authorized shopper and attempts to transact, or transacts, one or more food instruments.

(14) "Disqualification" means cancelling the WIC program participation of a vendor or farmer, as a punitive action.

(15) "Educational buy" means a single, on-site visit used for training purposes in which an Authority authorized representative poses as an authorized shopper, redeems WIC food instruments, and provides the vendor with immediate feedback about compliance with WIC procedures.

(16) "Expired food" means WIC-authorized food or formula that is defective, spoiled, or has exceeded its sell by, best if used by, or other date on the package limiting the sale or use of the food or formula.

(17) "Farmer" means an individual who owns, leases, rents or sharecrops land to grow, cultivate or harvest crops on that land.

(18) "Farmer agreement" means a standard written legal contract between the farmer and the Authority that sets forth responsibilities of the parties.

(19) "FNS" means the Food and Nutrition Service of the U. S. Department of Agriculture.

(20) "Food instrument" or "FI" means a WIC Program voucher, check, coupon, electronic benefit transfer (EBT) card or other document, which is used to obtain authorized foods.

(21) "Full administrative review" means a formal hearing that is held before an assigned administrative law judge from the state Office of Administrative Hearings in accordance with 7 CFR § 246.18 and ORS Chapter 183.

(22) "Incentive item" means a food or non-food item offered free of charge to WIC shoppers, but not other shoppers, or eligibility to receive an item is structured where the majority of those meeting the criteria are WIC shoppers, to motivate them to shop at a particular store. Examples of incentive items include, but are not limited to, cash gifts/prizes in any amount for any reason, lottery tickets, transportation, sales/specials such as a buy-one-get-one free or free additional ounces offer not offered to other shoppers, and other free food or merchandise not offered to other shoppers.

(23) "Inventory audit" means an examination of food invoices or other proofs of vendor purchases to determine whether a vendor has purchased sufficient quantities of authorized foods to support the vendor's claim for reimbursement for such foods from the Authority during a specific period of time.

(24) "Investigation" means a period of review, beginning with the start of an inventory audit or the first compliance buy and closing when the audit has been completed or a sufficient number of compliance buys have been completed to provide evidence of compliance or non-compliance, not to exceed 24 months, to determine a vendor or farmer's compliance with program rules and procedures.

(25) "Local agency" means:

(a) A public or private nonprofit health or human services agency that provides health services, either directly or through contract, in accordance with 7 CFR § 246.5;

(b) An Indian Health Service unit;

(c) An Indian tribe, band or group recognized by the Department of the Interior which operates a health clinic or is provided health services by an Indian Health Service unit; or

(d) An intertribal council or group that is an authorized representative of Indian tribes, bands or groups recognized by the Department of the Interior, which operates a health clinic or is provided health services by an Indian Health Service unit.

(26) "Notice of Non-compliance" means a letter notifying vendors when they commit a program violation. This notice is an explanation of the violation and a warning about repercussions of subsequent violations.

(27) "Overcharge" means intentionally or unintentionally charging the Authority more for authorized foods than the actual shelf price or the price charged to other shoppers.

(28) "Participant" means any pregnant woman, breastfeeding woman, post-partum non-lactating woman, infant or child who has been certified to receive benefits from the WIC Program.

(29) "Pattern" means three or more findings of the same rule violation that occurs within a single investigation or over the course of one or more routine monitoring(s).

(30) "Peer group" means a group of vendors considered to be in the same category by the Authority based on factors such as store type, size or business model, number of cash registers and geography.

(31) "Person" means a human being, a public or private corporation, an unincorporated association, a partnership, a Limited Liability Corporation, a sole proprietor, a government or a governmental instrumentality.

(32) "Person with an interest in the business" means an officer, director, partner, or manager of the business or a shareholder with 10 percent interest or more in the business.

(33) "Pharmacy — in-store" means a pharmacy that is located within a WIC authorized grocery store and is affiliated with that business entity.

(34) "Pharmacy — stand alone" means a pharmacy that is operated independently from or is not located in a WIC authorized grocery store.

(35) "Price adjustment" means an adjustment made by the Authority, in accordance with the vendor/farmer agreement, to the amount paid to the vendor/farmer on a food purchase, to ensure that the payment complies with the Authority price limitations.

(36) "Prominently displayed" means immediately noticeable by persons entering the vendor or farmer location.

(37) "Routine monitoring" means an overt, on-site visit in which the Authority authorized representatives or federal officials identify themselves to vendor or farm personnel.

(38) "Shelf Price Survey" or "SPS" means a tool used by the Authority to collect a sample of a WIC authorized vendor's current shelf prices.

(39) "SNAP" means the Supplemental Nutrition Assistance Program of the Food and Nutrition Services of the U.S. Department of Agriculture. This program was formerly known as the Food Stamp Program or "FSP."

(40) "Termination" means the cancellation of a vendor or farmer agreement which may or may not be linked to a disqualification.

(41) "Trafficking" means buying or selling WIC food instruments for cash.

(42) "U.S.C." means United States Code.

(43) "Unauthorized food item" means foods, brands and sizes not allowed on the WIC Authorized Food List. It also means foods not specified on a food instrument as eligible for purchase for that participant, with WIC benefits.

(44) "Vendor" means the current owner(s) or any person with an interest in the business, of any retail store location that is currently authorized by the Authority to participate in the WIC Program. Vendor may also refer to the authorized store location.

(45) "Vendor agreement" means a standard written legal contract between the vendor and the Authority that sets forth responsibilities of the parties.

(46) "Vendor Price List" means a form containing current authorized foods with current shelf prices completed by the vendor and submitted to the Authority and in which vendors document their shelf prices at the time of the application process.

(47) "Violation" means an activity that is prohibited by OAR 333-054-0000 through 333-054-0070 and is classified in OAR 333-054-0050 and 333-054-0055.

(48) "WIC Authorized Food List" means the supplemental foods approved by the State of Oregon.

(49) "WIC food benefit" means supplemental foods issued to a participant for purchase at an authorized vendor.

(50) "WIC Program" or "WIC" means the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) authorized by Section 17 of the Federal Child Nutrition Act of 1966, as amended, 42 U.S.C. § 1786.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: HD 7-1993, f. & cert. ef. 6-11-93; HD 31-1994, f. & cert. ef. 12-22-94; OHD 17-2001, f. 8-02-01, cert. ef. 8-15-01; OHD 22-2002, f. & cert. ef. 12-24-02; PH 19-2003(Temp), f. & cert. ef. 11-14-03 thru 5-12-04; PH 22-2003, f. 12-31-03, cert. ef. 1-5-04; PH 7-2005(Temp), f. & cert. ef. 5-2-05 thru 10-28-05; PH 16-2005, f. & cert. ef. 10-28-05; PH 30-2006, f. & cert. ef. 12-27-06; PH 5-2009, f. & cert. ef. 6-1-09; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 9-2011, f. & cert. ef. 9-30-11; PH 11-2013, f. 11-6-13, cert. ef. 12-1-13; PH 25-2015, f. 12-8-15, cert. ef. 1-1-16

333-054-0020
How a Vendor Becomes WIC Authorized

(1) Only vendors authorized by the Authority may accept Oregon food instruments in exchange for authorized foods.

(2) Application:

(a) An applicant shall submit a completed application to the Authority, which includes:

(A) An application form;

(B) A Vendor Price List;

(C) A current SNAP authorization number; and

(D) Any other documents or information required by the Authority.

(b) The Authority may limit the periods during which applications for vendor authorization will be accepted and processed. The Authority will process applications, outside of the limited application period, if it determines the applicant's store is necessary to ensure adequate participant access in a specific geographic location.

(c) The Authority may impose a moratorium on the authorization of new vendors. Notice will be provided to current vendors prior to such a moratorium. During the period of moratorium the Authority may choose to not accept applications, not process applications, and not to authorize new stores. A moratorium will not apply to a store that is necessary for participant access.

(3) Selection Criteria: In order for the Authority to consider authorizing an applicant, the applicant shall:

(a) Demonstrate and maintain competitive pricing as determined by the Authority based on the applicant's current existing shelf prices on the date of application, as charged to regular shoppers and as compared to data from the peer group appropriate to the applicant's characteristics. Such data may include redemption prices and shelf prices. If an applicant's store is necessary to ensure adequate participant access, it may be exempt from this requirement;

(b) Possess a current bank account number;

(c) Possess a current electronic mail address;

(d) Not have, within the previous six years, a criminal conviction or civil judgment involving fraud or any other offense related to the applicant's business integrity or honesty;

(e) Possess a current SNAP authorization number. Pharmacies, military commissaries, and stores that are determined by the Authority as necessary to provide adequate participant access shall be exempt from this selection requirement due to the nature of the services they provide for the WIC Program;

(f) Not have a history of serious violations with either the WIC Program or SNAP;

(g) Not be currently disqualified from participation in another state's WIC Program. The Authority shall not authorize an applicant

that has been assessed a CMP in lieu of disqualification by another state WIC Program until the period of the disqualification that would otherwise have been imposed has expired;

(h) Not be currently disqualified from participation in the SNAP. The Authority shall not authorize an applicant that has been assessed a SNAP civil money penalty in lieu of disqualification until the period of the disqualification that would otherwise have been imposed has expired unless this store has been determined necessary for participant access;

(i) Have a fixed location for each store that includes refrigeration and freezer equipment in the retail area;

(j) Carry foods intended for home preparation and consumption, in addition to WIC-required minimum stock items, that include:

(A) Fresh or frozen uncooked meat, fish, or poultry (or meat substitute);

(B) Bread and cereal products;

(C) Dairy products; and

(D) Fresh fruits and vegetables.

(k) Meet minimum stock requirements at the time of application to become an authorized vendor:

(A) A store that is applying for authorization must meet minimum stock requirements at the time of application, either on the shelf or with proof of order at the time of the on-site review;

(B) Expired foods will not be counted towards meeting minimum stock requirements.

(C) Stand-alone pharmacies and in-store pharmacies are exempt from minimum stock requirements; and

(D) Grocery stores with in-store pharmacies are required to meet all minimum stock requirements.

(l) Not have expired foods in three or more food categories that are on the minimum stock requirements.

(m) Obtain infant formula, including formula that requires a prescription, within 72 hours of an Authority, local agency or WIC shopper request if the vendor is a stand-alone pharmacy or has an in-store pharmacy.

(n) Purchase infant formula, which is to be sold to WIC shoppers, only from the Oregon WIC Program's list of approved manufacturers, wholesalers, distributors, and WIC-authorized retailers.

(A) Vendors must maintain and provide, when requested, documentation showing source(s) of infant formula purchases; and

(B) Vendors must not sell infant formula that is defective, spoiled, or has exceeded its "sell by," "best if used by," or other date on the package limiting the sale or use of the infant formula.

(o) Maintain and provide documentation of SNAP-eligible food sales throughout the contract period. According to USDA, CFR 245.2, "Food sales" means sales of all foods that are eligible items under the SNAP. These foods are intended for home preparation and consumption and include:

(A) Meat, fish, and poultry;

(B) Bread and cereal products;

(C) Dairy products; and

(D) Fruits and vegetables;

(E) Food items such as condiments and spices, coffee, tea, cocoa, and carbonated and noncarbonated beverages may be included in food sales when offered for sale along with foods in the four primary categories. Food sales do not include sales of any items that are not approved for purchase with SNAP benefits, such as alcoholic beverages, hot foods, or foods that will be eaten on the store premises; and

(p) Be open for business at least eight hours per day for five days per week.

(4) Authorization Requirements:

(a) The Authority or its designated representative shall conduct a documented on-site visit prior to, or at the time of, authorization of an applicant, including evaluating the inventory and condition of authorized foods and providing the applicant with the WIC Program information prior to or at the time of authorization;

(b) The Authority may grant a written exception to minimum stock requirements for cases where there is no participant need in the vendor's area for a specific authorized food item. The Authority shall determine participant need based on:

(A) Local agency's input regarding a vendor request for exception;

(B) Vendor redemption data relative to the vendor's request; and

(C) Number of participants prescribed the specific food item in the vendor's store's zip code.

(c) If a vendor with a stock exception is notified of a specific need for that authorized food item, the vendor will ensure that the authorized food item is available within seven days of the request.

(d) Once authorized, the vendor shall remain in compliance with the current selection criteria set forth in OAR 333-054-0020(3) for the duration of the vendor agreement.

(5) Application Denials: The Authority shall give the applicant written notification of denial, in conformance with ORS Chapter 183. As otherwise provided in these rules, the Authority may deny an applicant authorization for reasons including, but not limited to, the following:

(a) The applicant's failure to meet the selection criteria;

(b) The applicant's store or business has been sold by its previous owner in an attempt to circumvent a WIC program sanction. In making this determination, the Authority may consider such factors as whether the applicant's store or business was sold to a relative by blood or marriage of the previous owner(s) or sold to any person for less than its fair market value;

(c) The applicant's history of complaints, violations and sanctions;

(d) The applicant's refusal to accept training from the WIC program;

(e) The applicant's submission of prices to the Authority for WIC foods that are not the actual prices being charged to current customers;

(f) The applicant's submission of prices to the Authority for WIC foods that the vendor does not stock in the store;

(g) The applicant's failure to complete an application within an Authority-specified period of time, after notification of the application's deficiencies; or

(h) The applicant's misrepresentation of information on the application.

(6) Subsequent to authorization, an agreement may be terminated if it is found that the vendor provided false or omitted pertinent information during the authorization process.

(7) If the Authority denies an application it may require the applicant to wait some period of time before reapplying.

Stat. Auth.: ORS 413.500

Stats. Implemented: ORS 413.500

Hist.: HD 7-1993, f. & cert. ef. 6-11-93; OHD 17-2001, f. 8-02-01, cert. ef. 8-15-01; OHD 22-2002, f. & cert. ef. 12-24-02; PH 19-2003(Temp), f. & cert. ef. 11-14-03 thru 5-12-04; PH 22-2003, f. 12-31-03, cert. ef. 1-5-04; PH 7-2005(Temp), f. & cert. ef. 5-2-05 thru 10-28-05; PH 16-2005, f. & cert. ef. 10-28-05; PH 16-2006(Temp), f. 6-30-06, cert. ef. 7-1-06 thru 12-27-06; PH 30-2006, f. & cert. ef. 12-27-06; PH 5-2009, f. & cert. ef. 6-1-09; PH 9-2011, f. & cert. ef. 9-30-11; PH 11-2013, f. 11-6-13, cert. ef. 12-1-13; PH 25-2015, f. 12-8-15, cert. ef. 1-1-16

333-054-0025
Above 50% Vendors (A50)

(1) An applicant that is likely to derive more than 50 percent of the store's annual food sales from WIC transactions will not be authorized except for cases of participant access hardship as determined solely by the Authority.

(2) If a currently authorized vendor is found to derive more than 50 percent of the store's annual food sales from WIC transactions the Authority will terminate the vendor agreement unless the vendor is necessary for participant access.

Stat. Auth.: ORS 413.500

Stats. Implemented: ORS 413.500

Hist.: PH 30-2006, f. & cert. ef. 12-27-06; PH 5-2009, f. & cert. ef. 6-1-09; PH 9-2011, f. & cert. ef. 9-30-11; PH 11-2013, f. 11-6-13, cert. ef. 12-1-13

333-054-0027
How a Farmer Becomes WIC Authorized

(1) Only authorized farmers may accept CVBs from authorized shoppers in exchange for eligible foods. Authorized farmers may not accept CVBs from unauthorized farmers.

(2) In order to be eligible for participation in the WIC program, a farmer applicant must:

(a) Grow, cultivate, or harvest fresh fruits or vegetables in Oregon or a bordering county in a contiguous state to sell at a farmers' market or farm stand. Farmers are exempt from the minimum WIC authorized food stocking requirements as indicated for vendor authorization under OAR 333-054-0020(3);

(b) Complete the farmer application and return it to the appropriate state office to verify eligibility; and

(c) Agree to follow the terms and conditions of the farmer agreement.

(3) The Authority shall conduct an interactive training for all farmers who have never previously participated in the program prior to their commencing participation.

(4) The Authority and the WIC program are not required to authorize all applicants.

(5) Any individual who purchases all the produce they plan to sell is considered a distributor and is not allowed to participate in the WIC program as a farmer.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 5-2009, f. & cert. ef. 6-1-09; PH 9-2011, f. & cert. ef. 9-30-11; PH 11-2013, f. 11-6-13, cert. ef. 12-1-13

333-054-0030
Vendor Agreements

(1) Each applicant who has been approved for authorization shall sign a vendor agreement.

(a) The vendor agreement shall include the contractual obligations that must be met by an authorized vendor.

(b) Failure to adhere to the vendor agreement is a violation and may result in a sanction.

(c) The vendor agreement shall be signed by a representative of the Authority and a representative of the vendor who has the legal authority to sign the vendor agreement and obligate the applicant to the terms of the vendor agreement.

(d) The term of a vendor agreement shall not exceed three years.

(2) The Authority shall provide a vendor with not less than 15 days advance written notice of the expiration of its vendor agreement.

(3) The Authority shall immediately terminate the vendor agreement if it determines that the vendor has provided false information in connection with its application for authorization.

(4) When a vendor has more than one store location, the vendor agreement shall include a list of each store's name and location. Individual store locations may be added or deleted, by amendment to the vendor agreement or disqualification of an individual store location, without affecting the remaining store locations. Each store location included in the vendor agreement shall meet all applicable laws and rules.

(5) The vendor agreement does not constitute a license or property interest.

(6) The vendor agrees to comply with terms in a final order issued by the Authority or an investigation by federal or state officials.

(7) A vendor shall provide the Authority or a federal official access to food instruments negotiated on requested dates.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: HD 7-1993, f. & cert. ef. 6-11-93; OHD 17-2001, f. 8-2-01, cert. ef. 8-15-01; OHD 22-2002, f. & cert. ef. 12-24-02; PH 19-2003(Temp), f. & cert. ef. 11-14-03 thru 5-12-04; PH 22-2003, f. 12-31-03, cert. ef. 1-5-04; PH 7-2005(Temp), f. & cert. ef. 5-2-05 thru 10-28-05; PH 16-2005, f. & cert. ef. 10-28-05; PH 16-2006(Temp), f. 6-30-06, cert. ef. 7-1-06 thru 12-27-06; PH 30-2006, f. & cert. ef. 12-27-06; PH 5-2009, f. & cert. ef. 6-1-09; PH 11-2013, f. 11-6-13, cert. ef. 12-1-13

333-054-0033
Provision of Incentive Items

(1) Vendors shall not provide or advertise the provision of incentive items to WIC shoppers that are not offered to other shoppers.

(2) The Authority may approve any of the following incentive items to be provided by authorized vendors to WIC shoppers, at the discretion of the Authority:

(a) Food, merchandise, or services obtained at no cost to the vendor, subject to documentation;

(b) Food, merchandise, or services with a nominal value of $2 or less per item, which is subject to documentation;

(c) Food sales and specials which involve no cost or less than $2 in cost to the vendor for the food items involved, subject to documentation, and do not result in a charge to a WIC food instrument for foods in excess of the foods listed on the food instrument; and

(d) Minimal customary courtesies of the retail food trade, such as helping the shopper to obtain an item from a shelf or from behind a counter, bagging food for the shopper, and assisting the shopper with loading the food into a vehicle.

(3) The following incentive items are prohibited for authorized vendors to provide to WIC shoppers:

(a) Services which result in a conflict of interest or the appearance of such conflict for the authorized vendor, such as assistance with applying for WIC benefits;

(b) Lottery tickets provided to WIC shoppers at no charge or below face value;

(c) Cash gifts in any form, in any amount and for any reason;

(d) Anything made available in a public area as a complimentary gift which may be consumed or taken without charge;

(e) An allowable incentive item provided more than once per WIC shopper per visit, regardless of the number of shoppers or food instruments involved, unless the incentive items had been obtained by the vendor at no cost or the total value of the multiple incentive items provided during the shopping visit would not exceed the less than $2 nominal value limit;

(f) Food, merchandise, or services of greater than the nominal value provided to the WIC shopper;

(g) Food or merchandise sold to WIC shoppers, but not other shoppers, below fair market value;

(h) Any kind of incentive item which incurs a liability for the WIC Program; and

(i) Any kind of incentive item which violates federal, state, or local law or regulations.

(4) For-profit goods or services offered by the authorized vendor to WIC shoppers at fair market value based on comparable for-profit goods or services of other businesses are not incentive items subject to approval or prohibition, except that such goods or services must not constitute a conflict of interest or result in a liability for the WIC Program.

Stat. Auth: ORS 413.500
Stat Implemented: ORS 413.500
Hist.: PH 11-2013, f. 11-6-13, cert. ef. 12-1-13

333-054-0035
Farmer Agreements

(1) A farmer application/agreement must be signed by a representative who has legal authority to obligate the farmer.

(2) The farmer application/agreement must include a requirement that the farmer comply with OAR 333-054-0000 through 333-054-0070, as applicable to farmers.

(3) The farmer application/agreement will be valid for no more than three years.

(4) Neither the Authority nor the farmer is obligated to renew the agreement.

(5) An authorized farmer must comply with requirements contained in 7 CFR 246, OAR 333-054-0000 through 333-054-0070, and the terms and conditions of the farmer application/agreement.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 5-2009, f. & cert. ef. 6-1-09; PH 9-2011, f. & cert. ef. 9-30-11

333-054-0040
Vendor and Farmer Monitoring

(1) The Authority shall, at its sole discretion, monitor vendors and farmers for compliance with applicable laws and rules.

(2) The Authority or its authorized representative must conduct compliance buys or inventory audits to collect evidence of improper vendor practices.

(3) The Authority or its authorized representative shall conduct routine monitorings and survey current WIC authorized food shelf prices of selected vendors.

(4) The Authority or its authorized representative shall conduct covert compliance buys and routine monitorings of authorized farmers for compliance with the Authority rules and regulations.

(5) The Authority or its authorized representative may conduct educational buys at selected authorized vendors.

(6) The Authority or its authorized representative may conduct an inventory count of authorized WIC foods at select vendors. The inventory count may include any WIC authorized foods physically located within the store at the time of the visit as well as the foods' current shelf prices.

Stat. Auth.: ORS 413.500

Stats. Implemented: ORS 413.500

Hist.: HD 7-1993, f. & cert. ef. 6-11-93; OHD 17-2001, f. 8-2-01, cert. ef. 8-15-01; OHD 22-2002, f. & cert. ef. 12-24-02; PH 19-2003(Temp), f. & cert. ef. 11-14-03 thru 5-12-04; PH 22-2003, f. 12-31-03, cert. ef. 1-5-04; PH 16-2005, f. & cert. ef. 10-28-05; PH 30-2006, f. & cert. ef. 12-27-06; PH 5-2009, f. & cert. ef. 6-1-09; PH 9-2011, f. & cert. ef. 9-30-11; PH 11-2013, f. 11-6-13, cert. ef. 12-1-13

333-054-0050

Vendor Violation Notifications and Sanctions

(1) The Authority must notify a vendor in writing when an investigation reveals an initial incidence of a violation for which a pattern of incidences must be established in order to impose a sanction, before another such incidence is documented, unless the Authority determines, in its discretion, on a case-by-case basis, that notifying the vendor would compromise an investigation.

(2) Prior to imposing a sanction for a pattern of violative incidences, the Authority must either provide such notice to the vendor, or document in the vendor file the reason(s) for determining that such a notice would compromise an investigation.

(3) If notification is provided, the Authority may continue its investigation after the notice of violation is received by the vendor, or presumed to be received by the vendor consistent with the Authority's procedures for providing such notice.

(4) All incidences of a violation occurring during the first compliance buy visit must constitute only one incidence of that violation for the purpose of establishing a pattern of incidences.

(5) A single violative incidence may only be used to establish the violations as written in OAR 333-054-0050(4)(d) and 333-054-0050(4)(e).

(6) Vendors shall receive a written "Notice of Non-compliance" for a single instance of:

(a) Failing to comply with the vendor's current vendor agreement;

(b) Failing to complete and return the Shelf Price Survey (SPS) by the deadline set by the Authority;

(c) Failing to provide the authorized shopper with a receipt for foods purchased with a food instrument;

(d) Failing to ensure that within 60 days of a name change the outside sign bears the same name as that listed on the vendor agreement;

(e) Influencing an authorized shopper's selection of authorized foods;

(f) Failing to display prices;

(g) Requesting or requiring any identification or information from the authorized shopper other than the WIC Program identification card;

(h) Failing to respond to a request issued by the Authority;

(i) Failing to accept training when required by the Authority;

(j) Using the "WIC" acronym or logos without prior authorization by the Authority;

(k) Failing to maintain or provide, to the Authority upon request, invoices or receipts to show source(s) of formula purchase;

(l) Retaining WIC identification or any information that identifies a shopper as a WIC participant or disclosing information regarding a client of the WIC Program to any person other than the Authority, its representatives or a federal official;

(m) Failing to comply with the terms in a final order issued by the Authority;

(n) Failing to comply with an investigation by federal or state officials;

(o) Refusing the Authority or a federal official access to food instruments negotiated on the day of review;

(p) Failing to provide, within two business days of the Authority's request, purchasing/receiving records to substantiate the volume and prices charged to the Authority;

(q) Failing to stock appropriate quantities of authorized foods and infant formula;

(r) Violating the nondiscrimination clause listed in the vendor agreement;

(s) Failing to maintain or provide, to the Authority upon request, documentation for each incentive item;

(t) Failing to have at least one register that accepts WIC open during all of the vendor's operating hours;

(u) Failing to display signs at registers to indicate where WIC is accepted, if the vendor doesn't accept WIC in all lanes; or

(v) Stocking expired foods on the shelf in three or more food categories that are on the minimum stock requirements.

(7) The Authority shall issue the following civil penalties to vendors for program violations committed within a single contract period:

(a) The Authority shall issue a civil penalty of $100 to vendors for the first instance of seeking restitution from an authorized shopper or participant for a WIC transaction not reimbursed or partially reimbursed by the Authority, or for which the Authority has requested payment from the vendor.

(b) The Authority shall issue a civil penalty of $100 to vendors for second instances of the following violations:

(A) Failing to display prices for WIC-authorized items;

(B) Failing to stock appropriate quantities of authorized foods and infant formula;

(C) Requesting or requiring any identification or information from the authorized shopper other than the WIC Program identification card;

(D) Requiring a cash purchase in addition to the WIC transaction;

(E) Requiring authorized shoppers to pay for authorized foods during a WIC transaction other than with a food instrument. It is permissible for a vendor to request payment over the dollar amount listed on a CVB if the cost of the authorized purchase exceeds the CVB amount.

(F) Using the "WIC" acronym or logos without prior authorization by the Authority;

(G) Failing to attend training when required by the Authority;

(H) Failing to maintain or provide, to the Authority upon request, documentation for each incentive item;

(I) Failing to have at least one register that accepts WIC open during all of the vendor's operating hours;

(J) Failing to display signs at registers to indicate where WIC is accepted, if the vendor doesn't accept WIC in all lanes;

(K) Failing to provide the authorized shopper with a receipt for foods purchased with a food instrument; or

(L) Stocking expired foods on the shelf in three or more food categories that are on the minimum stock requirements.

(c) The Authority shall issue a civil penalty of $200 to vendors for a second instance of seeking restitution from an authorized shopper or participant for a WIC transaction not reimbursed or partially reimbursed by the Authority, or for which the Authority has requested payment from the vendor.

(d) The Authority shall issue a civil penalty of $200 to vendors for third instances of the following violations:

(A) Failing to display prices for WIC-authorized items;

(B) Using the "WIC" acronym or logos without prior authorization by the Authority;

(C) Requesting or requiring any identification or information from the authorized shopper other than the WIC Program identification card;

(D) Requiring a cash purchase in addition to the WIC transaction;

(E) Requiring authorized shoppers to pay for authorized foods during a WIC transaction other than with a food instrument. It is permissible for a vendor to request payment over the dollar amount listed on a CVB if the cost of the authorized purchase exceeds the CVB amount.

(F) Failing to have at least one register that accepts WIC open during all of the vendor's operating hours;

(G) Failing to display signs at registers to indicate where WIC is accepted, if the vendor doesn't accept WIC in all lanes; or

(H) Failing to provide the authorized shopper with a receipt for foods purchased with a food instrument.

(e) The Authority shall issue a civil penalty of $400 to vendors for the fourth offense of the following violations:

(A) Failing to display prices for WIC-authorized items;

(B) Failing to provide the authorized shopper with a receipt for foods purchased with a food instrument;

(C) Failing to have at least one register that accepts WIC open during all of the vendor's operating hours; or

(D) Failing to display signs at registers to indicate where WIC is accepted, if the vendor doesn't accept WIC in all lanes.

(f) The Authority shall issue a civil penalty of $800 to vendors for the fifth offense of the following violations:

(A) Failing to display prices for WIC-authorized items;

(B) Failing to provide the authorized shopper with a receipt for foods purchased with a food instrument;

(C) Failing to have at least one register that accepts WIC open during all of the vendor's operating hours; or

(D) Failing to display signs at registers to indicate where WIC is accepted, if the vendor doesn't accept WIC in all lanes.

(g) The Authority shall issue a civil penalty of $1600 to vendors for the sixth offense of the following violations:

(A) Failing to display prices for WIC-authorized items;

(B) Failing to provide the authorized shopper with a receipt for foods purchased with a food instrument;

(C) Failing to have at least one register that accepts WIC open during all of the vendor's operating hours; or

(D) Failing to display signs at registers to indicate where WIC is accepted, if the vendor doesn't accept WIC in all lanes.

(8) Sanctions:

(a) The Authority shall deny a vendor's application for authorization upon renewal and require a six-month waiting period before the vendor may reapply if a vendor fails for a third instance to attend training when required by the Authority.

(b) For the following violations, the Authority shall disqualify a vendor for one year:

(A) A pattern of providing unauthorized food items in exchange for food instruments, including charging for authorized food provided in excess of those listed on the food instrument;

(B) A pattern of failing to stock appropriate quantities of authorized foods and infant formula;

(C) A pattern of providing change when redeeming a food instrument;

(D) A pattern of allowing a refund or any other item of value in exchange for authorized foods or providing exchanges for authorized food items obtained with food instruments, except for exchanges of an identical authorized food item when the original authorized food item is defective, spoiled, or has exceeded its "sell by," "best if used by," or other date limiting the sale or use of the food item. An identical authorized food item means the exact brand and size as the original authorized food item obtained and returned by the authorized shopper;

(E) Providing WIC shoppers with incentive items or other merchandise or services not approved by the Authority;

(F) A pattern of failing to maintain or provide, to the Authority upon request, documentation for each incentive item;

(G) Failure to pay a civil penalty assessed by the Authority within the designated timeframe set forth in the notice of civil penalty;

(H) A pattern of failing to comply with the vendor's current vendor agreement; or

(I) A pattern of stocking expired foods on the shelf in three or more food categories that are on the minimum stock requirements.

(c) For the following violations, the Authority shall disqualify the vendor for three years:

(A) One incident of the sale of alcohol, an alcoholic beverage, or a tobacco product in exchange for a food instrument;

(B) Failing an Authority inventory audit;

(C) A pattern of claiming reimbursement for the sale of an amount of a specific authorized food item, which exceeds the store's documented inventory of that authorized food item for a specific period of time;

(D) A pattern of vendor overcharges;

(E) A pattern of receiving, transacting or redeeming food instruments outside of authorized channels or locations. This includes, but is not limited to use of an unauthorized vendor, use of an unauthorized person, or redemption of food instruments outside of an authorized store location;

(F) A pattern of seeking restitution from an authorized shopper or participant for a WIC transaction not reimbursed or partially reimbursed by the Authority, or for which the Authority has requested payment from the vendor;

(G) A pattern of charging for foods not received by the authorized shopper; or

(H) A pattern of providing credit or non-food items in exchange for food instruments, other than those items listed in OAR 333-054-0050(4)(d) and 333-054-0050(4)(e).

(d) For the following violations, the Authority shall disqualify the vendor for six years:

(A) One incident of buying or selling a food instrument for cash (trafficking); or

(B) One incident of selling a firearm, ammunition, explosive, or controlled substance, as defined in 21 U.S.C. § 802, in exchange for a food instrument.

(e) The Authority shall permanently disqualify a vendor convicted of trafficking in food instruments or selling firearms, ammunition, explosives, or controlled substances as defined in 21 U.S.C. § 802 in exchange for a food instrument.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 413.500

Stats. Implemented: ORS 413.500

Hist.: HD 7-1993, f. & cert. ef. 6-11-93; OHD 17-2001, f. 8-2-01, cert. ef. 8-15-01; OHD 22-2002, f. & cert. ef. 12-24-02; PH 19-2003(Temp), f. & cert. ef. 11-14-03 thru 5-12-04; PH 22-2003, f. 12-31-03, cert. ef. 1-5-04; PH 7-2005(Temp), f. & cert. ef. 5-2-05 thru 10-28-05; PH 16-2005, f. & cert. ef. 10-28-05; PH 30-2006, f. & cert. ef. 12-27-06; PH 5-2009, f. & cert. ef. 6-1-09; PH 9-2011, f. & cert. ef. 9-30-11; PH 11-2013, f. 11-6-13, cert. ef. 12-1-13; PH 25-2015, f. 12-8-15, cert. ef. 1-1-16

333-054-0052
Suspension of Vendor Agreements

(1) Notwithstanding any other rule in this division, WIC program benefits are suspended and all vendor agreements are suspended if there is a government or WIC program closure or if the government does not provide WIC funding. A suspension shall remain in effect until such time as funding is approved or as soon as the closure ends and only to the extent benefit issuance to participants is approved by the federal government.

(2) Suspensions apply to all WIC-authorized vendors, including farmers transacting cash value benefits. Suspensions do not apply to WIC-authorized farmers transacting Farm Direct Nutrition Program checks.

(3) Notice of suspensions shall be made by both electronic mail and United States Postal Service mail to all WIC-authorized vendors and farmers and shall include the suspension effective date. Notice of suspensions will be delivered with as much notice as possible. As soon as funding is restored or as soon as the closure has ended, the Authority shall notify vendors and farmers of the date that a suspension is lifted.

(4) Vendors and farmers shall not accept WIC food instruments, shall not provide food benefits and shall not deposit WIC food instruments for payment during a suspension.

(5) WIC-authorized vendors and farmers who disagree with a suspension are not entitled to a contested case hearing but may challenge a suspension through a rule challenge under ORS 183.335 or 183.400.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 5-2014, f. & cert. ef. 1-30-14

333-054-0055
Farmer Violations and Sanctions

(1) A farmer is in violation if a farmer fails to comply with WIC program rules and the terms and conditions of the farmer application/agreement or fails to respond to requests, implement corrective action, or comply with the terms in final orders as directed by the Authority.

(2) Farmer Sanctions:

(a) The Authority may issue a written notification of non-compliance to an authorized farmer for an initial incident of:

(A) Accepting CVBs for ineligible foods;

(B) Failing to prominently display the official sign provided by the Authority, each market day when at authorized farmers' markets or authorized farm stands;

(C) Failing to provide WIC shoppers with the full amount of product for the value of each CVB;

(D) Failing to ensure that WIC shoppers receive equitable treatment, including the availability of produce that is of the same quality and no greater price than sold to other shoppers;

(E) Failing to reimburse the Authority for CVBs that are improperly transacted;

(F) Charging sales tax on CVB purchases;

(G) Seeking restitution from WIC shoppers or participants for CVBs not paid by the Authority;

(H) Giving cash back for purchases less than the value of the CVB (providing change);

(I) Accepting CVBs from an unauthorized farmer;

(J) Failing to comply with WIC program rules and the terms and conditions of the farmer application/agreement;

(K) Failing to respond to requests, implement corrective action, or comply with the terms in final orders as directed by the Authority;

(L) Using CVBs for any purpose other than to deposit or cash them at the authorized farmer's financial institution; or

(M) Failing to cooperate with staff from the Authority, staff authorized to act on the Authority's behalf or the Oregon Department of Agriculture in monitoring for compliance with program requirements and failing to provide information that the Authority or the Oregon Department of Agriculture may require.

(b) The Authority may disqualify a farmer for six months for an initial incident of:

(A) Providing credit in exchange for CVBs; or

(B) Charging WIC shoppers higher prices than other shoppers.

(c) The Authority may disqualify a farmer for six months, for second or subsequent incidents of:

(A) Accepting CVBs for ineligible foods;

(B) Failing to prominently display the official sign provided by the Authority, each market day when at authorized farmers' markets or authorized farm stands;

(C) Failing to provide WIC shoppers with the full amount of product for the value of each CVB;

(D) Failing to ensure that WIC shoppers receive equitable treatment, including the availability of produce that is of the same quality and no greater price than sold to other shoppers;

(E) Charging sales tax on CVB purchases;

(F) Seeking restitution from WIC shoppers or participants for CVBs not paid by the Authority;

(G) Using CVBs for any purpose other than deposit or cash at the authorized farmer's financial institution;

(H) Giving cash back for purchases less than the value of the CVB (providing change);

(I) Accepting CVBs from an unauthorized farmer; or

(J) Failing to respond to requests, implement corrective action, or comply with the terms in final orders as directed by the Authority.

(d) The Authority may disqualify a farmer for one year following second or subsequent incidents of:

(A) Providing credit in exchange for CVBs;

(B) Charging WIC shoppers higher prices than other shoppers;

(C) Failing to reimburse the Authority for CVBs that are improperly transacted; or

(D) Failing to cooperate with staff from the Authority or the Oregon Department of Agriculture in monitoring for compliance with program requirements and failing to provide information required to be submitted by the Authority or the Oregon Department of Agriculture.

(e) The Authority may immediately disqualify a farmer for three years for an incident of:

(A) Trafficking in CVBs (exchanging checks for cash, controlled substances, tobacco products, firearms, or alcohol) in any amount; or

(B) A USDA substantiated violation of laws regarding non-discrimination, and applicable USDA instructions.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: PH 5-2009, f. & cert. ef. 6-1-09; PH 9-2011, f. & cert. ef. 9-30-11; PH 11-2013, f. 11-6-13, cert. ef. 12-1-13

333-054-0060
Vendor Disqualifications

(1) A vendor may not apply for authorization during a period of disqualification from the WIC Program.

(2) The Authority shall not accept a vendor's voluntary withdrawal from the WIC Program as an alternative to disqualification. In addition, the Authority may not use non-renewal as an alternative to disqualification.

(3) The Authority shall disqualify a vendor that does not pay, partially pays or fails to timely pay, a CMP assessed in lieu of disqualification, for the length of the disqualification corresponding to the violation for which the CMP was assessed.

(4) In order to participate in the WIC program after a vendor is disqualified, it must apply for authorization after the disqualification period has passed.

(5) The Authority shall disqualify a vendor for a period corresponding to the most serious sanction during the course of a single investigation when the Authority determines the vendor has committed multiple violations. The Authority shall include all violations in the notice of administrative action. If a sanction for a specific violation is not upheld after the hearing or appeal, the Authority may impose a sanction for any remaining violations.

(6) If the basis for disqualification of a vendor is for violation of OAR 333-054-0050(8)(d), the effective date of the disqualification is the date the vendor received notice, either actual or constructive, of the disqualification.

(7) The Authority may disqualify a vendor that has been disqualified or assessed a CMP in lieu of disqualification by another WIC state agency for a mandatory sanction.

(a) The length of the disqualification shall be for the same length of time as the disqualification by the other WIC state agency or, in the case of a CMP in lieu of disqualification assessed by the other WIC state agency, for the same length of time for which the vendor would otherwise have been disqualified. The disqualification may begin at a later date than the sanction imposed by the other WIC state agency.

(b) If the Authority determines that disqualification of a vendor would result in inadequate participant access, the Authority shall impose a CMP in lieu of disqualification.

(8) The Authority shall disqualify a vendor who has been disqualified from the SNAP. The disqualification shall be for the same length of time as the SNAP disqualification, although it may begin at a later date than the SNAP disqualification. Such disqualification

by the WIC program shall not be subject to administrative or judicial review under the WIC program.

(a) The Authority may disqualify a vendor who has been assessed a CMP in lieu of disqualification in the SNAP, as provided in 7 CFR § 278.6. The length of such disqualification shall correspond to the period for which the vendor would otherwise have been disqualified in the SNAP. The Authority shall determine if the disqualification of a vendor would result in inadequate participant access prior to disqualifying a vendor for SNAP disqualification pursuant to section (8) of this rule or for any of the violations listed in this rule. If the Authority determines that disqualification of the vendor would result in inadequate participant access, the Authority shall not disqualify or impose a CMP in lieu of disqualification. The Authority shall include participant access documentation in vendor files.

(b) The Authority shall provide the appropriate FNS office with a copy of the notice of adverse action and information on vendors it has disqualified. This information shall include the vendor's name, address, identification number, the type of violation(s), length of the disqualification, or the length of the disqualification corresponding to the violation for which a SNAP CMP was assessed.

(9) Disqualification from the WIC Program may result in disqualification as a retailer in the SNAP. Such disqualification may not be subject to administrative or judicial review under the SNAP.

(10) Prior to disqualifying a vendor, the Authority shall determine if disqualification of the vendor would result in inadequate participant access.

(a) If the Authority determines that disqualification of the vendor would result in inadequate participant access, the Authority shall not disqualify the vendor and shall impose a CMP in lieu of disqualification.

(b) The Authority shall include documentation of its participant access determination and any supporting documentation in the vendor's file.

(c) The Authority shall not impose a CMP in lieu of disqualification for third or subsequent sanctions, even if the disqualification results in inadequate participant access.

(d) The Authority shall not impose a CMP in lieu of disqualification for trafficking or an illegal sales conviction, even if the disqualification results in inadequate participant access.

(11) Pursuant to 7 CFR 246.12 (l)(1), the Authority shall use the following formula to calculate a CMP imposed in lieu of disqualification:

(a) Determine the vendor's average monthly redemptions for at least the six-month period ending with the month immediately preceding the month during which the notice of administrative action is dated;

(b) Multiply the average monthly redemptions figure by 10 percent (.10); and

(c) Multiply the product from subsection (11)(b) of this rule by the number of months for which the store would have been disqualified. This is the amount of the CMP, provided that the CMP shall not exceed $11,000 for each violation. For a violation that warrants permanent disqualification, the amount of the CMP shall be $11,000. The Authority shall impose a CMP for each violation when during the course of a single investigation the Authority determines a vendor has committed multiple violations. The total amount of CMPs imposed for violations cited as part of a single investigation shall not exceed $49,000.

(12) The Authority shall use the formula in subsections (11)(a) through (c) of this rule to calculate a CMP in lieu of disqualification for any violation under OAR 333-054-0050(4)(b). The Authority has the discretion to reduce the amount of this CMP in quarterly increments, after reviewing the following criteria:

(a) Whether the vendor had other WIC violations or complaints within the 12 months immediately preceding the month the notice of administrative action is dated;

(b) The degree of severity of the violations and complaints;

(c) If the vendor being sanctioned is part of a multi-store chain, whether there is a pattern within the corporation of violations and the seriousness of those violations; and

(d) The degree of cooperation shown by the vendor, demonstrated by the vendor's willingness to schedule staff training and to make changes in store operations based on the Authority recommendations.

(13) The Authority shall, where appropriate, refer vendors who abuse the WIC Program to appropriate federal, state or local authorities for prosecution under applicable statutes.

(14) A vendor who commits fraud or abuse of the program is subject to prosecution under applicable federal, state or local laws. A vendor who has embezzled, willfully misapplied, stolen or fraudulently obtained program funds, assets, or property shall be subject to a fine of not more than $25,000 or imprisonment for not more than five years or both, if the value of the funds is $100 or more. If the value is less than $100, the penalties are a fine of not more than $1,000 or imprisonment for not more than one year or both.

(15) A vendor may be subject to actions in addition to the sanctions in this rule, such as claims by the Authority of reimbursement for improperly redeemed food instruments and penalties outlined in 7 CFR § 246.12(1)(2)(i).

(16) The Authority shall use the following criteria to determine inadequate participant access:

(a) The availability of other authorized vendors within a 15-mile radius; and

(b) Geographic barriers.

(17) Any time the Authority uses criteria in section (16) of this rule, the Authority shall include participant access documentation in the vendor file.

(18) The Authority shall not reimburse for food instruments submitted by a vendor for payment during a period of disqualification.

(19) A vendor is not entitled to receive any compensation for revenues lost as a result of a disqualification.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 413.500

Stats. Implemented: ORS 413.500

Hist.: HD 7-1993, f. & cert. ef. 6-11-93; OHD 17-2001, f. 8-2-01, cert. ef. 8-15-01; OHD 22-2002, f. & cert. ef. 12-24-02; PH 19-2003(Temp), f. & cert. ef. 11-14-03 thru 5-12-04; PH 22-2003, f. 12-31-03, cert. ef. 1-5-04; PH 7-2005(Temp), f. & cert. ef. 5-2-05 thru 10-28-05; PH 16-2005, f. & cert. ef. 10-28-05; PH 30-2006, f. & cert. ef. 12-27-06; PH 5-2009, f. & cert. ef. 6-1-09; PH 9-2011, f. & cert. ef. 9-30-11; PH 11-2013, f. 11-6-13, cert. ef. 12-1-13; PH 25-2015, f. 12-8-15, cert. ef. 1-1-16

333-054-0065
Farmer Disqualifications

(1) Farmers who do not comply with WIC program requirements are subject to sanctions, including civil penalties, in addition to, or in lieu of, disqualification.

(2) Prior to disqualifying a farmer, the Authority may determine if disqualification of the farmer would result in inadequate participant access. If the Authority determines that disqualification of the farmer would result in inadequate participant access, the Authority may impose a CMP in lieu of disqualification in the amount of 5 percent of the farmer's CVBs sales over the last twelve months or $250, whichever is greater.

(3) The Authority must give written notice to a farmer of an action proposed to be taken against a farmer, not less than 15 days before the effective date of the action. The notice must state what action is being taken, the effective date of the action, and the procedure for requesting a hearing.

(4) A farmer that has been disqualified from the WIC program may reapply at the end of the disqualification period.

(5) The Authority may accept a farmer's voluntary withdrawal from the program as an alternative to disqualification. If a farmer chooses to withdraw in lieu of disqualification, the farmer may not apply for participation until the following year.

(6) The Authority will not reimburse farmers who have been disqualified or have withdrawn in lieu of disqualification.

(7) Civil penalties must be paid to the Authority within the time period specified in the Notice.

(8) A farmer who commits fraud or abuse of the WIC program is subject to prosecution under applicable federal, state or local laws.

Stat. Auth.: ORS 413.500

Stats. Implemented: ORS 413.500

Hist.: PH 5-2009, f. & cert. ef. 6-1-09; PH 11-2013, f. 11-6-13, cert. ef. 12-1-13

333-054-0070
Administrative Review

(1) The Authority shall provide a full administrative review in accordance with the provisions of ORS Chapter 183 for the following, as applicable:

(a) Denial of authorization based on a determination that the vendor or farmer is attempting to circumvent a sanction;

(b) Termination of an agreement for cause;

(c) Disqualification;

(d) Imposition of a civil penalty or a CMP in lieu of disqualification; and

(e) Denial of authorization based on the vendor selection criteria for competitive price or minimum variety and quantity of authorized WIC foods.

(2) The Authority may provide a vendor with an abbreviated or full administrative review in accordance with the provisions of ORS Chapter 183 for the following, as applicable:

(a) Denial of authorization based on selection criteria for business integrity or for a current SNAP disqualification or CMP penalty for hardship;

(b) Denial of authorization based on an Authority selection criteria for previous history of WIC sanctions or SNAP withdrawal of authorization or disqualification;

(c) Denial of authorization based on the Authority's limiting criteria;

(d) Termination of an agreement because of a change in ownership or location or cessation of operations;

(e) Disqualification based on a trafficking conviction;

(f) Disqualification based on the imposition of a SNAP CMP for hardship;

(g) Disqualification or CMP based on a USDA mandatory sanction from another state WIC agency; and

(h) Application of criteria used to determine whether a store is an A50.

(3) The vendor or farmer shall not be entitled to an administrative review for the following actions, as applicable:

(a) The validity or appropriateness of the Authority's limiting or selection criteria;

(b) The validity or appropriateness of the Authority's participant access criteria and the Authority's participant access determinations;

(c) The Authority's determination regarding whether an effective policy and program in effect to prevent trafficking regardless of the vendor or farmer's awareness, approval, or involvement in the violation activity;

(d) Denial of authorization if the Authority vendor authorization is subject to the procurement procedures applicable to the Authority;

(e) The expiration of the agreement;

(f) Disputes regarding food instrument payments and claims;

(g) Disqualification of a vendor as a result of disqualification from the SNAP;

(h) The Authority's determination whether to notify a vendor in writing when an investigation reveals an initial violation for which a pattern of violations must be established in order to impose a sanction;

(i) The Authority's determination to include or exclude an infant formula manufacturer, wholesaler, distributor, or retailer from the list required;

(j) The validity or appropriateness of the Authority's criteria used to determine whether or not a vendor is an A50 store; and

(k) The validity or appropriateness of the Authority's prohibition of incentive items and the Authority's denial of an A50 vendor's request to provide an incentive item to shoppers.

(4) A request for a hearing must be in writing and must be received within 30 days from the date of the notice describing the proposed action.

(5) The Authority may, at its discretion, permit the vendor or farmer to continue participating in the program pending the outcome of an administrative hearing. The vendor or farmer may be required to repay funds for FIs redeemed during the pendency of the hearing, depending on the hearing outcome.

(6) If an agreement expires during the appeal period, the Authority will accept application for renewal and delay determination until all appeals have been exhausted.

Stat. Auth.: ORS 413.500
Stats. Implemented: ORS 413.500
Hist.: HD 7-1993, f. & cert. ef. 6-11-93; OHD 17-2001, f. 8-2-01, cert. ef. 8-15-01; OHD 22-2002, f. & cert. ef. 12-24-02; PH 19-2003(Temp), f. & cert. ef. 11-14-03 thru 5-12-04; PH 22-2003, f. 12-31-03, cert. ef. 1-5-04; PH 16-2005, f. & cert. ef. 10-28-05; PH 30-2006, f. & cert. ef. 12-27-06; PH 5-2009, f. & cert. ef. 6-1-09; PH 9-2011, f. & cert. ef. 9-30-11; PH 11-2013, f. 11-6-13, cert. ef. 12-1-13; PH 25-2015, f. 12-8-15, cert. ef. 1-1-16

DIVISION 55

TRAINING ON LIFESAVING TREATMENTS

333-055-0000
Purpose

(1) The purpose of OAR 333-055-0000 through 333-055-0035 is to describe the circumstances under which these rules apply and to define the procedures for authorizing certain individuals, when a licensed health care professional is not immediately available, to administer:

(a) Epinephrine to a person who has a severe allergic response to an allergen;

(b) Glucagon to a person who is experiencing severe hypoglycemia when other treatment has failed or cannot be initiated; and

(c) Medication that treats adrenal insufficiency to a student who is experiencing an adrenal crisis.

(2) Severe allergic reactions requiring epinephrine will occur in a wide variety of circumstances.

(3) Severe hypoglycemia requiring glucagon, in settings where children prone to severe hypoglycemia are known to lay providers and where arrangements for the availability of glucagon have been made, will occur primarily in, but not limited to, school settings, sports activities, and camps.

(4) An adrenal crisis for students diagnosed with adrenal insufficiency will occur in a wide variety of circumstances. The administration of medication to treat a student experiencing an adrenal crisis may be provided by trained school personnel in accordance with OAR 581-021-0037 whose parent or guardian has provided the necessary medication and equipment for administration.

Stat. Auth.: ORS 433.805 & 433.810
Stats. Implemented: ORS 433.800 - 433.830
Hist.: HD 10-1982, f. & ef. 5-25-82; HD 23-1990(Temp), f. & cert. ef. 8-15-90; OHD 7-1998, f. & cert. ef. 7-28-98; OSHA 4-2012, f. 9-19-12, cert. ef. 1-1-13; PH 14-2012, f. & cert. ef. 9-19-12; PH 3-2016, f. & cert. ef. 2-8-16

333-055-0006
Definitions

(1) "Adrenal crisis" means a sudden, severe worsening of symptoms associated with adrenal insufficiency, such as severe pain in the lower back, abdomen or legs; vomiting; diarrhea; dehydration; low blood pressure or loss of consciousness.

(2) "Adrenal insufficiency" means a hormonal disorder that occurs when the adrenal glands do not produce enough adrenal hormones.

(3) "Allergen" means a substance, usually a protein, that evokes a particular adverse response in a sensitive individual.

(4) "Allergic response" means a medical condition caused by exposure to an allergen, with physical symptoms that range from localized itching to severe anaphylactic shock and that may be life threatening.

(5) "Emergency Medical Services Provider (EMS Provider)" means a person who has received formal training in pre-hospital and emergency care and is state-licensed to attend to any ill, injured or disabled person. Police officers, fire fighters, funeral home employees and other personnel serving in a dual capacity, one of which meets the definition of "emergency medical services provider" are "emergency medical services providers" within the meaning of ORS Chapter 682.

(6) "Hypoglycemia" means a condition in which a person experiences low blood sugar, producing symptoms such as drowsiness, loss of muscle control so that chewing or swallowing is impaired, irrational behavior in which food intake is resisted, convulsions, fainting or coma.

(7) "Other treatment" means oral administration of food containing glucose or other forms of carbohydrate, such as jelly or candy.

(8) "Other treatment has failed" means a hypoglycemic student's symptoms have worsened after the administration of a food containing glucose or other form of carbohydrate or a hypoglycemic student has become incoherent, unconscious or unresponsive.

(9) "Paramedic" means a person who is licensed by the Oregon Health Authority as a Paramedic.

(10) "Supervising professional" means a physician licensed under ORS Chapter 677, or a nurse practitioner licensed under ORS Chapter 678 to practice in this state and who has prescription writing authority.

Stat. Auth.: ORS 433.810
Stats. Implemented: ORS 433.800 - 433.830
Hist: PH 14-2012, f. & cert. ef. 9-19-12; PH 3-2016, f. & cert. ef. 2-8-16

333-055-0015
Educational Training

(1) Individuals to be trained to administer glucagon and school personnel to be trained to administer a medication that treats a student who has adrenal insufficiency and who is experiencing symptoms of adrenal crisis based on the student's health plan must be trained by:

(a) A physician licensed under ORS Chapter 677;

(b) A nurse practitioner licensed under ORS Chapter 678; or

(c) A registered nurse licensed under ORS Chapter 678.

(2) Individuals to be trained to administer epinephrine must be trained by:

(a) A physician licensed under ORS Chapter 677;

(b) A nurse practitioner licensed under ORS Chapter 678;

(c) A registered nurse licensed under ORS Chapter 678 as assigned by a supervising professional to teach the OHA-Public Health Division Treatment of Severe Allergic Reaction training and distributes a Certificate of Completion and Authorization to Obtain Epinephrine in accordance with OAR 333-055-0030(1); or

(d) A paramedic as delegated by an EMS Medical Director defined in OAR chapter 333, division 265.

(3) The training described in sections (1) and (2) of this rule must follow the Oregon Health Authority, Public Health Division training protocol, or an Authority approved equivalent. The Public Health Division approved training protocol for emergency glucagon providers is available on the Internet at http://healthoregon.org/diabetes. The training protocols for the treatment of severe allergic reaction or treatment of adrenal crisis are available on the Internet at http://healthoregon.org/ems.

Stat. Auth.: ORS 433.810
Stats. Implemented: ORS 433.815 & 433.817
Hist.: HD 10-1982, f. & ef. 5-25-82; HD 23-1990(Temp), f. & cert. ef. 8-15-90; OHD 7-1998, f. & cert. ef. 7-28-98; PH 10-2004, f. & cert. ef. 3-23-04; PH 14-2012, f. & cert. ef. 9-19-12; PH 3-2016, f. & cert. ef. 2-8-16

333-055-0021
Eligibility for Training

In order to be eligible for training under OAR 333-055-0015, a person must:

(1) Be 18 years of age or older; and

(2) Have, or reasonably expect to have, responsibility for or contact with at least one other person as a result of the eligible person's occupational or volunteer status, such as, but not limited to, a camp counselor, scout leader, forest ranger, school employee, tour guide or chaperone.

Stat. Auth.: ORS 433.810
Stats. Implemented: ORS 433.820
Hist: PH 14-2012, f. & cert. ef. 9-19-12; PH 3-2016, f. & cert. ef. 2-8-16

333-055-0030
Certificates of Completion of Training

(1) Persons who successfully complete educational training under OAR 333-055-0000 through 333-055-0035 shall be given a Public Health Division statement of completion signed by the individual conducting the training. The statement of completion for the treatment of allergic response training may also be used as an authorization to obtain epinephrine if fully completed and personally signed by a nurse practitioner or a physician responsible for the training program. (a) A statement of completion for the treatment of allergic response training may be obtained from the Oregon Health Authority, Public Health Division, 800 NE Oregon Street, Suite 290, Portland, Oregon 97232, Phone: (971) 673-1230.

(b) A statement of completion for emergency glucagon providers is included in the training protocol available at http://healthoregon.org/diabetes.

(c) A statement of completion for school personnel trained in the administration of a medication to treat adrenal crisis is included in the treatment of adrenal insufficiency protocol available at http://healthoregon.org/ems.

(2) The statement of completion and authorization to obtain epinephrine form allows a pharmacist to generate a prescription and dispense an emergency supply of epinephrine for not more than one child and one adult in an automatic injection device if signed by a nurse practitioner or physician. Whenever such a statement of completion form for an emergency supply of epinephrine is presented, the pharmacist shall write upon the back of the statement of completion form in non-erasable ink the date that the prescription was filled, returning the statement of completion to the holder. The prescription may be filled up to four times. The pharmacist who dispenses an emergency supply of epinephrine under this rule shall also reduce the prescription to writing for his files, as in the case of an oral prescription for a non-controlled substance, and file the same in the pharmacy.

(3) A person who has successfully competed educational training in the administration of glucagon may receive, from the parent or guardian of a student, doses of glucagon prescribed by a health care professional with appropriate prescriptive privileges licensed under ORS chapters 677 or 678, and the necessary paraphernalia for administration.

(4) A person who has successfully competed educational training in the administration of a medication to treat adrenal crisis may receive, from the parent or guardian of a student, medication that treats adrenal insufficiency prescribed by a health care professional with appropriate prescriptive privileges licensed under ORS Chapters 677 or 678, and the necessary paraphernalia for administration.

(5) Completion of a training program and receipt of a statement of completion does not guarantee the competency of the individual trained.

(6) A statement of completion and authorization to obtain epinephrine shall expire three years after the date of training identified on the statement of completion. Individuals trained to administer epinephrine, glucagon or a medication to treat adrenal insufficiency must be trained every three years in accordance with OAR 333-055-0015 in order to obtain a new statement of completion.

(7) Individuals trained to administer epinephrine, glucagon or a medication to treat adrenal crisis may be asked to provide copies of a current statement of completion to their employers or to organizations or entities to which they volunteer.

[ED. NOTE: Figures referenced are available from the agency.]

Stat. Auth.: ORS 433.810

Stats. Implemented: ORS 433.815, 433.817 & 433.825

Hist.: HD 10-1982, f. & ef. 5-25-82; HD 23-1990(Temp), f. & cert. ef. 8-15-90; OHD 7-1998, f. & cert. ef. 7-28-98; PH 10-2004, f. & cert. ef. 3-23-04; PH 14-2012, f. & cert. ef. 9-19-12; PH 3-2016, f. & cert. ef. 2-8-16

333-055-0035
Circumstances in Which Trained Persons May Administer Epinephrine, Glucagon or a Medication to Treat Adrenal Crisis

(1) A person who holds a current statement of completion pursuant to OAR 333-055-0030 may, in an emergency situation when a licensed health care professional is not immediately available, administer epinephrine to any person suffering a severe allergic response to an insect sting or other allergen. The decision to give epinephrine should be based upon recognition of the signs of a systemic allergic reaction and need not be postponed for purposes of identifying the specific antigen which caused the reaction.

(2) A person who holds a current statement of completion pursuant to OAR 333-055-0030 may, in an emergency situation involving an individual who is experiencing hypoglycemia and when a licensed health care professional is not immediately available, administer health care professional-prescribed glucagon to a person for whom glucagon is prescribed, when other treatment has failed or cannot be initiated. The decision to give glucagon should be based upon recognition of the signs of severe hypoglycemia and the inability to correct it with oral intake of food or drink.

(3) School personnel who hold a current statement of completion pursuant to OAR 333-055-0030 may, in an emergency situation involving a student diagnosed with adrenal insufficiency who is experiencing symptoms of adrenal crisis and when a licensed health care professional is not immediately available, administer health care professional-prescribed medication to treat adrenal insufficiency. The decision to give medication to a student with adrenal insufficiency should be based upon the student's health plan in accordance with OAR 581-021-0037 and recognition of the signs of adrenal crisis and need not be postponed.

Stat. Auth.: ORS 433.810

Stats. Implemented: ORS 433.825

Hist.: HD 10-1982, f. & ef. 5-25-82; OHD 7-1998, f. & cert. ef. 7-28-98; PH 10-2004, f. & cert. ef. 3-23-04; PH 14-2012, f. & cert. ef. 9-19-12; PH 3-2016, f. & cert. ef. 2-8-16

Opiate Overdose

333-055-0100
Purpose

(1) The purpose of OAR 333-055-0100 through 333-055-0110 is to define the protocols and criteria for training on lifesaving treatments for opiate overdose.

(2) Nothing in these rules is meant to require training for health care professionals that are otherwise authorized to administer naloxone within their scope of practice.

(3) Opiate overdose requiring lifesaving treatment occurs in a wide variety of settings and circumstances, creating a need for training a variety of overdose responders. In recognition of this need, Oregon law authorizes a wide range of organizations to provide training on lifesaving treatments for opiate overdose including public health authorities, and organizations and other appropriate entities that provide services to individuals who take opiates. The Oregon Public Health Division interprets providing services to opiate users broadly and includes but is not limited to clinical, substance abuse, social services, public health, law enforcement and criminal justice, and other providers.

Stat. Auth: ORS 689.681

Stats. Implemented: ORS 689.681

Hist.: PH 8-2013(Temp), f. & cert. ef. 7-1-13 thru 12-27-13; PH 12-2013, f. & cert. ef. 11-19-13

333-055-0105
Definitions

Unless otherwise stated in OAR 333-055-0100 through 333-055-0110, or the context of 333-055-0100 through 333-055-0110 requires otherwise, the following definitions apply to OAR 333-055-0100 through 333-055-0110:

(1) "Certified nurse practitioner" means a nurse practitioner licensed under ORS Chapter 678.

(2) "Licensed physician" means a physician licensed under ORS Chapter 677.

(3) "Opiate" has the same meaning given that term in Oregon Laws 2013, chapter 340.

(4) "Opiate overdose" has the same meaning given that term in Oregon Laws 2013, chapter 340.

(5) "Oversight" means ensuring, through periodic review, that the training on lifesaving treatments for opiate overdose is consistent with the scope and intent of the protocols and criteria established by Oregon Health Authority. 'Oversight' does not require the licensed physician or certified nurse practitioner to be present during the training.

Stat. Auth: ORS 689.681
Stats. Implemented: ORS 689.681
Hist.: PH 8-2013(Temp), f. & cert. ef. 7-1-13 thru 12-27-13; PH 12-2013, f. & cert. ef. 11-19-13

333-055-0110
Educational Training

(1) Training to administer naloxone is subject to oversight by a licensed physician or certified nurse practitioner with prescriptive privileges.

(2) Subject to the oversight required in section (1) of this rule, training may be conducted by a public health authority, an organization or other entity that provides services to individuals who take opiates.

(3) Individuals trained to respond to opiate overdose must be retrained at least every three years.

(4) The training must meet the protocols and criteria established by Oregon Health Authority, Public Health Division. The approved training protocol and criteria for the treatment of opiate overdose is available on the Internet at https://public.health.oregon.gov/ProviderPartnerResources/EMSTraumaSystems/Pages/Naloxone-Training-Protocol.aspx and is incorporated by reference.

Stat. Auth: ORS 689.681
Stats. Implemented: ORS 689.681
Hist.: PH 8-2013(Temp), f. & cert. ef. 7-1-13 thru 12-27-13; PH 12-2013, f. & cert. ef. 11-19-13

333-055-0115
Certificate of Completion of Training

(1) Persons who successfully complete opiate overdose response training under OAR 333-055-0000 through 333-055-0115 shall be given a statement of completion signed by the individual conducting the training. The statement of completion may be used as an authorization to obtain naloxone from a licensed pharmacy if fully completed and signed by a nurse practitioner or physician overseeing the training. The statement of completion for the treatment of opiate overdose response training is available on the Internet at https://public.health.oregon.gov/ProviderPartnerResources/EMSTraumaSystems/Pages/Naloxone-Training-Protocol.aspx and is incorporated by reference.

(2) The statement of completion authorizes a pharmacist to generate a prescription and dispense to the trained individual doses of naloxone if the statement of completion is signed by a nurse practitioner or physician. Whenever such a statement of completion is presented, the pharmacist may generate a prescription and dispense naloxone to the trained individual as specified under OAR 855-041-2330.

(3) A statement of completion and authorization to obtain naloxone shall expire three years after the date of training identified on the statement of completion. Individuals trained to respond to opiate overdose must be trained every three years in accordance with OAR 333-055-0110 to obtain a new statement of completion.

Stat. Auth: ORS 689.681
Stats. Implemented: ORS 689.681
Hist.: PH 12-2013, f. & cert. ef. 11-19-13

DIVISION 56

INFECTIOUS WASTE MANAGEMENT

333-056-0010
Purpose of Infectious Waste Administrative Rules

The purpose of OAR 333-056-0020 through 333-056-0050 is to define terms related to infectious waste and to prescribe acceptable methods of storage and treatment of infectious waste.

Stat. Auth.: ORS 431.110, 433.004 & 459.395
Stats. Implemented: ORS 459.395
Hist.: HD 15-1990, f. 6-5-90, cert. ef. 7-1-90; OHD 15-2001, f. & cert. ef. 7-12-01, Renumbered from 333-018-0040

333-056-0020
Definitions Relating to Infectious Waste

As used in OAR 333-056-0010 through 333-056-0050, unless the context requires otherwise, the following definitions apply:

(1) "Act" means chapter 763, Oregon Laws, 1989, codified as ORS 459.386 to 459.405.

(2) "Disposal" means the final placement of treated infectious waste in a disposal site operating under a permit issued by a state or federal agency.

(3) "Disposal site" means land and facilities used for the disposal, handling or transfer of, or resource recovery from solid wastes, including but not limited to dumps, landfills, sludge lagoons, sludge treatment facilities, disposal sites for septic tank pumping or cesspool cleaning service, transfer stations, resource recovery facilities, incinerators for solid waste delivered by the public or by a solid waste collection service, composting plants and land and facilities previously used for solid waste disposal at a land disposal site. "Disposal site" does not include:

(a) A facility subject to the permit requirements of ORS 468.740;

(b) A landfill site which is used by the owner or person in control of the premises to dispose of soil, rock, concrete or other similar non-decomposable materials, unless the site is used by the public either directly or through a solid waste collection service; or

(c) A site operated by a wrecker issued a certificate under ORS 822.110.

(4) "Division" means the Oregon Health Authority, Public Health Division.

(5) "Incineration" means the reduction in volume and weight of waste by combustion.

(6) "Infectious waste" means:

(a) "Biological waste", which includes blood and blood products, excretions, exudates, secretions, suctionings and other body fluids that cannot be directly discarded into the municipal sewer system, and waste materials saturated with blood or body fluids, but does not include diapers soiled with urine or feces. In addition, biological waste does not include articles contaminated with fully absorbed or dried blood, such as gauze, paper towels, and sanitary napkins;

(b) "Cultures and stocks", which includes etiologic agents and associated biologicals, including specimen cultures and dishes and devices used to transfer, inoculate and mix cultures, wastes from production of biologicals, and serums and discarded live and attenuated vaccines. "Cultures" does not include throat and urine cultures;

(c) "Pathological waste", which includes biopsy materials and all human tissues, anatomical parts that emanate from surgery, obstetrical procedures, autopsy and laboratory procedures and animal carcasses exposed to pathogens in research and the bedding and other waste from such animals. "Pathological waste" does not include teeth or formaldehyde or other preservative agents;

(d) "Sharps", which includes needles, IV tubing with needles attached, scalpel blades, lancets, glass tubes that could be broken during handling and syringes that have been removed from their original sterile containers;

(e) "Syringe" means an instrument for the injection of medicine or the withdrawal of body fluids that consists of a hollow barrel fitted with a plunger and a hollow needle.

(7) "Landfill" means a facility for the disposal of solid waste involving the placement of solid waste on or beneath the land surface.

(8) "Noninfectious" means a state in which a disease causing agent is not capable of causing an infection to occur.

(9) "Saturated Waste" means waste that contains enough body fluid that it would cause dripping of the body fluid from the waste container, with or without compaction.

(10) "Sterilization" means, for purposes of these rules, any process which changes infectious waste so that disease causing agents contained within it are rendered non-infectious at the time the process is completed.

(11) "Storage" means the temporary containment of infectious waste in a manner that does not constitute treatment or disposal of such waste.

(12) "Transportation" means the movement of infectious waste from the point of generation over a public highway to any intermediate point, to the point of final treatment, and to the point of final disposal.

(13) "Treatment" means incineration, sterilization or other method, technique or process approved by the Oregon Health Authority, Public Health Division that changes the character or composition of any infectious waste so as to render the waste noninfectious. Treatment also includes methods of rendering waste noninfectious, which are approved by the Environmental Quality Commission.

Stat. Auth.: ORS 431.110, 433.004 & 459.395
Stats. Implemented: ORS 431.110, 433.004 & 459.395
Hist.: HD 15-1990, f. 6-5-90, cert. ef. 7-1-90; OHD 15-2001, f. & cert. ef. 7-12-01, Renumbered from 333-018-0050; PH 16-2013, f. 12-26-13, cert. ef. 1-1-14; PH 10-2015, f. 7-2-15, cert. ef. 7-3-15

333-056-0030
Infectious Waste Treatment

(1) Pathological wastes shall be treated by incineration in an incinerator that provides complete combustion of waste to carbonized or mineralized ash. However, if the Department of Environmental Quality determines that incineration is not reasonably available within a wasteshed, pathological wastes may be disposed of in the same manner provided for cultures and stocks.

(2) Cultures, stocks, sharps and biological wastes must be treated using one of the following methods, as delineated in subsections (2)(a), (b) and (c) of this rule:

(a) Treated via incineration. If incineration is utilized, it shall be done in compliance with all applicable rules established by the Environmental Quality Commission;

(b) Sterilization with saturated steam in a pressurized vessel. If this method is employed, a vessel dedicated to infectious waste treatment must be utilized. Operating procedures which must be developed and implemented shall include at least the following:

(A) Adoption of standard written operating procedures for each steam sterilizer including time, temperature, pressure, type of waste, type of container(s), type of closure on container(s), pattern of loading, and maximum load quantity. The manufacturer's recommendations shall be taken into account;

(B) Methods for monitoring recording or temperature measuring devices during each complete cycle to ensure that the manufacturer's recommended temperature is attained for the recommended amount of time in order to achieve sterilization of the entire load. Temperature measuring devices shall be checked for calibration at least annually;

(C) Methods for using heat sensitive tape or other device designed to indicate attainment of adequate sterilization conditions, for each container;

(D) Methods for at least monthly use of the biological indicator Bacillus stearothermophilus, or equivalent, placed at the center of a load processed under standard operating conditions, to confirm the attainment of adequate sterilization conditions;

(E) Methods for maintenance of records pertaining to paragraphs (2)(a)(A), (B) and (D) of this rule. These records shall be maintained and available for Division review for a period of not less than one year.

(c) Treated by other methods that meet the following criteria:

(A) The specific processes of the method have been tested under the conditions in which the method would be used in Oregon for the treatment of infectious waste. Such testing has demonstrated that the method is effective in rendering infectious agents noninfectious by showing bactericidal efficacy against at least spore-forming bacteria and a Mycobacterium. The testing methodology, test results, and documentation thereof must be considered scientifically valid by the Division. The determination of validity requires, but is not limited to:

(i) The testing methodology follows basic scientific principles or objectivity and is fully documented;

(ii) The results of the testing are fully documented. Raw data are made available to the Division if they are requested by the Division;

(iii) The testing has been done by a scientist(s) with an advanced degree in microbiology and with a record of having published scientific research results in a peer reviewed journal;

(iv) The report of the testing methodology and results, together with the statement "This report is an accurate and complete account of the test methods I performed and the test results I obtained" have been signed by the scientist(s) who performed the testing; and

(B) Any discharges into air or water and any solid waste resulting from the method meet the requirements of the laws and administrative rules of the Oregon Department of Environmental Quality; or

(C) The Environmental Quality Commission has approved the method and has accepted that method by administrative rule.

(3) Liquid or soluble semi-solid biological wastes may be discharged into a sewage treatment system that provides secondary treatment of waste.

(4) After treatment approved by the Division or the Environmental Quality Commission, sharps may be disposed of directly into a permitted land disposal site only if the sharps are in a red, leak-proof, rigid, puncture-resistant container which is taped closed or tightly lidded to prevent loss of the contents. The containers may not be compacted or otherwise broken before placement in the landfill. They must be placed in a segregated area of the landfill.

(5) Methods of treatment which have not been delineated in this rule or approved by the Division or the Environmental Quality Commission, as applicable, are not permitted.

Stat. Auth.: ORS 431.110, 433.004 & 459.395
Stats. Implemented: ORS 431.110, 433.004 & 459.395
Hist.: HD 15-1990, f. 6-5-90, cert. ef. 7-1-90; HD 20-1991(Temp), f. & cert. ef. 11-8-91; HD 13-1992(Temp), f. & cert. ef. 12-23-92 (and corrected 12-30-92); HD 29-1994, f. & cert. ef. 12-2-94; OHD 15-2001, f. & cert. ef. 7-12-01, Renumbered from 333-018-0060; PH 16-2013, f. 12-26-13, cert. ef. 1-1-14

333-056-0040
Infectious Waste Storage Times and Temperature

(1) Infectious waste shall be segregated from other wastes by separate containment at the point of generation.

(2) Enclosures used for storage of infectious waste shall be secured to prevent access by unauthorized persons and marked with prominent warning signs.

(3) Pathological waste, biological waste and cultures/stocks shall be treated or disposed of pursuant to OAR 333-056-0010 through 333-056-0030 within seven days of generation, unless it is refrigerated (between 33 and 48 degrees Fahrenheit) or frozen (less than 32 degrees Fahrenheit). Refrigerated or frozen infectious waste may be stored 30 days prior to treatment or disposal.

(4) Prior to being treated pursuant to OAR 333-056-0010 through 333-056-0030, sharps contained in a leak proof, rigid, puncture resistant container which is taped closed or tightly lidded to prevent loss of the contents may be stored indefinitely.

(5) Generators that produce 50 pounds or less of infectious waste in any calendar month shall be exempt from the requirements pertaining to storage times and temperatures.

Stat. Auth.: ORS 431.110, 433.004 & 459.395
Stats. Implemented: ORS 431.110, 433.004 & 459.395

Hist.: HD 15-1990, f. 6-5-90, cert. ef. 7-1-90; OHD 15-2001, f. & cert. ef. 7-12-01, Renumbered from 333-018-0070; PH 16-2013, f. 12-26-13, cert. ef. 1-1-14

333-056-0045
Exemption for Placenta Removal from a Health Care Facility

(1) Notwithstanding any other provision in these rules, a health care facility or freestanding birthing center, as those terms are defined in ORS 442.015, may release a placenta to the woman from whom the placenta originated, or to her designee, if:

(a) The facility or birthing center has a written policy and procedure to ensure the safe management and transport of placentas;

(b) The woman tested negative for infection by hepatitis B and human immunodeficiency viruses by testing obtained since the beginning of the pregnancy; and

(c) The woman, or her designee, and the woman's health care provider sign a form that contains at least the following:

(A) The woman's name, date of birth, address and the name of the health care provider;

(B) An attestation by the woman or her designee that the placenta will not be used for commercial purposes; and

(C) An attestation by the health care provider that:

(i) Since the beginning of the pregnancy the woman tested negative for infection by hepatitis B and human immunodeficiency viruses;

(ii) The woman either tested negative for hepatitis C virus since the beginning of the pregnancy or is not at risk for hepatitis C; and

(iii) To the health care provider's knowledge, the woman has no infection that poses a threat to persons who handle the placenta.

(2) The health care facility or freestanding birthing center must keep a copy of the signed release form described in subsection (1)(c) of this rule in the mother's medical record.

(3) Health care facilities and freestanding birthing centers shall make policies and procedures developed in accordance with subsection (1)(a) of this rule available to the Division upon request.

(4) Nothing in this rule prohibits a health care facility or freestanding birthing center from having additional requirements for the removal of a placenta from the facility or center.

Stat. Auth.: ORS 431.110, 433.004, 459.400
Stats. Implemented: ORS 431.110, 433.004, 459.400
Hist.: PH 16-2013, f. 12-26-13, cert. ef. 1-1-14

333-056-0050
Prevention of Disease Transmission by Blood-Contaminated Sharp Objects

Any person using sharp instruments (for example, needles, lancets, scalpels) for purposes of drawing blood, administering medication, or medical/surgical procedures on humans, shall dispose of such items in a manner that will protect any other handlers of this waste from injury. The disposal of such waste shall be in accordance with current recommendations of the U.S. Centers for Disease Control and Prevention, and shall include the use of impervious, rigid, puncture-proof containers. This rule applies to but is not limited to blood banks, plasmapherisis centers, medical clinics, dental offices, outpatient care centers, inpatient care facilities, hospitals, and home health agencies.

Stat. Auth.: ORS 431.110, 433.004 & 459.395
Stats. Implemented: ORS 431.110, 433.004 & 459.395
Hist.: HD 4-1987, f. 6-12-87, ef. 6-19-87; OHD 15-2001, f. & cert. ef. 7-12-01, Renumbered from 333-019-0212; PH 16-2013, f. 12-26-13, cert. ef. 1-1-14

DIVISION 60

PUBLIC WATER SYSTEMS

Public Swimming Pools and Bathhouses

333-060-0005
Purpose

These rules adopted pursuant to the provisions of ORS 448.011, prescribe the requirements for the construction and operation of public swimming pools, public wading pools and bathhouses. They are for the purpose of protecting the health, safety, and welfare of persons using those facilities.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0076; HD 7-1986, f. & ef. 5-1-86

333-060-0010
Adoption by Reference

Outside standards, listings and publications referred to in these sections are by reference made a part of these rules.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 183.355
Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0081

333-060-0015
Definitions

As used in these rules unless otherwise required by context:

(1) "Administrator" means the State Public Health Director or designee of the Oregon Health Authority, Public Health Division.

(2) "Approved" means approved in writing by the Division.

(3) "Athletic club" means a facility constructed to provide athletic or physical conditioning for its members, guests and/or patrons. It includes but is not limited to racquetball clubs, health spas, fitness facilities, aerobics, etc.

(4) "Bathhouse" means a structure, which contains dressing rooms, showers and toilet facilities for use with an adjacent public swimming pool.

(5) "Builder" means a person who, in the pursuit of an independent business, undertakes, or offers to undertake, or submits a bid, to construct, alter, repair, or improve any public swimming pool, spa pool or bathhouse and the appurtenances thereto.

(6) "Certified Operator" means a person performing the duties of the responsible supervisor, and responsible for providing direction and training to non-certified responsible supervisors and other pool personnel in regards to pool maintenance and operation. This person shall be certified by an organization providing training in pool safety, maintenance and operation recognized by the Division. Such courses and organizations include the Certified Pool Operator Program, by the National Swimming Pool Foundation, and the Aquatic Facility Operator Program, by the National Recreation and Parks Association, or equivalent, as determined by the Division.

(7) "Cross connection" means an unprotected connection between the piping carrying potable water and the piping or fixtures which carry other water or other substances.

(8) "Division" means the Oregon Health Authority, Public Health Division.

(9) "General-use Public Swimming Pool" means any public swimming pool other than a limited-use public swimming pool. Public swimming pools operated in conjunction with a companion facility but not limited to use of the residents, patrons or members of the companion facility are general-use swimming pools.

(10) "Guest protection zone" means a defined and prescribed area of a swimming pool or aquatic feature. A designated lifeguard is responsible for scanning a guest protection zone. Scanning refers to the actions performed by the lifeguard to visually survey and continuously and comprehensively monitor the guest protection zone.

(11) "10/20 Guest Protection Standard" means using a lifeguard planning standard that will place guards in numbers and locations, with identified areas of responsibility, so that they can theoretically identify a victim within 10 seconds and reach the victim within 20 more seconds. This is only a planning tool and actual response times will vary depending on the abilities of the lifeguard, their alertness, their vigilance and what else is happening in the pool.

(12) "Horseplay" means any unsafe activity, which in the opinion of the Division or the pool operator endangers the pool users and/or bystanders.

(13) "Instructor" means a currently certified American Red Cross Water Safety Instructor, YMCA Swim Instructor, or a person having equivalent certification as determined by the Division.

(14) "Lifeguard" means a person holding current certification in the following three areas:

(a) Lifeguard certification. Certification in one of the following:

(A) American Red Cross Lifeguard Training;

(B) Young Men's Christian Association (YMCA) Lifeguarding;

(C) International Lifeguard Training Program (ILTP) for deep water;

(D) Starfish Aquatics Institute StarGuard; or

(E) Other lifeguard training approved by the Division.

(b) First aid certification. Certification in one of the following:

(A) American Red Cross First Aid;

(B) American Safety and Health Institute Universal Basic First Aid:

(C) Emergency Medical Planning America Medic First Aid (MFA); or

(D) Other equivalent First Aid Course approved by the Division.

(c) CPR certification. Certification in one of the following:

(A) American Red Cross CPR for the Professional Rescuer;

(B) American Heart Association Healthcare Provider CPR;

(C) American Safety and Health Institute CPR Pro for the Professional Rescuer; or

(D) Other equivalent CPR training approved by the Division.

(15) "Limited-use Public Swimming Pool" means any public swimming pool located at and operated in connection with a companion facility such as a residential housing facility having five or more living units, travelers' accommodations, mobile home park, recreation park, boarding school, organizational camp, dude ranch, club or association where use of the pool is limited to residents, patrons or members of the companion facility.

(16) "Person" includes, in addition to the definition in ORS 174.100, municipalities, recreation districts, counties and state agencies, instrumentalities, or builder.

(17) "Private Swimming Pool" means any swimming pool, wading pool or spray pool owned by no more than four individuals, either jointly, individually or through association, incorporation or otherwise, and operated and maintained in conjunction with a companion residential housing facility having no more than four living units, for the use of the occupants thereof and their personal friends only. Private pools shall not be subject to the provisions of these rules.

(18) "Public Spa Pool" means any public swimming pool or wading pool designed primarily to direct water or air-enriched water under pressure onto the bather's body with the intent of producing a relaxing or therapeutic effect.

(19) "Public Swimming Pool" means an artificial structure, and its appurtenances, which contains water more than two feet (600mm) deep which is expressly designated or which is used with the knowledge and consent of the owner or operator for swimming or recreational bathing and which is for the use of any segment of the public. "Public swimming pool" includes, but is not limited to, swimming pools owned or operated by:

(a) Traveler's accommodations;

(b) Recreation parks;

(c) Colleges;

(d) Schools;

(e) Organizational camps as defined in ORS 446.310;

(f) Clubs;

(g) Associations;

(h) Business establishments for their patrons or employees;

(i) Private persons and that are open to the public;

(j) Recreation districts;

(k) Municipalities;

(l) Counties; or

(m) A state agency.

(20) "Public Wading Pool" means an artificial structure, and its appurtenances, which contains water less than two feet (600mm) deep which is expressly designated or which is used with the knowledge and consent of the owner or operator for wading or recreational bathing and which is for the use of any segment of the public, whether limited to patrons of a companion facility or not. Special types of wading pools include but are not limited to:

(a) "Spray Pool" or "Water Playground" meaning a wading pool containing spray features intended for recreational use, but that does not allow water to pond in the basin. Spray pools or water playgrounds that do not pond water and use potable water once then send it to waste are not regulated by these rules.

(b) "Interactive Fountain" meaning a wading pool designed for esthetic appreciation, which is expressly designated or which is used with the knowledge and consent of the owner or operator for wading or recreational bathing by any segment of the public. Interactive fountains are a type of wading pool. Interactive fountains that do not pond water and use potable water once then send it to waste are not regulated by these rules.

(c) "Non-Regulated Fountain" means a fountain designed and operated solely for visual appreciation and for that function only. The Division does not license or regulate this type of fountain.

(21) "Responsible Supervisor" means a person, or persons, designated by the operator to provide emergency assistance to patrons, maintain order and enforce pool use regulations, governing safety and sanitation, including pool closure, and who is knowledgeable about pool maintenance and operation and the testing of pool water.

(22) "Shallow Water Lifeguard" means a person with training in the skills needed to lifeguard in four feet (1.2 m) of water or less. This person shall have current certification in:

(a) International Lifeguard Training Program (ILTP) for shallow water guards;

(b) Starfish Aquatics Institute StarGuard with a competency assessment designation of three feet of water or less, or;

(c) Equivalent training, as approved by the Division.

(23) "Special-use pool" means a public swimming pool which is designed specifically for sporting or recreational purposes and may include but are not limited to special features such as wave pools, diving pools, splash pools, zero depth pools, portable slides, and water slides.

(24) "Supplemental Disinfectant" means a disinfectant, which is intended to augment water quality in a public swimming pool or spa and will provide disinfection in conjunction with the approved disinfectant.

(25) "Swimming Pool" means an artificial structure, basin, chamber or tank used for wading, swimming, diving, water recreation, therapy or bathing. It does not include facilities where the water is drained after each use, when such facility has no heater, filter, or sanitizing equipment or spray pools that use potable water once and send to waste and that do not pond water in the basin. Types of pools are as follows:

(a) "Combination pool" means a pool used for swimming and diving, having both shallow and deep portions.

(b) "Diving pool" means a pool used exclusively for diving.

(c) "Exercise pool" means a pool small in area and of shallow depth usually associated with a health spa.

(d) "Mobile pool" means a pool constructed on a mobile structure, which can be transported from place to place.

(e) "Reverse flow pool" means a pool of a design in which the water enters at the bottom and leaves at the water line.

(f) "Spa" means a relatively small pool, which uses high temperature water and which may include a water agitation system or air-enriched water under pressure, with the intent of producing a relaxing or therapeutic effect. A spa is sometimes called a whirlpool.

(g) "Special-use pool" means a pool used for a purpose not otherwise defined, such as for apparatus swimming, diving, and underwater photography training, therapy, or other use by the public.

(h) "Spray Pool" means a type of wading pool that provides water for recreational bathing through the use of sprays, fountains, buckets or other means, that allows the water to run by gravity to a drain and does not pond water in the basin. Spray pools that use potable water once and waste it to the drain without ponding of the water are not regulated by these rules.

(i) "Wading Pool" means a shallow pool used primarily by children, and designed to have a water depth no greater than 24 inches.

(j) "Waterslide plunge pool" means a pool located at the exit end of a waterslide flume and intended and designed to receive sliders emerging from the flume.

(k) "Water recreation attraction" means a special-use pool designed and intended for recreational use with special design or operational features that provide the patron recreational activity which may be different from that associated with a conventional swimming pool, and that purposefully involves immersion of the body partially or totally in the water.

NOTE: Examples of water recreation attractions are waterslide plunge pools, lazy or slow rivers, tubing pools, and wave pools.

(l) "Wave pool" means a pool designed for generating waves for recreational purposes.

(m) "Zero-depth pool" means a pool having a bottom slope, which continues through decreasing depth until the bottom joins with the deck around either part or all of the pool perimeter. It may have no walls, or may have walls around part of the perimeter.

(26) "Variance" means written permission from the Division for a public swimming pool, public spa pool or public wading pool to be operated when it does not comply with all the applicable rules for public swimming pools, public spa pools or public wading pools.

(27) "Waterpark slide" means a slide at a public pool, which has a length of at least twenty feet (6.1m), not including the platform.

Stat. Auth.: ORS 448.011
Stats. Implemented:ORS 448.005 - 448.100, 448.990
Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0086; HD 7-1986, f. & ef. 5-1-86; HD 17-1991, f. & cert. ef. 10-15-91; HD 22-1994, f. 8-22-94, cert. ef. 9-1-94; PH 17-2006, f. 6-30-06, cert. ef. 7-1-06; PH 10-2007, f. & cert. ef. 7-13-07

333-060-0020
Compliance

(1) Swimming pools and wading pools which were in public use before May 13, 1959, shall not be required to comply with Structural Stability, OAR 333-060-0050(2); and Dimensions, 333-060-0060(3) and (4), provided such pools are operated in compliance with all other rules of the Division relating to public swimming pools.

(2) All swimming pools and wading pools which were constructed and in use but were not in public use as defined in Definitions, OAR 333-060-0015(19), and were not licensed by the State Board of Health before June 10, 1959, shall before being operated for any public use, have complete and detailed plans submitted to the Division. A license to operate as a public pool shall not be issued until the pool is made to comply with the requirements of these rules.

(3) Any public wading pool constructed before July 1, 2006, but not licensed by the Division or its agent health department before that date, must obtain a license to operate:

(a) Wading pools, other than spray pools, without water recirculation must comply with the requirements of OAR 333-060-0510(1) or must cease operation;

(b) All existing wading pools must provide protection against entrapment, hair entanglement and evisceration in compliance with OAR 333-060-0510(2), or cease operation by December 31, 2008.

(4) Any limited-use swimming pool operated in conjunction with a companion residential housing facility having five or more living units and which was operated and maintained for the use of the occupants thereof and their personal friends only, but which was not required to be licensed prior to February 25, 1971, shall not be required to comply with Structural Stability, OAR 333-060-0050(2); Dimensions, 333-060-0060(3), (4) and (5)(a); Piping, 333-060-0130(1), (2), and (3); and Overflow Systems, 333-060-0115(2)(b), (3) and (4); provided such pools are operated in compliance with all other requirements of these rules.

(5) Public swimming pools built prior to March 1, 1979, are exempt from the following requirements of these rules provided such pools are operated in continuous compliance with the rules in effect at the time such pools were constructed:

(a) Dimensions, OAR 333-060-0060(2), (5)(a)(B), (5)(b);

(b) Finishes, Markings and Lifelines, OAR 333-060-0065(3);

(c) Ladders, Recessed Steps and Stairways, OAR 333-060-0080(7), (8);

(d) Decks, OAR 333-060-0110(1)(a), (2), (6), (7);

(e) Overflow Systems, OAR 333-060-0115(3);

(f) Recirculation Systems, OAR 333-060-0120(2)(c);

(g) Inlets and Outlets, OAR 333-060-0125(2), (4);

(h) Piping, OAR 333-060-0130(1), (4);

(i) Pumps, OAR 333-060-0135(1)(a), (b), (4);

(j) Filters, OAR 333-060-0140(2)(a)–(d), (6), (7);

(k) Heaters, OAR 333-060-0145(1)(c);

(l) Disinfectant and Chemical Feeders, OAR 333-060-0150(4);

(m) Equipment Room, OAR 333-060-0160(1);

(n) Bathhouse and Sanitary Facilities, OAR 333-060-0170(3)(a), (b);

(o) Signs, OAR 333-060-0215(1), (2) and (3).

(6) The exemptions of sections (1), (2), (3), and (4) of this rule apply provided the exemption does not present a health or safety hazard. Exemptions do not apply to any alteration or replacement of affected component part.

Stat. Auth.: ORS 448.011

Stats. Implemented: ORS 448.005–448.100, 448.990

Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0088; HD 7-1986, f. & ef. 5-1-86; HD 22-1994, f. 8-22-94, cert. ef. 9-1-94; PH 17-2006, f. 6-30-06, cert. ef. 7-1-06; PH 20-2006(Temp), f. & cert. ef. 9-15-06 thru 3-13-07; PH 29-2006, f. & cert. ef. 12-13-06

333-060-0025
Permit to Construct

(1) No person shall construct a public swimming pool, public wading pool, or bathhouse adjacent thereto, or alter any such structures without:

(a) Submitting complete plans and specifications to the Division;

(b) Receiving a written plan approval or conditional approval from the Division;

(c) Paying a construction permit fee to the Division;

(d) Receiving a permit to construct from the Division.

(2) Plans, specifications, and fees required herein shall be submitted at the time of filing application for a construction permit.

(3) No person shall deviate from the approved or conditionally approved plans and specifications during the construction or alteration of a facility described in section (1) of this rule without written approval of the Division.

(4) Construction permits will be issued only to the owner or authorized agent of the owner.

(5) The Division may issue a conditional construction permit where the plans and specifications for the proposed public swimming pool demonstrate a new technology or alternative mode of operation not contemplated in these rules. Such a permit may be issued only when the proponent of the facility has provided information to the Division from which the Division determines that the swimming pool may be reasonably expected to:

(a) Operate continuously in a clean and sanitary manner;

(b) Not constitute a menace to public health and safety; and

(c) Provide health and safety protection equal to or greater than that required by these rules.

(6) The conditional permit may impose conditions which will be set forth in a license for operation. These conditions may include, but not be limited to, submission of monitoring reports, sampling requirements, use restrictions and such other conditions as the Division may deem necessary to protect the public health and safety or to establish further the Division's expectancy of such protection. Furthermore, any license issued subject to a conditional permit shall carry the condition that, by its acceptance, the holder understands that a conditional license may not be renewed, may be revoked or suspended, or a permanent license not issued in the future, if the Division determines that the provisions of subsections (5)(a), (b), and (c) of this rule are not met. Such conditional construction permit authority is not conferred upon any county notwithstanding any delegated or contractual authority in administration and enforcement of the public swimming pool statutes and rules.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.020
Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0091; HD 26-1982(Temp), f. & ef. 12-6-82; HD 8-1983, f. & ef. 5-27-83; HD 7-1986, f. & ef. 5-1-86; HD 22-1994, f. 8-22-94, cert. ef. 9-1-94

333-060-0030
Plans

(1) Plans and specifications shall be prepared by a professional engineer or architect registered in the State of Oregon. Specific exemptions to this requirement may be granted by the Division, where in the judgment of the Division no architectural or engineering problems are presented and the plans accurately depict the proposed pool and address all requirements of these rules.

(2) Plans shall be submitted in duplicate, drawn to scale and shall include:

(a) One plan view;

(b) One longitudinal section;

(c) One transverse section through the main drain;

(d) One overall plan showing the pool in relation to other facilities in the area. (This plan may be combined with subsection (2)(a) of this rule.);

(e) One detailed view of the equipment room layout;

(f) One vicinity map;

(g) One piping schematic showing piping, pipe size, inlets, main drains, skimmers, gutter outlets, vacuum fittings, and all other appurtenances connected to the pool piping system. (This plan may be combined with subsection (2)(a) of this rule);

(h) One cross section of the step treads and risers.

(3) Plan notes such as "fence by owner" or "deck to be under separate contract" shall not be acceptable as a substitute for scale drawings.

(4) Plans shall include the following information in tabulated form:

(a) Legal address of the facility;

(b) Location of the facility if different from legal address;

(c) Owner's name, address and telephone number;

(d) Surface area of pool;

(e) Pool volume, turn over time, flow rate, filter rate/unit area, type of filter and total system head loss;

(f) Manufacturer, make and model numbers of the pump, filter and automatic chemical feed apparatus, filter head loss (clean and dirty), and pump curve showing design flow rate and head;

(g) Source of water used at the pool;

(h) Means of disposing backwash water.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.030
Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0096; HD 7-1986, f. & ef. 5-1-86; HD 22-1994, f. 8-22-94, cert. ef. 9-1-94

333-060-0035
Licenses

(1) No person shall operate a public swimming pool or public wading pool without:

(a) Securing an approved final construction inspection from the Division or its agent; or, if an unlicensed wading pool constructed before July 1, 2006, a compliance inspection. The compliance inspection will show items of non-compliance that need to be corrected before license issuance or the need to comply with the requirements of OAR 333-060-0510;

(b) Making application for a license to operate such pool;

(c) Paying the license fee; and

(d) Securing a license from the Division or delegate county health department.

(2) Such license terminates and is renewable on December 31 of each year.

Stat. Auth.: ORS 448.035
Stats. Implemented: ORS 448.005 - 448.100, 448.990
Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0098; HD 24-1983(Temp), f. & ef. 12-16-83; HD 7-1986, f. & ef. 5-1-86; PH 17-2006, f. 6-30-06, cert. ef. 7-1-06

333-060-0040
Conditional Licenses

(1) Conditional licenses may be issued by the Division in circumstances where:

(a) There is substantial compliance with these rules;

(b) A written schedule for total compliance approved by the Division is instituted and maintained; and

(c) In the judgment of the Division, there is no immediate threat to the health and safety of bathers during the time in which complete compliance is attained. The Division may also require special safeguards to be instituted and maintained as a condition of the conditional license.

(2) Conditional licenses may also be issued by the Division, as provided in OAR 333-060-0025(5).

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.035
Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0101; HD 26-1982(Temp), f. & ef. 12-6-82; HD 8-1983, f. & ef. 5-27-83; HD 7-1986, f. & ef. 5-1-86; HD 22-1994, f. 8-22-94, cert. ef. 9-1-94

333-060-0045
Maintenance and Modification

(1) All equipment of public swimming pools and public wading pools shall be operational and shall be kept in good repair. Such equipment shall be maintained in conformance with the original design or better.

(2) The structural components of all public swimming pools and their appurtenances shall be maintained in good repair.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.005 - 448.100, 448.990
Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0103; PH 17-2006, f. 6-30-06, cert. ef. 7-1-06

333-060-0050
Structural Stability

(1) All public swimming pools and public wading pools shall be watertight, constructed of waterproof and enduring materials compatible with the swimming pool environment and shall be designed to withstand all anticipated loading for both pool-empty and pool-full conditions.

(2) Where a high water table may be encountered, provisions shall be made for relief of hydrostatic pressure from under the pool floor and/or around the pool walls.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.005 - 448.100, 448.990
Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0106; PH 17-2006, f. 6-30-06, cert. ef. 7-1-06

333-060-0055
Size

Public swimming pools shall be sized according to and shall not exceed the design limit of the user load functions shown below. User loads are specific in-pool loads only. Area of deep water, "D" equals the surface area of the pool greater than five feet (1.5m) deep. Area of shallow water, "S" equals the surface area of the pool less than five feet (1.5m) deep. Surface area, "A" equals the area of the entire pool:

(1) Outdoor swimming pools with a surface area of more than 2,000 square feet — Max. load = (D / 27) + (S / 15);

(2) Outdoor swimming pools with a surface area of less than 2,000 square feet — Max. load = A / 24;

(3) Indoor swimming pools — Max. load = A / 24;

(4) Spray pools, wading pools — Max. load = A / 24.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 440.011
Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0108; HD 7-1986, f. & ef. 5-1-86; HD 22-1994, f. 8-22-94, cert. ef. 9-1-94

333-060-0060
Dimensions

(1) Public swimming pools and public wading pools shall have no sharp edges or protrusions where walls meet at an acute angle. Public swimming pools and public wading pools shall be shaped so as to provide for complete water recirculation and mixing. Walls in public wading pools must be vertical with a 3 to 6-inch (75–150 mm) radius at the pool wall/ pool floor juncture.

(2) There shall be no wall ledges in public swimming pools.

(3) Public swimming pools shall be not less than 3' (90cm) nor more than 3'6" (105cm) in depth at their shallowest point.

(4) Walls in public swimming pools shall be vertical or within 11 degrees of vertical for a minimum distance of 2'9" (82.5cm) in deep areas or 2'6" (75cm) in shallow areas from which point they may be radius to join the floor.

(5)(a) Break in grade shall occur at dept no shallower than 5' (1.5m), except pools built prior to March 1, 1979, shall be uniform to a depth of 4'6" (1.4m), and shall not exceed the following:

(A) General-use pools: 1' of fall in 12' (30cm in 3.7m) horizontally;

(B) Limited-use pools: 1' of fall in 10' (30cm in 3m) horizontally.

(b) Floor slopes in the transition area between the deep and shallow portions of the pool shall not exceed 1' of fall in 3' (30cm in 90cm) horizontally.

(6) The wall-floor transition radius shall:

(a) Have its center no less than 2'9" (82.5cm) below the surface of the water in deep areas or 2'6" (75cm) in shallow areas;

(b) Be tangent to the wall;

(c) Be less than or equal to the depth of the pool minus the vertical wall depth measured from the water line in deep areas minus 3" (7.5cm), to allow draining to the main drain. (R maximum = Pool Depth — Vertical Wall Depth — 3" (7.5cm).)

(7) Pools intended for diving shall comply with OAR 333-060-0085.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.005 - 448.100, 448.990
Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0111; HD 7-1986, f. & ef. 5-1-86; HD 22-1994, f. 8-22-94, cert. ef. 9-1-94; PH 17-2006, f. 6-30-06, cert. ef. 7-1-06

333-060-0065
Finishes, Markings and Lifelines

(1)(a) Wall and floor finishes shall be of non-toxic materials, shall be impervious and enduring. Such finishes shall be smooth and easily cleanable.

(b) Floors and walls of public swimming pools and public wading pools shall be white, of a light color or a light-colored pattern.

(2) A lifeline shall be provided 2' (60cm) on the shallow side of the break in grade between shallow and deep portions of the pool. Where there is a uniform slope, a lifeline is not required.

(a) This lifeline shall be securely fastened to wall anchors. Wall anchors shall be of corrosion-resistant materials and shall be recessed or have no projections which constitute safety hazards when the lifeline is removed. Pools built prior to March 1, 1979 shall comply with this rule at such time as the interior pool finish is repaired.

(b) The lifeline shall be marked with visible floats at not greater than 7' (2.1m) intervals. The line shall be of sufficient size and strength to offer a good handhold and to support loads normally imposed by bathers.

(c) The lifeline shall lie in place except when pool use is restricted to lap swimming by competent swimmers or to supervised swimming instruction by a certified swim instruc-tor.

(3) The break in grade of the pool shall be marked with a 4" (10cm) minimum width of floor tile or painted stripe of a color contrasting with the bottom. Where there is a uniform slope, a stripe is not required.

(4) Depth of water (in feet) shall be plainly and conspicuously marked above or at the water level on the vertical pool wall except for splash-out (deck level overflow) pools and on the top of the coping or edge of the deck or walk next to the pool. There shall be such markers at the maximum and minimum depth points and at 1' (30cm) depth increments in the shallow portion of the pool. Depth markings shall be spaced at no more than 25' (7.6m) intervals. There shall be depth markings at slope breaks. Pools built prior to March 1, 1979 shall comply with this rule pertaining to vertical pool wall markings when the interior pool finish is repaired or resurfaced.

(5) Depth markings shall be at least 4" (10cm) in height and of a color contrasting with the background.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.005 - 448.100, 448.990
Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0113; HD 7-1986, f. & ef. 5-1-86; HD 22-1994, f. 8-22-94, cert. ef. 9-1-94; PH 17-2006, f. 6-30-06, cert. ef. 7-1-06

333-060-0070
Illumination

(1) Where underwater lighting is used, not less than 0.5 watts incandescent or the equivalent shall be employed per square foot of pool area.

(2) Where underwater lighting is used, and night or indoor swimming is permitted, area lighting shall be provided for the deck areas and directed away from the pool surface. No less than 0.6 watts incandescent or the equivalent per square foot of deck area shall be used.

(3) Where underwater lighting is not employed and night swimming is permitted, area and pool lighting combined shall be provided at not less than two watts incandescent or the equivalent per square foot of deck area.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0116; HD 7-1986, f. & ef. 5-1-86

333-060-0075
Ventilation

(1) A public swimming pool or public wading pool license holder must ensure that there is sufficient ventilation to prevent build-up of harmful amounts of moisture or chemical byproducts in the air of buildings enclosing swimming pools and public wading pools.

(2) A public swimming pool or public wading pool built or renovated after September 1, 2014, and enclosed in a building must have a ventilation system that complies with the requirements of the **Oregon Structural Specialty Code, 2014 Edition**, and the **Oregon Mechanical Specialty Code, 2014 Edition**, both incorporated by reference.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.005 - 448.100, 448.990
Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0118; HD 7-1986, f. & ef. 5-1-86; HD 22-1994, f. 8-22-94, cert. ef. 9-1-94; PH 17-2006, f. 6-30-06, cert. ef. 7-1-06; PH 23-2014, f. 8-15-14, cert. ef. 9-1-14

333-060-0080
Ladders, Recessed Steps and Stairways

(1) All public swimming pools shall have a ladder, set of recessed steps or stairway located at 75' (22.9m) intervals around the pool perimeter with a minimum of two such means of egress.

(2) There shall be at least one ladder, set of recessed steps or stairway at the shallow end and another at the deep end of the pool.

(3) Ladder treads, recessed step surfaces and stairs shall have slip-resistant surfaces.

(4)(a) Ladders and recessed steps shall be provided with two handrails;

(b) Stairways shall be provided with at least one handrail.

(5) Recessed steps shall drain into the pool.

(6) Ladders, recessed steps and stairways shall be located so as not to interfere with racing lanes.

(7) Stairway treads shall have a minimum unobstructed horizontal tread depth of 10" (25cm) and a minimum unobstructed surface area of 240 square inches.

(8) Risers at the centerline of the stairway treads shall have a maximum uniform height of 12" (30cm). The vertical riser height from deck surface down to the top of the first tread shall not exceed 12" (30cm).

(9) Ladders and handrails shall be securely mounted.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0121; HD 7-1986, f. & ef. 5-1-86; HD 22-1994, f. 8-22-94, cert. ef. 9-1-94

333-060-0085
Diving

(1) Public swimming pools used for diving shall provide water depths and lateral and vertical clearances as follows:

(a) Pools constructed after May 1, 1986, shall comply with the minimum dimensions of **Figure 1**, **Table 1**. [Table not included. See ED. Note.]

(b) Pools constructed prior to May 1, 1986, shall comply with the minimum dimensions of **Figure 2**, **Table 2**. [Table not included. See ED. Note.]

(2) There shall be at least 16' (4.9m) of unobstructed vertical clearance above any diving board measured from the center of the front end of the board. This clearance shall extend horizontally 8' (2.4m) behind, 16' (4.9m) in front, and 8' (2.4m) to each side of the end of the board.

(3)(a) Diving boards one meter or more in height above the water shall be equipped with a stairway or ladder and two handrails;

(b) Diving boards one meter or higher shall be protected with guard rails, one on each side of the board. Such guard rails shall extend to the edge of the pool wall.

(4) Diving platforms higher than three meters shall not be installed at public swimming pools without the approval of the Division.

[ED. NOTE: Tables referenced are available from the agency.]
Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0123; HD 7-1986, f. & ef. 5-1-86; HD 22-1994, f. 8-22-94, cert. ef. 9-1-94

333-060-0090
Slides

(1) Slides shall comply with the requirements of the U.S. Consumer Product Safety Commission Safety Standards for Swimming Pool Slides as published in the **Code of Federal Regulations Vol. 16, Part 1207, Pages 265-281 (16 CFR Part 1207)**.

(2) Slides shall:

(a) Be sturdily constructed or corrosion-resistant material;

(b) Be securely fastened to the pool deck;

(c) Have a ladder equipped with slip-resistant treads and rigidly attached handrails;

(d) Have runways which are smooth, of one piece, and free of cutting, pinching, puncturing or abrasion hazards;

(e) Have slide runways which are provided with side rails on both sides; such side rails shall be no less than 2" (5cm) in height.

(3) Slide runways shall be water lubricated when in use.

(4) There shall be no slides higher than 12" (30cm) above the water level.

(5) Water depths 4.5' (1.4m) beyond the end of the slide shall be based on the slide height as follows: Height — Minimum Water Depth:

(a) More than 3 feet (90cm) up to 7.5 feet — (2.3m);

(b) 4 feet (1.2m) — More than 7.5 (2.3m) feet;

(c) Up to 8 feet (2.4m) — 5 feet (1.5m);

(d) More than 8.0 feet (2.4m) up to 11 feet (3.4m) — 5.5 feet (1.7m);

(e) More than 11.0 feet (3.4m) up to 12 feet (3.7m) — 6 feet (1.8m).

(6) Slides shall be equipped with the warning signs found in **Figure 3**. [Figure not included. See ED. Note.]

(7) Portable toddler slides (3 feet or less)(90cm) shall have an entry into water depths which are recommended by the manufacturer and approved by the Division or delegate county. Water depths for slide entry are determined by but not limited to platform height, length of slide, and weight of bather.

[ED. NOTE: Figures referenced are available from the agency.]
[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 448.031
Stats. Implemented: ORS 448.011
Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0125; HD 7-1986, f. & ef. 5-1-86; HD 22-1994, f. 8-22-94, cert. ef. 9-1-94

333-060-0091
Waterpark Slides

(1) Water park slides installed after January 1, 1994 must comply with the requirements of the U.S. Consumer Products Safety Commission safety standards for Swimming Pool Slides as published in the **Code of Federal Regulations Vol. 16**, **Part 1207**, **Pages 265-281 (16 CFR Part 1207)**.

(2) Prior to entering the pool, the last ten feet (3m) of the slide must be horizontal.

(3) The slide shall be designed so that it enters the pool at or below the water level.

(4) The pool shall be constructed of concrete or other structurally rigid, impervious materials with a smooth, slip resistant finish:

(a) There shall be a three and a half (3.5) foot (1m) minimum distance between the exterior slide wall and the adjacent vertical pool wall;

(b) There shall be a minimum twenty (20) feet (6.1m) between the slide exit and the opposite side of the pool, excluding steps;

(c) Centerlines for multiple slides shall be parallel, a minimum of eight (8) feet (2.4m) apart, and not intersect for twenty (20) feet (6.1m);

(d) The water depth at the slide exit shall be a minimum of three (3) feet (1m). This depth shall be maintained for a minimum distance of ten (10) feet (3m).

(5) If a public pool is for the exclusive use of a waterpark slide splash area, the pool's recirculation system shall be designed to provide a 60 minute turnover rate.

(6) During operation:

(a) Lifeguards shall be on duty at the slide splash area;

(b) The platform area shall have an attendant in place.

(7) Entry shall be regulated at a minimum of ten (10) second intervals.

(8) A sign shall be posted describing the proper way to use the slide. The sign shall include at least the following:

(a) Slide feet first only!

(b) Slide sitting up or lying on your back!

(c) Slide one at a time only!

(d) Always enter the pool feet first! Do not somersault, twist, or dive from the end of the slide.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 22-1994, f. 8-22-94, cert. ef. 9-1-94

333-060-0095
Elevated Lifeguard Chairs

(1) Elevated lifeguard chairs or elevated lifeguard platforms shall be provided at all general-use swimming pools.

(2) There shall be one lifeguard chair or elevated lifeguard platform for each 120 (36.6m) feet of pool perimeter and with the exception of section (3) of this rule may be spaced at the discretion of the pool operator.

(3) Where more than one lifeguard chair or elevated lifeguard platform is required, there shall be one chair or platform located on each side of the pool.

(4) Portable lifeguard chairs or elevated lifeguard platforms shall be acceptable providing they are structurally sound and tilt proof.

(5) Lifeguard chairs shall be at least 6' (1.8m) in height from the deck surface to the chair seat or elevated lifeguard platforms shall be at least 34" (85cm) in height from the deck surface to the platform surface.

(6) Where pool decks are at least 6' (1.8m) in width, all general-use pools build prior to March 1, 1979, shall comply with section (2) of this rule. All pools shall comply with section (5) of this rule, at such time as new elevated chairs or platforms are installed and/or existing elevated chairs or platforms need replacement, providing existing chairs are a minimum of 4' (1.2m) in height.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0128; HD 7-1986, f. & ef. 5-1-86; HD 22-1994, f. 8-22-94, cert. ef. 9-1-94

333-060-0100
Life Saving Equipment

The following life saving equipment shall be provided at all public swimming pools:

(1) A non-adjustable reach-pole not less than twelve (12) feet (3.6m) in length with an attached life hook.

(2) One life buoy with an attached thirty (30) foot (9.2m) long line. Such equipment shall be mounted conspicuously within the pool enclosure or the pool room and be readily available to lifeguards and pool users.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0130; HD 7-1986, f. & ef. 5-1-86; HD 22-1994, f. 8-22-94, cert. ef. 9-1-94

333-060-0105
Swimming Pool Enclosure

A pool license holder must ensure that:

(1) A public swimming pool is protected by an enclosure such as a fence, wall, or building without private entrances to the pool area; and

(2) Swimming and wading pool enclosures, except as provided in OAR 333-060-0505(9), including windows, gates and doors are constructed in such a manner so as to discourage access to the pool by unsupervised children and domestic animals and incorporate the following construction standards:

(a) Enclosures shall be not less than four feet (1.2m) in height measured from the outside ground level at a point one foot (300 mm) horizontal from the base of the enclosure;

(b) There shall be not more than four inches (100 mm) of space between the bottom of the enclosure and the ground's surface or pool deck;

(c) Separation between vertical sections and bars shall be a maximum of four inches (100 mm);

(d) Horizontal rails shall be spaced with a minimum 42 inches (1065 mm) separation;

(e) All exterior projections or recessions shall be 42 inches (1065 mm) from either the top or bottom of the fence;

(f) Gates and doors in swimming pool enclosures shall be self-closing and shall be equipped with a lockable self-latching device. The operating controls for the self-latching device shall be located at least 42 inches (1065 mm) above the exterior ground surface or pool deck. Gates and doors on new pools must swing "out" of the pool enclosure, or away from the pool. Existing pools must make the door or gate swing change when the change is not highly burdensome or impractical due to special conditions or cause.

(g) Entrances with self-closing and self-locking devices requiring the use of a key, keycard, or combination code to gain access may have controls 36 inches to 54 inches (0.9 m to 1.35 m) above the exterior ground surface. The gates or doors cannot require a key, keycard or combination code to exit the pool area;

(h) Construction methods and materials shall be used that provide a durable and low maintenance structure; and

(i) Buildings constructed on or after September 1, 2014 and buildings enclosing swimming pools that are remodeled or renovated on or after September 1, 2014 shall be constructed in accordance with the requirements of the Oregon Structural Specialty Code 2014 Edition.

(3) The Division may approve alternate enclosure materials and methods where the Division finds such materials and methods equivalent to those described in section (2) of this rule.

(4) Swimming pool enclosures constructed prior to March 1, 1979, which are a minimum of 42 inches (105cm) in height; or with spacing not greater than five inches (13cm) between vertical boards (bars); or with spacing not greater than five inches (13cm) between the bottom of the fence and the pool deck; or with spaces between the horizontal rails not less than 38 inches (95cm), shall be acceptable until such time as the enclosure requires repair or replacement.

(a) Pools without constant supervision in the pool area may provide access through controlled entry points based on one of the following conditions:

(A) When only adults over the age of 18 are allowed access to the pool area through a controlled-access point such as a registration or check-in desk, they may have direct access to the pool without passing through closed doors or gates. The pool entry must be able to be locked and secured when the pool is closed.

(B) If persons under the age of 18 might have access to the pool area, then the operator must provide a lockable, self-closing door or gate with a self-latching device. The operating controls for the latch must be located 42 inches to 54 inches (1.2 m to 1.35 m) above the exterior ground surface; or

(b) When a pool is closed to patrons, all entry/exit points are to be properly maintained and secured against unauthorized entry.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 448.011

Stats. Implemented: ORS 448.005-448.100, 448.990

Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0133; HD 7-1986, f. & ef. 5-1-86; HD 22-1994, f. 8-22-94, cert. ef. 9-1-94; PH 10-2007, f. & cert. ef. 7-13-07; PH 23-2014, f. 8-15-14, cert. ef. 9-1-14

333-060-0110
Decks

(1) The following minimum continuous unobstructed deck widths, which may include the coping, shall be provided at all public pools and public wading pools:

(a) General-use swimming pools — 8' (2.4m).

(b) Limited-use swimming pools, spray pools, wading pools — 4' (1.2m).

(A) Pools built prior to March 1, 1979, shall have 4' (1.2m) of deck on at least two sides of the pool.

(B) Public wading pools and spray pools built prior to July 1, 2006 must have a minimum of 4' (1.2m) of deck around the pool. Wading pools built after July 1, 2006 must comply with the deck requirements of OAR 333-060-0505(8).

(2) A minimum of 4' (1.2m) unobstructed deck shall be provided on all sides of diving equipment and slides.

(3) Decks shall slope no less than 1/4" per foot (6mm per 30cm) and shall be drained to perimeter or area drains.

(4) Deck surfaces:

(a) Shall be constructed of concrete, non-slip tile, or equally impervious material with a slip-resistant, easily cleanable surface impervious to water.

(b) Surfaces meeting the requirements of (4)(a) of this rule must be maintained for a minimum width of 8' (2.4m) around the perimeter of general-use pools and 4' (1.2m) around the perimeter of limited-use pools or within the limits of the deck drainage area, whichever is greater. Wood decking, carpeting or artificial turf deck surfaces are prohibited within 8' (2.4m) of general-use pools or 4' (1.2m) of limited-use pools or within the limits of the deck drainage area, whichever is greater.

(c) Pools previously approved with deck surfaces not complying with (4)(a) of this rule shall comply at such time as the surface requires repair or is replaced.

(5) Joints between concrete deck slabs shall be watertight and shall be designed so as to protect the pool, coping and its mortar bed from movement of the deck.

(6) Decks shall be provided with expansion joints.

(7) Voids between adjoining concrete deck slabs shall be no greater than 3/16" (5mm).

(8) Adjoining deck surface elevations shall vary no more than 1/4" (6mm).

(9) New and replacement expansion joints shall not be constructed of wood.

Stat. Auth.: ORS 448.011

Stats. Implemented: ORS 448.005 - 448.100, 448.990

Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0135; HD 7-1986, f. & ef. 5-1-86; HD 22-1994, f. 8-22-94, cert. ef. 9-1-94; PH 17-2006, f. 6-30-06, cert. ef. 7-1-06

333-060-0115
Overflow Systems

All public swimming pools shall be operated with a continuous overflow. Overflow systems shall be either of the perimeter type or a series of surface skimmers:

(1) A perimeter type overflow system shall be used at all general-use public swimming pools and at limited-use public swimming pools which are greater than 30 feet (9.1m) in width or have more than 2,500 square feet of surface area. Such perimeter system shall:

(a) Extend completely around the pool;

(b) Have a gutter which is smooth, cleanable and provides positive drainage.

(2) A perimeter-type or skimmer-type overflow system shall be used at all limited-use public swimming pools less than 30 feet (9.1m) in width or with less than 2,500 square feet of surface area:

(a) Where skimmers are used, there shall be one skimmer for each 400 square feet of surface area, with a minimum of two skimmers;

(b) Skimmers shall be located so as to achieve effective skimming action over the entire surface area of the pool.

(3)(a) Perimeter overflow systems shall be connected to the recirculation system with a system surge capacity of at least one gallon per square foot of pool surface. External surge systems shall be capable of transferring water at a rate equal to 100 percent of the design pool flow rate. Gutters shall drain in two minutes or less after sudden flooding;

(b) Pools with perimeter overflow systems shall be provided with surge tanks unless predesigned and prefabricated to use in-gutter of in-pool surge. Surge tanks shall have a capacity of one gallon per square foot of pool surface.

(4) Overflow systems shall be designed so as to return overflow water to the recirculation system ahead of the filters. Pro-

visions shall be made for diverting gutter water to waste when cleaning the gutter.

(5) Pools built prior to 1971 which were constructed without the overflow system being connected to the recirculation system shall satisfy this requirement by overflowing at least daily provided the water quality parameters of Pool Water Quality OAR 333-060-0200 and **Table 3** are met.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 448.011

Stats. Implemented: ORS 448.011

Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0138; HD 7-1986, f. & ef. 5-1-86; HD 22-1994, f. 8-22-94, cert. ef. 9-1-94

333-060-0120
Recirculation System

(1) All public swimming and wading pools shall have recirculation and filtration systems with piping, pumps, filters, disinfection and other equipment to maintain pool water quality as required by these rules.

(2) The system of pumps, filters, disinfection facilities and other equipment shall be of adequate size to recirculate, filter and disinfect the entire volume of pool water in the following maximum time intervals: Maximum Turnover — Time

(a) General-use public pools and limited-use public pools of over 2,000 square feet of surface area — 6 hours.

(b) Limited-use public pools of less than 2,000 square feet of surface area — 8 hours.

(c) Public wading pools — See OAR 333-060-0505.

(d) Limited use pools operated in conjunction with athletic clubs and built after May 1, 1986 — 6 hours.

(3) Overflow water shall not be less than 50 percent of the total recirculated water.

(4) Recirculation and filtration systems shall be in operation con-tinuously while the facility is in use.

Stat. Auth.: ORS 448.011

Stats. Implemented: ORS 448.005 - 448.100, 448.990

Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0140; HD 7-1986, f. & ef. 5-1-86; HD 22-1994, f. 8-22-94, cert. ef. 9-1-94; PH 17-2006, f. 6-30-06, cert. ef. 7-1-06

333-060-0125
Inlets

(1) Pool inlets must be provided, sized and arranged to produce a uniform circulation of water so as to maintain a uniform disinfectant residual throughout the pool.

(2) There must be at least one inlet per 400 square feet of pool area or 10,000 gallons of water, whichever is greater.

(3) Pools more than 50 feet wide and reverse flow pools must use floor inlet fittings uniformly spaced no more than 20 feet apart and within 15 feet of the sidewalls.

(4) Grates must be designed so as to prevent entrapment of fingers.

(5) All recirculation inlet fittings must be adjustable for rate of flow. Wall inlet fittings must be directional.

(6) Inlet fittings must have tamper-proof screws that cannot be removed except with tools. Grates, vortex plates and inlet fittings must be in place whenever the pool is in use.

(7) Direct potable water pool inlets must:

(a) Be over-the-rim fill spouts with air gaps located under a diving board or beside grab rails;

(b) Be through-the-wall fill lines located above the water level and equipped with an appropriate backflow prevention device installed per OAR 333-061-0071; or

(c) Be directly connected to the recirculation water supply and equipped with reduced pressure device installed per OAR 333-061-0071 on the potable water supply adjacent to the connection with the pool recirculation water.

Stat. Auth.: ORS 448.011

Stats. Implemented: ORS 448.005 - 448.100 & 448.990

Hist.: HD 2-1979, f. 1-25-79, ef. 3-1-79, Renumbered from 333-042-0143; HD 7-1986, f. & ef. 5-1-86; HD 22-1994, f. 8-22-94, cert. ef. 9-1-94; PH 6-2009(Temp), f. 6-16-09, cert. ef. 6-17-09 thru 12-13-09; Administrative correction 12-23-09; PH 16-2009, f. & cert. ef. 12-23-09

333-060-0128
Submerged Suction Outlets and Drains

(1) The requirements in sections (2) and (3) of this rule apply to:

(a) A swimming pool constructed after December 25, 2009;

(b) A swimming pool constructed before December 25, 2009, that on or after July 1, 2015, has its submerged suction fittings renovated or remodeled.

(2) A swimming pool must have at least two outlets located at the lowest point of the pool floor to drain the entire floor area. Exceptions to this include:

(a) Reverse Flow Pools, where the drain is not connected to the recirculation system, but is provided for drainage of the pool through an air-gap connection to the sanitary sewer.

(b) Other suction-fitting arrangement that allows the drainage of the pool through an air-gap connection to the sanitary sewer, or other approved location, while also providing entrapment protection.

(c) Pools with no drain system, with provisions to completely drain the pool to the sanitary sewer or other approved location, by other means that have entrapment protection.

(3) A swimming pool must have submerged suction fittings installed according to the following standards:

(a) Pool main drains must be installed in the deepest part of the pool and designed to minimize tripping and toe stubbing hazards. Suction fittings must be installed to minimize tripping, toe stubbing and scrape hazards.

(b) Main drain and submerged suction outlets must be designed with sufficient open area that the maximum velocity through the cover does not exceed the cover's listed flowrate.

(c) All hardware and fittings must be supplied by the manufacturer and installed according to the manufacturer's directions.

(d) Main drain and submerged suction fitting systems must provide entrapment, hair entanglement and evisceration protection.

(A) Main drains and submerged suction fittings and sumps must be compliant with the requirements of ANSI/APSP-16, Suction Fittings for Use in Swimming Pools, Wading Pools, Spas, and Hot Tubs (2011). The cover must be labeled and include; "VGB 2008," the logo of the third party listing agency, the standard for which it was tested, the gallons per minute of flow for which it was approved and the location it is to be placed.

(B) All submerged suction fittings must be installed with a sump designed and approved by the manufacturer for that outlet cover.

(C) All field built sumps must be designed by an Oregon registered engineer and must be built so the opening of the suction pipe is no closer than 1.5 times the pipe's inside diameter from the bottom of the listed suction cover/plate.

(D) Main drains and submerged suction fittings must be separated by at least three feet (915mm) (measured from the main drain connector pipe centerline) between the furthest fittings, or be on separate planes, placed so the floor and wall suction fittings cannot be easily blocked at the same time.

DIVISION 61

PUBLIC WATER SYSTEMS

333-061-0005
Purpose

The purpose of these rules is to provide a basis for implementing the Oregon Drinking Water Quality Act of 1981, enacted to assure safe drinking water at all water systems which serve the public, and to promote coordination between the programs for supervising water systems which are conducted by the Authority and the U.S. Environmental Protection Agency.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 448.123 & 448.273
Hist.: HD 106, f. & ef. 2-6-76; HD 17-1981(Temp), f. & ef. 8-28-81; HD 4-1982, f. & ef. 2-26-82; Renumbered from 333-042-0200, HD 2-1983, f. & ef. 2-23-83; HD 9-1989, f. & cert. ef. 11-13-89; PH 7-2010, f. & cert. ef. 4-19-10

333-061-0010
Scope

(1) These rules apply to all public water systems providing piped water for human consumption as defined by the Act.

(2) These rules also apply to all public water systems providing water for human consumption through constructed conveyances other than pipes after Aug. 5, 1998 to at least 15 service connections or that regularly serves at least 25 individuals daily at least 60 days of the year. A water system which meets any of the following "service connection" exclusion criteria and thereby reduces the number of service connections to fewer than 15 and serving fewer than 25 individuals is not a Public Water System:

(a) Water provided by the supplier to the connection is not used for human consumption;

(b) Alternative water (i.e. bottled water, hauled water, or other source) meeting State and Federal water quality standards, as prescribed in OAR 333-061-0030 or 21CFR165, is provided by the supplier to the connection for drinking and cooking;

(c) Treated water meeting State standards, as prescribed in OAR 333-061-0030, applied centrally or at point-of-entry is provided by the supplier, pass-through entity or user to the connection for drinking, cooking and personal hygiene.

(3) These rules do not apply to:

(a) A public water system that:

(A) Consists only of distribution and storage facilities and does not have any source or treatment facilities installed to comply with the maximum contaminant levels covered by these rules; and

(B) Obtains all of its water from, but is not owned or operated by, a public water system to which these rules apply; and

(C) Does not sell water directly to any person; and

(D) Is not a carrier which conveys passengers in interstate commerce.

(b) An irrigation district in existence prior to May 18, 1994, that provides primarily agricultural service through a piped water system to at least 15 service connections or serving at least 25 individuals daily at least 60 days of the year with only incidental residential or similar use, and where all of the connections comply with the alternative or treated water exclusions prescribed in subsections (2)(b) or (c) of this rule.

(c) A public water system that distributes water through submeters if that water system:

(A) Receives all of its water from, but is not owned by, another public water system; and

(B) Consists only of distribution and storage facilities and where all such facilities and all submeters are located on a single parcel of property, and the water system does not have any source or treatment facilities installed to comply with the maximum contaminant levels covered by these rules.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 448.131
Hist.: HD 106, f. & ef. 2-6-76; HD 17-1981(Temp), f. & ef. 8-28-81; HD 4-1982, f. & ef. 2-26-82; Renumbered from 333-042-0201, HD 2-1983, f. & ef. 2-23-83; HD 20-1983, f. 10-20-83, ef. 11-1-83; HD 9-1989, f. & cert. ef. 11-13-89; OHD 3-2000, f. 3-8-00, cert. ef. 3-15-00; PH 33-2004, f. & cert. ef. 10-21-04; PH 7-2010, f. & cert. ef. 4-19-10

333-061-0015
Adoption by Reference

All standards, listings and publications referred to in these rules are, by those references, made a part of these rules as though fully set forth. Copies are available from the Authority.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 448.131
Hist.: HD 106, f. & ef. 2-6-76; HD 17-1981(Temp), f. & ef. 8-28-81; HD 4-1982, f. & ef. 2-26-82; Renumbered from 333-042-0202, HD 2-1983, f. & ef. 2-23-83; HD 9-1989, f. & cert. ef. 11-13-89; PH 7-2010, f. & cert. ef. 4-19-10

333-061-0020
Definitions

As used in these rules, unless the context indicates otherwise:

(1) "Act" means the Oregon Drinking Water Quality Act of 1981 (ORS 448.115-448.990 as amended).

(2) "Action Level" means the concentration of lead or copper in water which determines, in some cases, the treatment requirements that a water system is required to complete.

(3) "Administrator" means the Director of the Oregon Health Authority or his/her designee.

(4) "Analytical Run" means the process during which a set of analytical drinking water samples along with an appropriate number of blanks, matrix spikes, or quality control samples are analyzed according to National Environmental Laboratory Accreditation Conference (NELAC) requirements to determine the presence, absence, or concentration of a specific target analyte or analytes. An analytical run is complete when the instrument performing the sample analysis generates a report of the sample analysis.

(5) "Approval" or "Approved" means approved in writing.

(6) "Approved Air Gap (AG)" means a physical separation between the free-flowing discharge end of a potable water supply pipeline and an open or non-pressurized receiving vessel. An "Approved Air Gap" shall be at least twice the diameter of the supply pipe measured vertically above the overflow rim of the vessel and in no case less than 1 inch (2.54 cm), and in accord with Oregon Plumbing Specialty Code.

(7) "Approved Backflow Prevention Assembly" means a Reduced Pressure Principle Backflow Prevention Assembly, Reduced Pressure Principle-Detector Backflow Prevention Assembly, Double Check Valve Backflow Prevention Assembly, Double Check-Detector Backflow Prevention Assembly, Pressure Vacuum Breaker Backsiphonage Prevention Assembly, or Spill-Resistant Pressure Vacuum Breaker Backsiphonage Prevention Assembly, of a make, model, orientation, and size approved by the Authority. Assemblies listed in the currently approved backflow prevention assemblies list developed by the University of Southern California, Foundation for Cross-Connection Control and Hydraulic Research, or other testing laboratories using equivalent testing methods, are considered approved by the Authority.

(8) "Aquifer" means a water saturated and permeable geological formation, group of formations, or part of a formation that is capable of transmitting water in sufficient quantity to supply wells or springs.

(9) "Aquifer Parameter" means a characteristic of an aquifer, such as thickness, porosity or hydraulic conductivity.

(10) "Aquifer Test" means pumping a well in a manner that will provide information regarding the hydraulic characteristics of the aquifer.

(11) "Area of public health concern" means an area of the state with a confirmed presence of groundwater contaminants likely to cause adverse human health effects.

(12) "Atmospheric Vacuum Breaker (AVB)" means a non-testable device consisting of an air inlet valve or float check, a check seat and an air inlet port(s). This device is designed to protect against a non-health hazard or a health hazard under a back-siphonage condition only. Product and material approval is under the Oregon Plumbing Specialty Code.

(13) "Authority" means the Oregon Health Authority or its designee.

(14) "Auxiliary Water Supply" means any supply of water used to augment the supply obtained from the public water system, which serves the premises in question.

(15) "Average Groundwater Velocity" means the average velocity at which groundwater moves through the aquifer as a function of hydraulic gradient, hydraulic conductivity and porosity.

(16) "AWWA" means the American Water Works Association.

(17) "Backflow" means the flow of water or other liquids, mixtures, or substances into the distributing pipes of a potable supply of water from any sources other than its intended source, and is caused by backsiphonage or backpressure.

(18) "Backflow Preventer" means a device, assembly or method to prevent backflow into the potable water system.

(19) "Backflow Prevention Assembly" means a backflow prevention assembly such as a Pressure Vacuum Breaker Backsiphonage Prevention Assembly, Spill-Resistant Pressure Vacuum Breaker Backsiphonage Prevention Assembly, Double Check Valve Backflow Prevention Assembly, Double Check-Detector Backflow Prevention Assembly, Reduced Pressure Principle Backflow Prevention Assembly, or Reduced Pressure Principle-Detector Backflow Prevention Assembly and the attached shutoff valves on the inlet and outlet ends of the assembly, assembled as a complete unit.

(20) "Backpressure" means an elevation of pressure downstream of the distribution system that would cause, or tend to cause, water to flow opposite of its intended direction.

(21) "Backsiphonage" means a drop in distribution system pressure below atmospheric pressure (partial vacuum), that would cause, or tend to cause, water to flow opposite of its intended direction.

(22) "Bank Filtration" means a water treatment process that uses a horizontal or vertical well to recover surface water that has naturally infiltrated into groundwater through a river bed or bank(s). Infiltration is typically enhanced by the hydraulic gradient imposed by a nearby pumping water supply.

(23) "Best Available Technology" or "BAT" means the best technology, treatment techniques, or other means which the EPA finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration).

(24) "Bore-Sighted Drain to Daylight" means an unrestricted straight-line opening in an enclosure that vents to grade, and is sized and constructed to adequately drain the full flow discharge from a reduced pressure principle backflow prevention assembly thus preventing any potential for submersion of the assembly.

(25) "Bottled Water" means potable water from a source approved by the Authority for domestic use which is placed in small, easily transportable containers.

(26) "Calculated Fixed Radius" means a technique to delineate a wellhead protection area, based on the determination of the volume of the aquifer needed to supply groundwater to a well over a given length of time.

(27) "CFR" means the Code of Federal Regulations. Specifically, it refers to those sections of the code which deal with the National Primary and Secondary Drinking Water Regulations.

(28) "Check Valve" means a valve, which allows flow in only one direction.

(29) "Coagulation" means a process using coagulant chemicals and mixing by which colloidal and suspended materials are destabilized and agglomerated into floc.

(30) "Coliform Investigation" means an evaluation to identify the possible presence of sanitary defects, defects in distribution system coliform monitoring practices, and (when possible) the likely reason that the investigation was triggered at the water system. Coliform investigations are classified as level 1 or level 2 as prescribed by OAR 333-061-0078.

(31) "Coliform-Positive" means the presence of coliform bacteria in a water sample.

(32) "Combined distribution system" means the interconnected distribution system consisting of the distribution systems of wholesale water systems and of the purchasing water systems that receive finished water.

(33) "Community Water System" means a public water system that has 15 or more service connections used by year-round residents, or that regularly serves 25 or more year-round residents.

(34) "Compliance Cycle" means the nine-year calendar year cycle during which public water systems must monitor. Each compliance cycle consists of three three-year compliance periods. The first calendar year cycle begins January 1, 1993 and ends December 31, 2001.

(35) "Compliance Period" means a three-year calendar year period within a compliance cycle. Each compliance cycle has three three-year compliance periods. Within the first compliance cycle, the first compliance period runs from January 1, 1993 to December 31, 1995; the second from January 1, 1996 to December 31, 1998; and the third from January 1, 1999 to December 31, 2001.

(36) "Comprehensive performance evaluation (CPE)" means a thorough review and analysis of a treatment plant's performance-based capabilities and associated administrative, operation and maintenance practices. It is conducted to identify factors that may be adversely impacting a plant's capability to achieve compliance and emphasizes approaches that can be implemented without significant capital improvements. The CPE must consist of at least the following components: Assessment of plant performance; evaluations of major unit processes; identification and prioritization of performance limiting factors; assessment of the applicability of comprehensive technical assistance; and preparation of a CPE report.

(37) "Conceptual Model" means a three-dimensional representation of the groundwater system, including the location and extent of the hydrogeologic units, areas of recharge and discharge, hydrogeologic boundaries and hydraulic gradient.

(38) "Confined Well" means a well completed in a confined aquifer. More specifically, it is a well which produces water from a formation that is overlain by an impermeable material of extensive area. This well shall be constructed according to OAR chapter 690, division 200 "Well Construction and Maintenance" standards.

(39) "Confluent Growth" means a continuous bacterial growth covering the entire filtration area of a membrane filter, or a portion thereof, in which bacterial colonies are not discrete.

(40) "Constructed Conveyance" means any human-made conduit such as ditches, culverts, waterways, flumes, mine drains, canals or any human-altered natural water bodies or waterways as determined by the Authority.

(41) "Contaminant" means any physical, chemical, biological, or radiological substance or matter in water that creates a health hazard.

(42) "Contingency Plan" means a document setting out an organized, planned and coordinated course of action to be followed in the event of a loss of capacity to supply water to the distribution system or in case of a fire, explosion or release of hazardous waste which could threaten human health or the environment.

(43) "Continuing Education Unit (CEU)" means a nationally recognized unit of measurement for assigning credits for education or training that provides the participant with advanced or post high school learning. One CEU is awarded for every 10 classroom hours of lecture or the equivalent of participation in an organized education experience, conducted under responsible sponsorship, capable direction and qualified instruction as determined by the Authority or its designee.

(44) "Conventional Filtration Treatment Plant" means a water treatment plant using conventional or direct filtration to treat surface water or groundwater under the direct influence of surface water.

(45) "Corrosion Inhibitor" means a substance capable of reducing the corrosivity of water toward metal plumbing materials, especially lead and copper, by forming a protective film on the interior surface of those materials.

(46) "Cross Connection" means any actual or potential unprotected connection or structural arrangement between the public or user's potable water system and any other source or system through which it is possible to introduce into any part of the potable system any used water, industrial fluid, gas, or substances

other than the intended potable water with which the system is supplied. Bypass arrangements, jumper connections, removable sections, swivel, or change-over devices, and other temporary or permanent devices through which, or because of which, backflow can occur are considered to be cross connections.

(47) "CT" means the product of the residual disinfectant concentration "C" (measured in mg/l) and disinfectant contact time(s), "T" (measured in minutes).

(48) "Degree of Hazard" means either pollution (non-health hazard) or contamination (health hazard) and is determined by an evaluation of hazardous conditions within a system.

(49) "Delineation" means the determination of the extent, orientation and boundaries of a wellhead protection area using factors such as geology, aquifer characteristics, well pumping rates and time of travel.

(50) "Demonstration Study" means a series of tests performed to prove an overall effective removal or inactivation rate of a pathogenic organism through a treatment or disinfection process.

(51) "Direct Responsible Charge (DRC)" means an individual designated by the owner or authorized agent to make decisions regarding the daily operational activities of a public water system, water treatment facility or distribution system, that will directly impact the quality or quantity of drinking water.

(52) "Discharge" means the volume rate of loss of groundwater from the aquifer through wells, springs or to surface water.

(53) "Disinfectant Contact Time" means the time in minutes that it takes for water to move from the point of disinfectant application or the previous point of disinfection residual measurement to a point before or at the point where residual disinfectant concentration is measured.

(54) "Disinfectant Residual Maintenance" means a process where public water systems add chlorine (or other chemical oxidant) for the purpose of maintaining a disinfectant residual in the distribution system, when the source(s) is not at risk of microbial contamination.

(55) "Disinfection" means a process which inactivates pathogenic organisms in water by chemical oxidants or equivalent agents.

(56) "Disinfection profile" means a summary of Giardia lamblia inactivation through the treatment plant.

(57) "Distribution System" means that portion of the water system in which water is stored or conveyed from the water treatment plant or other supply point to the premises of a consumer.

(58) "Domestic" means provided for human consumption.

(59) "Domestic or other non-distribution system plumbing problem" means a coliform contamination problem in a public water system with more than one service connection that is limited to the specific service connection from which the coliform-positive sample was taken.

(60) "Dose Equivalent" means the product of the absorbed dose from ionizing radiation and such factors as account for differences in biological effectiveness due to the type of radiation and its distribution in the body as specified by the International Commission on Radiological Units and Measurements (ICRU).

(61) "Double Check-Detector Backflow Prevention Assembly (DCDA)" means a specially designed assembly composed of a line size approved double check valve assembly assembled with a bypass containing a specific water meter and an approved double check valve assembly. The meter shall register accurately for only very low rates of flow up to three gallons per minute and shall show a registration for all rates of flow. This assembly is designed to protect against a non-health hazard.

(62) "Double Check Valve Backflow Prevention Assembly (DC)" means an assembly of two independently acting approved check valves, including tightly closing resilient seated shutoff valves attached at each end of the assembly and fitted with properly located resilient seated test cocks. This assembly is designed to protect against a non-health hazard.

(63) "Drawdown" means the difference, measured vertically, between the static water level in the well and the water level during pumping.

(64) "Drinking Water Protection" means implementing strategies within a drinking water protection area to minimize the potential impact of contaminant sources on the quality of water being used as a drinking water source by a Public Water System.

(65) "Drinking Water Protection Area (DWPA)" means the source area supplying drinking water to a Public Water System. For a surface water-supplied drinking water source the DWPA is all or a specifically determined part of a lake's, reservoir's or stream's watershed that has been certified by the Department of Environmental Quality. For a groundwater-supplied drinking water source the DWPA is the area on the surface that directly overlies that part of the aquifer that supplies groundwater to a well, well field or spring that has been certified by the Authority.

(66) "Drinking Water Protection Plan" means a plan, certified by the Department of Environmental Quality according to OAR 340-040-0160 to 340-040-0180, which identifies the actions to be taken at the local level to protect a specifically defined and certified drinking water protection area. The plan is developed by the local Responsible Management Authority or team and includes a written description of each element, public participation efforts, and an implementation schedule.

(67) "Dual sample set" means a set of two samples collected at the same time and same location, with one sample analyzed for TTHM and the other for HAA5. Dual sample sets are collected for the purposes of conducting an Initial Distribution System Evaluation (IDSE) as prescribed in 333-061-0036(4)(b) of these rules, and for determining compliance with the maximum contaminant levels for TTHM and HAA5 listed in OAR 333-061-0030(2)(b).

(68) "Effective Corrosion Inhibitor Residual" means a concentration sufficient to form a passivating film on the interior walls of a pipe.

(69) "Effective Porosity" means the ratio of the volume of interconnected voids (openings) in a geological formation to the overall volume of the material.

(70) "Element" means one of seven objectives considered by the U.S. EPA as the minimum required components in any state wellhead protection program: specification of duties, delineation of the wellhead protection area, inventory of potential contaminant sources, specification of management approaches, development of contingency plans, addressing new (future) wells, and ensuring public participation.

(71) "Emergency" means a condition resulting from an unusual calamity such as a flood, storm, earthquake, drought, civil disorder, volcanic eruption, an accidental spill of hazardous material, or other occurrence which disrupts water service at a public water system or endangers the quality of water produced by a public water system.

(72) "Emergency Response Plan" means a written document establishing contacts, operating procedures, and actions taken for a public water system to minimize the impact or potential impact of a natural disaster, accident, or intentional act which disrupts or damages, or potentially disrupts or potentially damages the public water system or drinking water supply, and returns the public water system to normal operating condition.

(73) "Enhanced coagulation" means the addition of sufficient coagulant for improved removal of disinfection byproduct precursors by conventional filtration treatment.

(74) "Enhanced softening" means the improved removal of disinfection byproduct precursors by precipitative softening.

(75) "EPA" means the United States Environmental Protection Agency.

(76) "Filter profile" means a graphical representation of individual filter performance, based on continuous turbidity measurements or total particle counts versus time for an entire filter run, from start-up to backwash inclusively, that includes an assessment of filter performance while another filter is being backwashed.

(77) "Filtration" means a process for removing particulate matter from water through porous media.

(a) "Bag filtration" means a pressure-driven separation process that removes particulate matter using engineered media. It is typically constructed of a non-rigid, fabric filtration media housed

in a pressure vessel in which the direction of flow is from the inside of the bag to the outside.

(b) "Cartridge filtration" means a pressure-driven separation process that removes particulate matter using engineered media. It is typically constructed of rigid or semi-rigid, self-supporting filter elements housed in a pressure vessel in which flow is from the outside of the cartridge to the inside.

(c) "Conventional Filtration Treatment" means a series of processes including coagulation (requiring the use of a primary coagulant and rapid mix), flocculation, sedimentation, and filtration resulting in substantial particulate removal.

(d) "Direct Filtration Treatment" means a series of processes including coagulation (requiring the use of a primary coagulant and rapid mix) and filtration but excluding sedimentation resulting in substantial particulate removal.

(e) "Diatomaceous Earth Filtration" means a process resulting in substantial particulate removal in which:

(A) A precoat cake of diatomaceous earth filter media is deposited on a support membrane (septum); and

(B) While the water is filtered by passing through the cake on the septum, additional filter media, known as body feed, is continuously added to the feed water, in order to maintain the permeability of the filter cake.

(f) "Membrane filtration" means a pressure or vacuum driven separation process in which particulate matter larger than one micrometer is rejected by engineered media, primarily through a size-exclusion mechanism, and which has a measurable removal efficiency of a target organism that can be verified through the application of a direct integrity test. This definition includes the common membrane technologies of microfiltration, ultrafiltration, nanofiltration, and reverse osmosis.

(g) "Slow Sand Filtration" means a process involving passage of raw water through a bed of sand at low velocity (generally less than 235 gallons per square foot per day) resulting in substantial particulate removal by both physical and biological mechanisms.

(78) "Filtration Endorsement" means a special certification that may be added to an operator's water treatment level 2 certification, and is related to the operator's experience with and knowledge of the operation of conventional and direct filtration treatment.

(79) "Finished water" means water that is introduced into the distribution system of a public water system and intended for distribution and consumption without further treatment, except as necessary to maintain water quality in the distribution system such as booster disinfection or the addition of corrosion control chemicals.

(80) "First Customer" means the initial service connection or tap on a public water supply after any treatment processes.

(81) "First Draw Sample" means a one-liter sample of tap water that has been standing in plumbing pipes at least 6 hours and is collected without flushing the tap.

(82) "Flocculation" means a process to enhance agglomeration or collection of smaller floc particles into larger, more easily settleable particles through gentle stirring by hydraulic or mechanical means.

(83) "Flowing stream" means a course of running water flowing in a definite channel.

(84) "Future Groundwater Sources" means wells or springs that may be required by the public water system in the future to meet the needs of the system.

(85) "GAC 10" means granular activated carbon filter beds with an empty-bed contact time of 10 minutes based on average daily flow and a carbon reactivation frequency of every 180 days, except that the reactivation frequency for GAC10 used as a best available technology for compliance with OAR 333-061-0030(2)(b) shall be 120 days.

(86) "GAC 20" means granular activated carbon filter beds with an empty-bed contact time of 20 minutes based on average daily flow and a carbon reactivation frequency of every 240 days.

(87) "Gross Alpha Particle Activity" means the total radioactivity due to alpha particle emission as inferred from measurements on a dry sample.

(88) "Gross Beta Particle Activity" means the total radioactivity due to beta particle emission as inferred from measurements on a dry sample.

(89) "Groundwater" means any water, except capillary moisture, beneath the land surface or beneath the bed of any stream, lake, reservoir or other body of surface water within the boundaries of this state, whatever may be the geologic formation or structure in which such water stands, flows, percolates or otherwise moves.

(90) "Groundwater System" means any public water system that uses groundwater, including purchasing water systems that receive finished groundwater, but excluding public water systems that combine all of their groundwater with surface water or groundwater under the direct influence of surface water prior to treatment.

(91) "Groundwater under the direct influence of surface water" or "GWUDI" means any water beneath the surface of the ground with significant occurrence of insects or other macroorganisms, algae or large-diameter pathogens such as Giardia lamblia or Cryptosporidium, or significant and relatively rapid shifts in water characteristics such as turbidity, temperature, conductivity, or pH which closely correlate to climatological or surface water conditions.

(92) "Haloacetic acids (five)" or "HAA5" means the sum of the concentrations in milligrams per liter of the haloacetic acid compounds (monochloroacetic acid, dichloroacetic acid, trichloroacetic acid, monobromoacetic acid and dibromoacetic acid), rounded to two significant figures after addition.

(93) "Hauled Water" means water for human consumption transported from a Public Water System in a manner approved by the Authority.

(94) "Health Hazard (Contamination)" means an impairment of the quality of the water that could create an actual hazard to the public health through poisoning or through the spread of disease by sewage, industrial fluids, waste, or other substances.

(95) "Human Consumption" means water used for drinking, personal hygiene bathing, showering, cooking, dishwashing, and maintaining oral hygiene.

(96) "Hydraulic Conductivity" means the capacity of the medium, for example, soil, aquifer, or any hydrogeological unit of interest, to transmit water.

(97) "Hydraulic Connection" refers to a well, spring or other groundwater collection system in which it has been determined that part of the water supplied by the collection system is derived, either naturally or induced, from a surface water source.

(98) "Hydraulic Gradient" means the slope of the water table or potentiometric surface, calculated by dividing the change in hydraulic head between two points by the horizontal distance between the points in the direction of groundwater flow.

(99) "Hydraulic Head" means the energy possessed by the water mass at a given point, related to the height above the datum plane that water resides in a well drilled to that point. In a groundwater system, the hydraulic head is composed of elevation head and pressure head.

(100) "Hydrogeologic Boundary" means physical features that bound and control direction of groundwater flow in a groundwater system. Boundaries may be in the form of a constant head, for example, streams, or represent barriers to flow, for example, groundwater divides and impermeable geologic barriers.

(101) "Hydrogeologic Mapping" means characterizing hydrogeologic features (for example, hydrogeologic units, hydrogeologic boundaries, etc.) within an area and determining their location, areal extent and relationship to one another.

(102) "Hydrogeologic Unit" means a geologic formation, group of formations, or part of a formation that has consistent and definable hydraulic properties.

(103) "Impermeable Material" means a material that limits the passage of water.

(104) "Impounding Reservoir" means an uncovered body of water formed behind a dam across a river or stream, and in which water is stored.

(105) "Infiltration Gallery" means a system of perforated pipes laid along the banks or under the bed of a stream or lake

installed for the purpose of collecting water from the formation beneath the stream or lake.

(106) "Initial Compliance Period" means the 1993-95 three-year compliance period for systems with 150 or more service connections and the 1996-98 three-year compliance period for systems having fewer than 150 service connections for the contaminants prescribed in OAR 333-061-0036(2)(a), 333-061-0036(3)(a) and (3)(b).

(107) "Interfering Wells" means wells that, because of their proximity and pumping characteristics, and as a result of the aquifer's hydraulic properties, produce drawdown cones that overlap during simultaneous pumping. The result is a lowering of the pumping level in each well below what it would be if that well were pumping by itself.

(108) "Inventory of Potential Contaminant Sources" means the reconnaissance level location of land use activities within the Drinking Water Protection Area that as a category have been associated with groundwater or surface water contamination in Oregon and elsewhere in the United States.

(109) "Lake/reservoir" means a natural or man-made basin or hollow on the Earth's surface in which water collects or is stored that may or may not have a current or single direction of flow.

(110) "Lead Free" means:

(a) Not containing more than 0.2 percent lead when used with respect to solders and flux; and

(b) Not more than a weighted average of 0.25 percent lead when used with respect to the wetted surfaces of pipes, pipe fittings, plumbing fittings, and fixtures.

(111) "Lead Service Line" means a service line made of lead, which connects the water main to the building inlet and any pigtail, gooseneck or other fitting, which is connected to such lead line.

(112) "Legionella" means a genus of bacteria, some species of which have caused a type of pneumonia called Legionnaires Disease.

(113) "Local Administrative Authority" means the individual official, board, department or agency established and authorized by a state, county or city to administer and enforce the provisions of the Oregon State Plumbing Specialty Code adopted under OAR 918-750-0110.

(114) "Locational running annual average (LRAA)" means the arithmetic average of analytical results for samples taken at a specific monitoring location during the previous four calendar quarters.

(115) "Major Additions or Modifications" means changes of considerable extent or complexity including, but not limited to, projects involving water sources, treatment facilities, facilities for continuous disinfection, finished water storage, pumping facilities, transmission mains, and distribution mains, except main replacements of the same length and diameter.

(116) "Man-made Beta Particle and Photon Emitters" means all radionuclides emitting beta particles or photons listed in Maximum Permissible Body Burdens and Maximum Permissible Concentration of Radionuclides in Air or Water for Occupational Exposure, NBS Handbook 69, except the daughter products of Thorium-232, Uranium-235 and Uranium-238.

(117) "Master Plan" means an overall plan, which shows the projected development of a distribution system and alternatives for source development.

(118) "Maximum Contaminant Level" or "MCL" means the maximum allowable level of a contaminant in water delivered to the users of a public water system, except in the case of turbidity where the maximum allowable level is measured at the point of entry to the distribution system.

(119) "Maximum Residual Disinfectant Level (MRDL)" means a level of a disinfectant added for water treatment that may not be exceeded at the consumer's tap without an unacceptable possibility of adverse health effects.

(120) "Multi-purpose Piping System" means a piping system within residential dwellings intended to serve both domestic and fire protection needs. This type of system is considered part of a potable water system.

(121) "New Groundwater Sources" means additional or modified wells or springs owned by the Public Water System.

(122) "Non-Health Hazard (Pollution)" means an impairment of the quality of the water to a degree that does not create a hazard to the public health, but does adversely affect the aesthetic qualities of such water for potable use.

(123) "Non-Transient Non-Community Water System (NTNC)" means a public water system that is not a Community Water System and that regularly serves at least 25 of the same persons over 6 months per year.

(124) "Open Interval" means in a cased well, the sum of the length(s) of the screened or perforated zone(s) and in an uncased (open-hole) well, the sum of the thickness(es) of the water-bearing zones or, if undeterminable, 10 percent of the length of the open hole.

(125) "Operating Experience" means knowledge gained through the direct performance of duties, tasks, and responsibilities at a drinking water system or in a related field.

(126) "Operational Decision Making" means the act of making decisions about alternatives in the performance of a water treatment plant or distribution system relating to water quality or water quantity that may affect public health.

(127) "Operator," means a person responsible for the operation of a water treatment plant or distribution system.

(128) "Optimal Corrosion Control Treatment" means the corrosion control treatment that minimizes the lead and copper concentrations at users' taps while insuring that the treatment does not cause the water system to violate any national primary drinking water regulations.

(129) "Pathogenic" means a specific agent (bacterium, virus or parasite) causing or capable of causing disease.

(130) "Peak Daily Demand" means the maximum rate of water use, expressed in gallons per day, over the 24-hour period of heaviest consumption.

(131) "Permit" means official permission granted by the Authority for a public water system which exceeds maximum contaminant levels to delay, because of economic or other compelling factors, the installation of water treatment facilities which are necessary to produce water which does not exceed maximum contaminant levels.

(132) "Person" means any individual, corporation, association, firm, partnership, municipal, state or federal agency, or joint stock company and includes any receiver, special master, trustee, assignee, or other similar representative thereof.

(133) "Picocurie (pCi)" means that quantity of radioactive material producing 2.22 nuclear transformations per minute.

(134) "Pilot Study" means the construction and operation of a scaled down treatment system during a given period of time to determine the feasibility a full-scale treatment facility.

(135) "Plant intake" means the works or structures at the head of a conduit through which water is diverted from a source, such as a river or lake, into a treatment plant.

(136) "Plug Flow" means movement of water in a pipe such that particles pass through the pipe and are discharged in the same sequence in which they entered.

(137) "Point of Delivery (POD)" means the point of connection between a public water system and the user's water system. Beyond the point of delivery, the Oregon Plumbing Specialty Code applies. See "Service Connection."

(138) "Point of Disinfectant Application" is the point where the disinfectant is applied and water downstream of that point is not subject to recontamination by surface water runoff.

(139) "Point-of-Entry Treatment Device" is a treatment device applied to the drinking water entering a house or building for the purpose of reducing contaminants in the drinking water distributed throughout the house or building.

(140) "Point-of-Use Treatment Device" is a treatment device applied to a single tap used for the purpose of reducing contaminants in drinking water at that one tap.

(141) "Pollutant" means a substance that creates an impairment of the quality of the water to a degree which does not create a

hazard to the public health, but which does adversely affect the aesthetic qualities of the water.

(142) "Porous Media Assumption" means the assumption that groundwater moves in the aquifer as if the aquifer were granular in character, that is moves directly down-gradient, and the velocity of the groundwater can be described by Darcy's Law.

(143) "Post High School Education" means that education acquired through programs such as short schools, bona fide correspondence courses, trade schools, colleges, universities, formalized workshops or seminars that are acceptable to the Authority and for which college or continuing education credit is issued by the training sponsor.

(144) "Potable Water" See Safe Drinking Water.

(145) "Potential Contaminant Source Inventory" means the determination of the location within the wellhead protection area of activities known to use or produce materials that can contaminate groundwater.

(146) "Potential Cross Connection" means a cross connection that would most likely occur, but may not be taking place at the time of an inspection.

(147) "Potentiometric Surface" means a surface that denotes the variation of hydraulic head in the given aquifer across an area.

(148) "Premises" means real estate and the structures on it.

(149) "Premises Isolation" means the practice of protecting the public water supply from contamination or pollution by installing backflow prevention assemblies at, or near, the point of delivery where the water supply enters the premises. Premises isolation does not guarantee protection to persons on the premises.

(150) "Presedimentation" means a preliminary treatment process used to remove gravel, sand and other particulate material from the source water through settling before the water enters the primary clarification and filtration processes in a treatment plant.

(151) "Pressure Vacuum Breaker Backsiphonage Prevention Assembly (PVB)" means an assembly consisting of an independently operating, internally loaded check valve and an independently operating loaded air inlet valve located on the discharge side of the check valve. This assembly is to be equipped with properly located resilient seated test cocks and tightly closing resilient seated shutoff valves attached at each end of the assembly. This assembly is designed to protect against a non-health hazard or a health hazard under backsiphonage conditions only.

(152) "Provisional Delineation" means approximating the wellhead protection area for a well by using the wellhead protection area from another well in the same hydrogeologic setting or by using generalized values for the aquifer characteristics to generate an approximate wellhead protection area for the well. Used only for the purpose of evaluating potential siting of new or future groundwater sources. Not an acceptable way to formally delineate a wellhead protection area.

(153) "Public Health Hazard" means a condition, device or practice which is conducive to the introduction of waterborne disease organisms, or harmful chemical, physical, or radioactive substances into a public water system, and which presents an unreasonable risk to health.

(154) "Public Water System" means a system for the provision to the public of piped water for human consumption, if such system has more than three service connections, or supplies water to a public or commercial establishment that operates a total of at least 60 days per year, and that is used by 10 or more individuals per day. Public water system also means a system for the provision to the public of water through constructed conveyances other than pipes to at least 15 service connections or regularly serves at least 25 individuals daily at least 60 days of the year. A public water system is either a "Community Water System," a "Transient Non-Community Water System," a "Non-Transient Non-Community Water System" or a "State Regulated Water System."

(155) "Purchasing Water System" means a public water system which obtains its water in whole or in part from one or more public water systems. Delivery may be through a direct connection or through the distribution system of one or more purchasing water systems.

(156) "Recharge" means the process by which water is added to a zone of saturation, usually by downward infiltration from the surface.

(157) "Recharge Area" means a land area in which water percolates to the zone of saturation through infiltration from the surface.

(158) "Recovery" means the rise in water level in a well from the pumping level towards the original static water level after pumping has been discontinued.

(159) "Reduced Pressure Principle Backflow Prevention Assembly (RP)" means an assembly containing two independently acting approved check valves, together with a hydraulically operating, mechanically independent pressure differential relief valve located between the check valves and at the same time below the first check valve. The unit shall include properly located resilient seated test cocks and tightly closing resilient seated shutoff valves at each end of the assembly. This assembly is designed to protect against a non-health hazard or a health hazard.

(160) "Reduced Pressure Principle-Detector Backflow Prevention Assembly (RPDA)" means a specifically designed assembly composed of a line size approved reduced pressure principle backflow prevention assembly with a bypass containing a specific water meter and an approved reduced pressure principle backflow prevention assembly. The meter shall register accurately for only very low rates of flow up to three gallons per minute and shall show a registration for all rates of flow. This assembly is designed to protect against a non-health hazard or a health hazard.

(161) "Rem" means the unit of dose equivalent from ionizing radiation to the total body or any internal organ or organ system. A "millirem (mrem)" is 1/1000 of a rem.

(162) "Repeat Compliance Period" means any subsequent compliance period after the initial compliance period.

(163) "Residual disinfectant concentration" means the concentration of disinfectant measured in mg/l in a representative sample of water.

(164) "Responsible Management Authority" means the Public Water System whose water supply is being protected and any government entity having management, rule or ordinance-making authority to implement wellhead protection management strategies within the wellhead protection area. The Responsible Management Authority is responsible for implementation of the Wellhead Protection Plan and includes cities, counties, special districts, Indian tribes, state/federal entities as well as public water systems.

(165) "Safe Drinking Water" means water which has sufficiently low concentrations of microbiological, inorganic chemical, organic chemical, radiological or physical substances so that individuals drinking such water at normal levels of consumption, will not be exposed to disease organisms or other substances which may produce harmful physiological effects.

(166) "Sanitary Defect" means a defect that could provide a pathway of entry for microbial contamination into the distribution system or that is indicative of a failure or imminent failure in a barrier that is already in place.

(167) "Sanitary Survey (Water System Survey)" means an onsite review of the water source(s), facilities, equipment, operation, maintenance and monitoring compliance of a public water system to evaluate the adequacy of the water system, its sources and operations in the distribution of safe drinking water. The sanitary survey also identifies sources of contamination by using the results of source water assessments where available.

(168) "Seasonal water system" means a water system operated as a non-community public water system only part of each year and that is started up at the beginning and shut down at the end of each operating season.

(169) "Secondary Contaminant" means those contaminants, which, at the levels generally found in drinking water, do not present an unreasonable risk to health, but do:

(a) Have adverse effects on the taste, odor and color of water;

(b) Produce undesirable staining of plumbing fixtures; or

(c) Interfere with treatment processes applied by water suppliers.

(170) "Secondary Maximum Contaminant Level (SMCL)" means the level of a secondary contaminant which when exceeded may adversely affect the aesthetic quality of the drinking water which thereby may deter public acceptance of drinking water provided by public water systems or may interfere with water treatment methods.

(171) "Sedimentation" means a process for removal of solids before filtration by gravity or separation.

(172) "Seller's Designee" means the person assigned by the seller to complete the necessary paperwork and submit the lab results to the Authority and can be the seller's attorney, real estate agent or broker, the person conducting the tests or a private party.

(173) "Sensitivity" means the intrinsic characteristics of a drinking water source such as depth to the aquifer for groundwater or highly erodible soils in a watershed that increase the potential for contamination to take place if a contaminant source is present.

(174) "Service Connection" means the piping connection by means of which water is conveyed from a distribution main of a public water system to a user's premises. For a community water system, the portion of the service connection that conveys water from the distribution main to the user's property line, or to the service meter, where provided, is under the jurisdiction of the water supplier.

(175) "Significant Deficiency" means a defect in design, operation, or maintenance, or a malfunction of the source(s), treatment, storage, or distribution system that has been determined to cause or have the potential for causing the introduction of contamination into the water delivered to consumers.

(176) "Single Connection System" means a public water system serving only one installation, such as a restaurant, campground or place of employment.

(177) "Single Family Structure" means a building constructed as a single-family residence that is currently used as either a residence or a place of business.

(178) "Small Water System," for the purposes of OAR 333-061-0210 through 0272, means a community or non-transient non-community water system serving 150 service connections or less using only groundwater or purchasing finished water from another public water system.

(179) "Source Water Assessment" means the information compiled by the Authority and the Department of Environmental Quality (DEQ), consisting of the delineation, inventory and susceptibility analyses of the drinking water source, which enable public water systems to develop and implement drinking water protection plans.

(180) "Specific Ultraviolet Absorption (SUVA) at 254 nanometers" means an indicator of the humic content of water as a calculated parameter obtained by dividing a sample's ultraviolet absorption at a wavelength of 254 nanometers (UV254) by its concentration of dissolved organic carbon (DOC) (in milligrams per liter).

(181) "Spill Resistant Pressure Vacuum Breaker Backsiphonage Prevention Assembly (SVB)" means an assembly containing an independently operating, internally loaded check valve and independently operating loaded air inlet valve located on the discharge side of the check valve. The assembly is to be equipped with a properly located resilient seated test cock, a properly located bleed/vent valve, and tightly closing resilient seated shutoff valves attached at each end of the assembly. This assembly is designed to protect against a non-health hazard or a health hazard under a backsiphonage condition only.

(182) "Spring" means a naturally occurring discharge of flowing water at the ground surface, or into surface water where the flow of water is the result of gravity or artesian pressure. Springs can be derived from groundwater or they can be surface water influenced.

(183) "Stand-alone Fire Suppression System" means a piping system within a premises intended to only serve as a fire protection system separated from the potable water system.

(184) "State Regulated Water System" means a public water system, which serves 4 to 14 service connections or serves 10 to 24 people. Monitoring requirements for these systems are the same as those for Transient Non-Community water systems.

(185) "Static Water Level" means the vertical distance from ground surface to the water level in the well when the well is at rest, that is, the well has not been pumped recently and the water level is stable. This is the natural level of water in the well.

(186) "Submeter" means a water meter by which a property owner (or association of property owners) meters individual water use after the water passes through a master meter. For the purposes of OAR 333-061-0010, submetering does not constitute applying a direct charge for water or directly selling water to a person.

(187) "Surface Water" means all water, which is open to the atmosphere and subject to surface runoff.

(188) "Susceptibility" means the potential, as a result of the combination of land use activities and source water sensitivity, that contamination of the drinking water source may occur.

(189) "Team" means the local Wellhead Protection team, which includes representatives from the Responsible Management Authorities and various interests and stakeholders potentially affected by the Wellhead Protection Plan.

(190) "Thermal Expansion" means the pressure increase due to a rise in water temperature that occurs in water piping systems when such systems become "closed" by the installation of a backflow prevention assembly or other means, and will not allow for expansion beyond that point of installation.

(191) "These Rules" means the Oregon Administrative Rules encompassed by OAR 333-061-0005 through 333-061-0335.

(192) "Time-of-Travel (TOT)" means the amount of time it takes groundwater to flow to a given well. TOT is the criterion that effectively determines the radius in the calculated fixed radius method and the up-gradient distance to be used for the analytical and numerical models during delineation of the wellhead protection area.

(193) "Too Numerous to Count (TNTC)" means that the total number of bacterial colonies exceeds 200 on a 47 mm diameter membrane filter used for coliform bacteria detection.

(194) "Total Organic Carbon (TOC)" means total organic carbon in milligrams per liter measured using heat, oxygen, ultraviolet irradiation, chemical oxidants, or combinations of these oxidants that convert organic carbon to carbon dioxide, rounded to two significant figures.

(195) "Total Trihalomethanes" or "TTHM" means the sum of the concentrations in milligrams per liter of the trihalomethane compounds bromodichloromethane, dibromochloromethane, tribromomethane (bromoform) and trichloromethane (chloroform), rounded to two significant figures after addition.

(196) "Transient Non-Community Water System (TNC)" means a public water system that serves a transient population of 25 or more persons.

(197) "Turbidity" means a measure of the cloudiness of water caused by suspended particles. The units of measure for turbidity are nephelometric turbidity units (NTU).

(198) "Two-stage lime softening" means a process in which a chemical addition and hardness precipitation occur in each of two distinct unit clarification processes in series prior to filtration.

(199) "Unconfined Well" means a well completed in an unconfined aquifer, and more specifically, a well which produces water from a formation that is not overlaying by impermeable material. This well shall be constructed according to OAR chapter 690, division 200 "Well Construction and Maintenance" standards.

(200) "Uncovered finished water storage facility" means a tank, reservoir, or other facility used to store water that will undergo no further treatment to reduce microbial pathogens except residual disinfection and is directly open to the atmosphere.

(201) "University of Southern California, Foundation for Cross-Connection Control and Hydraulic Research (USC FCCCHR)" is an agency that conducts laboratory and field tests to evaluate and grant "Certificates of Approval" to backflow prevention assemblies meeting approved standards.

(202) "Vadose Zone" means the zone between the ground surface and the water table where the available open spaces between

soil and sediment particles, in rock fractures, etc., are most filled with air.

(203) "Variance" means official permission granted by the Authority for public water systems to exceed maximum contaminant levels because the quality of the raw water is such that the best available treatment techniques are not capable of treating the water so that it complies with maximum contaminant levels, and there is no unreasonable risk to health.

(204) "Vault" means an approved enclosure above or below ground to house a backflow prevention assembly that complies with the local administrative authority having jurisdiction.

(205) "Virus" means a virus of fecal origin, which is infectious to humans by waterborne transmission.

(206) "Vulnerability" has the same meaning as susceptibility.

(207) "Waiver" means official permission from the Authority for a public water system to deviate from the construction standards set forth in these rules.

(208) "Water-bearing Zone" means that part or parts of the aquifer encountered during drilling that yield(s) water to a well.

(209) "Waterborne disease outbreak" means the significant occurrence of acute infectious illness, epidemiologically associated with the ingestion of water from a public water system which is deficient in treatment, as determined by the Authority.

(210) "Water Source" means any lake, stream, spring, groundwater supply, impoundment or other source of water from which water is obtained for a public water system. In some cases, a public water system can be the source of supply for one or more other public water systems.

(211) "Water Supplier" means a person, group of persons, municipality, district, corporation or other entity, which owns or operates a public potable water system.

(212) "Water System" means a system for the provision of piped water for human consumption.

(213) "Water System Operations Manual" means a written document describing the actions and procedures necessary to operate and maintain the entire water system.

(214) "Water Table" means the upper surface of an unconfined aquifer, the surface of which is at atmospheric pressure and fluctuates seasonally. It is defined by the levels at which water stands in wells that penetrate the aquifer.

(215) "Water Treatment" means a process of altering water quality by physical or chemical means and may include domestic, industrial or commercial applications.

(216) "Water Treatment Plant" means that portion of a water system that in some way alters the physical, chemical, or bacteriological quality of the water being treated.

(217) "Well" means an artificial opening or artificially altered natural opening, however made, by which ground water is sought or through which ground water flows under natural pressure or is artificially withdrawn or injected, provided that this definition shall not include a natural spring, or wells drilled for the purpose of exploration or production of oil or gas.

(218) "Wellfield" means two or more drinking water wells, belonging to the same water system that are within 2,500 feet, or as determined by the Authority, and produce from the same and no other aquifer.

(219) "Wellhead Protection." See Drinking Water Protection.

(220) "Wellhead Protection Area (WHPA)." See Drinking Water Protection Area.

(221) "Wellhead Protection Plan." See Drinking Water Protection Plan.

(222) "Wholesale system" means a public water system that treats source water as necessary to produce finished water and then delivers some or all of that finished water to another public water system. Delivery may be through a direct connection or through the distribution system of one or more purchasing water systems.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 431.110, 431.150, 448.131, 448.150, 448.273, 448.279

Hist.: HD 106, f. & ef. 2-6-76; HD 4-1980, f. & ef. 3-21-80; HD 10-1981, f. & ef. 6-30-81; HD 17-1981(Temp), f. & ef. 8-28-81; HD 4-1982, f. & ef. 2-26-82; Renumbered from 333-042-0205, HD 2-1983, f. & ef. 2-23-83; HD 21-1983, f. 10-20-83, ef. 11-1-83; HD 11-1985, f. & ef. 7-2-85; HD 30-1985, f. & ef. 12-4-85; HD 3-1987, f. & ef. 2-17-87; HD 3-1988(Temp), f. & cert. ef. 2-12-88; HD 17-1988, f. & cert. ef. 7-27-88; HD 9-1989, f. & cert. ef. 11-13-89; HD 26-1990, f. 12-26-90, cert. ef. 12-29-90; HD 7-1992, f. & cert. ef. 6-9-92; HD 12-1992, f. & cert. ef. 12-7-92; HD 3-1994, f. & cert. ef. 1-14-94; HD 1-1996, f. 1-2-96, cert. ef. 1-5-96; HD 14-1997, f. & cert. ef. 10-31-97; OHD 4-1999, f. 7-14-99, cert. ef. 7-15-99; OHD 3-2000, f. 3-8-00, cert. ef. 3-15-00; OHD 7-2000, f. 7-11-00, cert. ef. 7-15-00; OHD 23-2001, f. & cert. ef. 10-31-01; OHD 17-2002, f. & cert. ef. 10-25-02; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 33-2004, f. & cert. ef. 10-21-04; PH 34-2004, f. & cert. ef. 11-2-04; PH 2-2006, f. & cert. ef. 1-31-06; PH 4-2009, f. & cert. ef. 5-18-09; PH 7-2010, f. & cert. ef. 4-19-10; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 11-2011, f. & cert. ef. 10-27-11; PH 13-2012, f. & cert. ef. 9-10-12; PH 14-2014, f. & cert. ef. 5-8-14; PH 5-2016, f. 2-10-16, cert. ef. 4-1-16

333-061-0025
Responsibilities of Water Suppliers

Water suppliers are responsible for taking all reasonable actions to assure that the water delivered to water users does not exceed maximum contaminant levels, to assure that water system facilities are free of public health hazards, and to assure that water system operation and maintenance are performed as required by these rules. Such actions include, but are not limited to:

(1) Routinely collecting and submitting water samples for laboratory analyses at the frequencies prescribed by OAR 333-061-0036;

(2) Taking immediate corrective action when the results of analyses or measurements indicate that maximum contaminant levels have been exceeded and report the results of these analyses as prescribed by OAR 333-061-0040;

(3) Reporting as prescribed by OAR 333-061-0040, the results of analyses or measurements which indicate that maximum contaminant levels have not been exceeded;

(4) Notifying all customers of the water system and the general public in the service area, as prescribed by OAR 333-061-0042, when the maximum contaminant levels have been exceeded;

(5) Notifying all customers served by the water system, as prescribed by OAR 333-061-0042, when reporting requirements are not being met, when public health hazards are found to exist in the system, or when the operation of the system is subject to a permit or a variance;

(6) Maintaining monitoring and operating records and making these records available for review when the system is inspected;

(7) Maintaining a pressure of at least 20 pounds per square inch (psi) at all service connections at all times;

(8) Following-up on complaints relating to water quality from users and maintaining records and reports on actions undertaken;

(9) Conducting an active program for systematically identifying and controlling cross connections;

(10) Submitting, to the Authority, plans prepared by a professional engineer registered in Oregon for review and approval before undertaking the construction of new water systems or major modifications to existing water systems, unless exempted from this requirement;

(11) Assuring that the water system is in compliance with OAR 333-061-0032 relating to water treatment;

(12) Assuring that the water system is in compliance with OAR 333-061-0210–333-061-0272 relating to certification of water system operators; and

(13) Assuring that Transient Non-Community water systems utilizing surface water sources or groundwater sources under the influence of surface water are in compliance with OAR 333-061-0065(2)(c) relating to required special training.

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 448.123, 448.131, 448.135, 448.150, 448.278, 448.279, 448.450, 448.455 & 448.460

Hist.: HD 4-1982, f. & ef. 2-26-82; Renumbered from 333-042-0206, HD 2-1983, f. & ef. 2-23-83; HD 9-1989, f. & cert. ef. 11-13-89; HD 7-1992, f. & cert. ef. 6-9-92; OHD 17-2002, f. & cert. ef. 10-25-02; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 4-2009, f. & cert. ef. 5-18-09; PH 3-2013, f. & cert. ef. 1-25-13

333-061-0030
Maximum Contaminant Levels and Action Levels

(1) Maximum contaminant levels (MCLs) and action levels (ALs) for inorganic chemicals apply to all community and non-transient non-community water systems and are listed in Table 1, except the MCL for fluoride which applies only to community water systems and the MCL for nitrate which applies to all water systems. [Table not included. See ED. NOTE.]

(a) Compliance with the maximum contaminant levels for inorganic contaminants is calculated pursuant to OAR 333-061-0036(2)(i).

(b) Exceeding the secondary contaminant level for fluoride as specified in section (6) of this rule requires a special public notice as specified in OAR 333-061-0042(7).

(c) The lead action level is exceeded if the concentration of lead in more than 10 percent of tap water samples collected during any monitoring period conducted in accordance with OAR 333-061-0036(2)(c)(A) through (E) is greater than 0.015 mg/L (that is, if the "90th percentile" lead level is greater than 0.015 mg/L). The copper action level is exceeded if the concentration of copper in more than 10 percent of tap water samples collected during any monitoring period conducted in accordance with OAR 333-061-0036(2)(c)(A) through (E) is greater than 1.3 mg/L (that is, if the "90th percentile" copper level is greater than 1.3 mg/L).

(A) The 90th percentile lead and copper levels shall be computed as follows: The results of all lead or copper samples taken during a monitoring period shall be placed in ascending order from the sample with the lowest concentration to the sample with the highest concentration. Each sampling result shall be assigned a number, ascending by single integers beginning with the number 1 for the sample with the lowest contaminant level. The number assigned to the sample with the highest contaminant level shall be equal to the total number of samples taken. The number of samples taken during the monitoring period shall be multiplied by 0.9. The contaminant concentration in the numbered sample yielded by this calculation is the 90th percentile contaminant level.

(B) For water systems serving fewer than 100 people that collect five samples per monitoring period, the 90th percentile is computed by taking the average of the highest and second highest concentrations. For a water system allowed by the Authority to collect fewer than five samples the sample result with the highest concentration is considered the 90th percentile value.

(2) Maximum contaminant levels for organic chemicals:

(a) The maximum contaminant levels for synthetic organic chemicals are shown in Table 2 and apply to all community and non-transient non-community water systems. Compliance with MCLs shall be calculated pursuant to OAR 333-061-0036(3)(a)(H) and (I). [Table not included. See ED. NOTE.]

(b) The maximum contaminant levels for disinfection byproducts are shown in Table 3 and apply to all community and non-transient non-community water systems that add a disinfectant (oxidant) to the water supply at any point in the treatment process or deliver water in which a disinfectant has been added to the water supply. [Table not included. See ED. NOTE.]

(A) Compliance with the MCLs for TTHM and HAA5 shall be calculated as a locational running annual arithmetic average according to OAR 333-061-0036(4)(c).

(B) Compliance with the MCL for bromate shall be calculated as a running annual arithmetic average pursuant to OAR 333-061-0036(4)(h).

(C) Compliance with the MCL for chlorite shall be calculated as a running annual arithmetic average pursuant to OAR 333-061-0036(4)(g).

(c) The maximum contaminant levels for volatile organic chemicals are indicated in Table 4 and apply to all community and non-transient non-community water systems. Compliance with MCLs shall be calculated pursuant to OAR 333-061-0036(3)(b)(H) and (I). [Table not included. See ED. NOTE.]

(d) When the Authority has reason to believe that a water supply has been contaminated by a toxic organic chemical, it will determine whether a public health hazard exists and whether control measures must be carried out;

(e) The Authority may establish maximum contaminant levels for additional organic chemicals as deemed necessary when there is reason to suspect that the use of those chemicals will impair water quality to an extent that poses an unreasonable risk to the health of the water users;

(f) Persons who apply pesticides within watersheds above surface water intakes of public water systems shall comply with federal and state pesticide application requirements. (Safe Drinking Water Act (EPA), Clean Water Act (EPA), Federal Insecticide, Fungicide and Rodenticide Act (EPA), ORS 536.220 to 536.360 (Water Resources), 468B.005 (DEQ), 527.610 to 527.990 (DOF), 634.016 to 634.992 (Department of Agriculture)). Any person who has reasonable cause to believe that his or her actions have led to organic chemical contamination of a public water system shall report that fact immediately to the water supplier.

(3) Maximum contaminant levels for turbidity are applicable to all public water systems using surface water sources or groundwater sources under the direct influence of surface water in whole or in part. Compliance with MCLs shall be calculated pursuant to OAR 333-061-0036(5).

(a) The maximum contaminant levels for turbidity at water systems where filtration treatment is not provided are as follows:

(A) The turbidity level cannot exceed 5 NTU in representative samples of the source water immediately prior to the first or only point of disinfectant application unless:

(i) The Authority determines that any such event was caused by circumstances that were unusual and unpredictable; and

(ii) As a result of any such event, there have not been more than two events in the past 12 months the system served water to the public, or more than five events in the past 120 months the system served water to the public, in which the turbidity level exceeded 5 NTU. An "event" is a series of consecutive days during which at least one turbidity measurement each day exceeds 5 NTU. Turbidity measurements must be collected as required by OAR 333-061-0036(5)(a)(B).

(b) Beginning no later than 18 months after the failure to meet the requirements of OAR 333-061-0032(1) through (3), the maximum contaminant levels for turbidity in drinking water measured at a point representing filtered water prior to any storage are as follows:

(A) Conventional filtration treatment or direct filtration treatment.

(i) At water systems where conventional filtration or direct filtration treatment is used, the turbidity level of representative samples of a system's filtered water, measured as soon after filtration as possible and prior to any storage, must be less than or equal to 0.3 NTU in at least 95 percent of the measurements taken each month, measured as specified in OAR 333-061-0036(5).

(ii) At water systems where conventional filtration or direct filtration treatment is used, the turbidity level of representative samples of a system's filtered water, measured as soon after filtration as possible and prior to any storage, must at no time exceed 1 NTU measured as specified in OAR 333-061-0036(5).

(B) Slow sand filtration.

(i) At water systems where slow sand filtration is used, the turbidity level of representative samples of filtered water, measured as soon after filtration as possible and prior to any storage, must be less than or equal to 1 NTU in at least 95 percent of the measurements taken each month, measured as specified in OAR 333-061-0036(5)(b), except that if the Authority determines there is no significant interference with disinfection at a higher turbidity level, the Authority may substitute this higher turbidity limit for that system.

(ii) The turbidity level of representative samples of filtered water must at no time exceed 5 NTU, measured as specified in OAR 333-061-0036(5)(b).

(C) Diatomaceous earth filtration.

(i) At water systems where diatomaceous earth filtration is used, the turbidity level of representative samples of filtered water,

measured as soon after filtration as possible and prior to any storage, must be less than or equal to 1 NTU in at least 95 percent of the measurements taken each month, measured as specified in OAR 333-061-0036(5)(b).

(ii) The turbidity level of representative samples of filtered water must at no time exceed 5 NTU, measured as specified in OAR 333-061-0036(5)(b).

(D) Other filtration technologies. At water systems where filtration technologies other than those listed in paragraphs (3)(b)(A) through (C) of this rule are used, the turbidity level must be less than or equal to 1 NTU in at least 95 percent of the measurements taken each month and at no time exceed 5 NTU, as specified in OAR 333-061-0036(5)(b)(A). The Authority may substitute a lower turbidity value(s) if it is determined that the above limit(s) cannot achieve the required level of treatment. The water supplier must demonstrate to the Authority that the alternative filtration technology in combination with disinfection treatment as specified in OAR 333-061-0032 and monitored as specified by OAR 333-061-0036 consistently achieves 99.9 percent removal or inactivation of Giardia lamblia cysts and 99.99 percent removal or inactivation of viruses, and for all of those systems serving at least 10,000 people and beginning January 1, 2005 for all of those systems serving less than 10,000 people, 99 percent removal of Cryptosporidium oocysts.

(4) The maximum contaminant level for E. coli applies to all public water systems as specified in this section.

(a) A water system exceeds or violates the MCL for E. coli if any of the conditions identified in paragraphs (4)(a)(A) through (4)(a)(D) of this rule occur.

(A) An E. coli-positive repeat sample follows a total coliform-positive routine sample.

(B) A total coliform-positive repeat sample follows an E. coli-positive routine sample.

(C) All required repeat samples are not collected following an E. coli-positive routine sample.

(D) Any repeat sample is not analyzed for E. coli when it tests positive for total coliform.

(b) Exceeding the MCL for E. coli may pose an acute risk to health and requires the distribution of public notification as specified in OAR 333-061-0042.

(5) Maximum contaminant levels for radionuclides are applicable only to community water systems and are indicated in Table 5: [Table not included. See ED. NOTE.]

(a) The average annual concentration of beta particle and photon radioactivity from man-made sources shall not produce an annual dose equivalent to the total body or any internal organ greater than 4 millirem per year according to the criteria listed in the National Bureau of Standards Handbook 69 as amended August, 1963. If two or more radionuclides are present, the sum total of their annual dose equivalent to the total body or to any organ shall not exceed 4 millirem/year.

(A) The average annual concentration of tritium assumed to produce a total body dose of 4 mrem/year is 20,000 pCi/L;

(B) The average annual concentration of strontium-90 assumed to produce a bone marrow dose of 4 mrem/year is 8 pCi/L.

(b) Compliance with the MCLs shall be calculated pursuant to OAR 333-061-0036(7)(c).

(6) Contaminant levels for secondary contaminants are applicable to all public water systems. These are indicated in Table 6. (Also note OAR 333-061-0036(8)). [Table not included. See ED. NOTE.]

(a) Exceeding the secondary contaminant level for fluoride requires a special public notice as specified in OAR 333-061-0042(7).

(b) Exceeding the maximum contaminant level for fluoride as specified in section (1) of this rule requires public notification as specified in OAR 333-061-0042(2)(b)(A).

(7) Acrylamide and Epichlorohydrin. For every public water system, the water supplier must certify annually to the state in writing, using third party certification approved by the state or manufacturer's certification, that when acrylamide and epichlorohydrin are used in drinking water systems, the combination, or product, of dose and monomer level does not exceed the levels specified as follows:

(a) Acrylamide: 0.05 percent dosed at 1 ppm or equivalent.

(b) Epichlorohydrin: 0.01 percent dosed at 20 ppm or equivalent.

[ED. NOTE: Tables and Publications referenced are available from the agency.]

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 431.110, 431.150, 448.131, 448.150 & 448.273

Hist.: HD 106, f. & ef. 2-6-76; HD 17-1981(Temp), f. & ef. 8-28-81; HD 4-1982, f. & ef. 2-26-82; Renumbered from 333-042-0210, HD 2-1983, f. & ef. 2-23-83; HD 21-1983, f. 10-20-83, ef. 11-1-83; HD 11-1985, f. & ef. 7-2-85; HD 30-1985, f. & ef 12-4-85; HD 9-1989, f. & cert, ef. 11-13-89; HD 26-1990, f. 12-26-90, cert. ef. 12-29-90; HD 9-1991(Temp), f. & cert. ef. 6-24-91; HD 1-1992, f. & cert. ef. 3-5-92; HD 7-1992, f. & cert. ef. 6-9-92; HD 12-1992, f. & cert. ef. 12-7-92; HD 3-1994, f. & cert. ef. 1-14-94; HD 11-1994, f. & cert. ef. 4-11-94; HD 1-1996, f. 1-2-96, cert. ef. 1-5-96; HD 1-1996, f. 1-2-96, cert. ef. 1-5-96; HD 14-1997, f. & cert. ef. 10-31-97; OHD 7-2000, f. 7-11-00, cert. ef. 7-15-00; OHD 23-2001, f. & cert. ef. 10-31-01; OHD 17-2002, f. & cert. ef. 10-25-02; PH 12-2003, f. & cert. ef. 8-15-03; PH 33-2004, f. & cert. ef. 10-21-04; PH 2-2006, f. & cert. ef. 1-31-06; PH 2-2008, f. & cert. ef. 2-15-08; PH 4-2009, f. & cert. ef. 5-18-09;PH 7-2010, f. & cert. ef. 4-19-10; PH 3-2013, f. & cert. ef. 1-25-13; PH 5-2016, f. 2-10-16, cert. ef. 4-1-16

333-061-0031
Maximum Residual Disinfectant Levels

Maximum residual disinfectant levels (MRDLs) are enforceable in the same manner as maximum contaminant levels and are specified in Table 7: [Table not included. See ED. NOTE.]

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 431.110, 431.150, 448.131, 448.150 & 448.273

Hist.: OHD 7-2000, f. 7-11-00, cert. ef. 7-15-00; OHD 23-2001, f. & cert. ef. 10-31-01; PH 4-2009, f. & cert. ef. 5-18-09; PH 5-2016, f. 2-10-16, cert. ef. 4-1-16

333-061-0032
Treatment Requirements and Performance Standards for Surface Water, Groundwater Under Direct Influence of Surface Water, and Groundwater

(1) General requirements for all public water systems supplied by a surface water source or a groundwater source under the direct influence of surface water.

(a) These regulations establish criteria under which filtration is required and treatment technique requirements in lieu of maximum contaminant levels for the following contaminants: Giardia lamblia, viruses, heterotrophic plate count bacteria, Legionella, Cryptosporidium, and turbidity. Each public water system with a surface water source or a groundwater source under the direct influence of surface water must provide treatment of that source water that complies with these treatment technique requirements. The treatment technique requirements consist of installing and properly operating water treatment processes which reliably achieve:

(A) At least 99.9 percent (3-log) removal or inactivation of Giardia lamblia cysts between a point where the raw water is not subject to recontamination by surface water runoff and a point downstream before or at the first customer, and

(B) At least 99.99 percent (4-log) removal or inactivation of viruses between a point where the raw water is not subject to recontamination by surface water runoff and a point downstream before or at the first customer.

(C) At least 99 percent (2-log) removal of Cryptosporidium between a point where the raw water is not subject to recontamination by surface water runoff and a point downstream before or at the first customer for filtered systems, or Cryptosporidium control under the watershed control plan for unfiltered systems; and

(D) Compliance with any applicable disinfection profiling and benchmark requirements as specified in OAR 333-061-0036(4)(l) and 333-061-0060(1)(e).

(E) Sampling and Bin Classification for Cryptosporidium:

(i) All water suppliers must conduct an initial and second round of source water monitoring, as prescribed in subsection 333-061-0036(5)(e) of these rules, for each plant that treats a surface

water or GWUDI source to determine what level, if any, of additional Cryptosporidium treatment they must provide.

(ii) Filtered systems must determine their Cryptosporidium treatment bin classification as prescribed in subsection (4)(f) of this rule and provide additional treatment for Cryptosporidium, if required, as prescribed in subsection (4)(g) of this rule. All unfiltered systems must provide treatment for Cryptosporidium as prescribed in subsections (3)(e) through (g) of this rule. Filtered and unfiltered systems must implement Cryptosporidium treatment according to the schedule in paragraph (1)(a)(F) of this rule.

(iii) Systems required to provide additional treatment for Cryptosporidium must implement microbial toolbox options that are designed and operated as prescribed in sections (13) through (17) of this rule and in OAR 333-061-0036(5)(c), 333-061-0050(4) and 333-061-0050(5)(k).

(F) Schedule for compliance with Cryptosporidium treatment requirements.

(i) Following initial bin classification as prescribed in subsection (4)(f) of this rule, filtered water systems must provide the level of treatment for Cryptosporidium required under subsection (4)(g) of this rule according to the schedule in subparagraph (1)(a)(F)(iii) of this rule.

(ii) Following initial determination of the mean Cryptosporidium level as prescribed by subsection (2)(c) of this rule, unfiltered water systems must provide the level of treatment for Cryptosporidium required under subsection (3)(e) of this rule according to the schedule in subparagraph (1)(a)(F)(iii) of this rule.

(iii) Cryptosporidium treatment compliance dates. The Authority may allow up to an additional two years from the date specified below for water systems making capital improvements.

(I) Water systems that serve at least 100,000 people must comply with Cryptosporidium treatment by April 1, 2012.

(II) Water systems that serve from 50,000 to 99,999 people must comply with Cryptosporidium treatment by October 1, 2012.

(III) Water systems that serve from 10,000 to 49,999 people must comply with Cryptosporidium treatment by October 1, 2013.

(IV) Water systems that serve fewer than 10,000 people must comply with Cryptosporidium treatment by October 1, 2014.

(V) State-Regulated public water systems must comply with Cryptosporidium treatment by October 1, 2015.

(iv) If the bin classification for a filtered water system changes following the second round of source water monitoring as prescribed in subsection (4)(f) of this rule, the water system must provide the level of treatment for Cryptosporidium required by subsection (4)(g) of this rule on a schedule approved by the Authority.

(v) If the mean Cryptosporidium level for an unfiltered water system changes following the second round of monitoring as prescribed by paragraph (2)(c)(A) of this rule, the water system must provide the level of Cryptosporidium treatment required by subsection (3)(e) of this rule, due to the change, following a schedule approved by the Authority.

(b) A public water system using a surface water source or a ground water source under the direct influence of surface water is considered to be in compliance with the requirements of this rule if:

(A) The system meets the requirements for avoiding filtration in section (2) of this rule and the disinfection requirements in section (3) of this rule, and the disinfection benchmarking requirements of OAR 333-061-0060(1)(e); or

(B) The system meets the filtration requirements in section (4) of this rule and the disinfection requirements in section (5) of this rule and the disinfection benchmarking requirements of OAR 333-061-0060(1)(e).

(c) Water systems that utilize sources that have been determined to be under the direct influence of surface water according to section (8) of this rule have 18 months to meet the requirements of sections (2) and (3) of this rule, or the requirements of sections (4) and (5) of this rule. During that time, the system must meet the following Interim Standards:

(A) The turbidity of water entering the distribution system must never exceed 5 NTU. Turbidity measurements must be taken a minimum of once per day. If continuous turbidimeters are in place, measurements should be taken every four hours; and

(B) Disinfection must be sufficient to reliably achieve at least 1.0 log inactivation of Giardia lamblia cysts prior to the first user. Daily disinfection "CT" values must be calculated and recorded daily, including pH and temperature measurements, and disinfection residuals at the first customer.

(C) Reports must be submitted to the Authority monthly as prescribed in OAR 333-061-0040.

(D) If these interim standards are not met, the owner or operator of the water system must notify customers of the failure as required in OAR 333-061-0042(2)(b)(A).

(2) Requirements for public water systems utilizing surface water or GWUDI sources without filtration.

(a) Source water quality conditions.

(A) The fecal coliform concentration must be equal to or less than 20/100 ml, or the total coliform concentration must be equal to or less than 100/100 ml, in samples collected as prescribed by OAR 333-061-0036(5)(a)(A), in at least 90 percent of the measurements made for the 6 previous months that a water system served water to the public on an ongoing basis. If a water supplier measures both fecal and total coliform as specified in this paragraph, only the fecal coliform criterion must be met.

(B) The turbidity level cannot exceed the maximum contaminant level prescribed in OAR 333-061-0030(3)(a)(A).

(b) Site-specific conditions.

(A) Water systems must meet the disinfection requirements as prescribed in section (3) of this rule at least 11 of the 12 previous months that the system served water to the public, on an ongoing basis, unless a system fails to meet the requirements during 2 of the 12 previous months that the system served water to the public, and the Authority determines that at least one of these failures was caused by circumstances that were unusual and unpredictable.

(B) Water suppliers must maintain a comprehensive watershed control program which minimizes the potential for contamination by Giardia lamblia cysts, Cryptosporidium oocysts, and viruses in the source water. For water systems using GWUDI, and at the discretion of the Authority, a certified drinking water protection plan (OAR 340-040-0160 to 340-040-0180) that addresses both the groundwater and surface water components of the drinking water supply may be substituted for a watershed control program. The watershed control program shall be developed according to guidelines in OAR 333-061-0075. The public water system must demonstrate through ownership or written agreements with landowners within the watershed that it can control all human activities which may have an adverse impact on the microbiological quality of the source water. The system must submit an annual report to the Authority identifying any special concerns about the watershed, the procedures used to resolve the concern, current activities affecting water quality, and projections of future adverse impacts or activities and the means to address them. At a minimum, the watershed control program must:

(i) Characterize the watershed hydrology and land ownership;

(ii) Identify watershed characteristics and activities which have or may have an adverse effect on source water quality; and

(iii) Monitor the occurrence of activities which may have an adverse effect on source water quality.

(C) Water systems must be subject to an annual on-site inspection of the watershed control program and the disinfection treatment process by the Authority. The on-site inspection must indicate to the Authority's satisfaction that the watershed control program and disinfection treatment process are adequately designed and maintained including the adequacy limiting the potential contamination by Cryptosporidium oocysts. The inspection must include:

(i) A review of the effectiveness of the watershed control program;

(ii) A review of the physical condition of the source intake and how well it is protected;

(iii) A review of the system's equipment maintenance program to ensure there is low probability for failure of the disinfection process;

(iv) An inspection of the disinfection equipment for physical deterioration;

(v) A review of operating procedures;

(vi) A review of data records to ensure that all required tests are being conducted and recorded and disinfection is effectively practiced; and

(vii) Identification of any improvements which are needed in the equipment, system maintenance and operation, or data collection.

(D) Water systems must not have been identified by the Authority as the source of waterborne disease outbreak under the system's current configuration. If such an outbreak occurs, the water system's treatment process must be sufficiently modified, as determined by the Authority, to prevent any future such occurrence.

(E) Water systems must meet each of the following conditions on an ongoing basis for at least 11 of the 12 previous months that the water system served water to the public unless the Authority determines that failure to meet this requirement was not caused by a deficiency in treatment of the source water.

(i) The MCL for E. coli as prescribed by OAR 333-061-0030(4) was not exceeded at the water system.

(ii) The equivalent to either of the level one coliform investigation triggers specified in OAR 333-061-0078(2)(a)(A) or (B) was not exceeded at the water system prior to March 31, 2016 if applicable.

(F) Water systems must be in compliance with the requirements for total trihalomethanes, haloacetic acids (five), bromate, chlorite, chlorine, chloramines, and chlorine dioxide as specified in OAR 333-061-0036(4).

(c) Determination of mean Cryptosporidium level.

(A) Unfiltered water systems must calculate the arithmetic average of all Cryptosporidium sample concentrations following completion of the initial and second round of source water monitoring conducted in accordance with OAR 333-061-0036(5)(e). Systems must report this value to the Authority for approval no later than 6 months after the date the system was required to complete the required monitoring.

(B) If the frequency of monthly Cryptosporidium sampling varies, water systems must calculate a monthly average for each month of sampling. Systems must then use these monthly average concentrations, rather than individual sample concentrations, in the calculation of the mean Cryptosporidium level prescribed in paragraph (2)(c)(A) of this rule.

(C) The report to the Authority of the mean Cryptosporidium levels calculated in accordance with paragraph (2)(c)(A) of this rule must include a summary of the source water monitoring data used for the calculation.

(D) Failure to comply with the conditions of subsection (2)(c) of this rule is a violation of treatment technique requirements.

(d) A public water system which fails to meet any of the criteria in section (2) of this rule is in violation of a treatment technique requirement. The Authority can require filtration to be installed where it determines necessary.

(3) Disinfection requirements for systems utilizing surface water or GWUDI sources without filtration. Each public water system that does not provide filtration treatment must provide disinfection treatment as follows:

(a) The disinfection treatment must be sufficient to ensure at least 99.9 percent (3-log) inactivation of Giardia lamblia cysts and 99.99 percent (4-log) inactivation of viruses, every day the system serves water to the public, except any one day each month. Each day a system serves water to the public, the public water system must calculate the CT value(s) from the system's treatment parameters, using the procedure specified in OAR 333-061-0036(5)(a)(C) and determine whether this value(s) is sufficient to achieve the specified inactivation rates for Giardia lamblia cysts and viruses. If a system uses a disinfectant other the chlorine, the system must demonstrate to the Authority through the use of an approved protocol for on-site disinfection demonstration studies or other information satisfactory to the Authority that the system is achieving the required inactivation rates on a daily basis instead of meeting the "CT" values in this rule.

(b) Systems for chemical disinfection must have either:

(A) Redundant components, including an auxiliary power supply with automatic start-up and alarm to ensure that disinfectant application is maintained continuously while water is being delivered to the distribution system; or

(B) Automatic shut-off of delivery of water to the distribution system whenever there is less than 0.2 mg/l of residual disinfectant concentration in the water, or if the ultraviolet light system fails. If the Authority determines than automatic shut-off would cause unreasonable risk to health or interfere with fire protection, the system must comply with paragraph (3)(b)(A) of this rule.

(c) The residual disinfectant concentration in the water entering the distribution system, measured as specified in OAR 333-061-0036(5)(a)(E), cannot be less than 0.2 mg/l for more than four hours.

(d) Disinfectant residuals in the distribution system. The residual disinfectant concentration in the distribution system, measured as total chlorine, combined chlorine, or chlorine dioxide, as specified in OAR 333-061-0036(5)(a)(F), cannot be undetectable in more than 5 percent of the samples each month, for any two consecutive months that the system serves water to the public.

(e) Unfiltered water systems must provide the level of Cryptosporidium inactivation specified in this subsection, based on their mean Cryptosporidium levels, and determined in accordance with subsection (2)(c) of this rule and according to the schedule in subsection (1)(a) of this rule.

(A) Unfiltered systems with a mean Cryptosporidium level of 0.01 oocysts/L or less must provide at least 2-log Cryptosporidium inactivation.

(B) Unfiltered systems with a mean Cryptosporidium level of greater than 0.01 oocysts/L must provide at least 3-log Cryptosporidium inactivation.

(f) Inactivation treatment technology requirements. Unfiltered systems must use chlorine dioxide, ozone, or UV as prescribed by OAR 333-061-0036(5)(c) to meet the Cryptosporidium inactivation requirements of this section.

(A) Systems that use chlorine dioxide or ozone and fail to achieve the Cryptosporidium inactivation required in subsection (3)(e) of this rule on more than one day in the calendar month are in violation of the treatment technique requirement.

(B) Systems that use UV light and fail to achieve the Cryptosporidium inactivation required in subsection (3)(e) of this rule because they do not to meet the criteria specified in subsection (18)(c) of this rule are in violation of the treatment technique requirement.

(g) Use of two disinfectants. Unfiltered water systems must meet the combined Cryptosporidium inactivation requirements of subsection (3)(e) of this rule, and the Giardia lamblia and virus inactivation requirements of subsection (3)(a) of this rule using a minimum of two disinfectants. Each of the two disinfectants must achieve by itself, the total inactivation required for at least one of the following pathogens: Cryptosporidium, Giardia lamblia, or viruses.

(4) Requirements for systems utilizing surface water or GWUDI sources that provide filtration:

(a) A public water system that uses a surface water source or a groundwater source under the direct influence of surface water, and does not meet all of the criteria in sections (1), (2), and (3) of this rule for avoiding filtration, violates a treatment technique and must provide treatment consisting of both disinfection, as specified in section (5) of this rule, and filtration treatment which complies with the requirements of either subsection (4)(b), (c), (d), or (e) of this rule by June 29, 1993 or within 18 months of the failure to meet the criteria in section (2) of this rule for avoiding filtration, whichever is later. Failure to install a required treatment by the prescribed dates is a violation of the treatment technique requirements.

(b) Conventional filtration treatment or direct filtration. Systems using conventional filtration treatment or direct filtration

treatment shall meet the turbidity requirements as specified in OAR 333-0061-0030(3)(b)(A)(i) and (ii).

(c) Slow sand filtration. Systems using slow sand filtration treatment shall meet the turbidity requirements prescribed in OAR 333-061-0030(3)(b)(B).

(d) Diatomaceous earth filtration. Systems using diatomaceous earth filtration treatment shall meet the turbidity requirements prescribed in OAR 333-061-0030(3)(b)(C).

(e) Other filtration technologies. Systems using other filtration technologies shall meet the turbidity requirements prescribed in OAR 333-061-0030(3)(b)(D).

(A) GWUDI systems using bank filtration as an alternate filtration technology must meet the requirements listed in section (9) of this rule.

(B) Systems using membrane filtration must conduct continuous indirect integrity testing and daily direct integrity testing in accordance with OAR 333-061-0036(5)(d)(B) and (C).

(f) Cryptosporidium Bin classification for filtered water systems. Following completion of the initial round of source water monitoring required by OAR 333-061-0036(5)(e), filtered water systems must calculate an initial Cryptosporidium bin concentration for each plant for which monitoring was required. Calculation of the bin concentration must be based upon the Cryptosporidium results reported in accordance with OAR 333-061-0036(5)(e), and must comply with paragraphs (4)(f)(A) through (F) of this rule.

(A) For water systems that collect 48 or more samples, the bin concentration is equal to the arithmetic average of all sample concentrations.

(B) For water systems that collect at least 24 samples, but not more than 47 samples, the bin concentration is equal to the highest arithmetic average of all sample concentrations in any 12 consecutive months during which Cryptosporidium samples were collected.

(C) For water systems that serve fewer than 10,000 people and only collect Cryptosporidium samples for 12 months, that is, collect 24 samples in 12 months, the bin concentration is equal to the arithmetic average of all sample concentrations.

(D) For water systems with plants operating only part of the year, and that monitor fewer than 12 months per year as prescribed by OAR 333-061-0036(5)(e)(E), the bin concentration is equal to the highest arithmetic average of all sample concentrations during any year of Cryptosporidium monitoring.

(E) If the monthly Cryptosporidium sampling frequency varies, water systems must first calculate a monthly average for each month of monitoring. Water systems must then use these monthly average concentrations, rather than individual sample concentrations, in the applicable calculation for bin classification of this subsection.

(F) Bin classification table.

(i) Filtered water systems must determine their initial bin classification from Table 8 as follows and using the Cryptosporidium bin concentration calculated under subsection (4)(f) of this rule: [Table not included. See ED. NOTE.]

(ii) Following completion of the second round of source water monitoring required as prescribed by OAR 333-061-0036(5)(e)(B), filtered water systems must recalculate their Cryptosporidium bin concentration based upon the sample results reported in accordance with OAR 333-061-0036(5)(e)(B) and following the procedures specified in paragraphs (4)(f)(A) through (D) of this rule. Water systems must then re-determine their bin classification using Table 8 in paragraph (4)(f)(F) of this rule. [Table not included. See ED. NOTE.]

(G) Filtered water systems must report their bin classification as prescribed by paragraph (4)(f)(F) of this rule to the Authority for approval no later than 6 months after the system is required to complete the initial and second round of source water monitoring based on the schedule in OAR 333-061-0036(5)(e)(C).

(H) The bin classification report to the Authority must include a summary of source water monitoring data and the calculation procedure used to determine bin classification. Failure to comply with the conditions of this paragraph is a violation of treatment technique requirements.

(g) Additional Cryptosporidium treatment requirements.

(A) Filtered water systems must provide the level of additional treatment for Cryptosporidium specified in Table 9 based on their bin classification as determined under subsection (4)(f) of this rule, and according to the schedule in paragraph (1)(a)(F) of this rule. [Table not included. See ED. NOTE.]

(B) Filtered water systems must use one or more of the treatment and management options listed in section (13) of this rule, termed the microbial toolbox, to comply with the additional Cryptosporidium treatment required by paragraph (4)(g)(A) of this rule.

(C) Systems classified in Bin 3 or Bin 4 must achieve at least 1-log of the additional Cryptosporidium treatment, as required by paragraph (4)(g)(A) of this rule, using either one or a combination of the following: bag filters, bank filtration, cartridge filters, chlorine dioxide, membranes, ozone, or UV, as described in sections (14) through (18) of this rule and in OAR 333-061-0036(5)(c).

(i) Failure by a water system, in any month, to achieve the treatment credit required by sections (14) through (18) of this rule and OAR 333-061-0036(5)(c) that is at least equal to the level of treatment required by paragraph (4)(g)(A) of this rule, is a violation of treatment technique requirements.

(ii) If the Authority determines during a sanitary survey or equivalent source water assessment, that after a system completed the monitoring conducted as required by OAR 333-061-0036(5)(e)(A) or (B), significant changes occurred in the system's watershed that could lead to increased contamination of the source water by Cryptosporidium, the system must take action as specified by the Authority to address the contamination. These actions may include additional source water monitoring or implementing microbial toolbox options specified in section (13) of this rule.

(5) Disinfection requirements for systems utilizing surface water or GWUDI sources with filtration:

(a) The disinfection treatment must be sufficient to ensure that the total treatment processes of that system achieve at least 99.9 percent (3-log) inactivation or removal of Giardia lamblia cysts and at least 99.99 percent (4-log) inactivation or removal of viruses as determined by the Authority.

(b) The residual disinfectant concentration in the water entering the distribution system, measured as specified in OAR 333-061-0036(5)(b)(D), cannot be less than 0.2 mg/l for more than 4 hours.

(c) The residual disinfectant concentration in the distribution system, measured as total chlorine, combined chlorine, or chlorine dioxide, as specified is OAR 333-061-0036(5)(b)(D) cannot be undetectable in more than 5 percent of the samples each month, for any two consecutive months that the system serves water to the public.

(6) Requirements for water systems using groundwater sources.

(a) Water suppliers responsible for groundwater systems as defined by OAR 333-061-0020(90) must comply with the requirements of this section when a significant deficiency is identified or a groundwater source sample collected according to OAR 333-061-0036(6)(j) is E. coli positive. The Authority may require a water supplier to comply with the provisions of this section when a groundwater source sample collected according to OAR 333-061-0036(6)(i) or (k) is E. coli positive.

(b) When a significant deficiency is identified at a public water system that uses both groundwater and surface water or groundwater under the direct influence of surface water, the water supplier must comply with provisions of this section except in cases where the Authority determines that the significant deficiency is in a portion of the distribution system that is served solely by surface water or groundwater under the direct influence of surface water.

(c) Water suppliers must consult with the Authority regarding the appropriate corrective action within 30 days of receiving written notice from the Authority of a significant deficiency, written notice from a laboratory that a groundwater source sample collected in accordance with OAR 333-061-0036(6)(j) was E. coli

-positive, or direction from the Authority that an E. coli -positive collected in accordance with OAR 333-061-0036(6)(i) or (k) requires corrective action.

(d) Within 120 days (or earlier if directed by the Authority) of receiving written notification from the Authority of a significant deficiency, written notice from a laboratory that a groundwater source sample collected in accordance with OAR 333-061-0036(6)(j) was found to be E. coli positive, or direction from the Authority that a E. coli -positive sample collected in accordance with OAR 333-061-0036(6)(i) or (k) requires corrective action, the water supplier must either:

(A) Have completed corrective action in accordance with applicable Authority plan review processes or other Authority guidance, including any Authority-specified interim measures; or

(B) Be in compliance with an Authority approved corrective action plan and schedule subject to the following conditions:

(i) Any subsequent modifications to an approved corrective action plan and schedule must be approved by the Authority; and

(ii) If the Authority specifies interim measures for the protection of public health pending Authority approval of the corrective action plan and schedule, or pending completion of the corrective action plan, the water supplier must comply with these interim measures as well as with any schedule specified by the Authority.

(e) Water suppliers subject to the requirements of this section must, upon approval by the Authority, implement one or more of the following corrective action alternatives:

(A) Correct all significant deficiencies;

(B) Disconnect the groundwater source from the water system and provide an alternate source of water. If a disconnected well is or will be within 100 feet of a public water supply well, the disconnected well must be abandoned in accordance with 333-061-0050(2)(a)(E);

(C) Eliminate the source of contamination; or

(D) Provide treatment for the groundwater source that reliably achieves at least 4-log inactivation, removal, or a combination of inactivation and removal of viruses before or at the first customer. If the groundwater source does not meet all of the applicable construction standards specified in OAR 333-061-0050(2)(a) or (b), and the Authority determines that reconstruction of the groundwater source will add a significant measure of public health protection, then the groundwater source must be made to meet all of the applicable construction standards specified in OAR 333-061-0050(2)(a) or (b) before treatment is applied as prescribed by OAR 333-061-0050(5)(b).

(f) Water suppliers responsible for water systems using fecally contaminated groundwater sources must provide continuous disinfection as prescribed by OAR 333-061-0050(5) when disinfection is approved by the Authority as a corrective action.

(g) If three or more coliform investigations are triggered within a rolling 12 month period or four or more coliform investigations are triggered within a rolling two year period, water suppliers must install and utilize treatment for disinfectant residual maintenance. For the purposes of this subsection, only coliform investigations triggered as specified in OAR 333-061-0078(2)(a)(A) or (B) or (2)(b)(A) will be considered.

(A) Treatment must be installed and operating within six months unless the Authority approves an alternate schedule.

(B) Disinfectant residuals must be monitored as prescribed by OAR 333-061-0036(9).

(h) A water supplier violates this rule if any of the situations specified in paragraphs (6)(h)(A) through (C) of this rule occur. Violation of this rule is a violation of treatment technique requirements and requires a tier two public notice be published as specified by OAR 333-061-0042.

(A) Within 120 days (or earlier if directed by the Authority) of receiving written notice from the Authority of a significant deficiency, a water supplier:

(i) Fails to complete corrective action in accordance with applicable Authority plan review processes or other Authority guidance, including Authority specified interim actions and measures; or

(ii) Fails to be in compliance with an Authority approved corrective action plan and schedule.

(B) Within 120 days (or earlier if directed by the Authority) of receiving notification of an E. coli-positive groundwater source sample collected according to OAR 333-061-0036(6)(j) and not invalidated according to OAR 333-061-0036(6)(l), a water supplier:

(i) Fails to complete corrective action according to applicable Authority plan review processes or other Authority guidance, including interim actions and measures; or

(ii) Fails to be in compliance with an Authority approved corrective action plan and schedule.

(C) A water supplier fails to correct any disruption in treatment within four hours of determining a disruption is occurring at a groundwater system subject to the requirements of subsection (7)(b) of this rule and required to maintain at least 4-log treatment of viruses (using inactivation, removal, or an Authority approved combination of 4-log virus inactivation and removal) before or at the first customer.

(7) Compliance monitoring requirements for groundwater systems that provide at least 4-log treatment of viruses. Water systems must comply with the requirements of (7)(a) through (7)(c) of this rule.

(a) A groundwater system that is not required to meet the source water monitoring requirements of 333-061-0036(6)(i) or (j) of these rules, because it provides at least 4-log treatment of viruses (using inactivation, removal, or an Authority-approved combination of 4-log virus inactivation and removal) before or at the first customer for any groundwater source, must comply with the requirements of this subsection within 30 days of placing the groundwater source in service, whichever is later.

(A) The water system must notify the Authority in writing, that it provides at least 4-log treatment of viruses (using inactivation, removal, or an Authority approved combination of 4-log virus inactivation and removal) before or at the first customer for the groundwater source. Notification to the Authority must include engineering, operational, or other information that the Authority requests to evaluate the submission.

(B) The system must conduct compliance monitoring as required by subsection (7)(b) of this rule.

(C) The system must conduct groundwater source monitoring under OAR 333-061-0036(6) if the system subsequently discontinues 4-log treatment of viruses (using inactivation, removal, or an Authority-approved combination of 4-log virus inactivation and removal) before or at the first customer for the groundwater source.

(b) Monitoring requirements. A groundwater system subject to the requirements of section (6) or subsection (7)(a) of this rule must monitor the effectiveness and reliability of treatment for that groundwater source before or at the first customer as follows:

(A) Chemical Disinfection:

(i) Groundwater systems serving greater than 3,300 people must continuously monitor the residual disinfectant concentration using analytical methods as specified in OAR 333-061-0036(1), at a location approved by the Authority, and must record the lowest residual disinfectant concentration each day that water from the groundwater source is served to the public. The groundwater system must maintain the Authority-determined residual disinfectant concentration every day the groundwater system serves water from the groundwater source to the public. If there is a failure in the continuous monitoring equipment, the groundwater system must conduct grab sampling every four hours until the continuous monitoring equipment is returned to service. The system must resume continuous residual disinfectant monitoring within 14 days.

(ii) Groundwater systems serving 3,300 or fewer people must monitor the residual disinfectant concentration using analytical methods as specified in OAR 333-061-0036(1), at a location approved by the Authority, and record the residual disinfection concentration each day that water from the groundwater source is served to the public. The groundwater system must maintain the

Authority-determined residual disinfectant concentration every day the groundwater system serves water from the groundwater source to the public. The groundwater system must take a daily grab sample during the hour of peak flow or at another time specified by the Authority. If any daily grab sample measurement falls below the Authority-determined residual disinfectant concentration, the groundwater system must take follow-up samples every four hours until the residual disinfectant concentration is restored to the Authority-determined level. Alternately, a groundwater system that serves 3,300 or fewer people may monitor continuously and meet the requirements of subparagraph (7)(b)(A)(i) of this rule.

(B) Membrane filtration. A groundwater system that uses membrane filtration to achieve at least 4-log removal of viruses must monitor and operate the membrane filtration process in accordance with all Authority-specified monitoring and compliance requirements. A groundwater system that uses membrane filtration is in compliance with the requirement to achieve at least 4-log removal of viruses when:

(i) The membrane has an absolute molecular weight cut-off (MWCO), or an alternate parameter describing the exclusion characteristics of the membrane, that can reliably achieve at least 4-log removal of viruses;

(ii) The membrane process is operated in accordance with Authority-specified compliance requirements; and

(iii) The integrity of the membrane is intact as verified per OAR 333-061-0050(4)(c)(I).

(C) Alternative treatment. A groundwater system that uses an Authority-approved alternative treatment to provide at least 4-log treatment of viruses (using inactivation, removal, or an Authority-approved combination of 4-log virus inactivation and removal) before or at the first customer must:

(i) Monitor the alternative treatment in accordance with all Authority-specified monitoring requirements; and

(ii) Operate the alternative treatment in accordance with all compliance requirements that the Authority determines to be necessary to achieve at least 4-log treatment of viruses.

(c) Discontinuing treatment. A groundwater system may discontinue 4-log treatment of viruses (using inactivation, removal, or an Authority-approved combination of 4-log virus inactivation and removal) before or at the first customer for a groundwater source if the Authority determines, and documents in writing, that 4-log treatment of viruses is no longer necessary for that groundwater source. A system that discontinues 4-log treatment of viruses is subject to the source water monitoring requirements of OAR 333-061-0036(6).

(8) Determination of groundwater under the direct influence of surface water (GWUDI)

(a) Except for wells using only a handpump, all groundwater sources must be evaluated for the potential of surface water influence if the source is in proximity to perennial or intermittent surface water and meets one of the hydrogeologic setting-surface water setback criteria identified in paragraph (A) and either paragraph (B) or (C). Hydrogeologic setting is identified by the Source Water Assessment or some other hydrogeologic study approved by the Authority.

(A) The groundwater source draws water from:

(i) A sand aquifer and is within 75 feet of surface water;

(ii) A sand and gravel aquifer and is within 100 feet of surface water;

(iii) A coarse sand, gravel, and boulder aquifer and is within 200 feet of surface water;

(iv) A fractured bedrock aquifer or layered volcanic aquifer and is within 500 feet of surface water; or

(v) Greater distances if geologic conditions or historical monitoring data indicate additional risk at the source; and

(B) There is a history of microbiological contamination in the source; or

(C) The Source Water Assessment or some other hydrogeologic study approved by the Authority determines the source is highly sensitive as a result of aquifer characteristics, vadose zone characteristics, monitoring history or well construction.

(b) Except as provided by subsection (8)(c) of this rule, water suppliers must conduct sampling for any groundwater source(s) meeting the criteria specified in subsection (8)(a) of this rule. Sampling must be conducted according to the following criteria:

(A) Collection of twelve consecutive monthly source water samples when the source is used year-round, or every month the source provides water to the public during one operational season for water sources used seasonally;

(B) Samples must be analyzed for E. coli in accordance with all the applicable provisions of OAR 333-061-0036(1); and

(C) Samples must be collected at the water source prior to any treatment unless the Authority approves an alternate sampling location that is representative of source water quality.

(c) Public water systems that are required to evaluate their source(s) for direct influence of surface water may submit results of a hydrogeologic assessment completed by an Oregon registered geologist or other licensed professional with demonstrated experience and competence in hydrogeology in accordance with ORS 672.505 through 672.705 to demonstrate that the source is not potentially under the direct influence of surface water. The assessment must be consistent with the Oregon State Board of Geologist Examiners "Hydrology Report Guidelines," must be completed within a timeframe specified by the Authority and must include the following:

(A) Well characteristics: well depth, screened or perforated interval, casing seal placement;

(B) Aquifer characteristics: thickness of the vadose zone, hydraulic conductivity of the vadose zone and the aquifer, presence of low permeability zones in the vadose zone, degree of connection between the aquifer and surface water;

(C) Hydraulic gradient: gradient between the aquifer and surface water source during pumping conditions, variation of static water level and surface water level with time; and

(D) Groundwater flow: flow of water from the surface water source to the groundwater source during pumping conditions, estimated time-of-travel for groundwater from the surface water source(s) to the well(s), spring(s), etc.

(d) If a source water sample collected in accordance with subsection (8)(b) of this rule is reported as E. coli positive, then the water supplier must collect five additional source water samples within 24 hours of receiving notification of the positive sample result.

(e) If any of the five additional source water samples specified in subsection (8)(d) of this rule is E. coli positive then the original E. coli positive sample is considered confirmed, and the water supplier must have the groundwater source analyzed for surface water influence according to subsection (8)(h) of this rule. Further E. coli monitoring is not required.

(f) A water supplier may be required to have the groundwater source analyzed for surface water influence according to subsection (8)(h) of this rule at the discretion of the Authority if source water samples are consistently total coliform positive.

(g) Emergency groundwater sources that meet the criteria of subsection (8)(a) of this rule can either be evaluated as prescribed in subsection 8(b) or (8)(c) of this rule, or the evaluation can be waived if a Tier 2 public notice as prescribed in OAR 333-061-0042 is issued each time the source is used. The notice must explain that the source has been identified as potentially under the direct influence of surface water, but has not been fully evaluated, and therefore may not be treated sufficiently to inactivate pathogens such as Giardia lamblia and Cryptosporidium.

(h) Determination of surface water influence on a groundwater source must be based upon a minimum of two samples conducted according to the "Consensus Method for Determining Groundwaters under the Direct Influence of Surface Water Using Microscopic Particulate Analysis (MPA)." Both water samples must be collected during a period of high runoff or streamflow and separated by a period of at least four weeks, or at other times as determined by the Authority. Scoring for diatoms, other algae, and insects/larvae is

partially modified according to Table 10. Scoring for Giardia lamblia, coccidia, rotifers, and plant debris remains unchanged. [Table not included. See ED. NOTE.]

(i) A water source will be classified as groundwater or GWUDI as follows:

(A) If the two initial microscopic particulate analyses have a risk score of less than 10, the water system source is classified as groundwater;

(B) If any microscopic particulate analysis (MPA) risk score is greater than 19, or each risk score is greater than 14, the water source is classified as GWUDI;

(C) If at least one of the two MPA risk scores is between 10 and 19, two additional microscopic particulate analyses must be conducted, and water source classification will be made as follows:

(i) If all of the MPA risk scores are less than 15, the water system source is classified as groundwater;

(ii) If any MPA risk score is greater than 19, or two or more are greater than 14, the water system source is classified as under the direct influence of surface water; or

(iii) If only one of four MPA risk scores is greater than 14, two additional microscopic particulate analyses must be conducted, and water source classification will be based upon further evaluation by the Authority.

(j) If an infiltration gallery, Ranney well, or dug well has been classified as groundwater under this rule, the turbidity of the source must be monitored and recorded daily and kept by the water system operator. If the turbidity exceeds 5 NTU or if the surface water body changes course such that risk to the groundwater source is increased, an MPA must be conducted at that time. Reevaluation may be required by the Authority at any time.

(k) The Authority may determine a groundwater source to be under the direct influence of surface water if the criteria in subsection (8)(a) of this rule are met and there are significant or relatively rapid shifts in groundwater characteristics, such as turbidity, which closely correlate to changes in weather or surface water conditions.

(l) The Authority may require reevaluation of a groundwater source, as specified in this section, if geologic conditions, water quality trends, or other indicators change despite any data previously collected or any determination previously made.

(m) The Authority may determine that a source is not under direct influence of surface water based on criteria other than MPAs including the Source Water Assessment, source water protection, and other water quality parameters. The determination shall be based on the criteria indicating that the water source has a very low susceptibility to contamination by parasites, including Giardia lamblia and Cryptosporidium. The Authority may impose additional monitoring or disinfection treatment requirements to ensure that the risk remains low.

(9) Requirements for groundwater sources under the direct influence of surface water seeking alternative filtration credit through bank filtration:

(a) Water systems with all MPA risk scores less than 30 may choose the option to evaluate for bank filtration credit. The water system must conduct a demonstration of performance study that includes an assessment of the ability of the local hydrogeologic setting to provide a minimum of 2-log reduction in the number of particles and microorganisms in the Giardia and Cryptosporidium size range between surface water and the groundwater source. The bank filtration study must include the following elements or other Authority approved methods:

(A) The bank filtration study must involve the collection of data on removal of biological surrogates and particles in the Cryptosporidium size range of 2–5 microns or other surrogates approved by the Authority, and related hydrogeologic and water quality parameters during the full range of operating conditions. The demonstration study methods shall be reviewed and approved by the Authority prior to implementation. Final assessment of removal credit granted to the well shall be made by the Authority based on the study results.

(b) If a GWUDI system using bank filtration as an alternative filtration technology violates the MCL for turbidity specified in OAR 333-061-0030(3)(b)(D), the water system must investigate the cause of the high turbidity within 24 hours of the exceedance. Pending the results of the investigation by the water system, the Authority may require a new bank filtration study.

(10) Disinfection Byproduct Control Requirements:

(a) This rule establishes criteria under which community water systems and Non-transient, Non-community water systems which add a chemical disinfectant to the water in any part of the drinking water treatment process must modify their practices to meet MCLs and MRDLs in OAR 333-061-0030 and 0031, respectively. This rule also establishes the treatment technique requirements for disinfection byproduct precursors, and the criteria under which transient non-community water systems that use chlorine dioxide as a disinfectant or oxidant must modify their practices to meet the MRDL for chlorine dioxide as specified in OAR 333-061-0031.

(b) Water systems may increase residual disinfectant levels in the distribution system of chlorine or chloramines (but not chlorine dioxide) to a level and for a time necessary to protect public health, to address specific microbiological contamination problems caused by circumstances such as, but not limited to, distribution line breaks, storm run-off events, source water contamination events, or cross connection events.

(c) Enhanced coagulation or enhanced softening are authorized treatment techniques to control the level of disinfection byproduct precursors for water systems using surface water or groundwater under the direct influence of surface water and conventional filtration treatment. Community and Non-transient Non-community water systems using conventional filtration treatment must operate with enhanced coagulation or enhanced softening to achieve the total organic carbon (TOC) percent removal levels specified in subsection (10)(d) of this rule unless the system meets at least one of the alternative compliance criteria listed in paragraph (10)(c)(A) or (10)(c)(B) of this rule.

(A) Alternative compliance criteria for enhanced coagulation and enhanced softening systems. Water systems may use the alternative compliance criteria in subparagraphs (10)(c)(A)(i) through (vi) of this rule in lieu of complying with the performance criteria specified in subsection (e) of this section. Systems must still comply with monitoring requirements specified in OAR 333-061-0036(4)(k).

(i) The system's source water TOC level is less than 2.0 mg/L, calculated quarterly as a running annual average.

(ii) The system's treated water TOC level is less than 2.0 mg/L, calculated quarterly as a running annual average.

(iii) The system's source water TOC is less than 4.0 mg/L, calculated quarterly as a running annual average; the source water alkalinity is greater than 60 mg/L (as CaCO3 calculated quarterly as a running annual average; and the TTHM and HAA5 running annual averages are no greater than 0.040 mg/L and 0.030 mg/L, respectively.

(iv) The TTHM and HAA5 running annual averages are no greater than 0.040 mg/L and 0.030 mg/L, respectively, and the system uses only chlorine for primary disinfection and maintenance of a residual in the distribution system.

(v) The system's source water SUVA, prior to any treatment and measured monthly is less than or equal to 2.0 L/mg-m, calculated quarterly as a running annual average.

(vi) The system's finished water SUVA, measured monthly is less than or equal to 2.0 L/mg-m, calculated quarterly as a running annual average.

(B) Additional alternative compliance criteria for softening systems. Systems practicing enhanced softening that cannot achieve the TOC removals required by paragraph (10)(d)(B) of this rule may use the alternative compliance criteria in subparagraphs (10)(c)(B)(i) and (ii) of this rule in lieu of complying with subsection (10)(d) of this rule. Systems must still comply with monitoring requirements in specified in OAR 333-061-0036(4)(k).

(i) Softening that results in lowering the treated water alkalinity to less than 60 mg/L (as CaCO3), measured monthly and calculated quarterly as a running annual average.

(ii) Softening that results in removing at least 10 mg/L of magnesium hardness (as CaCO3), measured monthly and calculated quarterly as a running annual average.

(d) Enhanced coagulation and enhanced softening performance requirements.

(A) Systems must achieve the percent reduction of TOC specified in paragraph (10)(d)(B) in this rule between the source water and the combined filter effluent, unless the Authority approves a system's request for alternate minimum TOC removal (Step 2) requirements under paragraph (10)(d)(C) of this rule.

(B) Required Step 1 TOC reductions, specified in Table 11, are based upon specified source water parameters. Systems practicing softening are required to meet the Step 1 TOC reductions in the far-right column (Source water alkalinity >120 mg/L) for the specified source water TOC: [Table not included. See ED. NOTE.]

(C) Water systems that cannot achieve the Step 1 TOC removals required by paragraph (10)(d)(B) of this rule due to water quality parameters or operational constraints must apply to the Authority, within three months of failure to achieve the TOC removals required by paragraph (10)(d)(B) of this rule, for approval of alternative minimum TOC (Step 2) removal requirements submitted by the water system. If the Authority approves the alternative minimum TOC removal (Step 2) requirements, the Authority may make those requirements retroactive for the purposes of determining compliance. Until the Authority approves the alternate minimum TOC removal (Step 2) requirements, the water system must meet the Step 1 TOC removals contained in paragraph (10)(d)(B) of this rule.

(D) Alternate minimum TOC removal (Step 2) requirements. Applications made to the Authority by enhanced coagulation systems for approval of alternative minimum TOC removal (Step 2) requirements under paragraph (10)(d)(C) of this rule must include, as a minimum, results of bench-scale or pilot-scale testing conducted under subparagraph (10)(d)(D)(i) of this rule. The submitted bench-scale or pilot scale testing must be used to determine the alternate enhanced coagulation level.

(i) Alternate enhanced coagulation level is defined as coagulation at a coagulant dose and pH as determined by the method described in subparagraphs (10)(d)(D)(i) through (v) of this rule such that an incremental addition of 10 mg/L of alum (or equivalent amount of ferric salt) results in a TOC removal of less than or equal to 0.3 mg/ L. The percent removal of TOC at this point on the "TOC removal versus coagulant dose" curve is then defined as the minimum TOC removal required for the system. Once approved by the Authority, this minimum requirement supersedes the minimum TOC removal required by the Table 11 in paragraph (10)(d)(B) of this rule. This requirement will be effective until such time as the Authority approves a new value based on the results of a new bench-scale and pilot-scale test. Failure to achieve Authority-set alternative minimum TOC removal levels is a violation. [Table not included. See ED. NOTE.]

(ii) Bench-scale or pilot-scale testing of enhanced coagulation must be conducted by using representative water samples and adding 10 mg/L increments of alum (or equivalent amounts of ferric salt) until the pH is reduced to a level less than or equal to the enhanced coagulation Step 2 target pH as specified in Table 12: [Table not included. See ED. NOTE.]

(iii) For waters with alkalinities of less than 60 mg/L for which addition of small amounts of alum or equivalent addition of iron coagulant drives the pH below 5.5 before significant TOC removal occurs, the system must add necessary chemicals to maintain the pH between 5.3 and 5.7 in samples until the TOC removal of 0.3 mg/L per 10 mg/L alum added (or equivalent addition of iron coagulant) is reached.

(iv) The system may operate at any coagulant dose or pH necessary, consistent with these rules to achieve the minimum TOC percent removal approved under paragraph (10)(d)(C) of this rule.

(v) If the TOC removal is consistently less than 0.3 mg/L of TOC per 10 mg/L of incremental alum dose at all dosages of alum (or equivalent addition of iron coagulant), the water is deemed to contain TOC not amenable to enhanced coagulation. The water system may then apply to the Authority for a waiver of enhanced coagulation requirements.

(e) Compliance calculations.

(A) Water systems other than those identified in paragraphs (10)(c)(A) or (d)(B) of this rule must comply with requirements contained in paragraph (10)(d)(B) or (C) of this rule. Systems must calculate compliance quarterly, beginning after the system has collected 12 months of data, by determining an annual average using the following method:

(i) Determine actual monthly TOC percent removal, equal to: {1- (treated water TOC/source water TOC)}x100

(ii) Determine the required monthly TOC percent removal (from either Table 11 in paragraph (10)(d)(B) of this rule or from paragraph (10)(d)(C) of this rule). [Table not included. See ED. NOTE.]

(iii) Divide the value in subparagraph (10)(e)(A)(i) of this rule by the value in subparagraph (10)(e)(A)(ii) of this rule.

(iv) Add together the results of subparagraph (10)(e)(A)(iii) of this rule for the last 12 months and divide by 12.

(v) If the value calculated in subparagraph (10)(e)(A)(iv) of this rule is less than 1.00, the water system is not in compliance with the TOC percent removal requirements.

(B) Water systems may use the provisions in subparagraphs (10)(e)(B)(i) through (v) of this rule in lieu of the calculations in subparagraph (10)(e)(A)(i) through (v) of this rule to determine compliance with TOC percent removal requirements.

(i) In any month that the water system's treated or source water TOC level is less than 2.0 mg/L, the water system may assign a monthly value of 1.0 (in lieu of the value calculated in subparagraph (10)(e)(A)(iii) of this rule) when calculating compliance under the provisions of paragraph (10)(e)(A) of this rule.

(ii) In any month that a system practicing softening removes at least 10 mg/L of magnesium hardness (as CaCO3), the water system may assign a monthly value of 1.0 (in lieu of the value calculated in subparagraph (10)(e)(A)(iii) of this rule) when calculating compliance under the provisions of paragraph (10)(e)(A) of this rule.

(iii) In any month that the water system's source water SUVA, prior to any treatment is less than or equal to 2.0 L/mg-m, the water system may assign a monthly value of 1.0 (in lieu of the value calculated in subparagraph (10)(e)(A)(iii) of this rule) when calculating compliance under the provisions of paragraph (10)(e)(A) of this rule.

(iv) In any month that the water system's finished water SUVA is less than or equal to 2.0 L/mg-m, the system may assign a monthly value of 1.0 (in lieu of the value calculated in subparagraph (10)(e)(A)(iii) of this rule) when calculating compliance under the provisions of paragraph (10)(e)(A) of this rule.

(v) In any month that a system practicing enhanced softening lowers alkalinity below 60 mg/L (as CaCO3), the water system may assign a monthly value of 1.0 (in lieu of the value calculated in subparagraph (10)(e)(A)(iii) of this rule) when calculating compliance under the provisions of paragraph (10)(e)(A) of this rule.

(C) Water systems using conventional treatment may also comply with the requirements of this section by meeting the criteria in paragraph (10)(c)(A) or (B) of this rule.

(11) Requirements for Water Treatment Plant Recycled Water

(a) Any water system using surface water or groundwater under the direct influence of surface water that uses conventional filtration treatment or direct filtration treatment and that recycles spent filter backwash water, thickener, supernatant, or liquids from dewatering processes must meet the requirements of subsections (11)(b) and (c) of this rule and OAR 333-061-0040(2)(i).

(b) A water system must notify the Authority in writing by December 8, 2003 if that water system recycles spent filter backwash water, thickener supernatant, or liquids from dewatering

processes. This notification must include, at a minimum, the information specified in paragraphs (11)(b)(A) and (B) of this rule.

(A) A water treatment plant schematic showing the origin of all flows which are recycled (including, but not limited to, spent filter backwash water, thickener supernatant, and liquids from dewatering processes), the hydraulic conveyance used to transport them, and the location where they are re-introduced back into the water treatment plant.

(B) Typical recycle flow in gallons per minute (gpm), the highest observed water treatment plant flow experienced in the previous year (gpm), the design flow for the water treatment plant (gpm), and the operating capacity of the water treatment plant (gpm) that has been determined by the Authority where the Authority has made such determinations.

(c) Any water system that recycles spent filter backwash water, thickener supernatant, or liquids from dewatering processes must return these flows through the processes of a system's existing conventional filtration treatment plant or direct filtration treatment plant as defined by these rules or at an alternate location approved by the Authority by June 8, 2004. If capital improvements are required to modify the recycle location to meet this requirement, all capital improvements must be completed no later than June 8, 2006.

(12) Water systems using uncovered finished water storage facilities must comply with the conditions of either subsections (12)(a) or (b) of this rule for each uncovered finished water storage facility, or be in compliance with an Authority approved schedule to meet these conditions no later than April 1, 2009.

(a) Water systems must cover any uncovered finished water storage facility; or

(b) Treat the discharge from the uncovered finished water storage facility into the distribution system to achieve at least 4-log virus, 3-log Giardia lamblia, and 2-log Cryptosporidium inactivation or removal using a protocol approved by the Authority.

(c) Failure to comply with the requirements of this section is a violation of the treatment technique requirement.

(13) Summary and General Requirements of Microbial toolbox options for meeting Cryptosporidium treatment requirements. Filtered water systems are eligible for the treatment credits listed in Table 13 of this section by meeting the conditions for microbial toolbox options described in sections (14) through (18) of this rule and in OAR 333-061-0036(5)(c). Unfiltered water systems are eligible only for the treatment credits specified as inactivation toolbox options in Table 13. Water systems apply these treatment credits to meet the requirements of subsections (3)(e) or (4)(g) of this rule, as applicable. [Table not included. See ED. NOTE.]

(14) Source toolbox components for meeting Cryptosporidium treatment requirements.

(a) Watershed control program. Water systems receive 0.5-log Cryptosporidium treatment credit for implementing a watershed control program that meets the requirements of this subsection.

(A) Water systems must notify the Authority of the intent to apply for the watershed control program credit no later than two years prior to the treatment compliance date applicable to the system in subsection (1)(a) of this rule.

(B) Water systems must submit a proposed watershed control plan to the Authority no later than one year before the applicable treatment compliance date in subsection (1)(a) of this rule. The Authority must approve the watershed control plan for the water system to receive the applicable treatment credit. The watershed control plan must include the following elements:

(i) Identification of an area of influence, outside of which the likelihood of Cryptosporidium or fecal contamination affecting the treatment plant intake is not significant. This is the area to be evaluated in future watershed surveys under subparagraph (14)(a)(E)(ii) of this rule;

(ii) Identification of both potential and actual sources of Cryptosporidium contamination, and an assessment of the relative impact of these contamination sources on the water system's source water quality;

(iii) An analysis of the effectiveness and feasibility of control measures that could reduce Cryptosporidium loading from sources of contamination to the system's source water; and

(iv) A statement of goals and specific actions the system will undertake to reduce source water Cryptosporidium levels. The plan must explain how the actions are expected to contribute to specific goals, identify watershed partners and their roles, identify resource requirements and commitments, and include a schedule for plan implementation with deadlines for completing specific actions identified in the plan.

(C) Water Systems with existing watershed control programs are eligible to seek this credit, but must meet the requirements prescribed in paragraph (14)(a)(B) of this rule, and must specify ongoing and future actions that will reduce source water Cryptosporidium levels.

(D) If the Authority does not respond to a water system regarding approval of a watershed control plan submitted in accordance with this section, and the system meets the other requirements of this section, the watershed control program will be considered approved and a 0.5 log Cryptosporidium treatment credit will be awarded unless the Authority subsequently withdraws such approval.

(E) Water systems must complete the actions specified in this paragraph to maintain the 0.5-log credit.

(i) Water systems must submit an annual watershed control program status report to the Authority. The status report must describe the water system's implementation of the approved plan, and assess the adequacy of the plan to meet its goals. It must explain how the water system is addressing any deficiencies in plan implementation, including those previously identified by the Authority, or as the result of the watershed survey conducted in accordance with subparagraph (14)(a)(E)(ii) of this rule. The watershed control program status report must also describe any significant changes that have occurred in the watershed since the last watershed sanitary survey.

(ii) Water systems must undergo a watershed sanitary survey every three years for community water systems and every five years for non-community water systems and submit the survey report to the Authority. The survey must be conducted according to Authority guidelines and by persons the Authority approves.

(I) The watershed sanitary survey must meet the following criteria: encompass the region identified in the Authority approved watershed control plan as the area of influence; assess the implementation of actions to reduce source water Cryptosporidium levels; and identify any significant new sources of Cryptosporidium.

(II) If the Authority determines that significant changes may have occurred in the watershed since the previous watershed sanitary survey, water systems must undergo another watershed sanitary survey by a date determined by the Authority regardless of the regular date specified in subparagraph (14)(a)(E)(ii) of this rule.

(iii) The water system must make the watershed control plan, annual status reports, and watershed sanitary survey reports available to the public upon request. These documents must be in a plain language style and include criteria by which to evaluate the success of the program in achieving plan goals. The Authority may approve withholding portions of the annual status report, watershed control plan, and watershed sanitary survey from the public based on water supply security considerations.

(F) If the Authority determines that a water system is not implementing the approved watershed control plan, the Authority may withdraw the watershed control program treatment credit.

(G) If a water system determines, during implementation, that making a significant change to its approved watershed control program is necessary, the system must notify the Authority prior to making any such changes. If any change is likely to reduce the level of source water protection, the system must notify the Authority of the actions the water system will take to mitigate this effect.

(b) Alternative source. A water system may conduct source water monitoring that reflects a different intake location (either in

the same source or from an alternate source), or a different procedure for the timing or level of withdrawal from the source. If the Authority approves, a system may determine its bin classification under subsection (4)(f) of this rule based on the alternative source monitoring results.

(A) If a water system conducts alternative source monitoring as prescribed by this subsection, the water system must also monitor their current plant intake concurrently as prescribed by OAR 333-061-0036(5)(e).

(B) Alternative source monitoring as prescribed by this subsection must meet the requirements for source monitoring to determine bin classification, as described in OAR 333-061-0036(1), 333-061-0036(5)(e) through (g), and 333-061-0040(1)(o). Water systems must report the alternative source monitoring results to the Authority, including supporting information that documents the operating conditions under which the samples were collected.

(C) If a system determines its bin classification according to subsection (4)(f) of this rule using alternative source monitoring results that reflect a different intake location or a different procedure for managing the timing or level of withdrawal from the source, the system must relocate the intake or permanently adopt the withdrawal procedure, as applicable, no later than the applicable treatment compliance date in subsection (1)(a) of this rule.

(15) Pre-filtration treatment toolbox components for meeting Cryptosporidium treatment requirements.

(a) Presedimentation. Systems receive 0.5-log Cryptosporidium treatment credit for a presedimentation basin during any month the process meets the criteria specified in this paragraph:

(A) The presedimentation basin must be in continuous operation, and must treat the entire plant flow taken from a surface water or GWUDI source;

(B) The water system must continuously add a coagulant to the presedimentation basin; and

(C) The presedimentation basin must achieve the performance criteria specified in this paragraph.

(i) The basin must demonstrate at least 0.5-log mean reduction of influent turbidity. This reduction must be determined using daily turbidity measurements of the presedimentation process influent and effluent, and must be calculated as follows: log10(monthly mean of daily influent turbidity)-log10(monthly mean of daily effluent turbidity).

(ii) The basin must also comply with Authority-approved performance criteria that demonstrates at least 0.5-log mean removal of micron-sized particulate material through the presedimentation process.

(b) Two-stage lime softening. Systems receive an additional 0.5-log Cryptosporidium treatment credit for a two-stage lime softening plant if chemical addition and hardness precipitation occur in two separate and sequential softening stages prior to filtration. Both softening stages must treat the entire plant flow taken from a surface water or GWUDI source.

(c) Bank filtration. Water systems receive Cryptosporidium treatment credit for bank filtration that serves as pretreatment to a filtration plant by meeting the criteria specified in this section. Water systems using bank filtration when they begin source water monitoring according to OAR 333-061-0036(5)(e) must collect samples as prescribed by OAR 333-061-0036(5)(g) and are not eligible for this credit.

(A) Wells with a groundwater flow path of at least 25 feet receive 0.5-log treatment credit. Wells with a groundwater flow path of at least 50 feet receive 1.0-log treatment credit. The groundwater flow path must be determined as specified in paragraph (D) of this subsection.

(B) Only wells in granular aquifers are eligible for treatment credit. Granular aquifers are those comprised of sand, clay, silt, rock fragments, pebbles or larger particles, and minor cement. A water system must characterize the aquifer at the well site to determine aquifer properties.

(i) Water systems must extract a core from the aquifer and demonstrate that in at least 90 percent of the core length, grains less than 1.0 mm in diameter constitute at least 10 percent of the core material.

(C) Only horizontal and vertical wells are eligible for treatment credit.

(D) For vertical wells, the groundwater flow path is the measured distance from the edge of the surface water body under high flow conditions (as determined by the 100 year floodplain elevation boundary or by the floodway, as defined in Federal Emergency Management Agency flood hazard maps) to the well screen. For horizontal wells, the groundwater flow path is the measured distance from the bed of the river under normal flow conditions to the closest horizontal well lateral screen.

(E) Water systems must monitor each wellhead for turbidity at least once every four hours while the bank filtration process is in operation. If monthly average turbidity levels, based on daily maximum values in the well, exceed 1 NTU, the system must report this result to the Authority and conduct an assessment within 30 days to determine the cause of the high turbidity levels in the well. If the Authority determines that microbial removal has been compromised, the Authority may revoke treatment credit until the water system implements Authority-approved corrective actions to remediate the problem.

(F) Springs and infiltration galleries are not eligible for treatment credit under this section, but are eligible for a treatment credit in accordance with subsection (16)(c) of this rule.

(G) Bank filtration demonstration of performance. The Authority may approve Cryptosporidium treatment credit for bank filtration based on a demonstration of performance study that meets the criteria in this paragraph. This treatment credit may be greater than 1.0-log and may be awarded to bank filtration that does not meet the criteria in (15)(c)(A) through (E) of this rule.

(i) The study must follow an Authority approved protocol, and must include the collection of data on the removal of Cryptosporidium or a surrogate for Cryptosporidium and related hydrogeologic and water quality parameters during the full range of operating conditions.

(ii) The study must include sampling from both the production well(s) and monitoring wells that are screened and located along the shortest flow path between the surface water source and the production well(s).

(16) Treatment performance toolbox components for meeting Cryptosporidium treatment requirements.

(a) Combined filter performance. Water systems using conventional filtration treatment or direct filtration treatment receive an additional 0.5-log Cryptosporidium treatment credit during any month that the water system meets the criteria in this subsection. Combined filter effluent (CFE) turbidity must be less than or equal to 0.15 NTU in at least 95 percent of the measurements. Turbidity must be measured as described in OAR 333-061-0036(5)(a)(B).

(b) Individual filter performance. Water systems using conventional filtration treatment or direct filtration treatment receive 0.5-log Cryptosporidium treatment credit, which can be in addition to the 0.5-log credit under subsection (16)(a) of this rule, during any month the system meets the criteria in this subsection. Compliance with this criteria must be based on individual filter turbidity monitoring as described in OAR 333-061-0036(5)(d).

(A) The filtered water turbidity for each individual filter must be less than or equal to 0.15 NTU in at least 95 percent of the measurements recorded each month.

(B) No individual filter may have a measured turbidity greater than 0.3 NTU in two consecutive measurements taken 15 minutes apart.

(C) Any system that has received treatment credit for individual filter performance and fails to meet the requirements of paragraphs (16)(b)(A) or (B) of this rule, during any month, is in violation of treatment technique requirements as prescribed by subsection (4)(g) of this rule unless the Authority determines the following:

(i) The failure was due to unusual and short-term circumstances that could not reasonably be prevented through optimizing treatment plant design, operation, or maintenance; and

(ii) The system has experienced no more than two such failures in any calendar year.

(c) Demonstration of performance. The Authority may approve Cryptosporidium treatment credit for water treatment processes based on a demonstration of performance study that meets the criteria in this subsection. This treatment credit may be greater than or less than the prescribed treatment credits in subsection (4)(g) or sections (15) through (18) of this rule and may be awarded to treatment processes that do not meet the criteria for the prescribed credits.

(A) Water systems cannot receive the prescribed treatment credit for any toolbox option in sections (15) through (18) of this rule, if that toolbox option is included in a demonstration of performance study for which treatment credit is awarded under this subsection.

(B) The demonstration of performance study must follow an Authority approved protocol, and must demonstrate the level of Cryptosporidium reduction achieved by the treatment process under the full range of expected operating conditions for the water system.

(C) Approval by the Authority must be in writing, and may include monitoring and treatment performance criteria that the system must demonstrate and report on an ongoing basis to remain eligible for the treatment credit. The Authority may require such criteria where necessary to verify that the conditions under which the demonstration of performance credit was approved are maintained during routine operation.

(17) Additional filtration toolbox components for meeting Cryptosporidium treatment requirements.

(a) Bag and cartridge filters. Systems receive Cryptosporidium treatment credit of up to 2.0-log for individual bag or cartridge filters and up to 2.5-log for bag or cartridge filters operated in series by meeting the requirements in OAR 333-061-0050(4)(c)(J). To be eligible for this credit, water systems must report to the Authority, the results of challenge testing conducted in accordance with OAR 333-061-0050(4)(c)(J). The filters must treat the entire plant flow.

(b) Membrane filtration. Systems receive Cryptosporidium treatment credit for membrane filtration that meets the requirements of this paragraph. Membrane cartridge filters that meet the definition of membrane filtration in OAR 333-061-0020(77)(f) are eligible for this credit. The level of treatment credit a system receives is equal to the lower of the values determined under OAR 333-061-0050(4)(c)(H)(i) and (ii).

(c) Second stage filtration. Water systems receive 0.5-log Cryptosporidium treatment credit for a separate second stage of Authority-approved filtration that consists of sand, dual media, GAC, or other fine grain media following granular media filtration. To be eligible for this credit, the first stage of filtration must be preceded by a coagulation step and, both filtration stages must treat the entire plant flow taken from a surface water or GWUDI source. The Authority must assign the treatment credit based on an assessment of the design characteristics of the filtration process. A cap (added layer of filter media), such as GAC, on a single stage of filtration is not eligible for this credit.

(d) Slow sand filtration (as secondary filter). Water systems are eligible to receive 2.5-log Cryptosporidium treatment credit for a slow sand filtration process that follows a separate stage of filtration if both filtration stages treat the entire plant flow taken from a surface water or GWUDI source, and no disinfectant residual is present in the influent water to the slow sand filtration process. The Authority must assign the treatment credit based on an assessment of the design characteristics of the filtration process. This subsection does not apply to treatment credit awarded to slow sand filtration used as a primary filtration process.

(18) Inactivation toolbox components for meeting Cryptosporidium treatment requirements.

(a) If Chlorine Dioxide is used, CT values in Table 30 must be met. [Table not included. See ED. NOTE.]

(b) If Ozone is used, CT values in Table 31 must be met. [Table not included. See ED. NOTE.]

(c) To receive treatment credit for UV light, water systems must treat at least 95 percent of the water delivered to the public during each month by UV reactors operating within validated conditions for the required UV dose, as prescribed by OAR 333-061-0036(5)(c)(D) and 333-061-0050(5)(k)(I). Systems must demonstrate compliance with this condition by the monitoring required in OAR 333-061-0036(5)(c)(D)(ii).

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 431.110, 431.150, 448.175 & 448.273

Hist.: HD 26-1990, f. 12-26-90, cert. ef. 12-29-90; HD 7-1992, f. & cert. ef. 6-9-92; HD 12-1992, f. & cert. ef. 12-7-92; HD 14-1997, f. & cert. ef. 10-31-97; OHD 4-1999, f. 7-14-99, cert. ef. 7-15-99; OHD 7-2000, f. 7-1-00, cert. ef. 7-15-00; OHD 23-2001, f. & cert. ef. 10-31-01; OHD 17-2002, f. & cert. ef. 10-25-02; PH 12-2003, f. & cert. ef. 8-15-03; PH 33-2004, f. & cert. ef. 10-21-04; PH 2-2006, f. & cert. ef. 1-31-06; PH 2-2008, f. & cert. ef. 2-15-08; PH 4-2009, f. & cert. ef. 5-18-09; PH 7-2010, f. & cert. ef. 4-19-10; PH 13-2012, f. & cert. ef. 9-10-12; PH 3-2013, f. & cert. ef. 1-25-13; PH 5-2016, f. 2-10-16, cert. ef. 4-1-16

333-061-0034

Treatment Requirements and Performance Standards for Corrosion Control

(1) General requirements:

(a) All Community and Non-Transient Non-Community water systems required to provide corrosion control shall install and operate optimal corrosion control treatment.

(b) Any water system that complies with the applicable corrosion control treatment requirements specified by the Authority under sections (2) and (3) of this rule shall be deemed in compliance with the treatment requirement contained in subsection (1)(a) of this rule.

(c) Any system exceeding the lead or copper action level shall implement all applicable source water treatment requirements specified by the Authority under section (4) of this rule.

(d) Any system exceeding the lead action level shall implement the public education requirements contained in section (5) of this rule.

(e) Tap water monitoring for lead and copper, monitoring for water quality parameters, source water monitoring for lead and copper, and analyses of the monitoring results shall be completed in accordance with OAR 333-061-0036(1)(a) and 333-061-0036(2)(c).

(f) Systems shall report to the Authority all required treatment provision information and maintain appropriate records as prescribed in OAR 333-061-0034 and 0040.

(g) Failure to comply with the applicable requirements prescribed in these rules, shall constitute a violation of the national primary drinking water regulations for lead and/or copper.

(2) Systems shall complete the corrosion control treatment requirements as prescribed in section (3) of this rule as follows:

(a) Large systems (serving >50,000 persons) shall complete the following corrosion control treatment steps, unless it is deemed to have optimized corrosion control as prescribed in paragraphs (d)(B) or (d)(C) of this section:

(A) Systems shall conduct initial tap and water quality parameter monitoring for two consecutive six-month periods as prescribed in OAR 333-061-0036(2)(c)(D)(i) and (2)(c)(F) beginning January 1, 1992;

(B) Systems shall complete corrosion control studies prescribed in subsection (3)(c) of this rule by July 1, 1994;

(C) The Authority shall designate optimal corrosion control treatment as prescribed in subsection (3)(i) of this rule by January 1, 1995;

(D) Systems shall install optimal corrosion control treatment as prescribed in subsection (3)(k) of this rule by January 1, 1997;

(E) Systems shall complete follow-up sampling as prescribed in OAR 333-061-0036(2)(c)(D)(ii) and (2)(c)(F)(iv) by January 1, 1998;

(F) The Authority shall review installation of treatment and designate optimal water quality control parameters as prescribed in subsection (3)(l) of this rule by July 1, 1998.

(G) Systems shall operate in compliance with the Authority-specified optimal water quality control parameters as prescribed in subsection (3)(m) of this rule and continue to conduct tap sampling.

(b) Medium systems (serving 3,301 to 50,000 persons) shall complete the following corrosion control treatment steps, unless it is deemed to have optimized corrosion control under paragraph (d)(A),(d)(B), or (d)(C) of this section:

(A) Systems shall conduct initial tap sampling beginning July 1,1992 until the system either exceeds the lead or copper action level or becomes eligible for reduced monitoring under OAR 333-061-0036(2)(c)(D)(iv). A system exceeding the lead or copper action level shall recommend optimal corrosion control treatment within six months after the end of the monitoring period during which it exceeds one of the action levels.

(B) Within 12 months after the end of the monitoring period during which a system exceeds the lead or copper action level, the Authority may require the system to perform corrosion control studies. If the Authority does not require the system to perform such studies, the Authority shall specify optimal corrosion control treatment within the following time frames:

(i) For medium systems, within 18 months after the end of the monitoring period during which such system exceeds the lead or copper action level;

(ii) For small systems, within 24 months after the end of the monitoring period during which such system exceeds the lead or copper action level.

(C) If the Authority requires a system to perform corrosion control studies under paragraph (2)(b)(B) of this rule, the system shall complete the studies within 18 months after the Authority requires that such studies be conducted.

(D) If the system has performed corrosion control studies under paragraph (2)(b)(B) of this rule, the Authority shall designate optimal corrosion control treatment within 6 months after completion of paragraph (2)(b)(C) of this rule.

(E) Systems shall install optimal corrosion control treatment within 24 months after the Authority designates such treatment.

(F) Systems shall complete follow-up sampling within 36 months after the Authority designates optimal corrosion control treatment.

(G) The Authority shall review the system's installation of treatment and designate optimal water quality control parameters within 6 months after completion of follow-up sampling.

(H) Systems shall operate in compliance with the Authority-designated optimal water quality control parameters and continue to conduct tap sampling.

(c) Small systems (serving 3,300 or less persons) shall complete the corrosion control treatment steps prescribed in subsection (2)(b) of this rule, unless it is deemed to have optimized corrosion control under paragraphs (d)(A), (d)(B), or (d)(C) of this section. Small systems shall conduct initial tap sampling beginning July 1, 1993.

(d) A system is deemed to have optimized corrosion control and is not required to complete the applicable corrosion control treatment steps identified in this section if the system satisfies one of the following criteria. Any system deemed to have optimized corrosion control under this rule, and which has treatment in place, shall continue to operate and maintain optimal corrosion control treatment and meet any requirements that the Authority determines appropriate to ensure optimal corrosion control treatment is maintained:

(A) A small or medium-size water system meets the lead and copper action levels during each of two consecutive six-month monitoring periods conducted in accordance with OAR 333-061-0036(2)(c)(A) through (E).

(B) Any water system that demonstrates to the satisfaction of the Authority that it has conducted activities equivalent to the corrosion control steps applicable to such system under this section. If the Authority makes this determination, it shall provide the system with written notice explaining the basis for its decision and shall specify the water quality control parameters representing optimal corrosion control in accordance with subsection (3)(l) of this rule. Water systems deemed to have optimized corrosion control under this paragraph shall operate in compliance with the Authority-designated optimal water quality control parameters in accordance with subsection (3)(m) of this rule and continue to conduct lead and copper tap and water quality parameter sampling in accordance with OAR 333-061-0036(2)(c)(D)(iii) and 333-061-0036(2)(c)(F)(v), respectively. A system shall provide the Authority with the following information in order to support a determination under this paragraph:

(i) The results of all test samples collected for each of the water quality parameters in subsection (3)(d) of this rule;

(ii) A report explaining the test methods used by the water system to evaluate the corrosion control treatments listed in subsection (3)(c) of this rule, the results of all tests conducted, and the basis for the system's selection of optimal corrosion control treatment;

(iii) A report explaining how corrosion control has been installed and how it is being maintained to insure minimal lead and copper concentrations at consumers' taps; and

(iv) The results of tap water samples collected in accordance with OAR 333-061-0036(2)(c)(A) through (E) at least once every six months for one year after corrosion control has been installed.

(C) Any water system is deemed to have optimized corrosion control if it submits results of tap water monitoring and source water monitoring conducted in accordance with OAR 333-061-0036(2)(c)(A) through (E), (G) and (H) that demonstrates for two consecutive six-month monitoring periods that the difference between the 90th percentile tap water lead level computed under OAR 333-061-0030(1)(c)(A) and the highest source water lead concentration, is less than 0.005 mg/l:

(i) Those systems whose highest source water lead level is below the MDL may also be deemed to have optimized corrosion control if the 90th percentile tap water lead level is less than or equal to the PQL for lead for two consecutive 6-month monitoring periods;

(ii) Any water system deemed to have optimized corrosion control shall continue monitoring for lead and copper at the tap no less frequently than once every three years using the reduced number of sampling sites and collecting the samples at the specified times and locations. Any such system that has not conducted a round of monitoring since September 30, 1997, shall complete a round of monitoring no later than September 30, 2000;

(iii) Any water system deemed to have optimized corrosion control shall notify the Authority in writing of any upcoming long-term change in treatment (eg. changing disinfectants or corrosion control chemicals) or the addition of a new source. The Authority must review and approve the addition of a new source or long-term change in water treatment before it is implemented by the water system. The Authority may require any such system to conduct additional monitoring or to take other action the Authority deems appropriate to ensure that such systems maintain minimal levels of corrosion in the distribution system;

(iv) As of July 2001, a system is not deemed to have optimized corrosion control unless it meets the copper action level.

(v) Any system triggered into corrosion control because it is no longer deemed to have optimized corrosion control shall implement corrosion control treatment in accordance with the deadlines prescribed in subsections (b) and (c) of this rule. Any such large system shall adhere to the schedule specified for medium size systems, with the time periods for completing each step being triggered by the date the system is no longer deemed to have optimized corrosion control.

(e) Any small or medium-size water system that is required to complete the corrosion control steps due to its exceedance of the lead or copper action level may cease completing the treatment steps whenever the system meets both action levels during each of two consecutive monitoring periods conducted pursuant to OAR 333-061-0036(2)(c)(A) through (E) and submits the results to the Authority. If any such water system thereafter exceeds the lead or copper action level during any monitoring period, the system (or the Authority, as the case may be) shall recommence completion of

the applicable treatment steps, beginning with the first treatment step which was not previously completed in its entirety. The Authority may require a system to repeat treatment steps previously completed by the system where the Authority determines that this is necessary to implement properly the treatment requirements of this section. The Authority shall notify the system in writing of such a determination and explain the basis for its decision. The requirement for any small- or medium- size system to implement corrosion control treatment steps in accordance with subsection (2)(b) of this rule (including systems deemed to have optimized corrosion control under paragraph (2)(d)(A) of this rule) is triggered whenever any small- or medium- size system exceeds the lead or copper action level.

(3) Each system shall complete the corrosion control treatment requirements described below which are applicable to such system under section (2) of this rule:

(a) Based upon the results of lead and copper tap monitoring and water quality parameter monitoring, small and medium-size water systems exceeding the lead or copper action level shall recommend installation of one or more of the corrosion control treatments listed in subsection (3)(c) of this rule which the system believes constitutes optimal corrosion control for that system. The Authority may require the system to conduct additional water quality parameter monitoring in accordance with OAR 333-061-0036(2)(c)(F)(iii) to assist the Authority in reviewing the system's recommendation.

(b) The Authority may require any small or medium-size system that exceeds the lead or copper action level to perform corrosion control studies under subsection (3)(c) of this rule to identify optimal corrosion control treatment for the system.

(c) Any public water system performing corrosion control studies shall evaluate the effectiveness of each of the treatments which follow, and, if appropriate, combinations of the treatments which follow to identify the optimal corrosion control treatment for that system. The water system shall evaluate each of the corrosion control treatments using either pipe rig/loop tests, metal coupon tests, partial-system tests, or analyses based on documented analogous treatments with other systems of similar size, water chemistry and distribution system configuration:

(A) Alkalinity and pH adjustment;

(B) Calcium hardness adjustment; and

(C) The addition of a phosphate or silicate based corrosion inhibitor at a concentration sufficient to maintain an effective residual concentration in all test tap samples.

(d) The water system shall measure the following water quality parameters in any tests conducted under this subsection before and after evaluating the corrosion control treatments listed in subsection (3)(c) of this rule:

(A) Lead;

(B) Copper;

(C) pH;

(D) Alkalinity;

(E) Calcium;

(F) Conductivity;

(G) Orthophosphate (when an inhibitor containing a phosphate compound is used);

(H) Silicate (when an inhibitor containing a silicate compound is used);

(I) Water temperature.

(e) Any additional chemical treatment approaches considered by the water system shall be evaluated by the water system by conducting appropriate studies and analyses approved by the Authority that are equivalent in scope to the studies and analyses required in this section.

(f) The water system shall identify all chemical or physical constraints that limit or prohibit the use of a particular corrosion control treatment and document such constraints with at least one of the following:

(A) Data and documentation showing that a particular corrosion control treatment has adversely affected other water treatment processes when used by another water system with comparable water quality characteristics; and/or

(B) Data and documentation demonstrating that the water system has previously attempted to evaluate a particular corrosion control treatment and has found that the treatment is ineffective or adversely affects other water quality treatment processes.

(g) The water system shall evaluate the effect of the chemicals used for corrosion control treatment on other water quality treatment processes.

(h) On the basis of an analysis of the data generated during each evaluation, the water system shall recommend to the Authority in writing the treatment option that the corrosion control studies indicate constitutes optimal corrosion control treatment for that system. The water system shall provide a rationale for its recommendation along with all supporting documentation specified in subsections (3)(c) through (g) of this rule.

(i) Based upon consideration of available information including, where applicable, studies performed under subsection (3)(c) through (g) of this rule and a system's recommended treatment alternative, the Authority shall either approve the corrosion control treatment option recommended by the system, or designate alternative corrosion control treatment(s) from among those listed in subsection (3)(c) of this rule. When designating optimal treatment the Authority shall consider the effects that additional corrosion control treatment will have on water quality parameters and on other water quality treatment processes.

(j) The Authority shall notify the system of its decision on optimal corrosion control treatment in writing and explain the basis for this determination. If the Authority requests additional information to aid its review, the water system shall provide the information.

(k) Each system shall properly install and operate throughout its distribution system the optimal corrosion control treatment designated by the Authority under subsection (3)(i) of this rule.

(l) The Authority shall evaluate the results of all lead and copper tap samples and water quality parameter samples submitted by the water system and determine whether the system has properly installed and operated the optimal corrosion control treatment designated by the Authority in subsection (3)(i) of this rule. Upon reviewing the results of tap water and water quality parameter monitoring by the system, both before and after the system installs optimal corrosion control treatment, the Authority shall designate values for the applicable water quality control parameters as listed below and shall be those that the Authority determines to reflect optimal corrosion control treatment for the system. The Authority may designate values for additional water quality control parameters determined by the Authority to reflect optimal corrosion control for the system. The Authority shall notify the system in writing of these determinations and explain the basis for its decisions.

(A) A minimum value or a range of values for pH measured at each entry point to the distribution system;

(B) A minimum pH value, measured in all tap samples. Such value shall be 7.0, unless the Authority determines that meeting a pH level of 7.0 is not technologically feasible or is not necessary for the system to optimize corrosion control;

(C) If a corrosion inhibitor is used, a minimum concentration or a range of concentrations for the inhibitor, measured at each entry point to the distribution system and in all tap samples, that the Authority determines is necessary to form a passivating film on the interior walls of the pipes of the distribution system;

(D) If alkalinity is adjusted as part of optimal corrosion control treatment, a minimum concentration or a range of concentrations for alkalinity, measured at each entry point to the distribution system and in all tap samples;

(E) If calcium carbonate stabilization is used as part of corrosion control, a minimum concentration or a range of concentrations for calcium, measured in all tap samples.

(m) All systems that have installed treatment optimizing corrosion control shall continue to operate and maintain optimal corrosion control treatment, including maintaining water quality parameters at or above minimum values or within ranges designated by the Authority under subsection (3)(l) of this rule for all samples

collected under OAR 333-061-0036(2)(c)(F)(v)-(vii). Compliance shall be determined every six months, as specified under OAR 333-061-0036(2)(c)(F)(v). A water system is out of compliance for a six-month period if it has excursions for any Authority-designated water quality parameter on more than nine days during the period. An excursion occurs whenever the daily value for one or more of the water quality parameters measured at a sampling location is below the minimum value or outside the range designated by the Authority. Daily values are calculated as follows:

(A) On days when more than one measurement for the water quality parameter is collected at the sampling location, the daily value shall be the average of all results collected during the day regardless of whether they are collected through continuous monitoring, grab sampling or a combination of both;

(B) On days when only one measurement for the water quality parameter is collected at the sampling location, the daily value shall be the result of that measurement.

(C) On days when no measurement is collected for the water quality parameter at the sampling location, the daily value shall be the daily value calculated on the most recent day on which the water quality parameter was measured at the sample site;

(n) Upon its own initiative or in response to a request by a water system or other interested party, the Authority may modify its determination of the optimal corrosion control treatment under subsection (3)(i) of this rule or optimal water quality control parameters under subsection (3)(l) of this rule. A request for modification by a system or other interested party shall be in writing, explain why the modification is appropriate, and provide supporting documentation. The Authority may modify its determination where it concludes that such change is necessary to ensure that the system continues to optimize corrosion control treatment. A revised determination shall be made in writing, set forth the new treatment requirements, explain the basis for the Authority's decision, and provide an implementation schedule for completing the treatment modifications.

(4) Source water treatment requirements:

(a) Systems shall complete the applicable source water monitoring and treatment requirements prescribed in subsection (4)(b) of this rule and OAR 333-061-0036(2)(c)(A) through (E), (G) and (H) by the following deadlines:

(A) A system exceeding the lead or copper action level shall complete lead and copper source water monitoring as prescribed in OAR 333-061-0036(2)(c)(G) and (H) and make a treatment recommendation to the Authority as prescribed in paragraph (4)(b)(A) of this rule no later than 180 days after the end of the monitoring period during which the lead or copper action level was exceeded.

(B) The Authority shall make a determination regarding source water treatment as prescribed in paragraph (4)(b)(B) of this rule within 6 months after submission of monitoring results required under paragraph (4)(a)(A) of this rule.

(C) If the Authority requires installation of source water treatment, the system shall install the treatment as prescribed in paragraph (4)(b)(C) of this rule within 24 months after completion of requirements prescribed in paragraph (4)(a)(B) of this rule.

(D) The system shall complete follow-up tap water monitoring as prescribed in OAR 333-061-0036(2)(c)(D)(ii) and source water monitoring as prescribed in OAR 333-061-0036(2)(c)(I) within 36 months after completion of requirements prescribed in paragraph (4)(a)(B) of this rule.

(E) The Authority shall review the system's installation and operation of source water treatment and specify maximum permissible source water levels as prescribed in paragraph (4)(b)(D) of this rule within 6 months after completion of requirements prescribed in paragraph (4)(a)(D) of this rule.

(F) The system shall operate in compliance with the Authority-specified maximum permissible lead and copper source water levels as prescribed in paragraph (4)(b)(D) of this rule and continue source water monitoring as prescribed in OAR 333-061-0036(2)(c)(J).

(b) Source water treatment description:

(A) Any system which exceeds the lead or copper action level shall recommend in writing to the Authority the installation and operation of one of the source water treatments listed in paragraph (4)(b)(B) of this rule. A system may recommend that no treatment be installed based upon a demonstration that source water treatment is not necessary to minimize lead and copper levels at users' taps.

(B) The Authority shall complete an evaluation of the results of all source water samples submitted by the water system to determine whether source water treatment is necessary to minimize lead or copper levels in water delivered to users' taps. If the Authority determines that treatment is needed, the Authority shall either require installation and operation of the source water treatment recommended by the system (if any) or require the installation and operation of another source water treatment from among the following: ion exchange, reverse osmosis, lime softening or coagulation/filtration. If the Authority requests additional information to aid in its review, the water system shall provide the information by the date specified by the Authority in its request. The Authority shall notify the system in writing of its determination and set forth the basis for its decision.

(C) Each system shall properly install and operate the source water treatment designated by the Authority under paragraph (4)(b)(B) of this rule.

(D) The Authority shall review the source water samples taken by the water system both before and after the system installs source water treatment, and determine whether the system has properly installed and operated the source water treatment designated by the Authority. Based upon its review, the Authority shall designate the maximum permissible lead and copper concentrations for finished water entering the distribution system. Such levels shall reflect the contaminant removal capability of the treatment properly operated and maintained. The Authority shall notify the system in writing and explain the basis for its decision.

(E) Each water system shall maintain lead and copper levels below the maximum permissible concentrations designated by the Authority at each sampling point monitored in accordance with OAR 333-061-0036(2)(c)(G) through (K). The system is out of compliance with this paragraph if the level of lead or copper at any sampling point is greater than the maximum permissible concentration designated by the Authority.

(F) Upon its own initiative or in response to a request by a water system or other interested party, the Authority may modify its determination of the source water treatment under paragraph (4)(b)(B) of this rule, or maximum permissible lead and copper concentrations for finished water entering the distribution system under paragraph (4)(b)(D) of this rule. A request for modification by a system or other interested party shall be in writing, explain why the modification is appropriate, and provide supporting documentation. The Authority may modify its determination where it concludes that such change is necessary to ensure that the system continues to minimize lead and copper concentrations in source water. A revised determination shall be made in writing, set forth the new treatment requirements, explain the basis for the Authority's decision, and provide an implementation schedule for completing the treatment modifications.

(5) All water systems must deliver a consumer notice of lead tap water monitoring results to persons served by the water system at sites that are tested, as specified in subsection (5)(e) of this rule. Water systems that exceed the lead action level must sample the tap water of any customer who requests it in accordance with subsection (5)(d) of this rule. A water system that exceeds the lead action level based on tap water samples collected in accordance with OAR 333-061-0036(2)(c)(A) through (E) shall deliver the public education materials contained in subsections (5)(a) and (b) of this rule in accordance with the requirements in subsection (5)(c) of this rule.

(a) Content of written materials. Community and non-transient non-community water system(s) shall include the following elements in all of the printed materials it distributes through its lead public education program in the same order listed below. Paragraphs (5)(a)(A), (B) and (F) of this rule must be included in the materials

exactly as written except for the text in braces in these paragraphs for which the system must include system-specific information. Any additional information presented by a system shall be consistent with the information below and be in plain language that can be understood by the general public. Water systems must submit all written public education materials to the Authority prior to delivery.

(A) IMPORTANT INFORMATION ABOUT LEAD IN YOUR DRINKING WATER. {INSERT NAME OF WATER SYSTEM} found elevated levels of lead in drinking water in some homes/buildings. Lead can cause serious health problems, especially for pregnant women and young children. Please read this information closely to see what you can do to reduce lead in your drinking water.

(B) HEALTH EFFECTS OF LEAD: Lead can cause serious health problems if too much enters your body from drinking water or other sources. It can cause damage to the brain and kidneys, and can interfere with the production of red blood cells that carry oxygen to all parts of the body. The greatest risk of lead exposure is to infants, young children and pregnant women. Scientists have linked the effects of lead on the brain with lowered IQ in children. Adults with kidney problems and high blood pressure can be affected by low levels of lead more than healthy adults. Lead is stored in the bones, and it can be released later in life. During pregnancy, the child receives lead from the mother's bones, which may affect brain development.

(C) SOURCES OF LEAD:

(i) Explain what lead is.

(ii) Explain the possible sources of lead in drinking water and how lead enters drinking water. Include information on home/building plumbing materials and service lines that contain lead.

(iii) Discuss other important sources of lead exposure in addition to drinking water (e.g., paint).

(D) STEPS THE CONSUMER CAN TAKE TO REDUCE THEIR EXPOSURE TO LEAD IN DRINKING WATER:

(i) Encourage running the water to flush out the lead.

(ii) Explain concerns with using hot water from the tap and specifically caution against the use of hot water for preparing baby formula.

(iii) Explain that boiling water does not reduce lead levels.

(iv) Discuss other options consumers can take to reduce exposure to lead in drinking water, such as alternative sources or treatment of water.

(v) Suggest that parents have their child's blood tested for lead.

(E) Explain why there are elevated levels of lead in the system's drinking water (if known) and what the water system is doing to reduce the lead levels in homes/buildings in this area.

(F) For more information, call us at {INSERT YOUR NUMBER}, {(if applicable include the following) or visit our web site at {INSERT YOUR WEB SITE HERE}}. For more information on reducing lead exposure around your home/building and the health effects of lead, visit EPA's web site at http://www.epa.gov/lead or contact your health care provider.

(b) Community water systems must also:

(A) Tell consumers how to get their water tested;

(B) Discuss lead in plumbing components and the difference between low lead and lead free.

(c) Delivery of public education materials.

(A) For public water systems serving a large proportion of non-English speaking consumers, as determined by the Authority, the public education materials must contain information in the appropriate language(s) regarding the importance of the notice or contain a telephone number or address where persons served may contact the water system to obtain a translated copy of the public education materials or to request assistance in the appropriate language.

(B) A community water system that exceeds the lead action level on the basis of tap water samples collected in accordance with tap water monitoring requirements of these rules and that is not already conducting public education tasks under this rule must conduct the public education tasks under this section within 60 days after the end of the monitoring period in which the exceedance occurred.

(i) Deliver printed materials meeting the content requirements of subsections (5)(a) and (5)(b) of this rule to all bill paying customers;

(ii) Contact customers who are most at risk by delivering education materials that meet the content requirements of subsections (5)(a) and (5)(b) of this rule to local public health agencies even if they are not located within the water system's service area, along with an informational notice that encourages distribution to all the organization's potentially affected customers or community water system's users. The water system must contact the local public health agencies directly by phone or in person. The local public health agencies may provide a specific list of additional community based organizations serving target populations, which may include organizations outside the service area of the water system. If such lists are provided, systems must deliver education materials that meet the content requirements of subsections (5)(a) and (5)(b) of this rule to all organizations on the provided lists.

(iii) Contact customers who are most at risk by delivering materials that meet the content requirements of subsections (5)(a) and (5)(b) of this rule to public and private schools or school boards; Women, Infants and children (WIC), and Head Start programs; public and private hospitals and medical clinics; Pediatricians; family planning clinics; and local welfare agencies located within the water system's service area along with an informational notice that encourages distribution to all of the organization's potentially affected customers or community water system's users.

(iv) Make a good faith effort to locate licensed childcare centers; public and private preschools; and Obstetricians-Gynecologists and Midwives within the service area and deliver materials that meet the content requirements of subsections (5)(a) and (5)(b) of this rule to them, along with an informational notice that encourages distribution to all potentially affected customers or users. The good faith effort to contact at-risk customers may include requesting a specific contact list of these organizations from the local public health agencies, even if the agencies are not located within the water system's service area.

(v) No less often than quarterly, provide information on or in each water bill as long as the system exceeds the action level for lead. The message on the water bill must include the following statement exactly as written except for the text in braces for which the water system must include system-specific information: {INSERT NAME OF WATER SYSTEM} found high levels of lead in drinking water in some homes. Lead can cause serious health problems. For more information please call {INSERT NAME OF WATER SYSTEM}, {(if applicable include the following) or visit our web site at {INSERT YOUR WEB SITE HERE}}. The message or delivery mechanisms can be modified in consultation with the Authority; specifically the Authority may allow a separate mailing of public education materials to customers if the water system cannot place the information on water bills.

(vi) Post material meeting the content requirements of subsection (5)(a) and (5)(b) of this rule on the water system's web site if the system serves a population greater than 100,000.

(vii) Submit a press release to newspaper, television and radio stations.

(viii) In addition to (5)(c)(B)(i) through (vii) of this rule systems must implement at least three activities from the following: public service announcements; paid advertisements; public area information displays; emails to customers; public meetings; household deliveries, targeted individual customer contact; direct material distribution to all multi-family homes and institutions or other methods approved by the Authority. The educational content and selection of these activities must be determined in consultation with the Authority.

(ix) For systems that are required to conduct monitoring annually or less frequently, the end of the monitoring period is September 30 of the calendar year in which the sampling occurs,

or, if the Authority has established an alternate monitoring period, the last day of that period.

(C) As long as a community water system exceeds the action level, it must repeat the activities in subsection (5)(c) of this rule as follows:

(i) A community water system shall repeat the tasks contained in (5)(c)(B)(i),(ii),(iii),(iv) and (viii) of this rule every 12 months.

(ii) A community water system shall repeat tasks contained in (5)(c)(B)(v) of this rule with each billing cycle.

(iii) A community water system serving a population greater than 100,000 shall post and retain material on a publicly accessible web site pursuant to (5)(c)(B)(vi) of this rule.

(iv) The community water system shall repeat the task in (5)(c)(B)(vii) of this rule twice every 12 months on a schedule agreed upon with the Authority. The Authority can allow activities in (5)(c)(B) of this rule to extend beyond the 60-day requirement if needed for implementation purposes on a case-by-case basis; however, this extension must be approved in writing by the Authority in advance of the 60-day deadline.

(D) Within 60 days after the end of the monitoring period in which the exceedance occurred (unless it already is repeating public education tasks), a non-transient non-community water system shall deliver the public education materials specified by (5)(a) of this rule as follows:

(i) Post informational posters on lead in drinking water in a public place or common area in each of the buildings served by the system; and

(ii) Distribute informational pamphlets and/or brochures on lead in drinking water to each person served by the non-transient non-community water system. The Authority may allow the system to utilize electronic transmission in lieu of or combined with printed materials as long as it achieves at least the same coverage.

(iii) For systems that are required to conduct monitoring annually or less frequently, the end of the monitoring period is September 30 of the calendar year in which the sampling occurs, or, if the Authority has established an alternate monitoring period, the last day of that period.

(E) A non-transient non-community water system shall repeat the tasks contained in (5)(c)(D) at least once during each calendar year in which the system exceeds the action level. The Authority can allow activities to extend beyond the 60-day requirement if needed for implementation purposes on a case-by-case basis, however, this extension must be approved in writing by the Authority in advance of the 60-day deadline.

(F) A water system may discontinue delivery of public education materials if the system has met the lead action level during the most recent six-month monitoring period conducted pursuant to the monitoring requirements of these rules. Such a system shall recommence public education requirements if it subsequently exceeds the lead action level during any monitoring period.

(G) A community water system may apply to the Authority, in writing to use only the text specified in (5)(a) of this rule in lieu of the text in (5)(a) and (5)(b) of this rule and to perform the tasks listed in (5)(c)(D) and (E) in lieu of the tasks in (5)(c)(B) and (C) of this rule if:

(i) The system is a facility, such as a prison or a hospital, where the population served is not capable of or is prevented from making improvements to plumbing or installing point of use treatment devices: and

(ii) The system provides water as part of the cost of services provided and does not separately charge for water consumption.

(H) A community water system serving 3,300 or fewer people may limit certain aspects of their public education programs as follows:

(i) With respect to the requirements of (5)(c)(B)(viii), a system serving 3,300 or fewer must implement at least one of the activities listed.

(ii) With respect to the requirements of (5)(c)(B)(ii), (iii) and (iv) of this rule, a system serving 3,300 or fewer people may limit the distribution of the public education materials required to facilities and organizations served by the system that are most likely to be visited regularly by pregnant women and children.

(iii) With respect to the requirements of (5)(c)(B)(vii) of this rule the Authority may waive this requirement for systems serving 3,300 or fewer persons as long as the system distributes notices to every household served by the system.

(d) Supplemental monitoring and notification of results. A water system that fails to meet the lead action level on the basis of tap samples collected in accordance with OAR 333-061-0036(2)(c)(A) through (E) shall offer to sample the tap water of any customer who requests it. The system is not required to pay for collecting or analyzing the sample, nor is the system required to collect and analyze the sample itself.

(e) Notification of results.

(A) All water systems must provide a notice of the individual tap results from lead tap water monitoring carried out under the monitoring requirements of these rules to the persons served by the water system at the specific sampling site from which the sample was taken (e.g. the occupants of the residence where the tap was tested).

(B) A water system must provide the consumer notice as soon as practical, but no later than 30 days after the system learns of the tap monitoring results.

(C) The consumer notice must include the results of lead tap water monitoring for the tap that was tested, an explanation of the health effects of lead, list steps consumers can take to reduce exposure to lead in drinking water and contact information for the water utility. The notice must also provide the maximum contaminant level goal and the action level for lead and the definitions for these two terms.

(D) The Consumer notice must be provided to persons served at the tap that was tested, either by mail or by another method approved by the Authority. For example, upon approval by the Authority, a non-transient, non-community water system could post the results on a bulletin board in the facility to allow users to review the information. The system must provide the notice to customers at sample taps tested, including consumers who do not receive water bills.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 431.110, 431.150, 448.131, 448.150 & 448.273

Hist.: HD 12-1992, f. & cert. ef. 12-7-92; HD 3-1994, f. & cert. ef. 1-14-94; HD 1-1996, f. 1-2-96, cert. ef. 1-5-96; OHD 7-2000, f. 7-1-00, cert. ef. 7-15-00; OHD 23-2001, f. & cert. ef. 10-31-01; OHD 17-2002, f. & cert. ef. 10-25-02; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 33-2004, f. & cert. ef. 10-21-04; PH 2-2008, f. & cert. ef. 2-15-08; PH 4-2009, f. & cert. ef. 5-18-09; PH 7-2010, f. & cert. ef. 4-19-10; PH 3-2013, f. & cert. ef. 1-25-13

333-061-0036
Sampling and Analytical Requirements

(1) General:

(a) Samples required by these rules must be analyzed using EPA approved methods set forth in 40 CFR 141 by a laboratory accredited according to OAR chapter 333, division 064 and the Oregon Environmental Laboratory Accreditation Program (ORELAP). The laboratory must be certified to analyze drinking water samples using the specific method for the contaminant being analyzed.

(A) The Authority will only accept sample results that have been handled and documented in accordance with ORELAP standards, except as prescribed by subsection (1)(i) of this rule.

(B) Samples required by these rules must be collected after the water has been allowed to flow from the sample tap for a sufficient length of time to assure that the collected sample is representative of water in the distribution system or from the water source as applicable, except samples for lead or copper in tap water which must be collected as prescribed by paragraph (2)(c)(B) of this rule.

(b) Accredited laboratories will be considered a primary or subcontracted laboratory as specified by paragraphs (1)(b)(A) and (B) of this rule.

(A) A primary laboratory is the first accredited laboratory that receives a compliance sample for analysis, and is responsible for

chain of custody documentation (if applicable), performing the analytical method on a compliance sample (if applicable), final report review, and submission of results to the water system and the Authority as specified in OAR 333-061-0040(1)(b)(B). Primary laboratories must hold primary or secondary ORELAP accreditation.

(B) A subcontracted laboratory is an accredited laboratory that performs the analytical method on a compliance sample, and is responsible for sample analysis and result reporting to the primary laboratory as specified in OAR 333-061-0040(1)(b)(B). Subcontracted laboratories must hold ORELAP primary or secondary accreditation for the appropriate method(s).

(c) Alternate Analytical Methods:

(A) With the written permission of the Authority, and concurred in by the Administrator of the U.S. EPA, an alternate analytical method may be employed on the condition that it is substantially equivalent to the prescribed test in both precision and accuracy as it relates to the determination of compliance with any MCL; and

(B) The use of the alternate analytical method shall not decrease the frequency of sampling required by these rules.

(d) Monitoring of purchasing water systems:

(A) When a public water system obtains its water, in whole or in part, from one or more public water systems, the monitoring requirements imposed by these rules on the purchasing water system may be modified by the Authority to the extent that the system supplying the water is in compliance with its source monitoring requirements. When a public water system supplies water to one or more other public water systems, the Authority may modify monitoring requirements imposed by this rule to the extent that the interconnection of the systems justifies treating them as a single system for monitoring purposes.

(B) Any modified monitoring shall be conducted pursuant to a schedule specified by the Authority and concurred in by the Administrator of the US Environmental Protection Agency.

(e) Water suppliers shall monitor each water source individually for contaminants listed in OAR 333-061-0030 (Maximum Contaminant Levels), except for coliform bacteria, HAA5s, TTHMs and corrosion by-products, at the entry point to the distribution system except as described below. Any such modified monitoring shall be conducted pursuant to a schedule prescribed by the Authority.

(A) If the system draws water from more than one source and sources are combined before distribution, the system may be allowed to sample at an entry point to the distribution system during normal operating conditions, where justified, taking into account operational considerations, geologic and hydrologic conditions, and other factors.

(B) If a system draws water from multiple ground water sources which are not combined before distribution, the system may be allowed to sample at a representative source or sources, where justified, taking into account geologic and hydrogeologic conditions, land uses, well construction, and other factors.

(f) Compliance with MCLs shall be based on each sampling point as described in this section. If any point is determined to be out of compliance, the system shall be deemed out of compliance. If an entirely separated portion of a water system is out of compliance, then only that portion of the system shall be deemed out of compliance.

(g) The Authority may require additional sampling and analysis for the contaminants included in OAR 333-061-0030 (Maximum Contaminant Levels) when necessary to determine whether an unreasonable risk to health exists. The Authority may also require sampling and analysis for additional contaminants not included in OAR 333-061-0030 (Maximum Contaminant Levels) when necessary for public health protection.

(h) Water suppliers and their appointed representatives shall collect water samples from representative locations in the water system as prescribed in this rule and shall employ proper sampling procedures and techniques. Samples submitted to laboratories for analysis shall be clearly identified and shall include the name of the water system, public water system identification number, sampling date, and time, sample location identifying the sample tap, the name of the person collecting the sample and be labeled as follows:

(A) Routine: These are samples collected from established sampling locations within a water system at specified frequencies to satisfy monitoring requirements as prescribed in this rule. These samples are used to calculate compliance with maximum contaminant levels prescribed in OAR 333-061-0030(4);

(B) Repeat: These are samples collected as a follow-up to a routine sample that has exceeded a maximum contaminant level as prescribed in OAR 333-061-0030. Repeat samples are also used to calculate compliance with maximum contaminant levels prescribed in OAR 333-061-0030(4);

(C) Special: These are samples collected to supplement routine monitoring samples and are not required to be reported to the Authority. Samples of this type are not considered representative of the water system and are outside the scope of normal quality assurance and control procedures or the established compliance monitoring program. Special samples include, but are not limited to, samples taken for special studies, user complaints, post construction/repair disinfection, sources not in service and raw water prior to treatment, except as required by this rule.

(i) Measurements for turbidity, disinfectant residual, temperature, alkalinity, calcium, conductivity, chlorite, bromide, TOC, SUVA, dissolved organic carbon, UV254, orthophosphate, silica and pH may be performed on site using approved methods by individuals trained in sampling and testing techniques. Daily chlorite samples measured at the entrance to the distribution system must be performed by a party approved by the Authority.

(j) Nothing in these rules shall be construed to preclude the Authority or any of its duly authorized representatives from taking samples and from using the results of such samples to determine compliance with applicable requirements of these rules.

(k) Wellfield Determination

(A) Water systems possessing two or more wells that separately supply water to the distribution system may be eligible to have those wells considered as a wellfield source for monitoring purposes provided the requirements of this rule are met. Information pertinent to determining whether the wellfield designation is appropriate can be found in the water system's Source Water Assessment Report.

(B) To be classified as a wellfield, the wells must meet the following criteria:

(i) The wells must be within 2,500 feet of one another or as determined in a state approved hydrogeological study to minimize inter-well interference drawdowns. For wells located in a low-impact land use area, this criterion may be waived at the discretion of the Authority.

(ii) The wells must produce from the same and no other aquifer. This criterion is determined using source water assessment results, based on well reports, maps and other hydrogeological information.

(C) To be considered for wellfield designation, the water supplier must submit the following to the Authority:

(i) A schematic drawing showing all sources, entry points and relevant sample taps;

(ii) A map and description of the land use activities within the respective wellhead protection areas (using the inventory section of the Source Water Assessment Report); and

(iii) A description of the pumping patterns.

(D) If a water system's wells are considered to comprise a wellfield, the susceptibility analysis conducted during the source water assessment is utilized to determine the sampling point(s). Table 14 summarizes the alternatives: [Table not included. See ED. NOTE.]

(E) To determine the most susceptible well, the area within the two-year time-of-travel is considered. The Authority will consider the potential contaminant source inventory determined during the source water assessment, the aquifer sensitivity, pumping patterns and other pertinent hydrogeological information.

(F) The Authority may still designate more than one entry point within the wellfield as a sampling point if well construction or land use practices warrant. For a large area containing numerous wells, sub-wellfields may be identified, each with its own sample site designation.

(2) Inorganic chemicals:

(a) Antimony, Arsenic, Barium, Beryllium, Cadmium, Chromium, Cyanide, Fluoride, Mercury, Nickel, Selenium and Thallium.

(A) Sampling of water systems for regulated Inorganic Chemicals shall be conducted as follows:

(i) Community and Non-Transient Non-Community Water systems using surface water sources or groundwater sources under the direct influence of surface water solely or a combination of surface and ground water sources shall sample at each point in the distribution system representative of each source after treatment or at entry points to the distribution system after any application of treatment. Surface water systems shall collect samples annually at each sampling point beginning in the initial compliance period according to the schedule in subsection (2)(j) of this rule. The water system shall take each sample at the same sampling point unless conditions make another sampling point more representative of each source or treatment plant.

(ii) Community and Non-Transient Non-Community Water systems using ground water sources shall sample at each point in the distribution system representative of each source after treatment or at entry points to the distribution system representative of each source after any application of treatment. Ground water systems shall collect samples once every three years at each sampling point beginning in the initial compliance period according to the schedule in subsection (2)(j) of this rule. The water system shall take each sample at the same sampling point unless conditions make another sampling point more representative of each source or treatment plant.

(iii) All new Transient Non-Community and State Regulated water systems or existing Transient Non-Community, and State Regulated water systems with new sources shall sample once for arsenic. Samples are to be collected at the entry points to the distribution system representative of each source after any application of treatment.

(iv) If a system draws water from more than one source and the sources are combined before distribution, the system must sample at an entry point to the distribution system during periods of normal operating conditions when water is representative of all the sources being used.

(v) A water system with two or more wells that have been determined to constitute a "wellfield" as specified in subsection (1)(k) of this rule may reduce sampling to only those entry point(s) designated by the Authority.

(B) The Authority may allow compositing of samples from a maximum of 5 sampling points, provided that the detection limit of the method used for analysis is less than one-fifth of the MCL. Compositing of samples is to be done in the laboratory. Composite samples must be analyzed within 14 days of collection. If the concentration in the composite sample is equal to or greater than one-fifth of the MCL of any inorganic chemical listed in section (2) of this rule, then a follow-up sample must be taken for the contaminants which exceeded one-fifth of the MCL within 14 days at each sampling point included in the composite. If duplicates of the original sample taken from each sampling point used in the composite are available, the system may use these instead of resampling. The duplicates must be analyzed and the results reported to the Authority within 14 days of collection. If the population served by the water system is >3,300 persons, then compositing can only be allowed within the system. In systems serving ≤3,300 persons, compositing is allowed among multiple systems provided the 5 sample limit is maintained.

(C) Water systems may apply to the Authority for a waiver from the monitoring frequencies specified in paragraph (2)(a)(A) of this rule on the condition that the system shall take a minimum of one sample while the waiver is effective and the effective period for the waiver shall not exceed one nine-year compliance cycle.

(i) The Authority may grant a waiver provided surface water systems have monitored annually for at least three years and groundwater systems have conducted a minimum of three rounds of monitoring (at least one sample shall have been taken since January 1, 1990), and all analytical results are less than the maximum contaminant levels prescribed in OAR 333-061-0030 for inorganic chemicals. Systems that use a new water source are not eligible for a waiver until three rounds of monitoring from the new source have been completed.

(ii) Waivers granted by the Authority shall be in writing and shall set forth the basis for the determination. The Authority shall review and revise, where appropriate, its determination of the appropriate monitoring frequency when the system submits new monitoring data or where other data relevant to the system's appropriate monitoring frequency become available. In determining the appropriate reduced monitoring frequency, the Authority shall consider the reported concentrations from all previous monitoring; the degree of variation in reported concentrations; and other factors which may affect concentrations such as changes in groundwater pumping rates, changes in the system's configuration, changes in the system's operating procedures, or changes in stream flows or characteristics.

(D) Systems which exceed the maximum contaminant levels as calculated in subsection (2)(i) of this rule shall monitor quarterly beginning in the next quarter after the violation occurred. The Authority may decrease the quarterly monitoring requirement to the frequencies prescribed in paragraph (2)(a)(A) of this rule when it is determined that the system is reliably and consistently below the maximum contaminant level. Before such a decrease is permitted a groundwater system must collect at least two quarterly samples and a surface water system must collect a minimum of four quarterly samples.

(E) All new systems or systems that use a new source of water must demonstrate compliance with the MCL within a period of time specified by the Authority. The system must also comply with the initial sampling frequencies specified by the Authority to ensure a system can demonstrate compliance with the MCL. Routine and increased monitoring frequencies shall be conducted in accordance with the requirements in this section.

(b) Asbestos:

(A) At community and non-transient non-community water systems regardless of source, sampling must be conducted for Asbestos at least once during the initial three-year compliance period of each nine-year compliance cycle unless a waiver is granted by the Authority according to paragraph (2)(b)(B) of this rule.

(B) The Authority may grant a waiver from the monitoring prescribed by paragraph (2)(b)(A) of this rule if a water system is determined not to be vulnerable to either asbestos contamination in its source water or due to corrosion of asbestos-cement pipe, or both. If granted, the water supplier will not be required to monitor while the waiver remains in effect. A waiver remains in effect until the completion of the three year compliance period.

(C) At water systems vulnerable to asbestos contamination due solely to corrosion of asbestos-cement pipe, one sample must be collected at a tap served by the asbestos-cement pipe under conditions where asbestos contamination is most likely to occur.

(D) At water systems vulnerable to asbestos contamination due solely to asbestos in source water shall, one sample must be collected at the entry point to the distribution system after any treatment.

(E) A system vulnerable to asbestos contamination due both to its source water supply and corrosion of asbestos-cement pipe shall take one sample at a tap served by asbestos-cement pipe and under conditions where asbestos contamination is most likely to occur.

(F) If a sample result exceeds the maximum contaminant level for asbestos as prescribed in subsection (2)(i) of this rule, the water supplier shall monitor quarterly beginning in the next quarter after the violation occurred. If the Authority determines that the sample results are reliably and consistently below the maximum contaminant level based on a minimum of two quarterly samples for groundwater

systems or a minimum of four quarterly samples for water systems using surface water sources, the monitoring may be returned to the frequency prescribed in paragraph (2)(b)(A) of this rule.

(c) Lead and Copper:

(A) At community and non-transient non-community water systems, monitoring for lead and copper in tap water must be conducted as specified in this subsection. Sample site location:

(i) Each water system shall complete a materials evaluation of its distribution system in order to identify a pool of targeted sampling sites that meets the requirements of this paragraph, and which is sufficiently large to ensure that the water system can collect the number of lead and copper tap samples required in paragraph (2)(c)(C) of this rule. All sites from which first draw samples are collected shall be selected from this pool of targeted sampling sites. Sampling sites may not include faucets that have point-of-use or point-of-entry treatment devices designed to remove inorganic contaminants.

(ii) In addition to any information that may have been gathered under the special corrosivity monitoring requirements, the water system shall review the sources of information listed below in order to identify a sufficient number of sampling sites:

(I) All plumbing codes, permits, and records in the files of the building department(s) which indicate the plumbing materials that are installed within publicly and privately owned structures connected to the distribution system; and

(II) All existing water quality information, which includes the results of all prior analyses of the system or individual structures connected to the system, indicating locations that may be particularly susceptible to high lead or copper concentrations.

(iii) The sampling sites selected for a community water system's sampling pool ("tier 1 sampling sites") shall consist of single family structures that contain copper pipes with lead solder installed from January 1, 1983 through June 30, 1985 or contain lead pipes. When multiple-family residences comprise at least 20 percent of the structures served by a water system, the system may include these types of structures in its sampling pool.

(iv) Any community water system with insufficient tier 1 sampling sites shall complete its sampling pool with "tier 2 sampling sites", consisting of buildings, including multiple-family residences that contain copper pipes with lead solder installed from January 1, 1983 through June 30, 1985 or contain lead pipes.

(v) Any community water system with insufficient tier 1 and tier 2 sampling sites shall complete its sampling pool with "tier 3 sampling sites", consisting of single family structures that contain copper pipes with lead solder installed before 1983. A community water system with insufficient tier 1, tier 2 and tier 3 sampling sites shall complete its sampling pool with representative sites throughout the distribution system. A representative site is a site in which the plumbing materials used at that site would be commonly found at other sites served by the system.

(vi) The sampling sites selected for a non-transient non-community water system ("tier 1 sampling sites") shall consist of buildings that contain copper pipes with lead solder installed from January 1, 1983 through June 30, 1985 or contain lead pipes.

(vii) A non-transient non-community water system with insufficient tier 1 sites that meet the targeting criteria in subparagraph (2)(c)(A)(vi) of this rule shall complete its sampling pool with sampling sites that contain copper pipes with lead solder installed before 1983. If additional sites are needed, the system shall use representative sites throughout the distribution system. A representative site is a site in which the plumbing materials used at that site would be commonly found at other sites served by the water system.

(viii) Any water system whose sampling pool does not consist exclusively of tier 1 sites shall demonstrate in a letter submitted to the Authority under OAR 333-061-0040(1)(g)(A)(i) why a review of the information listed in subparagraph (2)(c)(A)(ii) of this rule was inadequate to locate a sufficient number of tier 1 sites. Any community water system which includes tier 3 sampling sites in its sampling pool shall demonstrate in such a letter why it was unable to locate a sufficient number of tier 1 and tier 2 sampling sites.

(B) Monitoring requirements for lead and copper in tap water. Sample collection methods:

(i) All tap samples for lead and copper collected in accordance with this paragraph shall be first draw samples.

(ii) Each first-draw tap sample for lead and copper shall be one liter in volume and have stood motionless in the plumbing system of each sampling site for at least six hours. First-draw samples from residential housing shall be collected from the cold-water kitchen tap or bathroom sink tap. First-draw samples from a non-residential building shall be one liter in volume and shall be collected at an interior tap from which water is typically drawn for consumption. First-draw samples may be collected by the system or the system may allow residents to collect first-draw samples after instructing the residents of the sampling procedures specified in this paragraph. To avoid problems of residents handling nitric acid, acid fixation of first draw samples may be done up to 14 days after the sample is collected. If a system allows residents to perform sampling, the system may not challenge, based on alleged errors in sample collection, the accuracy of sampling results.

(iii) A water system shall collect each first-draw tap sample from the same sampling site from which it collected a previous sample. If, for any reason, the water system cannot gain entry to a sampling site in order to collect a follow-up tap sample, the system may collect the follow-up tap sample from another sampling site in its sampling pool as long as the new site meets the same targeting criteria, and is within reasonable proximity of the original site.

(C) Monitoring requirements for lead and copper in tap water. Number of samples: Water systems shall collect at least one sample during each monitoring period specified in paragraph (2)(c)(D) of this rule from the number of sites listed in the first column below ("standard monitoring"). A system conducting reduced monitoring under subparagraph (2)(c)(D)(iv) of this rule shall collect at least one sample from the number of sites specified in the second column below during each monitoring period specified in subparagraph (2)(c)(D)(iv) of this rule. Such reduced monitoring sites shall be representative of the sites required for standard monitoring. A system that has fewer than five drinking water taps, that can be used for human consumption meeting the sample site criteria of paragraph (2)(c)(A) of this rule to reach the required number of sample sites, must collect at least one sample from each tap and then must collect additional samples from those taps on different days during the monitoring period to meet the required number of sites. Alternatively the Authority may allow these public water systems to collect a number of samples less than the number of sites specified below provided that 100 percent of all taps that can be used for human consumption are sampled. The Authority must approve this reduction of the minimum number of samples in writing based on a request from the system or onsite verification by the Authority. The Authority may specify sampling locations when a system is conducting reduced monitoring.

System Size — # of sites — # of sites
(# People Served) — (Standard Monitoring) — (Reduced Monitoring)
>100,000 — 100 — 50
10,001 to 100,000 — 60 — 30
3,301 to 10,000 — 40 — 20
501 to 3,300 — 20 — 10
101 to 500 — 10 — 5
≤100 — 5 — 5

(D) Monitoring requirements for lead and copper in tap water. Timing of monitoring:

(i) Initial tap monitoring requirements:

(I) All large systems shall monitor during two consecutive six-month periods.

(II) All small and medium-size systems shall monitor during each six-month monitoring period until the system exceeds the lead or copper action level and is therefore required to implement the corrosion control treatment requirements specified in OAR 333-061-0034(2), in which case the system shall continue monitoring in accordance with subparagraph (2)(c)(D)(ii) of this rule, or the system meets the lead and copper action levels during two consecutive six-month monitoring periods, in which case the system may reduce monitoring in accordance with subparagraph (2)(c)(D)(iv) of this rule.

(ii) Monitoring after installation of corrosion control and source water treatment.

(I) Any large (serving more than 50,000 persons) system which installs optimal corrosion control treatment pursuant to OAR 333-061-0034(2)(a)(D) shall monitor during two consecutive six-month monitoring periods by the date specified in 333-061-0034(2)(a)(E).

(II) Any small (serving 3,300 people or less) or medium-size (serving 3,301 to 50,000 persons) system which installs optimal corrosion control treatment pursuant to OAR 333-061-0034(2)(b)(E) shall monitor during two consecutive six-month monitoring periods by the date specified in 333-061-0034(2)(b)(F).

(III) Any system which installs source water treatment pursuant to OAR 333-061-0034(4)(a)(C) shall monitor during two consecutive six-month monitoring periods by the date specified in 333-061-0034(4)(a)(D).

(iii) Monitoring after the Authority specifies water quality parameter values for optimal corrosion control. After the Authority specifies the values for water quality control parameters under OAR 333-061-0034(3)(l), the system shall monitor during each subsequent six-month monitoring period, with the first monitoring period to begin on the date the Authority specifies the optimal values.

(iv) Reduced monitoring

(I) A small or medium-size water system that meets the lead and copper action levels during each of two consecutive six-month monitoring periods may reduce the number of samples in accordance with paragraph (2)(c)(C) of this rule, and reduce the frequency of sampling to once per year. A small or medium water system collecting fewer than five samples as specified in (2)(c)(C) of this rule that meets the lead and copper action levels during each of two consecutive six-month monitoring periods may reduce the frequency of sampling to once per year. In no case can the system reduce the number of samples required below the minimum of one sample per available tap. This sampling shall begin during the calendar year immediately following the end of the second consecutive six-month monitoring period.

(II) Any water system that meets the lead action level and maintains the range of values for the water quality control parameters reflecting optimal corrosion control treatment specified by the Authority during each of two consecutive six-month monitoring periods may reduce the frequency of monitoring to once per year and reduce the number of lead and copper samples in accordance with paragraph (2)(c)(C) of this rule if it receives written approval from the Authority. This sampling shall begin during the calendar year immediately following the end of the second consecutive six-month monitoring period. The Authority shall review monitoring, treatment, and other relevant information submitted by the water system, and shall notify the system in writing when it determines the system is eligible to commence reduced monitoring. The Authority shall review, and where appropriate, revise its determination when the system submits new monitoring or treatment data, or when other data relevant to the number and frequency of tap sampling becomes available.

(III) A small or medium-size water system that meets the lead and copper action levels during three consecutive years of monitoring may reduce the frequency of monitoring for lead and copper from annually to once every three years. Any water system that meets the lead action level and maintains the range of values for the water quality control parameters reflecting optimal corrosion control treatment specified by the Authority during three consecutive years of monitoring may reduce the frequency of monitoring from annually to once every three years if it receives written approval from the Authority. Samples collected once every three years shall be collected no later than every third calendar year. The Authority shall review monitoring, treatment, and other relevant information submitted by the water system and shall notify the system in writing when it determines the system is eligible to reduce the frequency of monitoring to once every three years. The Authority shall review, and where appropriate, revise its determination when the system submits new monitoring or treatment data, or when other data relevant to the number and frequency of tap sampling becomes available.

(IV) A water system that reduces the number and frequency of sampling shall collect these samples from representative sites included in the pool of targeted sampling sites identified in paragraph (2)(c)(A) of this rule. Systems sampling annually or less frequently shall conduct the lead and copper tap sampling during the months of June, July, August or September. The Authority may approve a different period for conducting the lead and copper tap sampling for systems collecting a reduced number of samples. Such a period shall be no longer than four consecutive months and must represent a time of normal operation where the highest levels of lead are most likely to occur. For a non-transient non-community water system that does not operate during the months of June through September, and for which the period of normal operation where the highest levels of lead are most likely to occur is not known, the Authority shall designate a period that represents a time of normal operation for the system. This sampling shall begin during the period approved or designated by the Authority in the calendar year immediately following the end of the second consecutive six-month monitoring period for systems initiating annual monitoring and during the three-year period following the end of the third consecutive calendar year of annual monitoring for systems initiating triennial monitoring. Community and non-transient non- community water systems monitoring annually or triennially that have been collecting samples during the months of June through December and that receive Authority approval to alter their sample collection period must collect their next round of samples during a time period that ends no later than 21 months or 45 months, respectively, after the previous round of sampling. Subsequent rounds of sampling must be collected annually or triennially as required in this subsection.

(V) A small or medium-size water system subject to reduced monitoring that exceeds the lead or copper action level shall resume sampling in accordance with subparagraph (2)(c)(D)(iii) of this rule and collect the number of samples specified for standard lead and copper monitoring in paragraph (2)(c)(C) of this rule and shall also conduct water quality parameter monitoring in accordance with subparagraphs (2)(c)(F)(iii), (iv) or (v) of this rule, as appropriate, during the period in which the lead or copper action level was exceeded. Any such system may resume annual monitoring for lead and copper at the tap at the reduced number of sites after it has completed two subsequent consecutive six-month rounds of monitoring that meet the requirement of subparagraph (2)(c)(D)(iv)(I) of this rule. This sampling shall begin during the calendar year immediately following the end of the second consecutive six-month monitoring period. Any such system may resume triennial monitoring for lead and copper at the reduced number of sites after it demonstrates through subsequent rounds of monitoring that it meets the criteria prescribed in subparagraphs (2)(c)(D)(iv)(III) or (VI) of this rule. Any water system subject to reduced monitoring frequency that fails to meet the lead action level during any four-month monitoring period or that fails to operate at or above the minimum value or within the range of values for the water quality control parameters specified by the Authority for more than nine days in any six-month period specified in subparagraph (2)(c)(F)(v) of this rule shall conduct tap water sampling for lead and copper at the frequency specified in subparagraph (2)(c)(D)(iii) of this rule, collect the number of samples specified for standard monitoring, and shall resume monitoring for water quality parameters within the distribution system in accordance with subparagraph (2)(c)(F)(v) of this rule. This standard tap water sampling shall begin no later than the six-month monitoring period beginning January 1 of the calendar year following the lead action level exceedance or water quality parameter excursion. Such a system may resume reduced monitoring for lead and copper at the tap and for water quality parameters within the distribution system under the following conditions Such a system may, with written Authority approval, resume reduced annual monitoring for lead and copper at the tap after it has completed two subsequent six-month rounds of tap lead and copper monitoring that meet the criteria specified in subpara-

graph (2)(c)(D)(iv)(II) of this rule. This sampling shall begin during the calendar year immediately following the end of the second consecutive six-month monitoring period. Such a system, with written Authority approval, may resume reduced triennial monitoring for lead and copper at the tap if it meets the criteria specified in subparagraphs (2)(c)(D)(iv)(III) and (VI) of this rule. Such a system may reduce the number and frequency of water quality parameter distribution tap samples required in accordance with subparagraph (2)(c)(F)(vi)(I) and (II) of this rule. Such a system may not resume triennial monitoring for water quality parameters distribution tap samples until it demonstrates that it has re-qualified for triennial monitoring.

(VI) Any water system that demonstrates for two consecutive 6-month monitoring periods that the 90th percentile lead level is less than or equal to 0.005 mg/l and the 90th percentile copper level is less than or equal to 0.65 mg/l may reduce the number of samples in accordance with paragraph (2)(c)(C) of this rule and reduce the frequency of sampling to once every three calendar years.

(VII) Any water system subject to a reduced monitoring frequency under (2)(c)(D)(iv) of this rule shall notify the Authority in writing of any upcoming long-term change in treatment or addition of a new source. The Authority must review and approve the addition of a new source or long-term change in water treatment before it is implemented by the water system. The Authority may require the system to resume standard monitoring or take other appropriate steps such as increased water quality parameter monitoring or re-evaluation of its corrosion control treatment given the potentially different water quality considerations.

(E) Monitoring requirements for lead and copper in tap water. Additional monitoring by systems: The results of any monitoring conducted in addition to the minimum requirements of subsection (c) of this rule shall be considered by the system and the Authority in making any determinations (that is, calculating the 90th percentile lead or copper level). The Authority may invalidate lead and copper tap water samples as follows:

(i) The Authority may invalidate a lead or copper tap sample if at least one of the following conditions is met. The decision and the rationale for the decision must be documented in writing by the Authority. A sample invalidated by the Authority does not count toward determining lead or copper 90th percentile levels or toward meeting the minimum monitoring requirements:

(I) The laboratory establishes that improper sample analysis caused erroneous results; or

(II) A site that did not meet the site selection criteria; or

(III) The sample container was damaged in transit; or

(IV) There is substantial reason to believe that the sample was subject to tampering.

(ii) The system must report the results of all samples to the Authority and all supporting documentation for samples the system believes should be invalidated.

(iii) The Authority may not invalidate a sample solely on the grounds that a follow-up sample result is higher or lower than that of the original sample.

(iv) The water system must collect replacement samples for any samples invalidated if, after the invalidation of one or more samples, the system has too few samples to meet the minimum requirements. Any such replacement samples must be taken as soon as possible, but no later than 20 days after the date the Authority invalidates the sample. The replacement samples shall be taken at the same locations as the invalidated samples or, if that is not possible, at locations other than those already used for sampling during the monitoring period.

(F) Monitoring requirements for water quality parameters. All large water systems and all medium and small water systems that exceed the lead or copper action levels shall monitor water quality parameters in addition to lead and copper as follows:

(i) General Requirements. Sample collection methods:

(I) Tap samples shall be representative of water quality throughout the distribution system taking into account the number of persons served, the different sources of water, the different treatment methods employed by the system, and seasonal variability. Water quality parameter sampling is not required to be conducted at taps targeted for lead and copper sampling, however, established coliform sampling sites may be used to satisfy these requirements.

(II) Samples collected at the entry point(s) to the distribution system shall be from locations representative of each source after treatment. If a system draws water from more than one source and the sources are combined before distribution, the system must sample at an entry point to the distribution system during periods of normal operating conditions when water is representative of all sources being used.

(ii) General requirements. Number of samples:

(I) Systems shall collect two tap samples for applicable water quality parameters during each monitoring period specified under subparagraphs (2)(c)(F)(iii) through (vi) of this rule from the following number of sites.

System Size # People served — # of Sites For Water Quality Parameters
>100,000 — 25
10,001-100,000 — 10
3,301 to 10,000 — 3
501 to 3,300 — 2
101 to 500 — 1
<100 — 1

(II) Except as provided in subparagraph (2)(c)(F)(iv)(III) of this rule, systems shall collect two samples for each applicable water quality parameter at each entry point to the distribution system during each monitoring period specified in subparagraph (2)(c)(F)(iii) of this rule. During each monitoring period specified in subparagraphs (2)(c)(F)(iv) through (vi) of this rule, systems shall collect one sample for each applicable water quality parameter at each entry point to the distribution system.

(iii) Initial Sampling. All large water systems shall measure the applicable water quality parameters as specified below at taps and at each entry point to the distribution system during each six-month monitoring period specified in subparagraph (2)(c)(D)(i) of this rule. All small and medium-size systems shall measure the applicable water quality parameters at the locations specified below during each six-month monitoring period specified in subparagraph (2)(c)(D)(i) of this rule during which the system exceeds the lead or copper action level:

(I) At taps: pH, alkalinity, orthophosphate (when an inhibitor containing a phosphate compound is used), silica (when an inhibitor containing a silicate compound is used), calcium, conductivity, and water temperature.

(II) At each entry point to the distribution system: all of the applicable parameters listed in subparagraph (2)(c)(F)(iii)(I) of this rule.

(iv) Monitoring after installation of corrosion control. Any large system which installs optimal corrosion control treatment pursuant to OAR 333-061-0034(2)(a)(D) shall measure the water quality parameters at the locations and frequencies specified below during each six-month monitoring period specified in subparagraph (2)(c)(D)(ii)(I) of this rule. Any small or medium-size system which installs optimal corrosion control treatment shall conduct such monitoring during each six-month monitoring period specified in subparagraph (2)(c)(D)(ii)(II) of this rule in which the system exceeds the lead or copper action level.

(I) At taps, two samples for: pH, alkalinity, orthophosphate (when an inhibitor containing a phosphate compound is used), silica (when an inhibitor containing a silicate compound is used), calcium (when calcium carbonate stabilization is used as part of corrosion control).

(II) Except as provided in subparagraph (2)(c)(D)(iv)(III) of this rule, at each entry point to the distribution system, at least one sample, no less frequently than every two weeks (bi-weekly) for: pH; when alkalinity is adjusted as part of optimal corrosion control, a reading of the dosage rate of the chemical used to adjust alkalinity, and the alkalinity concentration; and when a corrosion inhibitor is used as part of optimal corrosion control, a reading of the dosage rate of the inhibitor used, and the concentration of orthophosphate or silica (whichever is applicable).

(III) Any ground water system can limit entry point sampling to those entry points that are representative of water quality and treatment conditions throughout the system. If water from untreated ground water sources mixes with water from treated ground water sources, the system must monitor for water quality parameters both at representative entry points receiving treatment and no treatment. Prior to the start of any monitoring, the system shall provide to the Authority written information identifying the selected entry points and documentation, including information on seasonal variability, sufficient to demonstrate that the sites are representative of water quality and treatment conditions throughout the system.

(v) Monitoring after Authority specifies water quality parameter values for optimal corrosion control. After the Authority specifies the values for applicable water quality control parameters reflecting optimal corrosion control treatment under OAR 333-061-0034(3)(l), all large systems shall measure the applicable water quality parameters in accordance with subparagraph (2)(c)(F)(iv) of this rule and determine compliance every six months with the first six-month period to begin on either January 1 or July 1, whichever comes first, after the Authority specifies optimal water quality parameter values. Any small or medium-size system shall conduct such monitoring during each monitoring period specified in this paragraph in which the system exceeds the lead or copper action level. For any such small and medium-size system that is subject to a reduced monitoring frequency pursuant to subparagraph (2)(c)(D)(iv) of this rule at the time of the action level exceedance, the start of the applicable six-month monitoring period shall coincide with the start of the applicable monitoring period under (2)(c)(D) of this rule. Compliance with Authority-designated optimal water quality parameter values shall be determined as specified under 333-061-0034(3)(m).

(vi) Reduced monitoring:

(I) Any water system that maintains the range of values for the water quality parameters reflecting optimal corrosion control treatment during each of two consecutive six-month monitoring periods under paragraph (2)(c)(D) of this rule shall continue monitoring at the entry point(s) to the distribution system as specified in subparagraph (2)(c)(F)(iv)(II) of this rule. Such system may collect two tap samples for applicable water quality parameters from the following reduced number of sites during each six-month monitoring period.

System Size# People served — Reduced # of Sites for Water Quality Parameters

>100,000 — 10
10,001-100,000 — 7
3,301 to 10,000 — 3
501 to 3,300 — 2
101 to 500 — 1
<100 — 1

(II) Any water system that maintains the minimum values or maintains the range of values for the water quality parameters reflecting optimal corrosion control treatment specified by the Authority under OAR 333-061-0034(3) (l) during three consecutive years of monitoring may reduce the frequency with which it collects the number of tap samples for applicable water quality parameters specified in subparagraph (2)(c)(F)(vi)(I) of this rule from every six months to annually. This sampling begins during the calendar year immediately following the end of the monitoring period in which the third consecutive year of six-month monitoring occurs. Any water system that maintains the minimum values or maintains the range of values for the water quality parameters reflecting optimal corrosion control treatment specified by the Authority under 333-061-0034(3)(l) during three consecutive years of annual monitoring may reduce the frequency with which it collects the number of tap samples for applicable water quality parameters from annually to every three years. This sampling begins no later than the third calendar year following the end of the monitoring period in which the third consecutive year of monitoring occurs.

(III) A water system may reduce the frequency with which it collects tap samples for applicable water quality parameters to every three years if it demonstrates during two consecutive monitoring periods that its tap water lead level at the 90th percentile is less than or equal to 0.005 mg/l, that its tap water copper level at the 90th percentile is less than or equal to 0.65 mg/l, and that it also has maintained the range of values for water quality parameters reflecting optimal corrosion control treatment specified by the Authority. Monitoring conducted every three years shall be done no later than every third calendar year.

(IV) A water system that conducts sampling annually shall collect these samples evenly throughout the year so as to reflect seasonal variability.

(V) Any water system subject to reduced monitoring frequency that fails to operate at or above the minimum value or within the range of values for the water quality parameters specified by the Authority under OAR 333-061-0034(3)(l) for more than nine days in any six-month period shall resume distribution system tap water sampling in accordance with the number and frequency requirements in subparagraph (2)(c)(F)(v) of this rule. Such a system may resume annual monitoring for water quality parameters at the tap at the reduced number of sites after it has completed two subsequent consecutive six-month rounds of monitoring that meet the criteria specified in subparagraph (2)(c)(F)(v) of this rule or may resume triennial monitoring at the reduced number of sites after it demonstrates through subsequent annual rounds that it meets the criteria of subparagraphs (2)(c)(F)(vi)(I) and (II) of this rule.

(vii) Additional monitoring by systems. The results of any monitoring conducted in addition to the minimum requirements of subsection (2)(c) of this rule shall be considered by the system and the Authority in making any determinations.

(G) Monitoring requirements for lead and copper in source water. Sample location, collection methods, and number of samples:

(i) A water system that fails to meet the lead or copper action level on the basis of tap samples collected in accordance with paragraphs (2)(c)(A) through (E) of this rule shall collect lead and copper source water samples in accordance with the following requirements regarding sample location, number of samples, and collection methods:

(I) Ground water systems shall take a minimum of one sample at every entry point to the distribution system which is representative of each well after treatment. The system shall take each sample at the same sampling point unless conditions make another sampling point more representative of each source or treatment plant;

(II) Surface water systems shall take a minimum of one sample at every entry point to the distribution system after any application of treatment or in the distribution system at a point which is representative of each source, after treatment. The system shall take each sample at the same sampling point unless conditions make another sampling point more representative of each source or treatment plant; Surface water systems include systems with a combination of surface and ground sources; and

(III) If a system draws water from more than one source and the sources are combined before distribution, the system must sample at an entry point to the distribution system during periods when water is representative of all sources being used.

(ii) Where the results of sampling indicate an exceedance of maximum permissible source water levels established under OAR 333-061-0034(4)(b)(D) the Authority may require that one additional sample be collected as soon as possible after the initial sample was taken (but not to exceed two weeks) at the same sampling point. If an Authority-required confirmation sample is taken for lead or copper, then the results of the initial and confirmation sample shall be averaged in determining compliance with the Authority-specified maximum permissible levels. Any sample value below the detection limit shall be considered to be zero. For lead any value above the detection limit but below the Practical Quantitation Level (PQL) (0.005 mg/l) shall either be considered as the measured value or be considered one-half the PQL (0.0025 mg/l). For copper any value above the detection limit but below the PQL (0.050 mg/l) shall either be considered as the measured value or be considered one-half the PQL (0.025 mg/l).

(H) Monitoring requirements for lead and copper in source water. Monitoring frequency after system exceeds tap water action level. Any system which exceeds the lead or copper action level at

the tap, shall collect one source water sample from each entry point to the distribution system no later than six months after the end of the monitoring period during which the lead or copper action level was exceeded. For monitoring periods that are annual or less frequent, the end of the monitoring period is September 30 of the calendar year in which the sampling occurs, or if the Authority has established an alternate monitoring period, the last day of that period.

(i) Monitoring frequency after installation of source water treatment. Any system which installs source water treatment pursuant to OAR 333-061-0034(4)(a)(C) shall collect an additional source water sample from each entry point to the distribution system during two consecutive six-month monitoring periods by the deadline specified in 333-061-0034(4)(a)(D).

(ii) Monitoring frequency after Authority specifies maximum permissible source water levels or determines that source water treatment is not needed.

(I) A system shall monitor at the frequency specified below in cases where the Authority specifies maximum permissible source water levels under OAR 333-061-0034(4)(b)(D) or determines that the system is not required to install source water treatment under 333-061-0034(4)(b)(B). A water system using only groundwater shall collect samples once during the three-year compliance period in effect when the applicable Authority determination is made. Such systems shall collect samples once during each subsequent compliance period. Triennial samples shall be collected every third calendar year. A water system using surface water (or a combination of surface and groundwater) shall collect samples once during each calendar year, the first annual monitoring period to begin during the year in which the applicable Authority determination is made.

(II) A system is not required to conduct source water sampling for lead or copper if the system meets the action level for the specific contaminant in tap water samples during the entire source water sampling period applicable to the system under subparagraph (2)(c)(H)(ii)(I) of this rule.

(iii) Reduced monitoring frequency:

(I) A water system using only groundwater may reduce the monitoring frequency for lead and copper in source water to once during each nine-year compliance cycle provided that the samples are collected no later than every ninth calendar year and it demonstrates that finished drinking water entering the distribution system has been maintained below the maximum permissible lead and copper concentrations specified by the Authority in OAR 333-061-0034(4)(b)(D) during at least three consecutive compliance periods under subparagraph (2)(c)(H)(ii)(I) of this rule or the Authority has determined that source water treatment is not needed and the system demonstrates during at least three consecutive compliance periods under subparagraph (2)(c)(H)(ii)(I) of this rule that the concentration of lead in source water was less than or equal to 0.005 mg/l and the concentration of copper in source water was less than or equal to 0.65 mg/l.

(II) A water system using surface water (or a combination of surface and ground waters) may reduce the monitoring frequency for lead and copper in source water to once during each nine-year compliance cycle provided that the samples are collected no later than every ninth calendar year and it demonstrates that finished drinking water entering the distribution system has been maintained below the maximum permissible lead and copper concentrations specified by the Authority in OAR 333-061-0034(4)(b)(D) for at least three consecutive years or the Authority has determined that source water treatment is not needed and the system demonstrates that during at least three consecutive years the concentration of lead in source water was less than or equal to 0.005 mg/l and the concentration of copper in source water was less than or equal to 0.65 mg/l.

(III) A water system that uses a new source of water is not eligible for reduced monitoring for lead or copper until concentrations in samples collected from the new source during three consecutive monitoring periods are below the maximum permissible lead and copper concentrations specified by the Authority in OAR 333-061-0034(4)(a)(E).

(d) Nitrate:

(A) Community and non-transient non-community water systems using surface water sources or groundwater sources under the direct influence of surface water shall monitor for Nitrate on a quarterly basis, at each point in the distribution system representative of each source after treatment or at entry points to the distribution system after any application of treatment, beginning January 1, 1993. The Authority may allow a surface water system to reduce the sampling frequency to annually provided that all analytical results from four consecutive quarters are less than 50 percent of the MCL. A surface water system shall return to quarterly monitoring if any one sample is 50 percent of the MCL.

(B) Community and non-transient non-community water systems using groundwater sources shall monitor for Nitrate annually, at each point in the distribution system representative of each source after treatment or at entry points to the distribution system after any application of treatment, beginning January 1, 1993. The Authority shall require quarterly monitoring for a least one year following any one sample in which the concentration is 50 percent of the MCL. The system may return to annual monitoring after four consecutive quarterly samples are found to be reliably and consistently below the MCL.

(C) Transient non-community and state regulated water systems shall monitor for Nitrate annually, at each point in the distribution system representative of each source after treatment or at entry points to the distribution system after any application of treatment, beginning January 1, 1993. Transient non-community water systems must monitor quarterly for at least one year following any one sample in which the concentration is 50 percent of the MCL. The system may return to annual monitoring after four consecutive quarterly samples are found to be reliably and consistently below the MCL.

(D) After the initial round of quarterly sampling is completed, each community and non-transient non-community water system which is monitoring annually shall take subsequent samples during the quarter(s) which previously resulted in the highest analytical result.

(e) Nitrite:

(A) Community, non-transient non-community, and transient non-community water systems shall collect one sample for Nitrite at each point in the distribution system representative of each source after treatment or at entry points to the distribution system after any application of treatment during the compliance period beginning January 1, 1993.

(B) After the initial sample, all systems where analytical results for Nitrite are <50 percent of the MCL, shall monitor once during each subsequent compliance period.

(C) Water systems must conduct quarterly monitoring for at least one year following any one sample in which the concentration is ≥50 percent of the MCL. A water system may change to annual monitoring after four consecutive quarterly samples are found to be reliably and consistently below 50 percent of the MCL.

(D) A water system with an analytical result ≥50 percent of the MCL may never monitor less frequently than annually. Systems which are monitoring annually must collect each subsequent sample during the quarter(s) which previously resulted in the highest analytical result.

(E) The Authority may grant a waiver from the monitoring frequency specified in paragraph (2)(e)(B) of this rule provided that water systems have conducted a minimum of three rounds of monitoring (at least one sample shall have been collected since January 1, 1993), and all analytical results are less than 50 percent of the MCL prescribed in OAR 333-061-0030. Water systems that have been granted a waiver must monitor once during each nine-year compliance cycle. Waivers must be granted as prescribed by subparagraph (2)(a)(C)(ii) of this rule.

(F) A water system with two or more wells that have been determined to constitute a "wellfield" as specified in subsection (1)(k) of this rule may reduce sampling to only those entry point(s) designated by the Authority.

(f) Sodium:

(A) Samples of water which is delivered to users shall be analyzed for Sodium as follows:

(i) Community and non-transient non-community water systems, surface water sources, once per year for each source;

(ii) Community and non-transient non-community water systems, ground water sources, once every three years for each source.

(B) The water supplier shall report to the Authority the results of the analyses for Sodium as prescribed in OAR 333-061-0040. The Authority shall notify local health officials of the test results.

(g) Confirmation Samples:

(A) Where the results of sampling for antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, selenium or thallium exceed the MCL prescribed in OAR 333-061-0030 for inorganic chemicals, the Authority may require one additional sample to be taken as soon as possible after the initial sample was taken (but not to exceed two weeks) at the same sampling point.

(B) Where the results of sampling for nitrate or nitrite exceed the MCL prescribed in OAR 333-061-0030 for inorganic chemicals, the system is required to collect one additional sample within 24 hours of notification of the results of the initial sample at the same sampling point. Systems unable to comply with the 24-hr sampling requirement must initiate consultation with the Authority as soon as practical, but no later than 24 hours after the system learns of the violation and must immediately notify their users as prescribed in OAR 333-061-0042(2)(a)(B), and collect one additional sample within two weeks of notification of the results of the initial sample.

(C) If a confirmation sample required by the Authority is taken for any contaminant then the results of the initial and confirmation sample shall be averaged. The resultant average shall be used to determine the system's compliance as prescribed in subsection (2)(i) of this rule.

(h) The Authority may require more frequent monitoring than specified in subsections (2)(a) through (f) of this rule or may require confirmation samples for positive and negative results. Systems may apply to the Authority to conduct more frequent monitoring than is required in this section.

(i) Compliance with the inorganic MCLs as listed in OAR 333-061-0030(1) (Table 1) shall be determined based on the analytical result(s) obtained at each sampling point as follows: [Table not included. See ED. NOTE.]

(A) For systems which are conducting monitoring at a frequency greater than annual, compliance with the MCLs for antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, selenium or thallium is determined by a running annual average at any sampling point. If the average at any sampling point rounded to the same number of significant figures as the MCL for the substance in question is greater than the MCL, then the system is out of compliance. If any one sample would cause the annual average to be exceeded, then the system is out of compliance immediately. Any sample with results below the detection limit specified for the approved EPA analytical method shall be calculated at zero for the purpose of determining the annual average. If a system fails to collect the required number of samples, compliance (average concentration) will be based on the total number of samples collected.

(B) Systems monitoring annually or less frequently for antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, selenium or thallium must begin quarterly sampling if the level of a contaminant at any sampling point is greater than the MCL listed in OAR 333-061-0030(1). The water system will then determine compliance with the MCL by running annual average at the sampling point. The water system will not be considered in violation of the MCL until it has completed one year of quarterly monitoring. If any sample result will cause the running annual average to exceed the MCL at any sampling point, the system is out of compliance with the MCL immediately. If a system fails to collect the required number of samples, compliance (average concentration) will be based on the total number of samples collected.

(C) Compliance with MCLs for nitrate and nitrite is determined based on one sample if the levels of these contaminants are below the MCLs. If the levels of nitrate or nitrite exceed the MCLs in the initial sample, a confirmation sample is required in accordance with paragraph (2)(g)(B) of this rule and compliance shall be determined based on the average of the initial and confirmation samples.

(D) If the results of an analysis as prescribed in this rule indicate the level of any contaminant exceeds the maximum contaminant level, the water supplier shall report the analysis results to the Authority within 48 hours as prescribed in OAR 333-061-0040 and initiate the public notice procedures as prescribed by OAR 333-061-0042.

(E) A water system's running annual average (RAA) is calculated by averaging the analytical results for the current monitoring period and the previous monitoring periods within a one-year time frame. For water systems monitoring less frequently than quarterly, the first sample result that exceeds the MCL is considered to be the initial sampling result for determination of the RAA. Multiple sample results within any monitoring period will be averaged and then rounded to the same number of significant figures as the MCL of the contaminant in question. For the purposes of calculating a RAA, a monitoring period may be a calendar month or calendar quarter. Special samples, as described by paragraph (1)(h)(C) of this rule, will not be included in the calculation of a system's running annual average.

(3) Organic chemicals:

(a) Water suppliers responsible for community and non-transient non-community water systems must conduct monitoring according to this section for the following regulated synthetic organic chemicals (SOC): Alachlor, Atrazine, Benzo(a)pyrene, Carbofuran, Chlordane, Dalapon, Dibromochloropropane, Dinoseb, Dioxin(2,3,7,8-TCDD), Diquat, Di(2-ethylhexyl)adipate, Di(2-ethylhexyl)phthalate, Endothall, Endrin, Ethylene dibromide, Glyphosate, Heptachlor, Heptachlor epoxide, Hexachlorobenzene, Hexachlorocyclopentadiene, Lindane(BHC-g), Methoxychlor, Oxamyl(Vydate), Picloram, Polychlorinated biphenyls, Pentachlorophenol, Simazine, Toxaphene, 2,4-D and 2,4,5-TP Silvex.

(A) Initial sampling

(i) At sampling points served by surface water or GWUDI sources, samples must be collected at each point in the distribution system representative of each source after treatment or at entry points to the distribution system after any application of treatment. At least four consecutive quarterly samples must be collected at each sampling point during each compliance period. Samples must be collected from the same sampling point unless conditions make another sampling point more representative of each source or treatment plant.

(ii) At sampling points served by groundwater sources only, samples must be collected at every entry point to the distribution system after any application of treatment. Samples must be collected annually for three consecutive years at each sampling point during each compliance period. Samples must be collected from the same sampling point unless conditions make another sampling point more representative of each source or treatment plant. New wells in an existing wellfield, within an existing drinking water protection area, or within an area well characterized by area-wide source water assessments or past monitoring results as determined by the Authority, may be eligible for a reduction in initial monitoring from three consecutive annual samples to one sample if no detections occur and if, based on the system's source water assessment, the Authority determines that the new well is producing from the same and only the same aquifer or does not significantly modify the existing drinking water protection area.

(iii) If a system draws water from more than one source and sources are combined before distribution, samples must be collected at an entry point to the distribution system during periods of normal operating conditions when water is representative of all the sources being used.

(iv) At water systems with two or more wells that have been determined to constitute a wellfield as specified in subsection

(1)(k) of this rule, sampling may be reduced to only those entry points designated by the Authority.

(B) If the initial analyses as specified in subparagraphs (3)(a)(A)(i) or (ii) of this rule does not detect any contaminant listed in subsection (3)(a) of this rule, then monitoring at each sampling point should be conducted as follows:

(i) At water systems serving more than 3,300 people, two quarterly samples in the same calendar year during each repeat 3-year compliance period; or

(ii) At systems serving 3,300 people or less, one sample in each repeat 3-year compliance period.

(C) Water suppliers may apply to the Authority for a waiver from the monitoring frequencies specified in subparagraphs (3)(a)(A)(i) or (ii) or paragraph (3)(a)(B) of this rule. If the Authority determines there was no previous use of a contaminant within a watershed or zone of influence, a waiver may be granted. If the Authority determines that a contaminant was used previously or the use of a contaminant is unknown then the factors specified in subparagraph (3)(a)(C)(iii) of this rule shall determine whether a waiver is granted. A waiver must be in place prior to the year in which the monitoring is to be conducted. Water suppliers must reapply for a waiver for each compliance period. Regardless of waiver status, monitoring must occur at the minimum frequencies specified in subparagraph (3)(a)(C)(v) or (vi) of this rule.

(i) The drinking water protection area delineated during the source water assessment must be used according to Authority procedures and guidance.

(ii) For waivers based on the use of a contaminant, the criteria considered by the Authority includes but is not limited to the use, storage, distribution, transport and disposal of the contaminant within the delineated recharge or watershed area.

(iii) For waivers based on susceptibility to contamination, the criteria considered by the Authority includes but is not limited to the history of bacteria or nitrate contamination, well construction, agricultural management practices, infiltration potential, contaminant mobility and persistence, previous analytical results, the proximity of the system to a potential point or non-point source of contamination, and use of PCBs in equipment used in the production, distribution, or storage of water.

(iv) The Authority may establish area-wide waivers based on historical monitoring data, land use activity, and the results of source water assessments or waivers based on use or susceptibility.

(v) Monitoring must be conducted at least once every six years for all SOCs if an Authority approved drinking water protection plan exists for the water system.

(vi) Monitoring must be conducted at least once every nine years for those SOCs not used within the drinking water protection area if no Authority approved drinking water protection plan exists for a water system. Monitoring must be conducted at least once every six years or once every nine years as determined by the Authority, for those SOCs used within the drinking water protection area based upon SOC chemical characteristics, aquifer characteristics and well construction.

(D) If a contaminant listed in subsection (3)(a) of this rule is detected at a water system equal to or greater than the minimum detection limit listed in Table 15, then the water supplier shall monitor quarterly at each sampling point where a detection occurred. If a contaminant is detected at a concentration greater than the maximum contaminant level, monitoring must be conducted as prescribed by paragraph (3)(a)(E) of this rule. [Table not included. See ED. NOTE.]

(i) The Authority may reduce the monitoring frequency required by paragraph (3)(a)(D) of this rule to annually if at least two quarterly samples for groundwater sources or four quarterly samples for surface water sources are reliably and consistently below the MCL. Annual monitoring according to this subparagraph must be conducted during the quarter that previously yielded the highest analytical result.

(ii) At systems where three consecutive annual samples are collected with no detection of a contaminant, water suppliers may apply to the Authority for a waiver as specified in paragraph (3)(a)(C) of this rule. Monitoring may not be reduced to less often than annually except upon receipt of a waiver granted by the Authority.

(iii) If monitoring required by paragraphs (3)(a)(A) through (D) of this rule results in the detection of either Heptachlor or Heptachlor epoxide, then subsequent monitoring shall analyze for both contaminants.

(E) If a contaminant listed in subsection (3)(a) of this rule is detected at a concentration greater than the maximum contaminant level, then the water supplier must monitor quarterly. After a minimum of four quarterly samples, if results are reliably and consistently below the MCL and in compliance with paragraph (3)(a)(H) of this rule, then the water supplier may monitor annually.

(F) The Authority may require confirmation samples for positive or negative results. If a confirmation sample is required by the Authority, the result must be averaged with the original sample result (unless the previous sample has been invalidated by the Authority) and the average used to determine compliance.

(G) The Authority may allow compositing of samples to reduce the number of samples to be analyzed at a water system. Composite samples from a maximum of five sampling points are allowed, provided that the detection limit of the method used for analysis is less than one-fifth of the MCL. Compositing of samples must be conducted in the laboratory and analyzed within 14 days of sample collections. If the concentration in the composite sample detects one or more contaminants listed in subsection (3)(a) of this rule, then a follow-up sample must be collected and analyzed within 14 days at each sampling point included in the composite, and be analyzed for that contaminant. Duplicates collected for the original composite samples may be used instead of re-sampling provided the duplicates are analyzed and the results reported to the Authority within 14 days of collection. For water systems serving more than 3,300 people, the Authority may allow compositing at sampling points only within a single system. For systems serving 3,300 people or less, the Authority may allow compositing among different systems, provided the 5-sample limit is maintained.

(H) Compliance with contaminants listed in OAR 333-061-0030(2)(a) shall be determined based on the analytical results obtained at each sampling point. If one sampling point is in violation of an MCL, the water system is in violation of the MCL. For systems which monitor more than once per year, compliance with the MCL is determined by a running annual average at each sampling point. At systems where annual or less frequent monitoring takes place, if sample results exceed the regulatory detection limit prescribed in paragraph (3)(a)(D) of this rule (Table 15), monitoring must be increased to quarterly. The system will not be considered in violation of the MCL until it has completed one year of quarterly monitoring. If any single sample result will cause the running annual average to exceed the MCL at any sampling point, the system is out of compliance with the MCL immediately. If a system fails to collect the required number of samples, compliance will be based on the total number of samples collected. If a sample result is less than the detection limit, zero will be used to calculate the annual average. If the system is out of compliance, the system shall follow the reporting and public notification procedures as prescribed in OAR 333-061-0040 and 333-061-0042(2)(b)(A). [Table not included. See ED. NOTE.]

(I) The running annual average (RAA) for a contaminant is calculated by averaging the analytical results for the current monitoring period and the previous monitoring periods within a one-year time frame. For water systems monitoring less frequently than quarterly, the first sample result that exceeds the detection limit or MCL is considered to be the initial sampling result for determination of the RAA. Multiple sample results within any monitoring period will be averaged and then rounded to the same number of significant figures as the MCL for the contaminant in question. For the purposes of calculating a RAA, a monitoring period may be a calendar month or calendar quarter. Special samples, as described by paragraph (1)(h)(C) of this rule, will not be included in the calculation of the running annual average at a water system.

(J) All new systems or systems that use a new source of water must demonstrate compliance with the MCL within a period of time specified by the Authority. The system must also comply with the initial sampling frequencies specified by the Authority to ensure a system can demonstrate compliance with the MCL.

(b) Water suppliers responsible for community and non-transient non-community water systems must conduct monitoring according to this section for the following regulated volatile organic chemicals (VOCs): Benzene, Carbon tetrachloride, cis-1,2-Dichloroethylene, Dichloromethane, Ethylbenzene, Monochlorobenzene, o-Dichlorobenzene, p-Dichlorobenzene, Styrene, Tetrachloroethylene(PCE), Toluene, trans-1,2-Dichloroethylene, Trichloroethylene(TCE), Vinyl chloride, Xylenes(total), 1,1-Dichloroethylene, 1,1,1-Trichloroethane, 1,1,2-Trichloroethane, 1,2-Dichloroethane, 1,2-Dichloropropane, and 1,2,4-Trichlorobenzene.

(A) Initial monitoring:

(i) At sampling points served by surface water or GWUDI sources, samples must be collected at each point in the distribution system representative of each source after treatment or at entry points to the distribution system after any application of treatment. At least four consecutive quarterly samples must be collected at each sampling point during each compliance period. Samples must be collected from the same sampling point unless conditions make another sampling point more representative of each source or treatment plant.

(ii) At sampling points served by groundwater sources only, samples must be collected at every entry point to the distribution system after any application of treatment. Samples must be collected annually for three consecutive years at each sampling point during each compliance period. Samples must be collected from the same sampling point unless conditions make another sampling point more representative of each source or treatment plant. New wells in an existing wellfield, within an existing drinking water protection area, or within an area well characterized by area-wide source water assessments or past monitoring results as determined by the Authority, may be eligible for a reduction in initial monitoring from three consecutive annual samples to one sample if no detections occur and if, based on the system's source water assessment, the Authority determines that the new well is producing from the same and only the same aquifer or does not significantly modify the existing drinking water protection area.

(iii) The Authority may designate additional sampling points within the distribution system or at the consumer's tap which more accurately determines consumer exposure to VOCs.

(iv) If a water system draws water from more than one source and the sources are combined before distribution, the samples must be collected at entry points to the distribution system during periods of normal operating conditions when water is representative of all sources being used.

(v) A water system with two or more wells that have been determined to constitute a wellfield as specified in subsection (1)(k) of this rule may reduce sampling to only those entry point(s) designated by the Authority.

(B) If the initial analyses conducted according to subparagraphs (3)(b)(A)(i) or (ii) of this rule do not detect any contaminant listed in subsection (3)(b) of this rule, then monitoring for all of the VOCs should be conducted as follows:

(i) For sampling points served by surface water or GWUDI sources, one sample every year per entry point; or

(ii) For sampling points served only by groundwater sources, one sample every three years per entry point.

(C) Water suppliers may apply to the Authority for a waiver from the monitoring frequencies specified in paragraph (3)(b)(B) of this rule. Waivers will be granted according to the criteria and procedures specified in subparagraphs (3)(a)(C)(i) through (vi) of this rule if the Authority determines there were no detections of any contaminant listed in subsection (3)(b) of this rule and if an Authority approved drinking water protection plan exists for the water system or for those VOCs used within a portion of the drinking water protection area that the Authority has determined is not susceptible to VOC contamination.

(i) Waivers granted for monitoring at groundwater systems shall be effective for no more than six years.

(I) Waivers must be in place prior to the year in which monitoring is to be conducted, and water suppliers must reapply for a waiver from VOC monitoring every two compliance periods (six years).

(II) As a condition of a waiver, water suppliers must collect one sample at each sampling point during the time the waiver is in effect and update the vulnerability assessment for the water system addressing those factors listed in subparagraphs (3)(a)(C)(ii) and (iii) of this rule. The Authority must be able to confirm that a system is not susceptible within three years of the original determination, and every time the vulnerability assessment is updated, or the waiver is invalidated and monitoring must be conducted as specified in paragraph (3)(b)(B) of this rule.

(ii) At water systems using surface water that have been determined not to be vulnerable to VOC contamination by the Authority, monitoring must be conducted at the frequency prescribed by the Authority. Water suppliers must update the vulnerability assessment for such water systems during each compliance period and submit the vulnerability assessment to the Authority regardless of the frequency of monitoring.

(iii) The Authority may establish area-wide waivers based on historical monitoring data, land use activity, the results of source water assessments or waivers granted for use of VOCs or susceptibility to VOC contamination.

(D) If a contaminant listed in subsection (3)(b) of this rule (except vinyl chloride) is detected in any sample at a concentration greater than the minimum detection limit of 0.0005 mg/l, then the water supplier shall monitor quarterly at each sampling point where a detection occurred except as provided in subparagraph (3)(b)(D)(i) of this rule.

(i) The Authority may reduce the monitoring frequency specified in this paragraph to annually if results for the water system are reliably and consistently below the MCL for at least two quarters for sample points served only by groundwater sources and four quarters for sample points served by surface water or GWUDI sources.

(I) For annual monitoring, samples must be collected during the quarter that previously yielded the highest analytical result.

(II) If a contaminant is detected at a concentration greater than 0.0005 mg/l but below the MCL in one of the annual samples as prescribed by subparagraph (3)(b)(D)(i) of this rule, the water supplier shall monitor at the frequency specified by the Authority but in no case less frequently than annually.

(ii) At water systems or sampling points where three consecutive annual samples are collected with no detection of a contaminant, water suppliers may apply to the Authority for a waiver as specified in paragraph (3)(b)(C) of this rule. Monitoring may not be reduced to less often than annually except upon by a waiver granted by the Authority.

(iii) At water systems using groundwater sources where one or more of the following two-carbon organic compounds was detected: trichloroethylene, tetrachloroethylene, 1,2-dichloroethane, 1,1,1-trichloroethane, cis-1,2-dichloroethylene, trans-1,2-dichloroethylene or 1,1-dichloroethylene, the water supplier shall monitor quarterly for vinyl chloride. A vinyl chloride sample shall be collected at each sampling point at which one or more of the two-carbon organic compounds was detected. If the results of the first analysis do not detect vinyl chloride, the Authority may reduce the quarterly monitoring frequency of vinyl chloride monitoring to one sample during each compliance period. Water suppliers responsible for surface water systems are required to monitor for vinyl chloride at the discretion of the Authority.

(E) If a contaminant listed in subsection (3)(b) of this rule is detected at a concentration greater than the maximum contaminant level, then the water supplier must monitor quarterly. After a minimum of four consecutive quarterly samples, if results are reliably and consistently below the MCL and in compliance with paragraph

(3)(b)(H) of this rule, then the water supplier may monitor annually. Annual samples must be collected during the quarter which previously yielded the highest analytical result.

(F) The Authority may require confirmation samples for positive or negative results. If a confirmation sample is required by the Authority, the result must be averaged with the original sample result and the average used to determine compliance.

(G) The Authority may allow compositing of samples to reduce the number of samples to be analyzed by the system. Composite samples from a maximum of five sampling points are allowed, provided that the detection limit of the method used for analysis is less than one-fifth of the MCL. Compositing of samples must be conducted in the laboratory and samples must be analyzed within 14 days of sample collections. If the concentration in the composite sample is 0.0005 mg/l or greater for any contaminant listed in subsection (3)(b) of this rule, then a follow-up sample must be collected and analyzed within 14 days at each sampling point included in the composite, and be analyzed for that contaminant. Duplicates collected for the original composite samples may be used instead of resampling provided the duplicates are analyzed and the results reported to the Authority within 14 days of collection. For water systems serving a population greater than 3,300 people, the Authority may allow compositing at sampling points only within a single water system. For water systems serving population of 3,300 people or less, the Authority may allow compositing among different water systems provided the 5-sample limit is maintained.

(H) Compliance with contaminants listed in OAR 333-061-0030(2)(c) shall be determined based on the analytical results obtained at each sampling point. If one sampling point is in violation of an MCL, the water system is in violation of the MCL. For systems which monitor more than once per year, compliance with the MCL is determined by a running annual average at each sampling point. At systems where annual or less frequent monitoring takes place, if sample results exceed the MCL, monitoring must be increased to quarterly. The system will not be considered in violation of the MCL until it has completed one year of quarterly sampling. If any single sample result will cause the running annual average to exceed the MCL at any sampling point, the system is out of compliance with the MCL immediately. If a system fails to collect the required number of samples, compliance will be based on the total number of samples collected. If a sample result is less than the detection limit, zero will be used to calculate the annual average. If the water system is out of compliance, the system shall follow the reporting and public notification procedures as prescribed in 333-061-0040 and 333-061-0042(2)(b)(A).

(I) The running annual average (RAA) for a contaminant is calculated by averaging the analytical results for the current monitoring period and the previous monitoring periods within a one-year time frame. For water systems monitoring less frequently than quarterly, the first sample result that exceeds the detection limit or MCL is considered to be the initial sampling result for determination of the RAA. Multiple sample results within any monitoring period will be averaged and then rounded to the same number of significant figures as the MCL for the contaminant in question. For the purposes of calculating a RAA, a monitoring period may be a calendar month or calendar quarter. Special samples, as described by paragraph (1)(h)(C) of this rule, will not be included in the calculation of the running annual average at a water system.

(J) All new water systems or systems that use a new source of water must demonstrate compliance with the MCL within a period of time specified by the Authority. The system must also comply with the initial sampling frequencies specified by the Authority to ensure a system can demonstrate compliance with the MCL.

(4) Disinfectant Residuals, Disinfection Byproducts, and Disinfection Byproduct Precursors

(a) General sampling and analytical requirements. The requirements of this section apply to all community and non-transient non-community water systems that add a disinfectant (oxidant) to the water supply at any point in the treatment process or deliver water in which a disinfectant (oxidant) has been added to the water supply except that compliance with paragraph (4)(i)(B) is required at transient non-community water systems where chlorine dioxide is used as a disinfectant or oxidant.

(A) Water systems must take all samples during normal operating conditions.

(B) Failure to monitor in accordance with the monitoring plan as specified in paragraph (4)(c)(B) of this rule is a monitoring violation.

(C) Failure to monitor will be treated as a violation for the entire period covered by the annual average where compliance is based on a running annual average (RAA) of monthly or quarterly samples or averages and the system's failure to monitor makes it impossible to determine compliance with MCLs or MRDLs.

(D) Systems must use only data collected under the provisions of this rule to qualify for reduced monitoring.

(E) All samples collected and analyzed under the provisions of section (4) of this rule must be included in determining compliance, even if that number is greater than the minimum required.

(b) Initial Distribution System Evaluation (IDSE) Requirements. This subsection establishes monitoring and other requirements for identifying monitoring locations which, in conjunction with the requirements of subsections (4)(c) and (4)(d) of this rule, determine compliance with the MCLs for TTHM and HAA5 as specified in OAR 333-061-0030. Non-transient non-community water systems serving less than 10,000 people are exempt from the requirements of this subsection.

(A) Water suppliers that begin adding a disinfectant to a water system must complete an IDSE by conducting either standard monitoring or a system specific study. Water suppliers must consult with the Authority after completing the IDSE to identify compliance monitoring locations prior to developing a monitoring plan as prescribed in paragraph (4)(c)(B) of this rule that includes monitoring locations identified through the IDSE process. Samples collected to conduct an IDSE will not be used for the purpose of determining compliance with MCLs as prescribed by OAR 333-061-0030(2)(b).

(B) Standard monitoring

(i) Standard monitoring plans must include the elements specified in subparagraphs (4)(b)(B)(i)(I) through (III) of this rule:

(I) A schematic of the distribution system (including distribution system water sources, entry points, and storage facilities), with notes indicating the locations and dates of all projected standard monitoring;

(II) An explanation of standard monitoring location selection, and a summary of data relied on to justify the selection; and

(III) The population served and source water classification for the water system.

(ii) Water systems must monitor as indicated in Table 16 below. Water systems must collect dual sample sets at each monitoring location, and at least one round of monitoring must be during the peak historical month for TTHM or HAA5 levels, or during the month of warmest water temperature. Water systems must review available compliance, study, or operational data to determine the peak historical month for TTHM or HAA5 levels or the month of warmest water temperature. [Table not included. See ED. NOTE.]

(iii) Samples must be collected at locations spread throughout the distribution system.

(iv) If the number of entry points to the distribution system is fewer than the number of entry point monitoring locations specified in Table 16, excess entry point samples must be replaced equally by samples collected at locations where you would expect to find high TTHM and HAA5 concentration. If there is an odd number of excess sampling locations, the additional sample must be collected at a location where you would expect to find high TTHM concentration. If the number of entry points to the distribution system is greater than the number of entry point monitoring locations specified in Table 16, the samples must be collected at entry points having the highest annual water flows. [Table not included. See ED. NOTE.]

(v) Monitoring in accordance with Table 16 may not be reduced according to the provisions of subsection (1)(d) of this rule. [Table not included. See ED. NOTE.]

(vi) IDSE report. Water suppliers must submit an IDSE report to the Authority within 90 days of completing standard monitoring that includes the following elements:

(I) All TTHM and HAA5 analytical results collected in accordance with this rule, and all standard monitoring analytical results collected during the period of the IDSE as individual analytical results and a locational running annual average (LRAA) presented in a format acceptable to the Authority. If changed from the standard monitoring plan prescribed by subparagraph (4)(b)(B)(i) of this rule, the report must also include a schematic of the distribution system, the population served, and the source water type.

(II) An explanation of any deviations from the approved standard monitoring plan.

(III) Recommended times and locations for the compliance monitoring required by subsections (4)(c) and (4)(d) of this rule, based on the protocol prescribed by subparagraph (4)(b)(D)(iii) of this rule, including an explanation for why the locations were selected.

(C) System Specific Study. A system specific study must be based on modeling as prescribed by subparagraph (4)(b)(C)(i) of this rule.

(i) Modeling. Water systems may conduct analysis of an extended period simulation hydraulic model. The hydraulic model and analysis must meet the following criteria:

(I) The model must simulate a 24-hour variation in demand and show a consistently repeating 24-hour pattern of residence time;

(II) The model must represent the following criteria: (1) 75 percent of pipe volume; (2) 50 percent of pipe length; (3) all pressure zones; (4) all 12-inch diameter and larger pipes; (5) all 8-inch and larger pipes that connect pressure zones, influence zones from different sources, storage facilities, major demand areas, pumps, and control valves, or are known or expected to be significant conveyors of water; (6) all 6-inch and larger pipes that connect remote areas of a distribution system to the main portion of the system; (7) all storage facilities with standard operations represented in the model; and (8) all active pump stations with controls represented in the model; and (9) all active control valves; and

(III) The model must be calibrated, or have calibration plans for the current configuration of the distribution system during the period of highest TTHM formation potential. All storage facilities must be evaluated as part of the calibration process. Calibration must be completed no later than 12-months after submission of the system specific study plan.

(IV) Reporting modeling. The system specific study plan must include: (1) tabular or spreadsheet data demonstrating that the model meets requirements in subparagraph (C)(i)(II) of this section; (2) a description of all calibration activities undertaken, and if calibration is complete, a graph of predicted tank levels versus measured tank levels for the storage facility with the highest residence time in each pressure zone, and a time series graph of the residence time at the longest residence time storage facility in the distribution system showing the predictions for the entire simulation period (that is, from time zero until the time it takes to for the model to reach a consistently repeating pattern of residence time); (3) model output showing preliminary 24 hour average residence time predictions throughout the distribution system; (4) timing and number of samples representative of the distribution system planned for at least one monitoring period of TTHM and HAA5 dual sample monitoring at a number of locations no less than would be required for the system under standard monitoring in paragraph (4)(b)(B) of this rule during the historical month of high TTHM; (5) description of how all requirements will be completed no later than 12 months after system submits the system specific study plan; (6) schematic of the distribution system (including distribution system entry points and their sources, and storage facilities), with notes indicating the locations and dates of all completed system specific study monitoring (if calibration is complete) and all compliance monitoring conducted in accordance with this rule; and (7) population served and system type (surface water, groundwater under the direct influence of surface water, or groundwater).

(V) If a model is submitted that does not meet the requirements of subparagraph (4)(b)(C)(i) of this rule, the system must correct the deficiencies and respond to Authority inquiries concerning the model. Failure to correct deficiencies or respond to inquiries by the Authority will result in the system having to conduct standard monitoring as prescribed by paragraph (4)(b)(B) of this rule.

(ii) IDSE report. Water suppliers must submit the IDSE report to the Authority within 90 days of completing the system specific study, and the report must include the following elements:

(I) The IDSE report must include all system specific study monitoring results collected during the period of the system specific study submitted in a tabular or spreadsheet format acceptable to the Authority. If changed from the system specific study plan submitted under paragraph (4)(b)(C) of this rule, the IDSE report must also include a schematic of the distribution system, the population served, and source water classification;

(II) If using the modeling provision prescribed by subparagraph (4)(b)(C)(i) of this rule, the water supplier must include final information for the elements described in subparagraphs (4)(b)(C)(i)(IV) and (V) of this rule, and a 24-hour time series graph of residence time for each location selected for monitoring in accordance with subsections (4)(c) and (4)(d) of this rule;

(III) The water supplier must recommend monitoring locations selected for monitoring in accordance with subsections (4)(c) and (4)(d) of this rule based on the protocol in paragraph (4)(b)(D) of this rule. It must also recommend and justify the timing of the monitoring to be conducted at these monitoring locations.

(IV) The IDSE report must include an explanation of any deviations from the approved system specific study plan.

(V) The IDSE report must include the analytical and modeling results, and the justification for recommending the monitoring locations selected for monitoring in accordance with subsections (4)(c) and (4)(d) of this rule.

(D) Monitoring location recommendations.

(i) The IDSE report must include recommendations and explanation for where and during what month(s) TTHM and HAA5 monitoring in accordance with subsections (4)(c) and (4)(d) of this rule should be conducted. Recommendations must be based on the criteria in subparagraphs (4)(b)(D)(ii) through (v) of this rule.

(ii) Water suppliers must collect samples as prescribed by Table 17 below. The number of samples and recommended locations must be used for monitoring in accordance with subsections (4)(c) and (4)(d) of this rule, unless the Authority requires different or additional locations. Monitoring locations should be dispersed throughout the distribution system to the maximum extent possible. [Table not included. See ED. NOTE.]

(iii) Water suppliers must recommend locations for monitoring in accordance with subsections (4)(c) and (4)(d) of this rule based on standard monitoring results or system specific study results. Water suppliers must comply with the protocol specified in subparagraphs (4)(b)(D)(iii)(I) through (VI) of this rule. If a water system is required to monitor at more than six locations, the protocol must be repeated as necessary. Water systems must select the:

(I) Location with the highest TTHM LRAA not previously selected through this protocol;

(II) Location with the highest HAA5 LRAA not previously selected through this protocol;

(III) Location with the highest TTHM LRAA not previously selected through this protocol;

(IV) Location with the highest TTHM LRAA not previously selected through this protocol;

(V) Location with the highest HAA5 LRAA not previously selected through this protocol; and

(VI) Location with the highest HAA5 LRAA not previously selected through this protocol.

(iv) A water supplier may recommend locations other than those determined through subparagraph (4)(b)(D)(iii) of this rule, if the system includes a rationale for selecting other locations. If the Authority approves the alternate locations, the water system must monitor at these locations to determine compliance with subsections (4)(c) and (4)(d) of this rule.

(v) The water system's recommended monitoring schedule must include the month of historically highest TTHM and HAA5 concentration, unless the Authority approves another month. Once the highest historical month has been identified, and if quarterly or more frequent routine monitoring is required, water systems must schedule monitoring at a regular frequency of at least every 90 days.

(c) Monitoring requirements for TTHM and HAA5:

(A) Routine Monitoring Frequency. At water systems for which an IDSE report was submitted, samples must be collected at the locations and during the months recommended in the IDSE report as prescribed by paragraph (4)(b)(D) of this rule, unless the Authority requires other or additional locations after its review. At non-transient non-community water systems serving less than 10,000 people and for water systems granted a waiver by the EPA exempting the water supplier from completing an IDSE, samples must be collected at the location(s) and dates identified in the monitoring plan developed as prescribed in paragraph (4)(c)(B) of this rule. Samples must be collected at no fewer than the number of locations identified in Table 18: [Table not included. See ED. NOTE.]

(B) A monitoring plan must be developed for every water system where monitoring is required according to this subsection, and must be maintained and made available for inspection by the Authority and the general public.

(i) The monitoring plan must include the following elements:

(I) Monitoring locations;

(II) Monitoring dates; and

(III) Compliance calculation procedures.

(ii) For water systems where an IDSE report was not required as prescribed in paragraphs (4)(b)(B) or (4)(b)(C) of this rule the monitoring plan must identify the required number of monitoring locations for monitoring in accordance with subsections (4)(c) and (4)(d) of this rule. Water suppliers must identify the locations by alternating the selection of locations representing high TTHM levels and high HAA5 levels until the required number of monitoring locations have been identified. Water suppliers must also provide a rationale for identifying the locations as having high levels of TTHM or HAA5.

(iii) For water systems using surface water or GWUDI sources serving more than 3,300 people, a copy of the monitoring plan must be submitted to the Authority prior to the date the water supplier conducts initial monitoring according to this subsection, unless the IDSE report submitted as prescribed in subsection (4)(b) of this rule contains all the information required in paragraph (4)(c)(B) of this rule.

(iv) Revisions to monitoring plans. Water suppliers may revise monitoring plans to reflect changes in treatment, distribution system operations, layout (including new service areas), or other factors that may affect TTHM or HAA5 formation, including Authority-approved reasons, after consultation with the Authority regarding the need and justification for the revision. If monitoring locations are changed, then water systems must replace existing monitoring locations with the lowest LRAA with new locations that reflect current distribution system locations expected to have high TTHM or HAA5 levels. The Authority may require modifications in monitoring plans. Surface water or groundwater under the direct influence of surface water systems serving > 3,300 people must submit a copy of their modified monitoring plan to the Authority prior to the date required to comply with the revised monitoring plan.

(C) A water system monitoring for TTHM or HAA5 in accordance with subsections (4)(c), (4)(d) or (4)(e) of this rule is in violation of the MCL specified in OAR 333-061-0030(2)(b) when the LRAA calculation at any monitoring location exceeds the MCL based on four consecutive quarters of monitoring (or fewer than four quarters of monitoring if the MCL would be exceeded regardless of monitoring results in subsequent quarters). A water system is in violation of the monitoring requirements every quarter that a monitoring result would be used in calculating an LRAA if the system fails to monitor.

(D) Compliance calculations and determinations. For water systems where quarterly monitoring is required, water suppliers must make compliance calculations at the end of every calendar quarter beginning with the fourth quarter of the initial monitoring period. The LRAA must be calculated prior to the fourth quarter if fewer than four quarters of data would cause the MCL to be exceeded, regardless of the monitoring results in subsequent quarters. Water suppliers required to conduct monitoring at a frequency less than quarterly must make compliance calculations every time samples are collected.

(i) Water suppliers must calculate the LRAA for TTHM and HAA5 to determine that each LRAA does not exceed the MCL listed in OAR 333-061-0030(2)(b) for water systems where quarterly monitoring is required. Water suppliers that fail to complete four consecutive quarters of monitoring must calculate the LRAA based on the available data from the most recent four quarters. Water suppliers that collect more than one sample per quarter at a specific monitoring location must average all samples collected in the quarter for that location to determine a quarterly average to be used in the LRAA calculation.

(ii) For water systems where monitoring is yearly or less frequent, water suppliers must determine that each sample collected is less than the MCL listed in OAR 333-061-0030(2)(b). If any sample exceeds the MCL, the water system must comply with the requirements of subsection (4)(e) of this rule. If no sample exceeds the MCL, the sample result for each monitoring location is considered the LRAA for that monitoring location.

(iii) A water supplier required to conduct quarterly monitoring at a water system is in violation of the monitoring requirements for each quarter that a monitoring result would be used in calculating an LRAA if monitor is not conducted.

(d) Reduced monitoring. Water suppliers may reduce monitoring to the frequency specified in Table 19 any time the LRAA is ≤0.040 mg/L for TTHM and ≤0.030 mg/L for HAA5 at all monitoring locations. [Table not included. See ED. NOTE.]

(A) Water suppliers may only use data collected under the provisions of subsections (4)(c) and (4)(d) of this rule to qualify for reduced monitoring. In addition, the annual source water average TOC level, before any treatment, must be less than or equal to 4.0 mg/L at each plant treating surface water or groundwater under the direct influence of surface water, based on monitoring conducted as prescribed in paragraph (4)(d)(D) and subsection (4)(k) of this rule.

(B) Water suppliers may remain on reduced monitoring so long as:

(i) The LRAA for water systems conducting quarterly monitoring is less than or equal to 0.040 mg/L for TTHM and less than or equal to 0.030 mg/L for HAA5 at each monitoring location; or

(ii) Samples collected by water systems conducting annual or less frequent monitoring are less than or equal to 0.060 mg/L for TTHM and less than or equal to 0.045 mg/L for HAA5.

(C) Water suppliers must resume routine monitoring as prescribed in subsection (4)(c) of this rule, or begin increased monitoring as prescribed in subsection (4)(e) of this rule if:

(i) The LRAA based on quarterly monitoring exceeds 0.040 mg/L for TTHM or 0.030 mg/L for HAA5 at any monitoring location; or

(ii) A sample collected at any location exceeds either 0.060 mg/L for TTHM or 0.045 mg/L for HAA5 when the monitoring frequency is annual or less frequent; or

(iii) The average annual source water TOC level, before any treatment, is greater than 4.0 mg/L at any treatment plant treating surface water or groundwater under the direct influence of surface water.

(D) Monitoring requirements for source water TOC. For water systems using surface water or GWUDI sources, TOC samples must be collected every 30 days at a location prior to any treatment in order to qualify for reduced TTHM and HAA5 monitoring as prescribed by this subsection, unless the water system is monitoring as prescribed by subsection (4)(k) of this rule. To remain on reduced monitoring, and in addition to meeting other criteria for reduced monitoring, the source water TOC running annual average must be ≤4.0 mg/L, based on the most recent four quarters of monitoring, on a continuing basis at a location prior to any treatment. Once qualified for reduced monitoring as prescribed by this subsection, a water system may reduce source water TOC monitoring to quarterly TOC samples collected every 90 days at a location prior to any treatment.

(E) A water system may be returned to routine monitoring at the Authority's discretion.

(e) Increased Monitoring

(A) At water systems where annual or less frequent monitoring is required according to subsections (4)(c) or (4)(d) of this rule, monitoring must be increased to dual sample sets collected every 90 days at all locations if a TTHM or HAA5 sample exceeds the MCL at any location.

(B) At water systems where increased monitoring is conducted according to paragraph (4)(e)(A) of this rule, samples must be collected at the monitoring locations specified in the monitoring plan developed according to paragraph (4)(c)(B) of this rule.

(C) Monitoring may be returned to routine if at least four consecutive quarters of increased monitoring has been conducted and the LRAA for every monitoring location is less than or equal to 0.060 mg/L for TTHM and 0.045 mg/L for HAA5.

(f) Operational Evaluation Levels:

(A) The Operational evaluation level for TTHM or HAA5 has been exceeded at a monitoring location when the sum of the two previous quarters' sample results plus twice the current quarter's sample result, divided by 4, exceeds the MCL.

(B) Operational evaluation and report.

(i) Systems that exceed the operational evaluation level for either TTHM or HAA5 must conduct an operational evaluation and submit a written report of the evaluation to the Authority no later than 90 days after being notified of the analytical result that causes the system to exceed the operational evaluation level. The written report must be made available to the public upon request.

(ii) Operational evaluations must include an examination of the water system's treatment and distribution practices, including but not limited to: storage tank operations, excess storage capacity, distribution system flushing, changes in sources or source water quality, and treatment changes or problems that may contribute to TTHM and HAA5 formation. The examination must also include what steps could be considered to minimize future exceedances.

(I) The Authority may allow water systems to limit the scope of the evaluation if the water system is able to identify the cause of the operational evaluation level exceedance.

(II) The request to limit the scope of the evaluation does not extend the schedule specified in subparagraph (4)(f)(B)(i) of this rule for submitting the written report. The Authority must approve this limited scope of evaluation in writing, and the water system must keep that approval with the completed report.

(g) Chlorite monitoring and compliance for community and non-transient non-community water systems where chlorine dioxide is used for disinfection or oxidation.

(A) Routine monitoring.

(i) Daily monitoring. Samples must be collected every day at the entrance to the distribution system. For any daily sample that exceeds the chlorite MCL, the water supplier must collect additional samples in the distribution system the following day at the locations required by paragraph (4)(g)(B) of this rule, in addition to the sample required at the entrance to the distribution system.

(ii) Monthly monitoring. A three sample set must be collected every month in the distribution system. The water supplier must collect one sample at each of the following locations: near the first customer, at a location representative of average residence time, and at a location reflecting maximum residence time in the distribution system. Any additional routine sampling must be conducted in the same manner (as three sample sets, at the specified locations). The water supplier may use the results of additional monitoring conducted under paragraph (4)(g)(B) of this rule to meet the requirement for monitoring in this paragraph.

(B) Additional monitoring. On each day following a routine sample monitoring result that exceeds the chlorite MCL at the entrance to the distribution system, the water supplier is required to collect three chlorite distribution system samples at the following locations: as close to the first customer as possible, in a location representative of average residence time, and as close to the end of the distribution system as possible (reflecting maximum residence time in the distribution system).

(C) Reduced monitoring.

(i) Chlorite monitoring at the entrance to the distribution system required by subparagraph (4)(g)(A)(i) of this rule may not be reduced.

(ii) Chlorite monitoring in the distribution system required by subparagraph (4)(g)(A)(ii) of this rule may be reduced to one three sample set per quarter after one year of monitoring where no individual chlorite sample taken in the distribution system under subparagraph (4)(g)(A)(ii) of this rule has exceeded the chlorite MCL and the system has not been required to conduct monitoring under paragraph (4)(g)(B) of this rule. The system may remain on the reduced monitoring schedule until either any of the three individual chlorite samples taken quarterly in the distribution system under subparagraph (4)(g)(A)(ii) of this rule exceeds the chlorite MCL or the system is required to conduct monitoring under paragraph (4)(g)(B) of this rule, at which time the system must revert to routine monitoring.

(D) Compliance must be based on an arithmetic average of each three sample set taken in the distribution system as required by subparagraph (4)(g)(A)(ii) of this rule and paragraph (4)(g)(B) of this rule. If the arithmetic average of any three sample set exceeds the MCL, the water system is in violation of the MCL and must notify the public as required by OAR 333-061-0042(2)(b)(A), in addition to reporting to the Authority as required by OAR 333-061-0040.

(h) Bromate monitoring and compliance for water systems where ozone is used for disinfection or oxidation.

(A) Routine monitoring. One sample must be collected every month for each treatment plant in the water system using ozone. Water suppliers must collect samples monthly at the entrance to the distribution system while the ozonation system is operating under normal conditions.

(B) Reduced monitoring. Bromate monitoring may be reduced from monthly to quarterly if the bromate concentration is less than or equal to 0.0025 mg/L as a running annual average based on monthly bromate measurements for the most recent four quarters. Water suppliers may continue reduced monitoring as long as the running annual average of quarterly bromate samples is less than or equal to 0.0025 mg/L. If the running annual average bromate concentration is >0.0025 mg/L, the water supplier must resume routine monitoring as required by paragraph (4)(h)(A) of this rule.

(C) Compliance must be based on a running annual arithmetic average, computed quarterly, of monthly samples (or, for months in which the system takes more than one sample, the average of all samples collected during the month) collected by the water supplier as required by this subsection. If the average of samples covering any consecutive four quarter period exceeds the MCL, the water system is in violation of the MCL and must notify the public as required by OAR 333-061-0042(2)(b)(A), in addition to reporting to the Authority as required by OAR 333-061-0040. If a water supplier fails to complete 12 consecutive months monitoring, compliance with the MCL for the last four quarter compliance period must be based on an average of the available data.

(i) Monitoring and compliance requirements for disinfectant residuals

(A) Chlorine and chloramines

(i) Routine monitoring. At water systems where chlorine or chloramines are used, water suppliers must measure the residual disinfectant level at the same points in the distribution system and at the same time when total coliforms are sampled as specified in OAR 333-061-0036(6). At water systems where surface water or GWUDI sources are used, results of residual disinfectant concentration sampling conducted as required by OAR 333-061-0036(5)(a)(F) for unfiltered systems or OAR 333-061-0036(5)(b)(E) for systems which filter, may be used in lieu of collecting separate samples. Compliance with this rule is achieved when the running annual average of monthly averages of samples collected in the distribution system, computed quarterly, is less than or equal to the MRDL. Operators may increase residual disinfectant levels of chlorine or chloramine (but not chlorine dioxide) in the distribution system to a level and for a time necessary to protect public health in order to address specific microbiological contaminant problems resulting from events in the source water or in the distribution system.

(ii) Reduced monitoring from subparagraph (4)(i)(A)(i) of this rule is not allowed.

(iii) Compliance requirements for chlorine and chloramines.

(I) Compliance must be based on a running annual arithmetic average, computed quarterly, of monthly averages of all samples collected by the water supplier as required by paragraph (4)(i)(A) of this rule. If the average covering any consecutive four quarter period exceeds the MRDL, the MRDL is exceeded and the water supplier must notify the public as required by OAR 333-061-0042(2)(b)(A), in addition to reporting to the Authority as required by OAR 333-061-0040.

(II) In cases where water suppliers switch between the use of chlorine and chloramines for residual disinfection at a water system during the year, compliance must be determined by including together all monitoring results of both chlorine and chloramines in calculating compliance. Reports submitted as required by OAR 333-061-0040(1) must clearly indicate which residual disinfectant was analyzed for each sample.

(B) Chlorine dioxide

(i) Routine monitoring. At water systems where chlorine dioxide is used for disinfection or oxidation, water suppliers must collect daily samples at the entrance to the distribution system. For any daily sample that exceeds the MRDL, the water supplier must collect samples in the distribution system the following day at the locations required by subparagraph (4)(i)(B)(ii) of this rule, in addition to the sample required at the entrance to the distribution system. Compliance with this rule is achieved when daily samples are taken at the entrance to the distribution system and no two consecutive daily samples exceed the MRDL.

(ii) Additional monitoring. On each day following a routine sample monitoring result that exceeds the MRDL, the water supplier is required to collect three chlorine dioxide distribution system samples. If chlorine dioxide or chloramines are used to maintain a disinfectant residual in the distribution system, or if chlorine is used to maintain a disinfectant residual in the distribution system and there are no disinfection addition points after the entrance to the distribution system (that is, no booster chlorination), the water supplier must collect three samples as close to the first customer as possible, at intervals of at least six hours. If chlorine is used to maintain a disinfectant residual in the distribution system and there are one or more disinfection addition points after the entrance to the distribution system (that is, booster chlorination), the water supplier must collect one sample at each of the following locations: as close to the first customer as possible, in a location representative of average residence time, and as close to the end of the distribution system as possible (reflecting maximum residence time in the distribution system).

(iii) Chlorine dioxide monitoring may not be reduced from subparagraph (4)(i)(B)(ii) of this rule.

(iv) Compliance requirements for chlorine dioxide

(I) Acute violations. Compliance must be based on consecutive daily samples collected by the water system as required by paragraph (4)(i)(B) of this rule. If any daily sample taken at the entrance to the distribution system exceeds the MRDL, and on the following day one (or more) of the three samples taken in the distribution system exceed the MRDL, the water system is in violation of the MRDL and must take immediate corrective action to lower the level of chlorine dioxide below the MRDL and must notify the public pursuant to the procedures for acute health risks as required by OAR 333-061-0042(2)(a)(C) in addition to reporting to the Authority as required by OAR 333-061-0040. Failure to take samples in the distribution system the day following an exceedance of the chlorine dioxide MRDL at the entrance to the distribution system will also be considered an MRDL violation and the water system must notify the public of the violation in accordance with the provisions for acute violations as required by OAR 333-061-0042(2)(a)(C) in addition to reporting to the Authority as required by OAR 333-061-0040.

(II) Non-acute violations. Compliance must be based on consecutive daily samples collected by the system as required by paragraph (4)(i)(B) of this rule. If any two consecutive daily samples taken at the entrance to the distribution system exceed the MRDL and all distribution system samples taken are below the MRDL, the water system is in violation of the MRDL and must take corrective action to lower the level of chlorine dioxide below the MRDL at the point of sampling and will notify the public pursuant to the procedures for non-acute health risks specified by OAR 333-061-0042(2)(b)(A), in addition to reporting to the Authority as required by OAR 333-061-0040. Failure to monitor at the entrance to the distribution system the day following an exceedance of the chlorine dioxide MRDL at the entrance to the distribution system is also an MRDL violation and the water system must notify the public of the violation in accordance with the provisions for non-acute violations specified by OAR 333-061-0042(2)(b)(A) in addition to reporting to the Authority as required by OAR 333-061-0040.

(j) Additional requirements for purchasing water systems. Purchasing water systems that do not add a disinfectant, but deliver water where a disinfectant (oxidant) has been added to the water supply at any point in the treatment process must comply with analytical and monitoring requirements for chlorine and chloramines as prescribed in subsection (4)(i) of this rule.

(k) Monitoring requirements for disinfection byproduct precursors (DBPP)

(A) Routine monitoring. At water systems where surface water or GWUDI sources are used and where conventional filtration treatment is used, monitoring must be conducted at each treatment plant for TOC no later than the point of combined filter effluent turbidity monitoring and representative of the treated water. Monitoring for TOC must be conducted in the source water prior to any treatment at the same time as monitoring for TOC in the treated water. These samples (source water and treated water) are referred to as paired samples. At the same time as the source water sample is collected, all water suppliers must also measure alkalinity in the source water prior to any treatment. Water suppliers must collect one paired sample and one source water alkalinity sample per month per treatment plant at a time representative of normal operating conditions and influent water quality.

(B) Reduced monitoring. At water systems using surface water or GWUDI sources with an average treated water TOC of less than 2.0 mg/L for two consecutive years, or less than 1.0 mg/L for one year, monitoring may be reduced to one paired sample and one source water alkalinity sample per plant per quarter. The water system must revert to routine monitoring in the month following the quarter when the annual average treated water TOC is greater than or equal to 2.0 mg/L.

(C) Compliance must be determined as specified by OAR 333-061-0032(10)(e). Water suppliers may begin monitoring to determine whether Step 1 TOC removals can be met 12 months prior to the compliance date for the system. This monitoring is not required and failure to monitor during this period is not a violation. However, any water system that does not monitor during this period, and then determines in the first 12 months after the compliance date that it is not able to meet the Step 1 requirements as specified in OAR 333-061-0032(10)(d)(B) and must therefore apply for

alternate minimum TOC removal (Step 2) requirements, is not eligible for retroactive approval of alternate minimum TOC removal (Step 2) requirements as allowed by OAR 333-061-0032(10)(d)(C) and is in violation. Water systems may apply for alternate minimum TOC removal (Step 2) requirements any time after the compliance date. For systems required to meet step 1 TOC removals, if the value calculated under OAR 333-061-0032(10)(e)(A)(iv) is less than 1.00, the system is in violation of the treatment technique requirements and must notify the public pursuant to OAR 333-061-0042(2)(b)(A), in addition to reporting to the Authority pursuant to OAR 333-061-0040.

(l) Disinfection Profiling and Disinfection Benchmarking. For any community, non-transient non-community, or transient non-community water system utilizing surface water or GWUDI sources where a significant change to the disinfection treatment process as defined by OAR 333-061-0060(1)(e)(A) through (1)(e)(D) is proposed, the water supplier must conduct disinfection profiling and benchmarking for Giardia lamblia and viruses. For any community or non-transient non-community water system where surface water or GWUDI sources are used and where the running annual average greater than or equal to 0.064 mg/l for TTHM or 0.048 mg/l for HAA5, the water supplier must conduct disinfection profiling for Giardia lamblia.

(A) For water systems serving at least 10,000 people, water suppliers must conduct the disinfection profiling in accordance with the USEPA Disinfection Profiling and Benchmarking Guidance Manual. The profile must be based on daily inactivation rate calculations over a period of 12 consecutive months. If chloramines, ozone, or chlorine dioxide is used as a primary disinfectant, the log inactivation for viruses must be calculated and an additional disinfection profile must be developed using a method approved by the Authority.

(B) At water systems serving less than 10,000 people, the disinfection profiling must be conducted in accordance with or the USEPA LT1-ESWTR Disinfection Profiling and Benchmarking Technical Guidance Manual. The profile must be based on weekly inactivation rate calculations collected on the same calendar day over a period of 12 consecutive months. If chloramines, ozone, or chlorine dioxide are used as a primary disinfectant, the log inactivation for viruses must be calculated and an additional disinfection profile must be developed using a method approved by the Authority.

(C) At water systems using either a single or multiple points of disinfection, monitoring must be conducted according to the following parameters to determine total log inactivation for each disinfection segment:

(i) The temperature of the disinfected water at each residual disinfectant concentration sampling point during peak hourly flow;

(ii) The pH of the disinfected water at each residual disinfectant concentration sampling point during peak hourly flow for systems using chlorine;

(iii) The disinfectant contact time(s) ("T") during peak hourly flow; and

(iv) The residual disinfectant concentration(s) ("C") of the water before or at the first customer and prior to each additional point of disinfection during peak hourly flow.

(D) Water suppliers required to develop disinfection profiles as prescribed by OAR 333-061-0060(1)(e) must meet the requirements of subparagraphs (4)(l)(D)(i) through (iii) of this rule:

(i) Water systems must monitor at least weekly for a period of 12 consecutive months to determine the total log inactivation for Giardia lamblia and viruses. If water systems monitor more frequently, the monitoring frequency must be evenly spaced. Water systems that operate for fewer than 12 months per year must monitor weekly during the period of operation;

(ii) Water systems must determine log inactivation for Giardia lamblia through the entire plant, based on CT99.9 values in Tables 21 through 28 in OAR 333-061-0036(5) as applicable; and [Table not included. See ED. NOTE.]

(iii) Water systems must determine log inactivation for viruses through the entire treatment plant based on a protocol approved by the Authority.

(E) Water suppliers must calculate the total inactivation ratio for Giardia lamblia as specified in this paragraph.

(i) Water systems using only one point of disinfectant application must determine the total inactivation ratio for the disinfection segment based on the methods specified in this paragraph.

(I) Water systems must determine one inactivation ratio (CTcalc/CT99.9) before or at the first customer during peak hourly flow; or

(II) Must determine successive (CTcalc/CT99.9) values, representing sequential inactivation ratios, between the point of disinfectant application and a point before or at the first customer during peak hourly flow. Water systems must calculate the total inactivation ratio by determining (CTcalc/CT99.9) for each sequence and then adding the (CTcalc/CT99.9) values together to determine Σ(CTcalc/CT99.9).

(ii) For water systems where there is more than one point of disinfectant application before the first customer, water suppliers must determine the (CTcalc/CT99.9) value of each disinfection segment immediately prior to the next point of disinfectant application, or for the final segment, before or at the first customer, during peak hourly flow. The (CTcalc/CT99.9) value of each segment and Σ(CTcalc/CT99.9) must be calculated using the method in subparagraph (4)(l)(E)(i)(II) of this rule.

(iii) The system must determine the total log of inactivation by multiplying the value calculated in subparagraphs (4)(l)(E)(i) or (ii) of this rule by 3.0.

(F) In lieu of conducting new monitoring as prescribed by paragraph (4)(l)(C) of this rule, water suppliers may elect to meet the requirements of subparagraphs (4)(l)(F)(i) or (ii) of this rule as follows:

(i) For water systems that have at least one year of existing data that are substantially equivalent to data collected in accordance with the provisions of this subsection may use these data to develop disinfection profiles as specified in this section if the water supplier has not made a significant change to treatment practices nor changed sources since the data were collected. Water suppliers may develop disinfection profiles using up to three years of existing data.

(ii) Water suppliers may use disinfection profile(s) developed as prescribed by this subsection in lieu of developing a new profile if the system has neither made a significant change to its treatment practice nor changed sources since the profile was developed. Water systems that have not developed a virus profile as prescribed by paragraph (4)(l)(G) of this rule must develop a virus profile using the same monitoring data on which the Giardia lamblia profile is based.

(G) Water suppliers must calculate the log of inactivation for viruses using a similar protocol as described in paragraph (4)(l)(D) of this rule, using a CT99.99 and a multiplication factor of 4.0.

(H) A water system subject to OAR 333-061-0060(1)(e) must calculate a disinfection benchmark using the procedures specified in subparagraphs (4)(l)(H)(i) and (ii) of this rule to calculate a disinfection benchmark.

(i) For each year of profiling data collected and calculated as prescribed by paragraphs (4)(l)(A) through (G) of this rule, systems must determine the lowest mean monthly level of both Giardia lamblia and virus inactivation. Water systems must determine the mean Giardia lamblia and virus inactivation for each calendar month for each year of profiling data by dividing the sum of daily or weekly Giardia lamblia and virus log inactivation by the number of values calculated for that month.

(ii) The disinfection benchmark is the lowest monthly mean value (for water systems with one year of profiling data) or the mean of the lowest monthly mean values (for water systems with more than one year of profiling data) of Giardia lamblia and virus log inactivation in each year of profiling data.

(I) Water systems must retain the disinfection profile data in graphic form, such as a spreadsheet, which must be available for

review by the Authority as part of a sanitary survey or other field visit contact.

(5) Surface Water Treatment.

(a) A public water system that uses a surface water source or a groundwater source under the direct influence of surface water that does not provide filtration treatment must monitor water quality as specified in this subsection beginning January 1, 1991 for systems using a surface water source and January 1, 1991 or 6 months after the Authority has identified a source as being under the direct influence of surface water for groundwater sources, whichever is later.

(A) Fecal coliform or total coliform density measurements as required by OAR 333-061-0032(2)(a)(A) must be performed on representative source water samples immediately prior to the first or only point of disinfectant application. The system must sample for fecal or total coliforms at the minimum frequency shown in Table 20 each week the system serves water to the public. These samples must be collected on separate days. Also one fecal or total coliform density measurement must be made every day the system serves water to the public when the turbidity of the source water exceeds 1 NTU (these samples count towards the weekly coliform sampling requirement) unless the Authority determines that the system, for logistical reasons outside of its control, cannot have the sample analyzed within 30 hours of collection. [Table not included. See ED. NOTE.]

(B) Turbidity measurements to determine compliance with OAR 333-061-0030(3)(a) must be performed on representative grab samples of source water immediately prior to the first or only point of disinfectant application every four hours (or more frequently) that the system serves water to the public. A public water system may substitute continuous turbidity monitoring for grab sample monitoring if it validates the continuous measurement for accuracy on a regular basis using a protocol approved by the Authority. Systems using continuous turbidity monitoring must report the turbidity data to the Authority in the same manner that grab sample results are reported. The Authority will furnish report forms upon request.

(C) The total inactivation ratio for each day that the system is in operation must be determined based on the CT99.9 values in Tables 21 through 28. The parameters necessary to determine the total inactivation ratio must be monitored as follows: [Table not included. See ED. NOTE.]

(i) The temperature of the disinfected water must be measured at least once per day at each residual disinfectant concentration sampling point.

(ii) If the system uses chlorine, the pH of the disinfected water must be measured at least once per day at each chlorine residual disinfectant concentration sampling point.

(iii) The disinfectant contact time(s) ("T") in minutes must be determined for each day during peak hourly flow.

(iv) The residual disinfectant concentration(s) ("C") in mg/l before or at the first customer must be measured each day during peak hourly flow.

(v) If a system uses a disinfectant other than chlorine or UV, the system may demonstrate to the Authority, through the use of protocol approved by the Authority for on-site disinfection challenge studies or other information satisfactory to the Authority, that CT99.9 values other than those specified in the Tables 27 and 28 or other operational parameters are adequate to demonstrate that the system is achieving the minimum inactivation rates required by OAR 333-061-0032(3)(a). [Table not included. See ED. NOTE.]

(D) The total inactivation ratio must be calculated as follows:

(i) If the system uses only one point of disinfectant application, the system may determine the total inactivation ratio based on either of the following two methods:

(I) One inactivation ratio (CTcalc/CTrequired) is determined before or at the first customer during peak hourly flow and if the CTcalc/CTrequired is greater than or equal to 1.0, the Giardia lamblia inactivation requirement has been achieved; or

(II) Successive CTcalc/CTrequired values representing sequential inactivation ratios, are determined between the point of disinfection application and a point before or at the first customer during peak hourly flow. Under this alternative, the following method must be used to calculate the total inactivation ratio:

Step 1: Determine CTcalc/CTrequired for each sequence
Step 2: Add the CTcalc/CTrequired values together
Step 3: If (CTcalc/CTrequired) is greater than or equal to 1.0, the Giardia lamblia inactivation requirement has been achieved.

(ii) If the system uses more than one point of disinfectant application before or at the first customer, the system must determine the CT value of each disinfection sequence immediately prior to the next point of disinfectant application during peak hourly flow. The CTcalc/CTrequired value of each sequence and CTcalc/CTrequired must be calculated using the methods in subparagraph (5)(a)(D)(i)(II) of this rule to determine if the system is in compliance with OAR 333-061-0032(3)(a) or (5)(a).

(E) The residual disinfectant concentration of the water entering the distribution system must be monitored continuously, and the lowest value must be recorded each day. If there is a failure in the continuous monitoring equipment, grab sampling every 4 hours may be conducted in lieu of continuous monitoring, but for no more than 5 working days following the failure of the equipment, and systems serving 3,300 or fewer persons may take grab samples in lieu of providing continuous monitoring on an ongoing basis at the frequencies prescribed in Table 29. The day's samples cannot be taken at the same time. The sampling intervals are subject to Authority review and approval. If at any time the residual disinfectant concentration falls below 0.2 mg/l in a system using grab sampling in lieu of continuous monitoring, the system must take a grab sample every 4 hours until the residual disinfectant concentration is > 0.2 mg/l. [Table not included. See ED. NOTE.]

(F) The residual disinfectant concentration must be measured at least at the same points in the distribution system and at the same time as total coliforms are sampled as specified in section (6) of this rule, except that the Authority may allow a public water system which uses both a surface water source or a groundwater source under the direct influence of surface water, and a groundwater source, to take disinfectant residual samples at points other than the total coliform sampling points if the Authority determines that such points are more representative of treated (disinfected) water quality within the distribution system.

(b) A public water system that uses a surface water source or a groundwater source under the direct influence of surface water that does provide filtration treatment must monitor water quality as specified in this subsection when filtration treatment is installed.

(A) Turbidity

(i) Turbidity measurements as required by section OAR 333-061-0032(4) must be performed on representative samples of the system's filtered water, measured prior to any storage, every four hours (or more frequently) that the system serves water to the public. A public water system may substitute continuous turbidity monitoring for grab sample monitoring if it validates the continuous measurement for accuracy on a regular basis using a protocol approved by the Authority.

(ii) Calibration of all turbidimeters must be performed according to manufacturer's specifications, but no less frequently than quarterly.

(iii) Water systems using conventional filtration must measure settled water turbidity every day.

(iv) Water systems using conventional or direct filtration must conduct turbidity profiles for individual filters every calendar quarter.

(v) For any systems using slow sand filtration or filtration treatment other than conventional treatment, direct filtration, or diatomaceous earth filtration, the Authority may reduce the sampling frequency to once per day if it determines that less frequent monitoring is sufficient to indicate effective filtration performance.

(vi) Systems using lime softening may acidify representative samples prior to analysis using a method approved by the Authority.

(B) The actual CT value achieved must be calculated each day the treatment plant is in operation. The parameters necessary to determine the actual CT value must be monitored as follows:

(i) The temperature of the disinfected water must be measured at least once per day at each residual disinfectant concentration sampling point as prescribed in subparagraph (5)(b)(B)(iv) of this rule.

(ii) If the system uses chlorine, the pH of the disinfected water must be measured at least once per day at each chlorine residual disinfectant concentration sampling point.

(iii) The disinfectant contact time(s) ("T") in minutes must be determined for each day during peak hourly flow, based on results of a tracer study conducted according to OAR 333-061-0050(6)(a)(R), or other method approved by the Authority.

(iv) The residual disinfectant concentration(s) ("C") in mg/l before or at the first customer must be measured each day during peak hourly flow.

(v) If a system uses a disinfectant other than chlorine, the system may demonstrate to the Authority, through the use of protocol approved by the Authority for on-site disinfection challenge studies or other information satisfactory to the Authority, or other operational parameters are adequate to demonstrate that the system is achieving the minimum inactivation rates required by OAR 333-061-0032(5)(a).

(C) The inactivation ratio calculations as prescribed in paragraph (5)(a)(D) of this rule.

(D) Monitoring for the residual disinfectant concentration entering the distribution system shall be performed as prescribed in paragraph (5)(a)(E) of this rule.

(E) Monitoring for the residual disinfectant concentration in the distribution system shall be performed as prescribed in paragraph (5)(a)(F) of this rule.

(F) Water systems using membrane filtration must perform direct integrity testing on each filter canister at least daily, per OAR 333-061-0036(5)(d)(B).

(c) Inactivation credit for water systems using a disinfectant other than chlorine for pathogen inactivation.

(A) Calculation of CT values.

(i) CT is the product of the disinfectant concentration (C, in milligrams per liter) and actual disinfectant contact time (T, in minutes). Systems with treatment credit for chlorine dioxide or ozone as prescribed by paragraphs (5)(c)(B) or (C) of this rule must calculate CT at least once per day, with both C and T measured during peak hourly flow as specified in paragraph (5)(b)(B) of this rule.

(ii) Systems with several disinfection segments in sequence must calculate CT for each segment where treatment credit is sought, where a disinfection segment is defined as a treatment unit process with a measurable disinfectant residual level and a liquid volume. If using this approach, water systems must add the Cryptosporidium CT values in each segment to determine the total CT for the treatment plant.

(B) CT values for chlorine dioxide and ozone.

(i) Systems receive the Cryptosporidium treatment credit listed in Table 30 by meeting the corresponding chlorine dioxide CT value for the applicable water temperature, as described in paragraph (5)(c)(A) of this rule. [Table not included. See ED. NOTE.]

(ii) Systems receive the Cryptosporidium treatment credit listed in Table 31 by meeting the corresponding ozone CT values for the applicable water temperature, as described in paragraph (5)(c)(A) of this rule. [Table not included. See ED. NOTE.]

(C) Site-specific study. The Authority may approve alternative chlorine dioxide or ozone CT values to those listed in Table 30 or Table 31 on a site-specific basis. The Authority must base this approval on a site-specific study conducted by a water system that follows an Authority approved protocol. [Table not included. See ED. NOTE.]

(D) Ultraviolet light. Systems receive Cryptosporidium, Giardia lamblia, and virus treatment credits for ultraviolet light (UV) reactors by achieving the corresponding UV dose values shown in subparagraph (5)(c)(D)(i) of this rule. Systems must validate and monitor UV reactors as described in OAR 333-061-0050(5)(k) and subparagraphs (5)(c)(D)(ii) and (iii) of this rule to demonstrate that they are achieving a particular UV dose value for treatment credit.

(i) UV dose table. The treatment credits listed in this table are for UV light at a wavelength of 254 nm as produced by a low pressure mercury vapor lamp. To receive treatment credit for other lamp types, systems must demonstrate an equivalent germicidal dose through reactor validation testing as specified in OAR 333-061-0050(5)(k). The UV dose values in Table 32 are applicable to post-filter applications of UV in filtered water systems, unfiltered water systems, and groundwater systems required to disinfect as prescribed by OAR 333-061-0032(6). [Table not included. See ED. NOTE.]

(ii) Reactor monitoring. Systems must monitor their UV reactors to determine if the reactors are operating within validated conditions, as prescribed by OAR 333-061-0050(5)(k). This monitoring must include UV intensity as measured by a UV sensor, flow rate, lamp status, UV Transmittance, and other parameters the Authority designates based on UV reactor operation. Water systems must verify the calibration of UV sensors at least monthly, and must recalibrate sensors in accordance with the EPA UV Disinfection Guidance Manual as necessary.

(iii) Water systems must monitor the percentage of water delivered to the public that was treated within validated conditions for the required UV dose. If less than 95 percent of water delivered was within validated conditions, a Tier 2 public notice must be issued as prescribed by OAR 333-061-0042(3)(b).

(d) Requirements for individual filter effluent turbidity monitoring

(A) In addition to subsection (5)(b) of this rule, water systems using surface water or groundwater under the direct influence of surface water where treatment includes conventional filtration treatment or direct filtration treatment must conduct continuous turbidity monitoring for each individual filter and must calibrate turbidimeters using the procedure specified by the manufacturer. Individual filter monitoring results must be recorded every 15 minutes. If there is a failure in the continuous turbidity monitoring equipment, the water system must conduct grab sampling every four hours in lieu of continuous monitoring until the turbidimeter is repaired and back on-line. The water system serving at least 10,000 people has a maximum of five working days after failure to repair the equipment or the water system is in violation. The water system serving less than 10,000 people has a maximum of 14 days to resume continuous monitoring before a violation is incurred. If the water system's conventional or direct filtration treatment plant consists of two or fewer filters, continuous monitoring of the combined filter effluent turbidity may be substituted for continuous monitoring of individual filter effluent turbidity. For systems serving less than 10,000 people, the recording and calibration requirements that apply to individual filters also apply when continuous monitoring of the combined filter effluent turbidity is substituted for the continuous monitoring of individual filter effluent turbidity;

(B) Direct integrity testing for membrane filtration. Water systems must conduct direct integrity testing in a manner that demonstrates a removal efficiency equal to or greater than the removal credit awarded to the membrane filtration process, and that meets the requirements described in this paragraph. A direct integrity test is defined as a physical test applied to a membrane unit in order to identify and isolate integrity breaches (that is, one or more leaks that could result in contamination of the filtrate).

(i) The direct integrity test must be independently applied to each membrane unit in service. A membrane unit is defined as a group of membrane modules that share common valving that allows the unit to be isolated from the rest of the water system for the purpose of integrity testing or other maintenance.

(ii) The direct integrity method must have a resolution of three micrometers or less, where resolution is defined as the size of the smallest integrity breach that contributes to a response from the direct integrity test.

(iii) The direct integrity test must have a sensitivity sufficient to verify the log treatment credit awarded to the membrane

filtration process by the Authority, where sensitivity is defined as the maximum log removal value that can be reliably verified by a direct integrity test. Sensitivity must be determined using the approach in either subparagraphs (5)(d)(B)(iii)(I) or (II) of this rule as applicable to the type of direct integrity test the system uses.

(I) For direct integrity tests that use an applied pressure or vacuum, the direct integrity test sensitivity must be calculated according to the following equation:

LRVDIT = LOG10 (Qp /(VCF x Qbreach))

Where:

LRVDIT = the sensitivity of the direct integrity test;

Qp = total design filtrate flow from the membrane unit;

Qbreach = flow of water from an integrity breach associated with the smallest integrity test response that can be reliably measured; and

VCF = volumetric concentration factor. The volumetric concentration factor is the ratio of the suspended solids concentration on the high pressure side of the membrane relative to that in the feed water.

(II) For direct integrity tests that use a particulate or molecular marker, the direct integrity test sensitivity must be calculated according to the following equation:

LRVDIT = LOG10(Cf)-LOG10(Cp)

Where:

LRVDIT = the sensitivity of the direct integrity test;

Cf = the typical feed concentration of the marker used in the test; and

Cp = the filtrate concentration of the marker from an integral membrane unit.

(iv) Water systems must establish a control limit within the sensitivity limits of the direct integrity test that is indicative of an integral membrane unit capable of meeting the removal credit awarded by the Authority.

(v) If the result of a direct integrity test exceeds the control limit established under subparagraph (5)(d)(B)(iv) of this rule, the water system must remove the membrane unit from service. Water systems must conduct a direct integrity test to verify any repairs, and may return the membrane unit to service only if the direct integrity test is within the established control limit.

(vi) Water systems must conduct direct integrity testing on each membrane unit at a frequency of not less than once each day that the membrane unit is in operation. The Authority may approve less frequent testing, based on demonstrated process reliability, the use of multiple barriers effective for Cryptosporidium, or reliable process safeguards.

(C) Indirect integrity monitoring for membrane filtration. Water systems must conduct continuous indirect integrity monitoring on each membrane unit according to the criteria specified in this paragraph. Indirect integrity monitoring is defined as monitoring some aspect of filtrate water quality that is indicative of the removal of particulate matter. A water system that implements continuous direct integrity testing of membrane units in accordance with the criteria specified in subparagraphs (5)(d)(B)(i) through (v) of this rule is not subject to the requirements for continuous indirect integrity monitoring. Water systems must submit a monthly report to the Authority summarizing all continuous indirect integrity monitoring results triggering direct integrity testing and the corrective action that was taken in each case.

(i) Unless the Authority approves an alternative parameter, continuous indirect integrity monitoring must include continuous filtrate turbidity monitoring.

(ii) Continuous monitoring must be conducted at a frequency of no less than once every 15 minutes.

(iii) Continuous monitoring must be separately conducted on each membrane unit.

(iv) If indirect integrity monitoring includes turbidity and the filtrate turbidity readings are above 0.15 NTU for a period greater than 15 minutes (that is, two consecutive 15-minute readings above 0.15 NTU), direct integrity testing in accordance with subparagraphs (5)(d)(B)(i) through (v) of this rule must immediately be performed on the associated membrane unit.

(v) If indirect integrity monitoring includes an Authority-approved alternative parameter and if the alternative parameter exceeds an Authority approved control limit for a period greater than 15 minutes, direct integrity testing in accordance with subparagraphs (5)(d)(B)(i) through (v) of this rule must immediately be performed on the associated membrane unit.

(e) Source water monitoring. Wholesale water systems, as defined in OAR 333-061-0020(222), must comply with the requirements of this rule based on the population of the largest water system in the combined distribution system. Water systems required to provide filtration treatment must comply with the requirements of this rule whether or not the water system is currently operating filtration treatment. The requirements of this rule for unfiltered water systems only apply to those water systems that met and continue to meet the requirements of OAR 333-061-0032(2) and (3).

(A) Initial round. Water systems must conduct monitoring as prescribed by this paragraph, and following the schedule specified in paragraph (5)(e)(C) of this rule, unless the system meets the monitoring exemption criteria specified in paragraph (5)(e)(D) of this rule.

(i) Filtered water systems serving at least 10,000 people must sample their source water for Cryptosporidium, E. coli, and turbidity at least monthly for 24 months.

(ii) Unfiltered water systems serving at least 10,000 people must sample their source water for Cryptosporidium at least monthly for 24 months.

(iii) Filtered water systems serving less than 10,000 people must sample their source water for E. coli at least once every two weeks for 12 months.

(I) Filtered water systems serving fewer than 10,000 people may avoid E. coli monitoring if the system monitors for Cryptosporidium as prescribed in subparagraph (5)(e)(A)(iv) of this rule. The water system must notify the Authority no later than three months prior to the date the system is otherwise required to start E. coli monitoring under paragraph (5)(e)(C) of this rule.

(iv) Filtered water systems serving fewer than 10,000 people must sample their source water for Cryptosporidium at least twice per month for 12 months or at least monthly for 24 months if they meet one of the following, based on monitoring conducted in accordance with subparagraph (5)(e)(A)(iii) of this rule:

(I) The annual mean E. coli concentration, in the surface water source, is greater than 100 E. coli/100 mL;

(II) The water system does not conduct E. coli monitoring as described in subparagraph (5)(e)(A)(iii) of this rule; or

(III) Water systems using groundwater under the direct influence of surface water must comply with the requirements of this paragraph based on the E. coli level specified in subparagraph (5)(e)(A)(iv)(I) of this rule.

(v) Unfiltered water systems serving fewer than 10,000 people must sample their source water for Cryptosporidium at least twice per month for 12 months or at least monthly for 24 months.

(vi) Water systems may sample more frequently than required under this section if the sampling frequency is evenly spaced throughout the monitoring period.

(vii) The Authority may approve monitoring for an indicator other than E. coli to comply with the monitoring prescribed by subparagraph (5)(e)(A)(iii) of this rule for filtered water systems serving fewer than 10,000 people. The Authority may approve an alternative to the E. coli concentrations that trigger Cryptosporidium monitoring as specified in subparagraphs (5)(e)(A)(iv)(I) and (III) of this rule. The Authority's approval to the system will be in writing and will include the basis for the Authority's determination that the alternative indicator or trigger level will provide a more accurate identification of whether a water system will exceed the Bin 1 Cryptosporidium level specified in Table 8 in OAR 333-061-0032(4)(f)(F). [Table not included. See ED. NOTE.]

(B) Water systems must conduct a second round of source water monitoring that meets the requirements for monitoring parameters, frequency, and duration described in paragraph (5)(e)(A) of this rule, and according to the schedule in paragraph (5)(e)(C) of this rule, unless they meet the monitoring exemption criteria specified in paragraph (5)(e)(D) of this rule.

(C) Monitoring schedule. Systems must begin monitoring as required in paragraphs (5)(e)(A) and (B) of this rule no later than the month beginning with the date listed in Table 33. [Table not included. See ED. NOTE.]

(D) Monitoring avoidance.

(i) Filtered water systems are not required to conduct source water monitoring as prescribed by this subsection if the system will provide a total of at least 5.5-log of treatment for Cryptosporidium, equivalent to meeting the treatment requirements of Bin 4 in OAR 333-061-0032(4)(g) and 333-061-0032(13) through (18).

(ii) Unfiltered water systems are not required to conduct source water monitoring as prescribed by this subsection if the system will provide a total of at least 3-log Cryptosporidium inactivation, equivalent to meeting the treatment requirements for unfiltered systems with a mean Cryptosporidium concentration of greater than 0.01 oocysts/L in OAR 333-061-0032(3)(e).

(iii) If a water system chooses to provide the level of treatment specified in subparagraph (5)(e)(D)(i) or (ii) of this rule, rather than conducting source water monitoring, the water system must notify the Authority in writing no later than the date the system is otherwise required to submit a sampling schedule for monitoring as prescribed by OAR 333-061-0036(5)(f)(A). A water system may choose to cease source water monitoring at any point after it has initiated monitoring if it notifies the Authority in writing that it will provide this level of treatment. Water systems must install and operate technologies to provide this level of treatment by the applicable treatment compliance date in OAR 333-061-0032(1)(a)(F).

(E) Seasonal plants. Systems with surface water or GWUDI treatment plants that operate for only part of the year must conduct source water monitoring in accordance with this subsection, but with the following modifications:

(i) Water systems must sample their source water only during the months that the plant is in use unless the Authority specifies another monitoring period based on plant operating practices.

(ii) Water systems with treatment plants that operate less than six months per year, and that monitor for Cryptosporidium, must collect at least six Cryptosporidium samples per year for two years of monitoring. Samples must be evenly spaced throughout the period the plant operates.

(F) New sources. A water system that begins using a new source of surface water or GWUDI after the system is required to begin monitoring as prescribed in paragraph (5)(e)(C) of this rule must monitor the new source on a schedule the Authority approves. Source water monitoring must meet the requirements of this subsection, and the water system must also meet the bin classification and Cryptosporidium treatment requirements of OAR 333-061-0032 for the new source on a schedule the Authority approves.

(i) This applies to water systems using surface water or GWUDI sources that begin operation after the monitoring start date applicable to the system's size specified in Table 33.

(ii) The water system must begin a second round of source water monitoring no later than six years following determination of the mean Cryptosporidium level or initial bin classification as prescribed by OAR 333-061-0032(2) or (4) respectively, as applicable.

(G) Failure to collect any source water sample in accordance with the sampling requirements, schedule, sampling location, analytical method, approved laboratory, and reporting requirements of this section is a monitoring violation.

(H) Grandfathering monitoring data. Systems may use monitoring data collected prior to the applicable monitoring start date in paragraph (5)(e)(C) of this rule to meet the initial source water monitoring requirements in paragraph (5)(e)(A) of this rule. Grandfathered data may substitute for an equivalent number of months at the end of the monitoring period. All data submitted under this paragraph must meet the requirements in subsection (5)(h) of this rule.

(f) Source water sampling schedules.

(A) Water systems required to conduct source water monitoring as prescribed in subsection (5)(e) of this rule must submit a sampling schedule that specifies the calendar dates when the system will collect each required sample.

(i) Water systems must submit sampling schedules to the Authority, no later than three months prior to the applicable date listed in paragraph (5)(e)(C) of this rule, for each round of required monitoring.

(ii) If the Authority does not respond to a water system regarding its sampling schedule, the system must sample at the reported schedule.

(B) Water systems must collect samples within a five-day period, starting two days before the scheduled sampling date and ending two days after. The five-day period applies to each of the dates indicated in the sampling schedule unless one of the following conditions applies:

(i) An extreme condition or situation exists that may pose danger to the sample collector or that cannot be avoided, and that prevents the water system from sampling in the scheduled five-day period. In this case, the water system must sample as close to the scheduled date as possible unless the Authority approves an alternative sampling date. The water system must submit an explanation for the delayed sampling date to the Authority concurrent with the submittal of the sample to the laboratory; or

(ii) A water system is unable to report a valid analytical result for the scheduled sampling date due to equipment failure, loss of or damage to the sample, failure to comply with the analytical method requirements (including the quality control requirements), or the failure of an approved laboratory to analyze the sample.

(I) In this case the water system must collect a replacement sample as prescribed in subparagraph (5)(f)(B)(ii)(II) of this rule.

(II) The system must collect the replacement sample not later than 21 days after receiving information that an analytical result cannot be reported for the scheduled date unless the water system demonstrates that collecting a replacement sample within this time frame is not feasible or the Authority approves an alternative resampling date. The system must submit an explanation for the delayed sampling date to the Authority concurrent with the submittal of the sample to the laboratory.

(iii) Water systems that fail to meet the criteria of paragraph (5)(f)(B) of this rule for any required source water sample must revise their sampling schedules to add dates for collecting all missed samples. Water systems must submit the revised sampling schedule to the Authority for approval prior to beginning collecting the missed samples.

(g) Source water sampling locations.

(A) Water systems required to conduct source water monitoring as prescribed in subsection (5)(e) of this rule must collect samples for each plant that treats a surface water or GWUDI source. Where multiple plants draw water from the same influent, such as the same pipe or intake, the Authority may approve one set of monitoring results to be used to satisfy the requirements for all treatment plants.

(B) Water systems must collect source water samples prior to chemical treatment, such as coagulants, oxidants and disinfectants, unless the system meets the following condition:

(i) The Authority may approve a water system to collect a source water sample after chemical treatment if the Authority determines that collecting a sample prior to chemical treatment is not feasible for the system and that the chemical treatment is unlikely to have a significant adverse effect on the analysis of the sample.

(C) Water systems that recycle filter backwash water must collect source water samples prior to the point of filter backwash water addition.

(D) Bank filtration.

(i) Water systems that receive Cryptosporidium treatment credit for bank filtration as an alternate filtration technology as specified by OAR 333-061-0032(9) must collect source water samples in the surface water source prior to bank filtration.

(ii) Water systems that use bank filtration as pretreatment to a filtration plant must collect source water samples from the well, after bank filtration. Use of bank filtration during monitoring must be consistent with routine operational practice. Water systems collecting samples after a bank filtration process may not receive treatment credit for the bank filtration prescribed by OAR 333-061-0032(9).

(E) Multiple sources. Water systems with treatment plants that use multiple water sources, including multiple surface water sources and blended surface water and groundwater sources, must collect samples as specified in subparagraph (5)(g)(E)(i) or (ii) of this rule. The use of multiple sources during monitoring must be consistent with routine operational practice.

(i) If a sampling tap is available where the sources are combined prior to treatment, water systems must collect samples from this tap.

(ii) If a sampling tap where the sources are combined prior to treatment is not available, systems must collect samples at each source near the intake on the same day and must comply with either subparagraph (5)(g)(E)(ii)(I) or (II) below for sample analysis.

(I) Water systems may composite samples from each source into one sample prior to analysis. The volume of sample from each source must be weighted according to the proportion of the source in the total plant flow at the time the sample is collected.

(II) Water systems may analyze samples from each source separately and calculate a weighted average of the analysis results for each sampling date. The weighted average must be calculated by multiplying the analysis result for each source by the fraction the source contributed to total plant flow at the time the sample was collected and then adding these values.

(F) Additional requirements. Water systems must submit a description of their sampling location(s) to the Authority at the same time as the sampling schedule required under subsection (5)(f) of this rule. This description must address the position of the sampling location in relation to the system's water source(s) and treatment processes, including pretreatment, points of chemical treatment, and filter backwash recycle. If the Authority does not respond to a water system regarding sampling location(s), the system must sample at the reported location(s).

(h) Grandfathering previously collected data.

(A) Water systems may comply with the initial source water monitoring requirements of paragraph (5)(e)(A) of this rule by grandfathering sample results collected before the system is required to begin monitoring. To be grandfathered, the sample results and analysis must meet the criteria in this section and the Authority must approve the previously sampled data.

(i) A filtered water system may grandfather Cryptosporidium samples to meet the monitoring requirements of paragraph (5)(e)(A) of this rule when the system does not have corresponding E. coli and turbidity samples.

(ii) A water system that grandfathers Cryptosporidium samples is not required to collect the E. coli and turbidity samples when the system completes the requirements for Cryptosporidium monitoring under paragraph (5)(e)(A) of this rule.

(B) The analysis of grandfathered E. coli and Cryptosporidium samples must meet the analytical method and approved laboratory requirements of subsections (1)(a) and (1)(c) of this rule.

(C) The sampling location of grandfathered samples must meet the conditions specified in subsection (5)(g) of this rule.

(D) Grandfathered Cryptosporidium samples must have been collected no less frequently than each calendar month on a regular schedule, and no earlier than January 1999. Sample collection intervals may vary for the conditions specified in subparagraph (5)(f)(B)(i) through (ii) of this rule if the system provides documentation of the condition when reporting monitoring results.

(i) The Authority may approve grandfathering of previously collected data where there are time gaps in the sampling frequency if the water system conducts additional monitoring as specified by the Authority to ensure that the data used to comply with the initial source water monitoring requirements of paragraph (5)(e)(A) of this rule are seasonally representative and unbiased.

(ii) Water systems may grandfather previously collected data where the sampling frequency within each month varied. If the Cryptosporidium sampling frequency varied, water systems must follow the monthly averaging procedure in OAR 333-061-0032(2)(c)(B) or OAR-333-061-0032(4)(f)(E) as applicable, when calculating the bin classification for filtered water systems or the mean Cryptosporidium concentration for unfiltered water systems.

(E) Reporting monitoring results for grandfathering. Water systems that request to grandfather previously collected monitoring results must report the following information by the applicable dates listed in this paragraph.

(i) Water systems must report that they intend to submit previously collected monitoring. This report must specify the number of previously collected results the system will submit, the dates of the first and last sample, and whether a system will conduct additional source water monitoring to meet the requirements of paragraph (5)(e)(A) of this rule. Water systems must report this information no later than the date the sampling schedule is required as prescribed by subsection (5)(f) of this rule.

(ii) Water systems must report previously collected monitoring results for grandfathering, along with the associated documentation listed in subparagraphs (5)(h)(E)(ii)(I) through (IV) of this rule, no later than two months after the applicable date listed in paragraph (5)(e)(C) of this rule.

(I) For each sample result, water systems must report the applicable data elements specified by OAR 333-061-0040(1)(o).

(II) Water systems must certify that the reported monitoring results include all results the system generated during the time period beginning with the first reported result and ending with the final reported result. This applies to samples that were collected from the sampling location specified for source water monitoring under this paragraph and analyzed in accordance with subsection (1)(a) of this rule.

(III) Water systems must certify that the samples were representative of a plant's source water(s) and that the source water(s) have not changed. Water systems must report a description of the sampling location(s), which must address the position of the sampling location in relation to the system's water source(s) and treatment processes, including points of chemical addition and filter backwash recycle.

(IV) For Cryptosporidium samples, the laboratory or laboratories that analyzed the samples must provide a letter certifying that the quality control criteria in accordance with subsection (1)(a) of this rule were met for each sample batch associated with the reported results. Alternatively, the laboratory may provide bench sheets and sample examination report forms for each field, matrix spike, IPR, OPR, and method blank sample associated with the reported results.

(F) If the Authority determines that a previously collected data set submitted for grandfathering was generated during source water conditions that were not normal for the system, such as a drought, the Authority may disapprove the data. Alternatively, the Authority may approve the previously collected data if the water system reports additional source water monitoring data, as determined by the Authority, to ensure that the data set used under OAR 333-061-0032(4)(f) or 0032(2)(c) represents average source water conditions for the system.

(G) If a water system submits previously collected data that fully meets the number of samples required for initial source water monitoring required by paragraph (5)(e)(A) of this rule, and some of the data is rejected due to not meeting the requirements of this subsection, systems must conduct additional monitoring to replace rejected data on a schedule the Authority approves. Water systems are not required to begin this additional monitoring until two months after notification that data has been rejected and that additional monitoring is necessary.

(6) Coliform Bacteria and Microbiological Contaminants

(a) General requirements for coliform bacteria sampling

(A) Sample Handling Requirements

(i) The standard sample volume required for analysis, regardless of analytical method used, is 100 ml.

(ii) Only the presence or absence of total coliforms and E. coli is required to be determined, not a determination of density.

(iii) Test medium incubation must be initiated within 30 hours of sample collection. Samples should be held below 10 deg. C during transit.

(iv) If water having residual chlorine (measured as free, combined, or total chlorine) is to be analyzed, sufficient sodium thiosulfate (Na2S2O3) must be added to the sample bottle before sterilization to neutralize any residual chlorine in the water sample. Dechlorination procedures are addressed in Section 9060A.2 of Standard Methods for the Examination of Water and Wastewater (20th and 21st editions).

(B) Water suppliers must comply with the repeat monitoring requirements and E. coli analytical requirements specified in subsection (6)(g) of this rule following any total coliform-positive sample collected according to subsections (6)(b) through (6)(f) of this rule.

(C) Water suppliers must determine whether a coliform investigation trigger as specified in OAR 333-061-0078(2) has been exceeded once all monitoring as required by subsections (6)(b) through (6)(g) of this rule has been completed for a calendar month.

(D) If a routine or repeat sample is total coliform-positive, the sample must be analyzed to determine if E. coli are present. If E. coli are present, the water supplier must notify the Authority by the end of the day when the water supplier is notified of the test result, unless the water supplier is notified of the result after the Authority office is closed, in which case the water supplier must notify the Authority before the end of the next business day.

(E) The Authority may, on a case-by-case basis, allow a water supplier to forgo E. coli testing on a total coliform-positive sample if that water supplier assumes that the total coliform-positive sample is E. coli-positive. Accordingly, the water supplier must notify the Authority as specified in paragraph (6)(a)(D) of this rule and take action appropriate for exceeding the MCL for E. coli as specified in OAR 333-061-0030(4).

(F) The Authority may invalidate a total coliform-positive sample only if the conditions specified in subparagraph (6)(a)(F)(i), (ii), or (iii) of this rule are met. A total coliform-positive sample invalidated according to this paragraph does not count toward meeting the minimum monitoring requirements of this rule.

(i) The laboratory establishes that improper sample analysis caused the total coliform-positive result.

(ii) The Authority, on the basis of the results of repeat samples collected as required by subsection (6)(g) of this rule, determines that the total coliform-positive sample resulted from a domestic or other non-distribution system plumbing problem. The Authority cannot invalidate a sample on the basis of repeat sample results unless all repeat sample(s) collected at the same tap as the original total coliform-positive sample are also total coliform-positive, and all repeat samples collected at a location other than the original tap are total coliform-negative (for example, the Authority cannot invalidate a total coliform-positive sample on the basis of repeat samples if all the repeat samples are total coliform-negative, or if the water system has only one service connection).

(iii) The Authority has substantial grounds to believe that a total coliform-positive result is due to a circumstance or condition that does not reflect water quality in the distribution system. In this case, the water supplier must still collect all repeat samples required by subsection (6)(g) of this rule, and use them to determine whether a coliform investigation trigger as specified in OAR 333-061-0078(2) has been exceeded. To invalidate a total coliform-positive sample under this paragraph, the decision and supporting rationale must be documented in writing, and approved and signed by the supervisor of the Authority official who recommended the decision. The written documentation must state the specific cause of the total coliform-positive sample, and what action the water supplier has taken, or will take, to correct this problem. The Authority will not invalidate a total coliform-positive sample solely on the grounds that all repeat samples are total coliform-negative. If the Authority invalidates a sample according to this subparagraph the written documentation will be made available to the EPA or the public upon request.

(G) A laboratory must invalidate a total coliform sample (unless total coliforms are detected) if the sample produces a turbid culture in the absence of gas production using an analytical method where gas formation is examined (for example, the Multiple-Tube Fermentation Technique), produces a turbid culture in the absence of an acid reaction in the Presence-Absence (P–A) Coliform Test, or exhibits confluent growth or produces colonies too numerous to count with an analytical method using a membrane filter (for example, Membrane Filter Technique). If a laboratory invalidates a sample because of such interference, the system must collect another sample from the same location as the original sample within 24 hours of being notified of the interference problem, and have it analyzed for the presence of total coliforms. The water supplier must continue to re-sample within 24 hours and have the samples analyzed until it obtains a valid result. The Authority may waive the 24-hour time limit on a case-by-case basis.

(H) A total coliform-positive sample invalidated according to paragraphs (6)(a)(F) or (G) of this rule does not count toward meeting the minimum monitoring requirements specified in this section.

(I) Water suppliers must develop a written coliform sampling plan for every water system that they own or operate or for which they are responsible according to the criteria in this paragraph by March 31, 2016. The plan must identify sampling sites and a sample collection schedule that is representative of water throughout the distribution system. Water suppliers must collect total coliform samples according to the plan. Plans are subject to Authority review and revision.

(i) Monitoring required by subsections (6)(b) through (6)(g) of this rule may take place at a customer's premises, dedicated sampling station, or other designated sampling location. Routine and repeat sample sites and any sampling points necessary to meet the requirements of subsection (6)(i) of this rule must be reflected in the coliform sampling plan.

(ii) Samples must be collected at regular time intervals throughout the month, except that groundwater systems serving 4,900 or fewer people may collect all required samples on a single day if they are collected at different sites.

(iii) Water suppliers must collect at least the minimum number of required samples every month even if the MCL for E. coli as specified in OAR 333-061-0030(4) was exceeded or a coliform investigation trigger as specified in OAR 333-061-0078(2) was exceeded.

(iv) Water suppliers may use monitoring as a tool to assist in investigating problems whereby additional samples beyond the number required by this section may be collected to investigate potential problems in the distribution system. A water supplier collecting more routine samples than required in a month must include the results of the additional sampling in calculating whether a coliform investigation trigger as specified in OAR 333-061-0078(2) has been exceeded only if the samples are collected in accordance with an existing coliform sampling plan and are representative of water throughout the distribution system.

(v) Water suppliers must identify repeat monitoring locations in the coliform sampling plan. At least one repeat sample must be collected from the sampling tap where the original total coliform-positive sample was collected, at least one repeat sample must be collected at a tap within five service connections upstream and at least one repeat sample must be collected at a tap within five service connections downstream of the original sampling site unless the provisions of subparagraphs (6)(a)(I)(v)(I) or (6)(a)(I)(v)(II) of this rule are met. If a total coliform-positive sample is at the end of the distribution system, or one service connection away from the end of the distribution system, the Authority may allow an alternative sampling location in lieu of the requirement to collect at least one repeat sample upstream or downstream of the original sampling site. Except as provided for in subparagraph (6)(a)(I)(v)(II) of this rule, at water systems where triggered source water monitoring is required according to paragraph (6)(i)(A), groundwater source samples must be collected in addition to repeat samples as required by subsection (6)(g) of this rule.

(I) Water suppliers may propose repeat monitoring locations to the Authority that the water supplier believes to be representative of a pathway for contamination of the distribution system. A water supplier may elect to specify either alternative fixed locations or

criteria for selecting repeat sampling sites on a situational basis in a standard operating procedure (SOP) in its coliform sampling plan. The water supplier must design its SOP to focus the repeat samples at locations that best verify and determine the extent of potential contamination of the distribution system area based on specific situations. The Authority may modify the SOP or require alternative monitoring locations as needed.

(II) For groundwater systems serving 1,000 people or less, repeat sampling locations may be proposed that differentiate potential source water and distribution system contamination (for example, by sampling at entry points to the distribution system). A water system with a single groundwater source and a single service connection may request to collect repeat samples at the location for triggered source water monitoring. The Authority may approve the request if the water supplier demonstrates that the coliform sampling plan remains representative of water quality in the distribution system. If approved by the Authority, the sample result may be used to meet the monitoring requirements in both subsection (6)(g) and (6)(i) of this rule.

(III) Triggered source water monitoring locations as required by subsection (6)(i) of this rule must be identified in the plan in addition to the repeat samples required by subsection (6)(g) of this rule.

(IV) The Authority may review, revise, and approve, as appropriate, repeat sampling proposed by systems under subparagraphs (6)(a)(I)(v)(I) and (II) of this rule. The water supplier must demonstrate that the coliform sampling plan remains representative of the water quality in the distribution system. The Authority may determine that monitoring at the entry point to the distribution system (especially for groundwater systems without disinfection) is effective to differentiate between potential source water and distribution system problems.

(b) At non-transient non-community, transient non-community and state regulated water systems using only groundwater as defined in OAR 333-061-0020(89) and serving 1,000 people or less, one sample must be collected for coliform bacteria every calendar quarter the water system provides water to the public. At seasonal water systems as defined in OAR 333-061-0020(168), monitoring is increased to one sample every month the system is in operation.

(A) For the purpose of determining a water supplier's eligibility to continue or qualify for quarterly monitoring according to the provisions of subparagraphs (6)(b)(C)(iv) or (6)(b)(D)(ii) of this rule at a transient non-community water system, the Authority may elect to not consider monitoring violations according to paragraph (6)(p)(A) of this rule if the missed sample is collected no later than the end of the monitoring period following the monitoring period in which the sample was missed. The water supplier must collect the make-up sample in a different week than the routine sample for that monitoring period and should collect the sample as soon as possible during the monitoring period.

(B) Water suppliers must submit to a special monitoring evaluation during each sanitary survey as specified in OAR 333-061-0076 to review the status of a water system, including the distribution system, and determine whether the system is on an appropriate monitoring schedule. After the Authority has performed the special monitoring evaluation, it may modify the system's monitoring schedule, as necessary, or it may allow the system to stay on its existing monitoring schedule, consistent with the provisions of this subsection.

(C) Monitoring must be increased to monthly the month following any of the events identified in subparagraphs (6)(b)(C)(i) through (6)(b)(C)(iv) of this rule. Monthly monitoring must continue until the requirements in subparagraph (6)(b)(D) of this rule are met. A water system prescribed monthly monitoring for reasons other than those identified in paragraphs (6)(b)(C)(i) through (6)(b)(C)(iv) of this rule is not considered to be on increased monitoring for the purposes of this paragraph and will be restored to quarterly monitoring at the discretion of the Authority.

(i) One level 2 coliform investigation or two level 1 coliform investigations are triggered as specified in OAR 333-061-0078(2) at a water system in a rolling 12 month period.

(ii) The MCL for E. coli is exceeded at a water system.

(iii) A violation as specified in OAR 333-061-0078(5) occurs at a water system.

(iv) Two violations as specified in subsection (6)(p) of this rule occur, or one violation as specified in subsection (6)(p) of this rule occurs and one level 1 coliform investigation as prescribed by OAR 333-061-0078(2) is triggered during a rolling 12-month period for a water system.

(D) The Authority may reduce the monitoring frequency from monthly monitoring as specified in paragraph (6)(b)(C) of this rule to quarterly monitoring if the criteria specified in subparagraphs (6)(b)(D)(i) and (6)(b)(D)(ii) of this rule are met.

(i) A sanitary survey, level 2 coliform investigation or an equivalent site visit was completed by the Authority or another party authorized by the Authority within the previous 12 months, and the water system was found to be free of sanitary defects and to have a protected water source; and

(ii) The water supplier ensured the following at the water system for at least the previous 12 consecutive months:

(I) No MCL exceedances as prescribed by OAR 333-061-0030(4) or 40 CFR 141.63;

(II) That all samples required by this rule and 40 CFR 141.21 were collected and reported to the Authority;

(III) No coliform investigation trigger exceedances as prescribed by OAR 333-061-0078(2); and

(IV) No coliform investigation violations as prescribed by OAR 333-061-0078(5).

(E) Additional routine monitoring the month following a total coliform-positive sample. At least three routine samples must be collected during the next month following one or more total coliform-positive samples at water systems prescribed quarterly monitoring. The Authority may waive this requirement if the conditions of subparagraphs (6)(b)(E)(i), (6)(b)(E)(ii), or (6)(b)(E)(iii) of this rule are met. Samples may either be collected at regular time intervals throughout the month or may be collected on a single day if samples are collected at different sites. The results from the analysis of additional routine samples must be used to determine if a coliform investigation trigger was exceeded as specified in OAR 333-061-0078(2).

(i) The Authority may waive the requirement to collect three routine samples as required by paragraph (6)(b)(E) of this rule if the Authority, or a party authorized by the Authority, performs a site visit before the end of the next month in which the system provides water to the public. The site visit must be sufficiently detailed to allow the Authority to determine whether additional monitoring or any corrective action is needed. A representative of the water supplier may not perform this site visit, even if the representative is a party authorized by the Authority to perform sanitary surveys.

(ii) The Authority may waive the requirement to collect three routine samples as required by paragraph (6)(b)(E) of this rule if the Authority has determined why the sample was total coliform-positive and has established that the water supplier has corrected the problem or will correct the problem before the end of the next month in which the water system serves water to the public. In this case, the Authority must document this decision to waive the following month's additional monitoring requirement in writing, have it approved and signed by an Authority supervisor who recommends such a decision, and make this document available to the EPA and public. The written documentation must describe the specific cause of the total coliform-positive sample and what action the water supplier has taken or will take to correct this problem.

(iii) The Authority will not waive the requirement to collect three additional routine samples the next month in which the system provides water to the public solely on the grounds that all repeat samples are total coliform-negative. If the Authority determines that the water supplier has corrected the contamination problem before the set of repeat samples required by subsection (6)(g) of this rule is collected, and all repeat samples were total coliform-

negative, the Authority may waive the requirement for additional routine monitoring the next month.

(c) At community water systems using only groundwater as defined in OAR 333-061-0020(89) serving 1,000 people or less, one sample must be collected for coliform bacteria every month.

(d) At water systems using surface water or GWUDI serving 1,000 people or less, one sample must be collected for coliform bacteria every month.

(e) At public water systems serving more than 1,000 people, the monitoring frequency for total coliform bacteria is based on the population served by the system, as specified in Table 34: [Table not included. See ED. NOTE.]

(f) At water systems using surface water or GWUDI without filtration treatment as specified in OAR 333-061-0032(2) and (3), at least one sample must be collected near the first service connection every day the turbidity level measured as specified in OAR 333-061-0036(5)(a)(B) exceeds 1 NTU. The sample must be analyzed for the presence of total coliform bacteria and must be collected within 24 hours of the first exceedance, unless the Authority determines that the water supplier, for logistical reasons beyond its control, cannot have the sample analyzed within 30 hours of collection and identifies an alternative sample collection schedule. Sample results from this coliform monitoring must be included in determining whether a coliform investigation trigger as specified in OAR 333-061-0078(2) was exceeded.

(g) If a sample collected as prescribed by subsections (6)(b) through (6)(f) of this rule is total coliform-positive, a set of repeat samples must be collected within 24 hours of being notified of the positive result. No fewer than three repeat samples must be collected for each total coliform-positive sample found.

(A) The Authority may extend the 24-hour limit on a case-by-case basis if a logistical problem beyond its control prevents a water supplier from collecting the repeat samples within 24 hours.

(B) All repeat samples must be collected on the same day, except that at water systems with only a single service connection the Authority may allow the required set of repeat samples to be collected over a three-day period, or the collection of a larger volume repeat sample(s) in one or more sample containers of any size as long as the total volume collected is at least 300 ml.

(C) An additional set of repeat samples must be collected if one or more repeat samples in the current set of repeat samples is total coliform-positive. The additional set of repeat samples must be collected within 24 hours of being notified of the positive result, unless the Authority extends the limit as specified in paragraph (6)(g)(A) of this rule. Water suppliers must continue to collect additional sets of repeat samples until either total coliforms are not detected in one complete set of repeat samples or the water supplier determines that a coliform investigation trigger as specified in OAR 333-061-0078(2) was exceeded as a result of a repeat sample being total coliform-positive and notifies the Authority. If a trigger identified in OAR 333-061-0078(2) is exceeded as a result of a routine sample being total coliform-positive, water suppliers are required to conduct only one round of repeat monitoring for each total coliform-positive routine sample.

(D) After a water supplier collects a routine sample and before it learns the results of the analysis of that sample, if it collects another routine sample(s) from within five adjacent service connections of the initial sample, and the initial sample, after analysis, is found to be total coliform-positive, then the water supplier may count the subsequent sample(s) as a repeat sample instead of as a routine sample.

(E) Repeat samples collected at a groundwater source

(i) If a repeat sample as specified in this subsection was collected at the location for triggered source water monitoring as specified in paragraph (6)(i)(A) of this rule and is E. coli-positive, the MCL for E. coli as specified in OAR 333-061-0030(4) was exceeded and the water supplier must also comply with subsection (6)(j) of this rule. If more than one repeat sample is collected at the monitoring location required for triggered source water monitoring, the water supplier may reduce the number of additional source water samples required by subsection (6)(j) of this rule by the number of repeat samples taken at that location that were not E. coli-positive.

(ii) If more than one repeat sample is collected at the location for triggered source water monitoring as specified in paragraph (6)(i)(A) of this rule, and more than one repeat sample is E. coli-positive, the MCL for E. coli was exceeded and the water supplier must also comply with OAR 333-061-0032(6).

(iii) If all repeat samples collected at the location for triggered source water monitoring as specified in paragraph (6)(i)(A) of this rule are E. coli-negative and a repeat sample collected at a monitoring location other than one required for triggered source water monitoring is E. coli-positive, the MCL for E. coli was exceeded, but the water supplier is not required to comply with subsection (6)(j) of this rule.

(h) Sampling for additional pathogens may be required by the Authority when specific evidence indicates the possible presence of such organisms.

(i) Groundwater source sampling requirements:

(A) At least one sample must be collected from every groundwater source for which at least 4-log treatment of viruses is not applied before or at the first customer within 24 hours of notification of a total coliform-positive sample collected as prescribed by subsections (6)(b) through (6)(f) of this rule that is not invalidated according to paragraphs (6)(a)(F) or (G) of this rule.

(i) The sample must be collected from every groundwater source in use at the time the total coliform-positive sample was collected, except as provided by subparagraph (6)(i)(A)(ii) of this rule.

(ii) If approved by the Authority, the sampling required by this subsection may be conducted at a representative groundwater source or sources at water systems with more than one ground water source. If directed by the Authority, water suppliers must request approval of a triggered source water monitoring plan that identifies one or more ground water sources that are representative of each monitoring site in a system's coliform sampling plan according to paragraph (6)(a)(I) of this rule and that the water supplier intends to use for representative sampling under this paragraph.

(iii) The Authority may extend the 24-hour time limit for the collection of samples on a case-by-case basis if the water supplier cannot collect the sample(s) within 24 hours due to circumstances beyond its control. In the case of an extension, the Authority will specify how much time the water supplier has to collect the sample(s).

(iv) A water supplier is not required to comply with the source water monitoring requirements specified in this paragraph if either of the following conditions exists:

(I) The Authority determines, and documents in writing, that the total coliform-positive sample collected as prescribed by subsections (6)(b) through (6)(f) of this rule is caused by a distribution system deficiency; or

(II) The total coliform-positive sample collected as prescribed by subsections (6)(b) through (6)(f) of this rule is collected at a location that meets Authority criteria for distribution system conditions that will cause total coliform-positive samples.

(v) Groundwater source samples required by this subsection must be collected at a location prior to any treatment unless the Authority approves an alternative sampling location. If the water system's configuration does not allow for sampling at the groundwater source, the water system must collect a sample at an Authority-approved location representative of source water quality.

(B) Additional Requirements related to wholesale water systems that use groundwater sources without providing at least 4-log inactivation of viruses for each groundwater source and purchasing water systems.

(i) If a sample collected according to subsections (6)(b) through (6)(f) of this rule at a purchasing water system is total coliform-positive, the water supplier for that purchasing system must notify the water supplier for the wholesale system(s) within 24 hours of being notified of the total coliform-positive sample.

(ii) If the water supplier for a wholesale system receives notice that a sample collected according to subsections (6)(b)

through (6)(f) of this rule at a purchasing water system it serves is total coliform-positive, the wholesaler must collect a sample from its groundwater source(s) as prescribed by paragraph (6)(i)(A) of this rule and have it analyzed for E. coli within 24 hours of notification.

(iii) If a sample collected according to subparagraph (6)(i)(A) of this rule at a wholesale system is E. coli-positive, the water supplier must notify the water supplier(s) for all purchasing water systems served by the groundwater source of the E. coli-positive source water sample within 24 hours of being notified of the result. The water supplier for the wholesale system must also meet the requirements of subsection (6)(j) of this rule.

(j) Five additional samples must be collected from the same source within 24 hours of notification of an E. coli-positive sample collected as prescribed by paragraph (6)(i)(A) or (6)(k) of this rule at a groundwater source and not invalidated according to subsection (6)(l) of this rule if the Authority does not require corrective action as prescribed by OAR 333-061-0032(6).

(k) At groundwater systems where chlorine, ultraviolet light, or another oxidant is used for disinfection, but where 4-log inactivation of viruses is not achieved, assessment monitoring must be conducted at the groundwater source to determine the potential for viral contamination.

(A) Assessment monitoring according to this subsection must include thecollection of at least one sample from each groundwater source every year. The Authority may grant written approval to conduct monitoring at one or more representative groundwater sources within a water system that draw water from the same hydrogeologic setting.

(B) A sample collected according to paragraph (6)(i)(A) of this rule or a sample collected for GWUDI determination according to OAR 333-061-0032(8) may be used to meet the requirements of this subsection.

(C) Additional Source Water Assessment Monitoring

(i) The Authority may require additional source water assessment monitoring if at least one of the following conditions occur:

(I) At least one total coliform-positive sample was collected from the groundwater source;

(II) A groundwater source having been determined by the Authority to be susceptible to fecal contamination through a Source Water Assessment (or equivalent hydrogeologic assessment wherein susceptibility is defined as a result of a highly sensitive source due to aquifer characteristics, vadose zone characteristics, monitoring history, or well construction) and the presence of a fecal contaminant source within the two-year time-of-travel zone, outreach area, or zone one area;

(III) A source that draws water from an aquifer that the Authority has identified as being fecally contaminated;

(IV) A determination by a source water assessment or equivalent hydrogeologic analysis that the groundwater source is highly sensitive, and that the source is located within an area that has a high density of underground injection control wells; or

(V) Other criteria at the discretion of the Authority.

(ii) Requirements for additional source water assessment monitoring include, but are not limited to:

(I) Collecting 12 consecutive monthly groundwater source samples for water systems that operate year-round, or monthly samples that represent each month the water system provides groundwater to the public for water systems that operate seasonally;

(II) Collecting a standard sample volume of at least 100 mL for E. coli analysis regardless of the analytical method used;

(III) Analysis of all samples for the presence of E. coli, using an analytical method as prescribed by section (1) of this rule;

(IV) Collecting samples at a location prior to any treatment unless the Authority approves a sampling location after treatment; and

(V) Collecting samples at the groundwater source, unless the water system's configuration does not allow for raw water sampling and the Authority approves an alternate sampling location that is representative of the water quality of that groundwater source.

(D) The Authority may require a groundwater source to be re-evaluated as prescribed by this subsection if geologic conditions, source pumping conditions, or fecal contaminant source conditions change over time.

(l) The Authority may invalidate an E. coli-positive groundwater source sample collected according to subsections (6)(i), (j) or (k) of this rule only under the following conditions:

(A) The water supplier or laboratory notifies the Authority in writing that improper sample analysis occurred; or

(B) The Authority determines and documents in writing that there is substantial evidence that an E. coli -positive sample is not related to source water quality.

(m) If the Authority invalidates an E. coli -positive groundwater source sample according to subsection (6)(l) of this rule, the water supplier must collect another source water sample as prescribed by subsection (6)(i) of this rule within 24 hours of being notified of the invalidation. The Authority may extend the 24-hour time limit on a case-by-case basis if the system cannot collect the source water sample within 24 hours due to circumstances beyond its control. In the case of an extension, the Authority must specify how much time the system has to collect the sample.

(n) The Authority may direct a water supplier to conduct source water assessment monitoring as prescribed by subsection (6)(k) of this rule when a new groundwater source is placed into service. Monitoring as prescribed by this subsection must begin before the groundwater source is used to provide water to the public.

(o) The Authority may require a water supplier to provide any existing information that will enable the Authority to perform an assessment to determine whether the groundwater system obtains water from a hydrogeologically sensitive aquifer.

(p) Monitoring violations.

(A) Failure to collect every required routine or additional routine sample in a compliance period is a violation of this rule.

(B) Failure to analyze for E. coli following a total coliform-positive routine sample is a violation of this rule.

(q) Every water system must undergo a sanitary survey at least every five years at a frequency determined by the authority. The Authority will review the results of each survey to determine whether the existing monitoring frequency is adequate and what additional measures, if any, the water supplier needs to undertake to improve drinking water quality.

(r) For any samples collected or analyzed for coliform bacteria on March 31, 2016 or earlier or for any repeat samples collected or analyzed for coliform bacteria after March 31, 2016 in response to a positive sample collected on March 31, 2016 or earlier, the provisions of 40 CFR 141.21(b), (c), (e), (f) and (g) apply to processing and analysis of that sample.

(7) Radionuclides:

(a) Gross alpha particle activity, Radium 226, Radium 228, and Uranium:

(A) Initial Monitoring. Community Water Systems without acceptable historical data, as defined below, must conduct initial monitoring to determine compliance with OAR 333-061-0030(5) by December 31, 2007.

(i) Samples must be collected from each entry point to the distribution system during 4 consecutive quarters before December 31, 2007 according to the following schedule:

Population — Begin initial monitoring - Complete initial monitoring by
300 or More — First quarter 2005 — Fourth quarter 2005
100-299 — First quarter 2006 — Fourth quarter 2006
Less than 100 — First quarter 2007 — Fourth quarter 2007

(ii) New systems or systems using a new source must conduct initial monitoring beginning the first quarter of operation, followed by three consecutive quarterly samples.

(iii) The Authority may waive the final two quarters of the initial monitoring at an entry point if the results of the samples from the first two quarters are below the method detection limit.

(iv) Grandparenting of historical data. A system may use monitoring data from each source or entry point collected between June 2000 and December 8, 2003 to satisfy the initial monitoring requirements.

(v) If the average of the initial monitoring results for a sampling point is above the MCL, the system must collect and analyze quarterly samples at the entry point until the system has results from four consecutive quarters that are at or below the MCL, unless the system enters into another schedule as part of a formal compliance agreement with the Authority.

(B) Reduced Monitoring. Radionuclide monitoring may be reduced to once every three years, once every six years, or once every nine years based on the following criteria:

(i) If the average of the initial monitoring result for each contaminant (gross alpha particle activity, radium-226, radium-228, and uranium) at a given entry point is below the detection limit, sampling for that contaminant may be reduced to once every nine years.

(ii) For gross alpha particle activity, combined radium 226 and radium 228, and uranium, if the average of the initial monitoring results is at or above the detection limit but at or below one-half the MCL, sampling for that contaminant may be reduced to once every six years.

(iii) For gross alpha particle activity, combined radium 226 and radium 228, and uranium, if the average of the initial monitoring results is above one-half the MCL but at or below the MCL, the system must collect one sample at that sampling point at least once every three years.

(iv) Systems must use the samples collected during the reduced monitoring period to determine the monitoring frequency for subsequent monitoring periods.

(v) If a system has a monitoring result that exceeds the MCL while on reduced monitoring, the system must collect and analyze quarterly samples at that entry point until the system has results from four consecutive quarters that are below the MCL, unless the system enters into another schedule as part of a formal compliance agreement with the Authority.

(vi) A water system with two or more wells that have been determined to constitute a "wellfield" as specified in subsection (1)(k) of this rule may reduce sampling to only those entry point(s) designated by the Authority.

(C) Compositing of samples. A system may composite up to four consecutive quarterly samples from a single entry point if the analysis is done within a year of the first sample. If the analytical result from the composited sample is greater than one-half the MCL, the Authority may direct the system to take additional quarterly samples before allowing the system to sample under a reduced monitoring schedule.

(D) Substitution of results.

(i) A gross alpha particle activity measurement may be substituted for the required radium-226 measurement if the gross alpha particle activity does not exceed 5 pCi/L.

(ii) A gross alpha particle activity measurement may be substituted for the required uranium measurement if the gross alpha particle activity does not exceed 15 pCi/L.

(iii) The gross alpha measurement shall have a confidence interval of 95 percent (1.65 where one-half is the standard deviation of the net counting rate of the sample) for radium-226 and uranium.

(iv) When a system uses a gross alpha particle activity measurement in lieu of a radium-226 or uranium measurement, the gross alpha particle activity analytical result will be used to determine the future monitoring frequency for radium-226 or uranium. If the gross alpha particle activity result is less than detection, half the method detection limit will be used to determine compliance and the future monitoring frequency.

(b) Beta particle and photon radioactivity:

(A) Community water systems designated by the Authority as "vulnerable" must sample for beta particle and photon radioactivity as follows. No waivers shall be granted:

(i) Initial samples must be collected by December 31, 2007.

(ii) Quarterly samples for beta emitters and annual samples for tritium and strontium-90 must be taken at each entry point to the distribution system. Systems already designated by the state must continue to sample until the state removes the designation.

(iii) If the gross beta particle activity minus the naturally occurring potassium-40 beta particle activity at a sample point has a running annual average less than or equal to 50 pCi/l , sampling for contaminants prescribed in subparagraph (7)(b)(A)(i) of this rule maybe reduced to once every three years.

(B) Community water systems designated by the Authority as "contaminated" by effluents from nuclear facilities and must sample for beta particle and photon radioactivity as follows. No waivers shall be granted.

(i) Systems must collect quarterly samples for beta emitters as detailed below and iodine-131 and annual samples for tritium and strontium-90 at each entry point to the distribution system. Sampling must continue until the Authority removes the designation.

(ii) Quarterly monitoring for gross beta particle activity is based on the analysis of monthly samples or the analysis of a composite of three monthly samples.

(iii) For iodine-131, a composite of five consecutive daily samples shall be analyzed once each quarter. More frequent monitoring may be required if iodine-131 is detected.

(iv) Annual monitoring for strontium-90 and tritium shall be conducted by means of the analysis of a composite of four consecutive quarterly samples or analysis of four quarterly samples.

(v) If the gross beta particle activity minus the naturally occurring potassium-40 beta particle activity at an entry point has a running annual average less than or equal to 15 pCi/l, the Authority may reduce the frequency of monitoring for contaminants prescribed in subparagraph (7)(b)(B)(i) of this rule at that entry point to every three years.

(C) For systems in the vicinity of a nuclear facility, the Authority may allow the substitution of appropriate environmental surveillance data taken in conjunction with operation of a nuclear facility for direct monitoring of man-made radioactivity by the water supplier where such data is applicable to a particular Community water system. In the event of a release, monitoring must be done at the water system's entry points.

(D) Systems may analyze for naturally occurring potassium-40 beta particle activity from the same or equivalent sample used for the gross beta particle activity analysis. Systems are allowed to subtract the potassium-40 beta particle activity value from the total gross beta particle activity value to determine if the screening level is exceeded. The potassium-40 beta particle activity must be calculated by multiplying elemental potassium concentrations (in mg/l) by a factor of 0.82.

(E) If the gross beta particle activity minus the naturally occurring potassium-40 beta particle activity exceeds the screening level, an analysis of the sample must be performed to identify the major radioactive constituents present in the sample and the appropriate doses must be calculated and summed to determine compliance with OAR 333-061-0030(5). Doses must also be calculated and combined for measured levels of tritium and strontium to determine compliance.

(F) Systems must monitor monthly at the entry point(s) which exceed the MCL listed in OAR 333-061-0030(5) beginning the month after the exceedance occurs. Systems must continue monthly monitoring until the system has established, by a rolling average of three monthly samples, that the MCL is being met. Systems who establish that the MCL is being met must return to quarterly monitoring until they meet the requirements set forth in subparagraph (7)(b)(A)(ii) or (7)(b)(B)(v) of this rule.

(c) General monitoring and compliance requirements for radionuclides.

(A) The Authority may require more frequent monitoring than specified in subsections (7)(a) and (b) of this rule, or may require confirmation samples at its discretion. The results of the initial and confirmation samples will be averaged for use in compliance determinations.

(B) Each system shall monitor at the time designated by the Authority during each compliance period. To determine compliance with 333-061-0030(5), averages of data shall be used and shall be rounded to the same number of significant figures as the MCL of the contaminant in question.

(C) Compliance.

(i) For systems monitoring more than once per year, compliance with the MCL is determined by a running annual average at each sampling point. If the average of any sampling point is greater than the MCL, then the system is out of compliance with the MCL.

(ii) For systems monitoring more than once per year, if any sample result will cause the running average to exceed the MCL at any entry point, the system is out of compliance with the MCL immediately.

(iii) Systems must include all samples taken and analyzed under the provisions of this section in determining compliance, even if that number is greater than the minimum required.

(iv) If a system does not collect all required samples when compliance is based on a running annual average of quarterly samples, compliance will be based on the running average of the samples collected.

(v) If a sample is less than the detection limit, zero will be used to calculate the annual average, unless a gross alpha particle activity is being used in lieu of radium-226 or uranium. In that case, if the gross alpha particle activity result is less than detection, one-half the detection limit will be used to calculate the annual average.

(D) The Authority has the discretion to delete results of obvious sampling or analytical errors.

(E) When the average annual maximum contaminant level for radionuclides as specified in Table 5 is exceeded, the water supplier shall, within 48 hours, report the analysis results to the Authority as prescribed in OAR 333-061-0040 and initiate the public notification procedures prescribed in 333-061-0042(2)(b)(A). [Table not included. See ED. NOTE.]

(8) Secondary contaminants:

(a) The levels listed in Table 6 of OAR 333-061-0030 represent reasonable goals for drinking water quality, but routine sampling for these secondary contaminants is not required. [Table not included. See ED. NOTE.]

(b) The Authority may however, require sampling and analysis under the following circumstances:

(A) User complaints of taste, odor or staining of plumbing fixtures.

(B) Where treatment of the water is proposed and the levels of secondary contaminants are needed to determine the method and degree of treatment.

(C) Where levels of secondary contaminants are determined by the Authority to present an unreasonable risk to health.

(c) If the results of the analyses do not exceed levels for secondary contaminants, listed in Table 6 of OAR 333-061-0030, subsequent sampling and analysis shall be at the discretion of the Authority. [Table not included. See ED. NOTE.]

(d) If the results of the analyses indicate that the levels for secondary contaminants, listed in Table 6 of OAR 333-061-0030 are exceeded, the Authority shall determine whether the contaminant levels pose an unreasonable risk to health or interfere with the ability of a water treatment facility to produce a quality of water complying with the Maximum Contaminant Levels of these rules and specify follow-up actions to be taken. [Table not included. See ED. NOTE.]

(e) During the period while any measures called for in subsection (8)(d) of this rule are being implemented, the water supplier shall follow the procedures relating to variances and permits which are prescribed in OAR 333-061-0045.

(9) Monitoring of disinfectant residuals in the distribution system

(a) All public water systems that add a disinfectant to the water supply at any point in the treatment process, or deliver water in which a disinfectant has been added to the water supply, must maintain a detectable disinfectant residual throughout the distribution system and shall measure and record the residual:

(A) At one or more representative points at a frequency that is sufficient to detect variations in chlorine demand and changes in water flow but in no case less often than twice per week; and

(B) At the same points in the distribution system and at the same times as total coliforms are sampled as prescribed by subsections (6)(b) through (6)(f) of this rule.

(b) The Authority may allow a water supplier to collect disinfectant residual samples as specified in paragraph (9)(a)(B) of this rule at points other than the total coliform sampling points at public water systems which use both a surface water source or GWUDI source and a groundwater source, if the Authority determines that such points are more representative of treated (disinfected) water quality within the distribution system. At water systems where surface water or GWUDI is used, the results of residual disinfectant concentration sampling conducted as prescribed by subsection (5)(a) of this rule for unfiltered systems or subsection (5)(b) of this rule for systems which filter, may be used in lieu of collecting separate samples.

(c) All public water systems that add chlorine for any purpose must ensure that the chlorine residual entering the distribution system after treatment is less than 4.0 mg/l.

(d) The Authority may waive the monitoring requirements specified in subsection (9)(a) of this rule for water systems that add chlorine for purposes such as the oxidation of metals or taste and odor control if a water system measures and records the residual daily and verifies that there is no remaining disinfectant residual at or before the first customer.

(e) Where chlorine is used as the disinfectant, the measurement of residual chlorine shall be by the DPD or other EPA-approved method in accordance with Standard Methods for the Examination of Water and Waste-water, and shall measure the free chlorine residual or total chlorine residual as applicable;

(f) The water supplier shall maintain a summary report of the residual disinfectant measurements and shall retain this summary report at a convenient location within or near the area served by the water system.

[ED. NOTE: Tables referenced are available from the agency.]

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 431.110, 431.150, 448.131, 448.150 & 448.273

Hist.: HD 9-1989, f. & cert. ef. 11-13-89; HD 26-1990, f. 23-26-90, cert. ef. 12-29-90; HD 7-1992, f. & cert. ef. 6-9-92; HD 12-1992, f. & cert. ef. 12-7-92; HD 3-1994, f. & cert. ef. 1-14-94; HD 11-1994, f. & cert. ef. 4-11-94; HD 1-1996, f. 1-2-96, cert. ef. 1-5-96; HD 14-1997, f. & cert. ef. 10-31-97; OHD 4-1999, f. 7-14-99, cert. ef. 7-15-99; OHD 4-1999, f. 7-14-99, cert. ef. 7-15-99; OHD 7-2000, f. 7-11-00, cert. ef. 7-15-00; OHD 23-2001, f. & cert. ef. 10-31-01; OHD 17-2002, f. & cert. ef. 10-25-02; PH 12-2003, f. & cert. ef. 8-15-03; PH 33-2004, f. & cert. ef. 10-21-04; PH 2-2006, f. & cert. ef. 1-31-06; PH 2-2008, f. & cert. ef. 2-15-08; PH 4-2009, f. & cert. ef. 5-18-09; PH 7-2010, f. & cert. ef. 4-19-10; PH 13-2012, f. & cert. ef. 9-10-12; PH 3-2013, f. & cert. ef. 1-25-13; PH 5-2016, f. 2-10-16, cert. ef. 4-1-16

333-061-0040
Reporting and Record Keeping

(1) Reporting requirements:

(a) Any person who has reason to believe that his or her actions have led to contamination of a public water system shall report that fact immediately to the water supplier and the Authority.

(b) Laboratory Reporting

(A) Analyses required by OAR 333-061-0036 and performed by an accredited laboratory as defined in OAR 333-061-0036(1)(b) must be reported on a form produced by the accredited laboratory. The laboratory analysis report must be submitted to the Authority within 10 days of the end of the month, or within 10 days of the end of the required monitoring period.

(B) Mandatory reporting requirements for primary laboratories as defined in OAR 333-061-0036(1)(b)(A). These laboratories must:

(i) Validate the results of any sample analysis and report that analysis directly to the Authority and to the water supplier within 48 hours or two business days of completing the analytical run if the samples analysis:

(I) Exceeds the MCL for nitrate as specified in OAR 333-061-0030(1); or

(II) Is positive for coliform bacteria.

(ii) Report any sample analysis directly to the Authority and to the water supplier within 24 hours or on the next business day

after validating a sample result that exceeds the MCL for any chemical analyte specified in OAR 333-061-0030 other than nitrate.

(iii) Report any sample analysis directly to the Authority and to the water supplier within 24 hours or on the next business day after obtaining a sample result from a subcontracted laboratory, if the sample analysis:

(I) Exceeds the MCL for nitrate as specified in OAR 333-061-0030(1) or is positive for coliform bacteria; or

(II) Exceeds the MCL for any chemical analyte specified in OAR 333-061-0030 other than nitrate upon validating the sample analysis.

(C) Mandatory reporting requirements for subcontracted laboratories as defined in OAR 333-061-0036(1)(b)(B). These laboratories must:

(i) Validate the results of any sample analysis and report that analysis to their client laboratory within 48 hours or two business days of completing the analytical run if the analysis:

(I) Exceeds the MCL for nitrate as specified in OAR 333-061-0030(1); or

(II) Is positive for coliform bacteria.

(ii) Report any sample analysis to their client laboratory within 24 hours or on the next business day after validating a sample result that exceeds the MCL for any chemical analyte specified in OAR 333-061-0030 other than nitrate.

(c) Water suppliers must report the following events to the Authority within 24 hours or sooner as prescribed in this subsection.

(A) The detection of any substance or pathogenic organisms in the water that has caused or is likely to cause physical suffering or illness.

(B) An exceedance of the MCL for E. coli, which must be reported to the Authority by the end of the day when the water supplier learns of the exceedance and which must be followed by public notice according to OAR 333-061-0042.

(C) Notification of an E. coli-positive routine sample, which must be reported to the Authority according to by the end of the day when the water supplier learns of the result, unless the water supplier is notified of the result after the Authority office is closed, in which case the water supplier must notify the Authority before the end of the next business day.

(D) Violation of a coliform investigation requirement as specified in OAR 333-061-0078(5), which must be followed by public notice according to OAR 333-061-0042.

(d) The water supplier using a surface water source or a groundwater source under direct influence of surface water which provides filtration treatment shall report monthly beginning June 29, 1993 or when filtration is installed, whichever is later, to the Authority the results of any test, measurement or analysis required by OAR 333-061-0036(5)(b) of these rules within 10 days after the end of the month.

(A) All systems using surface water or groundwater under the direct influence of surface water shall consult with the Authority within 24 hours, after learning:

(i) That the turbidity exceeded 5 NTU;

(ii) Of a waterborne disease outbreak potentially attributable to that water system;

(iii) That the disinfectant residual concentration in the water entering the distribution system fell below 0.2 mg/l and whether or not the residual was restored to at least 0.2 mg/l within four hours.

(B) In addition to the reporting and recordkeeping requirements in paragraph (1)(d)(A) of this rule, a public water system which provides conventional filtration treatment or direct filtration serving at least 10,000 people must report monthly to the Authority the information specified in subparagraphs (1)(d)(B)(i) and (ii) of this rule. Public water systems which provide filtration treatment other than conventional filtration treatment, direct filtration, slow sand filtration, and diatomaceous earth filtration, regardless of population served, must also meet the requirements of paragraph (1)(d)(A) of this rule and must report monthly to the Authority the information specified in subparagraph (1)(d)(B)(i) of this rule.

(i) Turbidity measurements as required by OAR 333-061-0036(5) must be reported within 10 days after the end of each month the system serves water to the public. Information that must be reported includes:

(I) The total number of filtered water turbidity measurements taken during the month;

(II) The number and percentage of filtered water turbidity measurements taken during the month which are less than or equal to the turbidity limits specified by OAR 333-061-0030(3)(b)(A) through (D);

(III) The date and value of any turbidity measurements taken during the month which exceed 1 NTU for systems using conventional filtration treatment or direct filtration, or which exceed the maximum level set by the Authority specified in OAR 333-061-0030(3)(b)(D).

(IV) The date and value of any turbidity measurements taken during the month which exceed 5 NTU for systems using slow sand filtration or diatomaceous earth filtration.

(ii) Water systems must maintain the results of individual filter monitoring for at least three years. Water systems must report that they have conducted individual filter turbidity monitoring within 10 days after the end of each month the system serves water to the public. Water systems must also report individual filter turbidity measurement results within 10 days after the end of each month the system serves water to the public only if measurements demonstrate one or more of the conditions in subparagraphs (1)(d)(B)(ii)(I) through (IV) of this rule. Water systems that use lime softening may apply to the Authority for alternative exceedance levels for the levels specified in subparagraphs (1)(d)(B)(ii)(I) through (IV) of this rule if the water system can demonstrate that higher turbidity levels in individual filters are due to lime carryover only and not due to degraded filter performance.

(I) For any individual filter that has a measured turbidity level of greater than 1.0 NTU in two consecutive measurements taken 15 minutes apart, the water system must report the filter number, the turbidity measurement, and the date(s) on which the exceedance occurred. In addition, the water system must either produce a filter profile for the filter within seven days of the exceedance (if the water system is not able to identify an obvious reason for the abnormal filter performance) and report that the profile has been produced or report the obvious reason for the exceedance.

(II) For any individual filter that has a measured turbidity level of greater than 0.5 NTU in two consecutive measurements taken 15 minutes apart at the end of the first four hours of continuous filter operation after the filter has been backwashed or otherwise taken offline, the system must report the filter number, the turbidity, and the date(s) on which the exceedance occurred. In addition, the system must either produce a filter profile for the filter within seven days of the exceedance (if the system is not able to identify an obvious reason for the abnormal filter performance) and report that the profile has been produced or report the obvious reason for the exceedance.

(III) For any individual filter that has a measured turbidity level of greater than 1.0 NTU in two consecutive measurements taken 15 minutes apart at any time in each of three consecutive months, the water system must report the filter number, the turbidity measurement, and the date(s) on which the exceedance occurred. In addition, the water system must conduct a self-assessment of the filter within 14 days of the exceedance and report that the self-assessment was conducted. The self assessment must consist of at least the following components: assessment of filter performance; development of a filter profile; identification and prioritization of factors limiting filter performance; assessment of the applicability of corrections; and preparation of a filter self-assessment report.

(IV) For any individual filter that has a measured turbidity level of greater than 2.0 NTU in two consecutive measurements taken 15 minutes apart at any time in each of two consecutive months, the water system must report the filter number, the turbidity measurement, and the date(s) on which the exceedance occurred. In addition, the water system must arrange to have a

comprehensive performance evaluation by the Authority or a third party approved by the Authority conducted no later than 30 days following the exceedance and have the evaluation completed and submitted to the Authority no later than 90 days following the exceedance.

(iii) If at any time the turbidity exceeds 1 NTU in representative samples of filtered water in a system using conventional filtration treatment or direct filtration, the system must inform the Authority as soon as possible, but no later than the end of the next business day.

(iv) If at any time the turbidity in representative samples of filtered water exceed the maximum level set by the Authority as specified in OAR 333-061-0030(3)(b)(D) for filtration technologies other than conventional filtration treatment, direct filtration, slow sand filtration, or diatomaceous earth filtration, the water system must inform the Authority as soon as possible, but no later than the end of the next business day.

(C) In addition to the reporting and recordkeeping requirements in paragraph (1)(d)(A) of this rule, a public water system which provides conventional filtration treatment or direct filtration treatment serving less than 10,000 people must report monthly to the Authority the information specified in subparagraphs (1)(d)(B)(i) of this rule and beginning January 1, 2005 the information specified in subparagraph(1)(d)(C)(i) of this rule. Public water systems which provide filtration treatment other than conventional filtration treatment, direct filtration, slow sand filtration, and diatomaceous earth filtration regardless of population served must also meet the requirements of paragraph (1)(d)(A) of this rule and must report monthly to the Authority the information specified in subparagraph (1)(d)(B)(i) of this rule.

(i) Water systems must maintain the results of individual filter monitoring for at least three years. Water systems must report that they have conducted individual filter turbidity monitoring within 10 days after the end of each month the system serves water to the public. Water systems must also report individual filter turbidity measurement results within 10 days after the end of each month the system serves water to the public only if measurements demonstrate one or more of the conditions in subparagraphs (1)(d)(C)(i)(I) through (III) of this rule. Water systems that use lime softening may apply to the Authority for alternative exceedance levels for the levels specified in subparagraphs (1)(d)(C)(i)(I) through (III) of this rule if the water system can demonstrate that higher turbidity levels in individual filters are due to lime carryover only and not due to degraded filter performance.

(I) If the turbidity of an individual filter (or the turbidity of the combined filter effluent (CFE) for systems with two or less filters that monitor CFE in lieu of individual filter monitoring) is greater than 1.0 NTU in two consecutive measurements taken 15 minutes apart, the water system must report to the Authority by the 10th day of the following month the filter number(s), the turbidity value(s) that exceeded 1.0 NTU, the corresponding date(s) of occurrence, and the cause (if known) for the elevated turbidity values. The Authority may request the water system produce a turbidity profile for the filter(s) in question.

(II) If the turbidity of an individual filter (or the turbidity of the combined filter effluent (CFE) for systems with two or less filters that monitor CFE in lieu of individual filter monitoring) is greater than 1.0 NTU in two consecutive measurements taken 15 minutes apart for three consecutive months, the water system must conduct a filter self-assessment within 14 days of the date the turbidity exceeded 1.0 NTU during the third month, unless a CPE is performed in lieu of a filter self-assessment. Systems with two filters monitoring the CFE must conduct a filter self-assessment for both filters. The self-assessment must consist of the following components: assessment of filter performance; development of a filter profile; identification and prioritization of factors limiting filter performance; assessment of the applicability of corrections; and preparation of a filter self-assessment report. When a self-assessment is required, the water system must report the date the self-assessment was triggered, the date the self-assessment was completed, and the conclusion(s) of the self-assessment by the 10th of the following month or 14 days after the self-assessment was triggered only if the self-assessment was triggered during the last four days of the month.

(III) If the turbidity of an individual filter (or the turbidity of the combined filter effluent (CFE) for systems with two or less filters that monitor CFE in lieu of individual filter monitoring) is greater than 2.0 NTU in two consecutive measurements taken 15 minutes apart for two consecutive months, the water system must report these turbidity results to the Authority by the 10th of the following month and arrange to have a comprehensive performance evaluation (CPE) by the Authority or a third party approved by the Authority conducted within 60 days of the date the turbidity exceeded 2.0 NTU during the second month. The CPE report must be submitted to the Authority no later than 120 days following the date the turbidity exceeded 2.0 NTU during the second month. A CPE is not needed if the Authority or approved third party has conducted a CPE within the last 12 months or the Authority and the water system are jointly participating in an on-going Comprehensive Technical Assistance (CTA) project as part of the Composite Correction Program with the water system. When a CPE is required, the water system must report that a CPE is required and the date that the CPE was triggered by the 10th day of the following month.

(e) The water supplier for water systems using a surface water source or a groundwater source under direct influence of a surface source which does not provide filtration treatment shall report according to subsection (1)(d) of this rule in addition to the requirements of this subsection. Monthly reporting to the Authority will begin January 1, 1991 for systems using surface water sources and January 1, 1991 or six months after the Authority determines surface influence for systems using groundwater under the direct influence of surface water.

(A) Report to the Authority within 10 days after the end of each month, the results or analysis of:

(i) Fecal coliform or total coliform bacteria test results on raw (untreated) source water.

(ii) Daily disinfection "CT" values including parameters such as pH measurements, temperature, and disinfectant residuals at the first customer used to compute the "CT" values.

(iii) Daily determinations using the "CT" values of the adequacy of disinfectant available for inactivation of Giardia lamblia or viruses as specified in OAR 333-061-0032(1)(a).

(B) Report to the Authority within 10 days after the end of each Federal Fiscal year (September 30), the results of:

(i) The watershed control program requirements as specified in OAR 333-061-0032(2)(b)(B).

(ii) The on-site inspection summary requirements as specified in OAR 333-061-0032(2)(b)(C).

(f) Special reporting requirements for groundwater systems.

(A) Groundwater systems conducting compliance monitoring in accordance with OAR 333-061-0032(7)(b) must notify the Authority any time the water system fails to meet any Authority-specified operating requirements including, but not limited to, minimum residual disinfectant concentration, membrane operating criteria or membrane integrity, and alternative treatment operating criteria, if operation in accordance with the specified criteria is not restored within four hours. The groundwater system must notify the Authority as soon as possible, but in no case later than the end of the next business day.

(B) A groundwater system must notify the Authority within 30 days of completing any corrective action as prescribed by OAR 333-061-0032(6).

(C) A groundwater system subject to the requirements of OAR 333-061-0036(6)(i) must provide documentation to the Authority within 30 days that a total coliform-positive sample met Authority criteria for exceptions to triggered source water monitoring requirements because the total coliform-positive sample was attributed to distribution system conditions.

(D) A groundwater system conducting compliance monitoring as prescribed by OAR 333-061-0032(7)(b) must report the results of daily residual disinfectant concentration measurements at the entry point within 10 days after the end of each month.

(g) All Community and Non-Transient Non-Community public water systems shall report all of the following information pertaining to lead and copper to the Authority in accordance with the requirements of this subsection.

(A) Except as provided in subparagraph (1)(h)(A)(vii) of this rule, a public water system shall report the information below for all tap water samples and for all water quality parameter samples within 10 days following the end of each applicable monitoring period. For monitoring periods with a duration less than six-months, the end of the monitoring period is the last date samples can be collected during that period.

(i) The results of all tap samples for lead and copper including the location of each site and the criteria under which the site was selected for the system's sampling pool. With the exception of initial tap sampling, the system shall designate any site which was not sampled during previous monitoring periods, and include an explanation of why sampling sites have changed. By the applicable date specified in OAR 333-061-0036(2)(c)(D)(i) for commencement of initial monitoring, each Community Water System which does not complete its targeted sampling pool meeting the criteria for tier 1 sampling sites shall send a letter to the Authority justifying its selection of tier 2 or tier 3 sampling sites. By the applicable date specified in OAR 333-061-0036(2)(c)(D)(i) for commencement of initial monitoring, each Non-Transient Non-Community water system which does not complete its sampling pool meeting the criteria for tier 1 sampling sites shall send a letter to the Authority justifying its selection of sampling sites.

(ii) A certification that each first draw sample collected by the water system is one-liter in volume and, to the best of their knowledge, has stood motionless in the service line, or in the interior plumbing of a sampling site, for at least six hours. Where residents collected samples, a certification that each tap sample collected by the residents was taken after the water system informed them of proper sampling procedures according to OAR 333-061-0036(2)(c)(B)(ii).

(iii) The results of all tap samples for pH, and where applicable, alkalinity, calcium, conductivity, temperature, and orthophosphate or silica, and the results of all samples collected at the entry point(s) to the distribution system for applicable water quality parameters according to OAR 333-061-0036(2)(c)(F)(iii) through (vi).

(iv) Each water system that requests that the Authority reduce the number and frequency of sampling shall provide the information required in OAR 333-061-0036(2)(c)(D)(iv).

(v) Documentation for each tap water lead and copper sample for which the water system requests invalidation.

(vi) The 90th percentile lead and copper tap water samples collected during each monitoring period.

(vii) A water system shall report the results of all water quality parameter samples collected for follow-up tap monitoring prescribed in OAR 333-061-0036(2)(c)(F)(iv) through (vii) during each six-month monitoring period within 10 days following the end of the monitoring period unless the Authority specifies a more frequent monitoring requirement.

(B) A water system shall report the sampling results for all source water samples collected for lead and copper within the first 10 days following the end of each source water monitoring period according to OAR 333-061-0036(2)(c)(G). With the exception of the first round of source water sampling, the system shall specify any site which was not sampled during previous monitoring periods, and include an explanation of why the sampling point has changed.

(C) Corrosion control treatment reporting requirements. By the applicable dates according to OAR 333-061-0034(2)(a) through (e), systems shall report the following information: for systems demonstrating that they have already optimized corrosion control, the information required in OAR 333-061-0034(2)(d)(B) or (C); for systems required to optimize corrosion control, their recommendation regarding optimal corrosion control treatment according to OAR 333-061-0034(3)(a); for systems required to evaluate the effectiveness of corrosion control treatments, the information required in OAR 333-061-0034(3)(c) of these rules; for systems required to install optimal corrosion control designated by the Authority according to OAR 333-061-0034(3)(i), a letter certifying that the system has completed the installation.

(D) Source water treatment reporting requirements. By the applicable dates according to OAR 333-061-0034(4)(a), systems shall report the following information to the Authority: the system's recommendation regarding source water treatment if required according to OAR 333-061-0034(4)(b)(A); for systems required to install source water treatment according to OAR 333-061-0034(4)(b)(B), a letter certifying that the system has completed the installation of the treatment designated by the Authority within 24 months after the Authority designated the treatment.

(E) Public education program reporting requirements.

(i) Any water system that is subject to the public education requirements in OAR 333-061-0034(5) shall, within 10 days after the end of each period in which the system is required to perform public education tasks in accordance with OAR 333-061-0034(5)(c), send written documentation to the Authority that contains:

(I) A demonstration that the system has delivered the public education materials that meet the content and delivery requirements specified in OAR 333-061-0034(5)(a) through (c); and

(II) A list of all the newspapers, radio stations, television stations, and facilities and organizations to which the system delivered public education materials during the period in which the system was required to perform public education tasks.

(ii) Unless required by the Authority, a system that previously has submitted the information in subparagraph (1)(g)(E)(i)(II) of this rule need not resubmit the information, as long as there have been no changes in the distribution list and the system certifies that the public education materials were distributed to the same list submitted previously.

(iii) No later than three months following the end of the monitoring period, each system must mail a sample copy of the consumer notification of tap results to the Authority along with a certification that the notification has been distributed in a manner consistent with the requirements of OAR 333-061-0034(5)(e).

(F) Any system which collects sampling data in addition to that required by this subsection shall report the results to the Authority within the first 10 days following the end of the applicable monitoring period under OAR 333-061-0036(2)(c)(A) through (H) during which the samples are collected.

(G) At a time specified by the Authority prior to the addition of a new source or any long-term change in water treatment, a water system deemed to have optimized corrosion control, or is subject to reduced monitoring, shall submit written documentation to the Authority describing the change or addition. The Authority must review and approve the addition or change before it is implemented by the water system.

(H) Each ground water system that limits water quality parameter monitoring to a subset of entry points shall provide written correspondence to the Authority that identifies the selected entry points and includes information sufficient to demonstrate that the sites are representative of water quality and treatment conditions throughout the system. This correspondence must be submitted to the Authority prior to commencement of such monitoring.

(h) The water supplier shall report to the Authority the results of any test, measurement or analysis required by these rules that is performed on site (for example, supplemental fluoride) by trained personnel within 10 days after the end of the month, except that reports which indicate that fluoride levels exceed 4.0 mg/l shall be reported within 48 hours:

(i) The water supplier shall submit to the Authority within 10 days after completing any public notification action as prescribed in OAR 333-061-0042 a representative copy of each type of notice distributed to the water users or made available to the public and the media along with certification that the system has fully complied with the distribution and public notification requirements.

(j) Water systems required to sample for the contaminants listed in OAR 333-061-0036(4)(c) through (4)(e) or (4)(g) through (4)(k) must report the information listed in Tables 35 through 37 to

the Authority. Water systems monitoring quarterly or more frequently must report to the Authority within 10 days after the end of each quarter in which samples were collected. Water systems required to sample less frequently than quarterly must report to the Authority within 10 days after the end of each monitoring period in which samples were collected. Water systems are required to submit the information listed in Tables 35 through 37, within 10 days of the end of any quarter in which monitoring is required. [Table not included. See ED. NOTE.]

(A) Disinfection byproducts. Water systems must report the information specified in Table 35 as follows: [Table not included. See ED. NOTE.]

(B) Disinfectants. Water systems must report the information specified in Table 36 as follows: [Table not included. See ED. NOTE.]

(C) Disinfection byproduct precursors and enhanced coagulation or enhanced softening. Water systems must report the information specified in Table 37 as follows: [Table not included. See ED. NOTE.]

(D) The Authority may choose to perform calculations and determine whether the MCL was exceeded or the system is eligible for reduced monitoring in lieu of having the system report that information.

(k) Systems using surface water or GWUDI sources must respond to the Authority within 45 days of receiving a sanitary survey report or comprehensive performance evaluation report that identifies significant deficiencies. The response must meet the criteria specified in OAR 333-061-0076(6)(a). Failure to report to the Authority requires a Tier 2 public notice as prescribed in OAR 333-061-0042(2)(b)(D).

(l) Reporting requirements related to triggered coliform investigations

(A) Water suppliers required to conduct a level 1 coliform investigation as prescribed by OAR 333-061-0078 must submit a completed investigation report as prescribed by OAR 333-061-0078(3) to the Authority within 30 days of learning a trigger as specified in OAR 333-061-0078(2) was exceeded. Water suppliers subject to a level 2 coliform investigation as prescribed by OAR 333-061-0078(3) must ensure a completed investigation report is submitted to the Authority within 30 days of learning a trigger as specified in OAR 333-061-0078(2) was exceeded.

(B) Water suppliers must report to the Authority the completion of every scheduled corrective action within 30 days for corrections not completed by the time the investigation report was reported to the Authority as specified in paragraph (1)(l)(A) of this rule.

(m) Water suppliers that have failed to comply with a coliform monitoring requirement as prescribed by OAR 333-061-0036(6) must report the monitoring violation to the Authority within 10 days after the water supplier discovers the violation, and notify the public in accordance with OAR 333-061-0042.

(n) Water suppliers responsible for seasonal water systems must certify in a manner determined by the Authority, that an Authority-approved start-up procedure has been completed prior to serving water to the public. Water suppliers must submit the certification to the Authority prior to the seasonal water system opening for the season and serving water to the public.

(o) Reporting source water monitoring results for Cryptosporidium and E. coli collected in accordance with OAR 333-061-0036(5)(e). Water systems must report results from the source water monitoring no later than 10 days after the end of the first month following the month when the sample is collected as prescribed by this subsection.

(A) Water systems must report the following data elements for each Cryptosporidium analysis: PWS ID, facility ID, sample collection date, sample type (field or matrix spike), sample volume filtered in Liters (to nearest 250 mL), whether 100 percent of the filtered volume was examined, and the number of oocysts counted.

(i) For matrix spike samples, water systems must also report the sample volume spiked and estimated number of oocysts spiked. These data are not required for field samples.

(ii) For samples in which less than 10 L is filtered or less than 100 percent of the sample volume is examined, systems must also report the number of filters used and the packed pellet volume.

(iii) For samples in which less than 100 percent of sample volume is examined, systems must also report the volume of re-suspended concentrate and volume of this re-suspension processed through immunomagnetic separation.

(B) Water systems must report the following data elements for each E. coli analysis: PWS ID, facility ID, sample collection date, analytical method number, method type, source type (flowing stream, lake/reservoir, or GWUDI), E. coli/100 mL, and turbidity (if required).

(p) Reporting requirements relating to Cryptosporidium protection.

(A) Water systems must report sampling schedules prescribed by OAR 333-061-0036(5)(f) and source water monitoring results in accordance with subsection (1)(p) of this rule unless they notify the Authority that they will not conduct source water monitoring due to meeting the criteria of OAR 333-061-0036(5)(e)(D).

(B) Filtered water systems must report their Cryptosporidium bin classification as described in OAR 333-061-0032(4)(f).

(C) Unfiltered water systems must report their mean source water Cryptosporidium level as described in OAR 333-061-0032(2)(c).

(D) Water systems must report disinfection profiles and benchmarks to the Authority as prescribed by OAR 333-061-0036(4)(l) and 333-061-0060(1)(e) prior to making a significant change in disinfection practice.

(E) Water systems must report to the Authority any microbial toolbox options as specified in Table 38 used to comply with treatment requirements under OAR 333-061-0032(2)(c), (3)(e) through (g), and (4)(g). Alternatively, the Authority may approve a water system to operate within required parameters for treatment credit rather than reporting monthly operational data for toolbox options. [Table not included. See ED. NOTE.]

(q) Water systems must report the use of uncovered finished water storage facilities to the Authority as described in OAR 333-061-0032(12).

(r) Reporting violations

(A) Failure to report coliform sampling results as required by OAR 333-061-0036(6) after monitoring was properly conducted in a timely manner is a violation of this rule.

(B) Failure to submit a completed coliform investigation report form after conducting an investigation or failure to ensure a coliform investigation report is submitted following a level 2 coliform investigation is a violation of this rule.

(C) Failure to notify the Authority following an E. coli-positive sample as required by paragraph (1)(c)(C) of this rule is a violation of this rule.

(D) Failure to certify and report completion of an Authority-approved start-up procedure at a seasonal water system as required by subsection (1)(n) of this rule is a violation of this rule.

(2) Record Maintenance by Water Suppliers:

(a) Water suppliers of public water systems shall retain records relating to the quality of the water produced and the condition of the physical components of the system. These records shall be kept at a convenient location within or near the area served by the water system;

(b) Records of microbiological analyses shall be kept for at least five years. Records of chemical analyses, secondary contaminants, turbidity, radioactive substances, and monitoring plans shall be kept for at least 10 years. Data may be transferred to tabular summaries provided the following information is included:

(A) Date, place and time of sampling, and the name of the person who collected the sample;

(B) Identification of the sample as to whether it was a routine finished water sample, repeat sample, raw water sample or special purpose sample;

(C) Date and time of the analysis, the laboratory and person performing the analysis; and,

(D) Analytical method used and results of the analysis.

(c) Records of actions taken to correct items of non-compliance shall be kept for at least three years after the last action taken with respect to the particular violation;

(d) Reports, summaries or communications on sanitary surveys shall be kept for at least 10 years;

(e) Records concerning variances or permits shall be kept for at least five years after the expiration of the variance or permit;

(f) Records of residual disinfectant measurements shall be kept for at least two years.

(g) All public water systems subject to the requirements of subsection (1)(f) of this rule shall retain the original records of all sampling data and analyses, reports, surveys, letters, evaluations, schedules, Authority determinations, and any other information required for no fewer than 12 years.

(h) Copies of public notices issued pursuant to OAR 333-061-0042 and certifications made to the Authority must be kept for three years after issuance.

(i) For water systems using surface water or groundwater under the direct influence of surface water that uses conventional filtration treatment or direct filtration treatment and that recycles spent filter backwash water, thickener, supernatant, or liquids from dewatering processes, water suppliers must collect and retain on file recycle flow information specified in paragraphs (2)(i)(A) through (F) of this rule for review and evaluation by the Authority:

(A) Copy of the recycle notification and information submitted to the Authority as required by OAR 333-061-0032(11);

(B) List of all recycle flows and the frequency with which they are returned;

(C) Average and maximum backwash flow rate through the filters and the average and maximum duration of the filter backwash process in minutes;

(D) Typical filter run length and a written summary of how filter run length is determined;

(E) The type of treatment provided for the recycle flow;

(F) Data on the physical dimensions of the equalization or treatment units, typical and maximum hydraulic loading rates, type of treatment chemicals used and average dose and frequency of use, and frequency at which solids are removed, if applicable.

(j) Water suppliers must maintain the following information in their records relating to water systems using groundwater sources:

(A) Documentation of corrective actions for a period of not less than 10 years;

(B) Documentation of notice to the public as prescribed by OAR 333-061-0042(8) for a period of not less than three years;

(C) Records of decisions made in accordance with OAR 333-061-0036(6)(i)(A)(iv) and records of invalidation of E. coli - positive groundwater source samples in accordance with OAR 333-061-0036(6)(l) for a period of not less than five years;

(D) For purchasing water systems, documentation of notification to the wholesale system(s) of total-coliform positive samples not invalidated in accordance under OAR 333-061-0036(6)(a)(F) for a period of not less than five years; and

(E) For any water system required to perform compliance monitoring in accordance with OAR 333-061-0032(7)(b):

(i) Records of the Authority-specified minimum disinfectant residual for a period of not less than ten years;

(ii) Records of the lowest daily residual disinfectant concentration and records of the date and duration of any failure to maintain the Authority-prescribed minimum residual disinfectant concentration for a period of more than four hours for a period of not less than five years; and

(iii) Records of Authority-specified compliance requirements for membrane filtration, parameters specified by the Authority for Authority-approved alternative treatment, and records of the date and duration of any failure to meet the membrane operating, membrane integrity, or alternative treatment operating requirements for more than four hours for a period of not less than five years.

(k) For systems required to compile a disinfection profile, the results of the profile (including raw data and analysis) must be kept indefinitely as well as the disinfection benchmark (including raw data and analysis) determined from the profile.

(l) Recordkeeping requirements pertaining to Cryptosporidium protection. Water systems must keep:

(A) Results from the source water monitoring prescribed by OAR 333-061-0036(5)(e) for three years after bin classification in accordance with OAR 333-061-0032(4)(f) for filtered systems, or determination of the mean Cryptosporidium level in accordance with OAR 333-061-0032(2)(c) for unfiltered systems for the particular round of monitoring.

(B) Any notification to the Authority that they will not conduct source water monitoring due to meeting the criteria specified in OAR 333-061-0036(5)(e)(D) for three years.

(C) The results of treatment monitoring associated with microbial toolbox options as prescribed by OAR 333-061-0032(14) through (18) and with uncovered finished water reservoirs in accordance with OAR 333-061-0032(12)(b), as applicable, for three years.

(m) IDSE reports (including Authority modifications) must be kept for at least 10 years. IDSE standard monitoring plans and IDSE system specific study plans must be retained at least as long as the IDSE report or any Authority modifications, whichever is longer. IDSE reports and any Authority modification must be made available for review by the Authority or the public.

(n) Water systems must retain a complete copy of any 40/30 certification submitted to the EPA for 10 years after the date the certification was submitted. The certification, all data upon which the certification is based, and any EPA notification must be available for review by the Authority or the public.

(o) Water suppliers must maintain any coliform investigation form, regardless of who conducts the investigation, and documentation of corrective actions completed as a result of those investigations, or other available summary documentation of the sanitary defects and corrective actions taken as specified in OAR 333-061-0078 for Authority review. This record must be maintained for a period not less than five years after completion of the coliform investigation or corrective action, whichever is later.

(p) Water suppliers must maintain a record of any repeat sample collected that meets Authority criteria for an extension of the 24-hour period for collecting repeat samples as provided for in OAR 333-061-0036(6)(g).

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 431.110, 431.150, 448.175 & 448.273

Hist.: HD 17-1981(Temp), f. & ef. 8-28-81; HD 4-1982, f. & ef. 2-26-82; Renumbered from 333-042-0212, HD 2-1983, f. & ef. 2-23-83; HD 21-1983, f. 10-20-83, ef. 11-1-83; HD 11-1985, f. & ef. 7-2-85; HD 30-1985, f. & ef. 12-4-85; HD 3-1987, f. & ef. 2-17-87; HD 3-1988(Temp), f. & cert. ef. 2-12-88; HD 17-1988, f. & cert. ef. 7-27-88; HD 9-1989, f. & cert. ef. 11-13-89; HD 26-1990, f. 12-26-90, cert. ef. 12-29-90; HD 12-1992, f. & cert. ef. 12-7-92; HD 3-1994, f. & cert. ef. 1-14-94; HD 1-1996, f. 1-2-96, cert. ef. 1-5-96; OHD 7-2000, f. 7-11-00, cert. ef. 7-15-00; OHD 23-2001, f. & cert. ef. 10-31-01; OHD 17-2002, f. & cert. ef. 10-25-02; PH 12-2003, f. & cert. ef. 8-15-03; PH 33-2004, f. & cert. ef. 10-21-04; PH 2-2006, f. & cert. ef. 1-31-06; PH 2-2008, f. & cert. ef. 2-15-08; PH 4-2009, f. & cert. ef. 5-18-09; PH 7-2010, f. & cert. ef. 4-19-10; PH 3-2013, f. & cert. ef. 1-25-13; PH 5-2016, f. 2-10-16, cert. ef. 4-1-16

333-061-0042
Public Notice

(1) The owner or operator of a public water system must provide public notice to persons served by the water system for all violations and situations established by these rules.

(a) Public water systems that provide drinking water to purchasing water systems are required to give public notice to the owner or operator of the purchasing water system who is responsible for providing public notice to the persons it serves.

(b) If a public water system has a violation in a portion of the distribution system that is physically or hydraulically isolated from other parts of the distribution system, the Authority may, in writing, allow the system to limit distribution of the public notice to only persons served by that portion of the system which is out of compliance.

(c) A copy of any public notice must be sent to the Authority as required in OAR 333-061-0040(1)(i).

(2) Public notice requirements are divided into three tiers to take into account the seriousness of the violation or situation and of any potential adverse health effects that may be involved:

(a) Tier 1: A Tier 1 notice is required for violations and situations with significant potential to have serious adverse effects on human health as a result of short-term exposure, including but not limited to the following:

(A) Exceeding the MCL for E. Coli as specified in OAR 333-061-0030(4);

(B) Exceeding the MCL for nitrate, nitrite, or total nitrate and nitrite, or when the water system fails to take a confirmation sample within 24 hours of the system's receipt of the first sample showing an exceedance of the nitrate or nitrite MCL;

(C) Exceeding the MRDL for chlorine dioxide as prescribed in OAR 333-061-0031 when one or more samples taken in the distribution system the day following an exceedance of the MRDL at the entrance of the distribution system exceed the MRDL, or when the water system does not take the required samples in the distribution system;

(D) Violation of the interim operating plan for turbidity for a surface water system that does not meet the exception criteria for avoiding filtration under OAR 333-061-0032 nor has installed filtration treatment as defined by these rules when the Authority determines after consultation that a Tier 1 notice is required or where consultation does not take place within 24 hours after the system learns of the violation;

(E) Violation of a surface water treatment requirement as prescribed in OAR 333-061-0032, resulting from a single exceedance of the maximum allowable turbidity limit, where the Authority determines after consultation that a Tier 1 notice is required or where consultation does not take place within 24 hours after the system learns of the violation;

(F) Occurrence of a waterborne disease outbreak or other waterborne emergency, such as a failure or significant interruption in key water treatment processes, a natural disaster that disrupts the water supply or distribution system, or a chemical spill or unexpected loading of possible pathogens into the source water that significantly increases the potential for drinking water contamination;

(G) Detection of E. coli in source water samples collected as specified in OAR 333-061-0036(6)(i) through (k); and

(H) Other violations or situations with significant potential to have serious adverse effects on human health as a result of short term exposure, as determined by the Authority.

(b) Tier 2: required for all violations and situations with potential to have serious adverse effects on human health, including but not limited to:

(A) All violations of the MCL, MRDL, and treatment technique requirements, except where a Tier 1 notice is required or where the Authority determines that a Tier 1 notice is required.

(B) Violations of the monitoring and testing procedure requirements, where the Authority determines that a Tier 2 rather than a Tier 3 public notice is required, taking into account potential health impacts and persistence of the violation.

(C) Failure to comply with the terms and conditions of any variance or permit in place.

(D) Failure to respond to sanitary survey reports or comprehensive performance evaluation reports prepared by the Authority as required in OAR 333-061-0076 and 333-061-0077.

(E) Use of an emergency groundwater source that has been identified as potentially under the direct influence of surface water, but has not been fully evaluated.

(F) Failing to comply with groundwater treatment or corrective action requirements specified in OAR 333-061-0032.

(G) Failing to complete a coliform investigation or corrective action related to a coliform investigation as prescribed by OAR 333-061-0078.

(H) Failing to complete or follow an Authority approved start-up procedure prior to serving water to the public at a seasonal water system.

(c) Tier 3: required for other violations or situations not included in Tier 1 and 2, including but not limited to:

(A) Failing to conduct monitoring or reporting as prescribed by these rules except where the Authority determines a Tier 1 or Tier 2 notice is required;

(B) Failure to comply with a testing procedure established in these rules except where a Tier 1 notice is required or where the Authority determines that a Tier 2 notice is required;

(C) Operation under a variance or permit granted by the Authority;

(D) Availability of unregulated contaminant monitoring results as required under section (6) of this rule;

(E) Exceedance of the fluoride secondary MCL as required under section (7) of this rule; and

(F) Disinfection profiling and benchmarking monitoring and testing violations.

(G) Failing to submit a completed investigation report or notify the Authority when corrective action is completed related to a coliform investigation as prescribed by OAR 333-061-0078.

(H) Failing to certify to the Authority upon completing an Authority approved start-up procedure at a seasonal water system.

(I) Failure to analyze for E. coli following a total coliform-positive routine sample collected according to OAR 333-061-0036(6)(b) through (g).

(J) Failure to notify the Authority following an E. coli-positive sample in a timely manner as required by OAR 333-061-0036(6)(a)(D).

(K) Failure to conduct recordkeeping as prescribed by OAR 333-061-0040(2)(o) or (p).

(d) The Authority may require public notice for violations or other situations not listed in this section, or a higher tier of public notice for specific violations and situations listed in this section.

(3) All public notices established by these rules shall be distributed in the form, manner and frequency as described in this section:

(a) Tier 1 notices: public water systems required to distribute Tier 1 notices must:

(A) Provide the notice as soon as practical, but no later than 24 hours after learning of the violation or situation;

(B) Initiate consultation with the Authority as soon as practical, but no later than 24 hours after learning of the violation or situation;

(C) Comply with any additional notification requirements established as a result of consultation with the Authority;

(D) The form and manner used by the public water system are to fit the specific situation, but must be designed to reach residential, transient, and non-transient users of the water system. In order to reach all persons served, one or more of the following forms of delivery must be used:

(i) Appropriate broadcast media such as radio and television;

(ii) Posting of the notice in conspicuous locations throughout the area served by the water system;

(iii) Hand delivery of the notice to persons served by the water system; or

(iv) Another delivery method approved in writing by the Authority.

(b) Tier 2 notices: water suppliers required to distribute Tier 2 notices must:

(A) Provide the public notice as soon as practical, but no later than 30 days after learning of the violation or situation. The Authority may, in writing, extend additional time for the initial notice of up to three months in appropriate circumstances;

(B) If the public notice is posted, leave the notice in place as long as the violation or situation exists, but in no case for less than seven days, even if the violation or situation is resolved;

(C) Repeat the notice every three months as long as the violation or situation persists.

(D) For the turbidity violations specified in subparagraphs (3)(b)(D)(i) and (ii) of this rule, public water systems must consult with the Authority as soon as practical, but no later than 24 hours after learning of the violation to determine whether a Tier 1 public

notice is required to protect public health. When consultation with the Authority does not take place within the 24 hour period, the water system must distribute a Tier 1 notice of the violation within the next 24 hours as prescribed in subsection (3)(a) of this rule:

(i) Violation of the interim operating plan for turbidity for a surface water system that does not meet the exception criteria for avoiding filtration under OAR 333-061-0032 nor has installed treatment as defined by these rules; or

(ii) Violation of the SWTR, LT1ESWTR, or IESWTR treatment technique requirement as prescribed in OAR 333-061-0032, resulting from a single exceedance of the maximum allowable turbidity limit.

(E) The form and manner used by the public water system for initial and repeat notices must be calculated to reach persons served by the system in the required time period. The form and manner may vary based on the specific situation and type of water system, but it must at a minimum meet the following requirements:

(i) Unless directed otherwise by the Authority in writing, community water systems must provide notice by:

(I) Mail or other direct delivery to each customer receiving a bill and to other service connections to which water is delivered by the public water system; and

(II) Any other method reasonably calculated to reach other persons regularly served by the water system who would not normally be reached by mail or direct delivery. Other methods may include: local newspapers, delivery of multiple copies for distribution, posting, e-mail and community organizations.

(ii) Unless directed otherwise by the Authority in writing, non-community water systems must provide notice by:

(I) Posting the notice in conspicuous locations frequented by users throughout the distribution system, or by mail or direct delivery to each customer or connection; and

(II) Any other method reasonably calculated to reach other persons not normally reached by posting, mail or direct delivery. Other methods may include: local newspaper, newsletter, e-mail and multiple copies in central locations.

(c) Tier 3 notices: public water systems required to distribute Tier 3 notices must:

(A) Provide the public notice not later than one year after learning of the violation or situation or begins operating under a variance or permit. Following the initial notice, the system must repeat the notice annually for as long as the violation, variance, permit or other situation persists. If the public notice is posted, the notice must remain in place for as long as the violation, variance, permit, or other situation persists, but in no case less than seven days even if the violation or situation is resolved.

(B) Instead of individual Tier 3 public notices, a community public water system may use its annual Consumer Confidence Report (CCR) for the initial and all repeat notices detailing all violations and situations that occurred during the previous twelve months. This method may be used as long as it is distributed within the one year requirement in paragraph (3)(c)(A) of this rule, follows the public notice content required under section (4) of this rule and is delivered to users as required under paragraph (3)(c)(C) of this rule.

(C) The form and manner used by the public water system for initial and repeat notices must be calculated to reach persons served by the system in the required time period. The form and manner may vary based on the specific situation and type of water system, but it must at a minimum meet the following requirements:

(i) Unless directed otherwise by the Authority in writing, community water systems must provide notice by:

(I) Mail or other direct delivery to each customer receiving a bill and to other service connections to which water is delivered by the public water system; and

(II) Any other method reasonably calculated to reach other persons regularly served by the water system who would not normally be reached by mail or direct delivery. Other methods may include: local newspapers, delivery of multiple copies for distribution, posting, e-mail and community organizations.

(ii) Unless directed otherwise by the Authority in writing, non-community water systems must provide notice by:

(I) Posting the notice in conspicuous locations frequented by users throughout the distribution system, or by mail or direct delivery to each customer or connection; and

(II) Any other method reasonably calculated to reach other persons not normally reached by posting, mail or direct delivery. Other methods may include: local newspaper, newsletter, e-mail and delivery of multiple copies in central locations.

(4) Content of Public Notice:

(a) When a public water system has a violation or situation prescribed in these rules requiring a public notice, each public notice must include the following elements:

(A) A description of the violation or situation, including the contaminant(s) of concern, and the contaminant level;

(B) When the violation or situation occurred;

(C) Any potential adverse health effects including the standard language required under paragraphs (4)(d)(A) and (B) of this rule;

(D) The population at risk, including subpopulations particularly vulnerable if exposed to the contaminant in their drinking water;

(E) Whether alternative water supplies should be used;

(F) What actions consumers should take, including when they should seek medical help, if known;

(G) What the system is doing to correct the violation or situation;

(H) When the water system expects to return to compliance or resolve the situation;

(I) The name, business address, and phone number of the water system owner, operator, or designee of the public water system as a source of additional information concerning the notice; and

(J) A statement to encourage the notice recipient to distribute the public notice to other persons served, using the standard language under paragraph (4)(d)(C) of this rule.

(b) Content of public notices for public water systems operating under a variance or permit:

(A) If a public water system has been granted a variance or permit, the public notice must contain:

(i) An explanation of the reasons for the variance or permit;

(ii) The date on which the variance of permit was issued;

(iii) A brief status report on the steps the system is taking to install treatment, find alternative sources of water or otherwise comply with the terms and schedules of the variance or permit; and

(iv) A notice of any opportunity for public input in the review of the variance or permit.

(B) If a public water system violates the conditions of a variance or permit, the public notice must contain the ten elements listed in subsection (4)(a) of this rule.

(c) Public notice presentation:

(A) Each public notice required by these rules must:

(I)Be displayed in a conspicuous way when printed or posted;

(ii) Not contain overly technical language or very small print;

(iii) Not be formatted in a way that defeats the purpose of the notice;

(iv) Not contain language which nullifies the purpose of the notice.

(B) Each public notice required by these rules must comply with multilingual requirements as follows:

(i) For public water systems serving a large proportion of non-English speaking consumers, as determined by the Authority, the public notice must contain information in the appropriate language(s) regarding the importance of the notice or contain a telephone number or address where persons served may contact the water system to obtain a translated copy of the notice or to request assistance in the appropriate language.

(ii) In cases where the Authority has not determined what constitutes a large proportion of non-English speaking consumers, the public water system must include in the public notice the same information required in subparagraph (4)(c)(B)(i) of this rule

where appropriate to reach a large proportion of non-English speaking persons served by the water system.

(d) Standard language: public water systems are required to include the following standard language in their public notice:

(A) Public water systems must include in each public notice the specific health effects language as prescribed in OAR 333-061-0097 for each MCL, MRDL, and treatment technique violation and for each violation of a condition of a variance or permit.

(B) Public water systems must include the following language in their notice, including the language necessary to fill in the blanks, for all monitoring and testing procedure violations:

We are required to monitor your drinking water for specific contaminants on a regular basis. Results of regular monitoring are an indicator of whether or not your drinking water meets health standards. During {compliance period}, we "did not monitor or test" or "did not complete all monitoring or testing" for {contaminants(s)}, and therefore cannot be sure of the quality of your drinking water during that time.

(C) Public water systems are required where applicable to include the following standard language to encourage the distribution of the public notice to all persons served:

Please share this information with all the other people who drink this water, especially those who may not have received this notice directly (for example, people in apartments, nursing homes, schools, and businesses). You can do this by posting this notice in a public place or distributing copies by hand or mail.

(5) Notice to new billing units or new customers:

(a) Community water systems must give a copy of the most recent public notice for any continuing violation, the existence of a variance or permit, or other ongoing situations requiring a public notice to all new billing units or new customers prior to or at the time service begins.

(b) Non-community water systems must continuously post the public notice in conspicuous locations in order to inform new consumers of any continuing violation, variance or permit, or other situations requiring a public notice for as long as the violation, variance, permit, or other situation persists.

(6) Special notice of availability of unregulated contaminant monitoring results:

(a) The owner or operator of a community water system or non-transient, non-community water systems required by EPA to monitor for unregulated contaminants must notify persons served by the system of the availability of the results of such sampling no later than 12 months after the monitoring results are known.

(b) The form and manner of the public notice must follow the requirements for a tier 3 public notice as prescribed in paragraphs (3)(c)(B) and (C) of this rule. The notice must also identify a person and provide the telephone number to contact for information on the monitoring results.

(7) Special notice for exceedance of the SMCL for fluoride:

(a) Community water systems that exceed the fluoride secondary MCL of 2 mg/l, determined by the last single sample taken in accordance with OAR 333-061-0036(2), but do not exceed the MCL of 4 mg/l for fluoride must provide the public notice in subsection (7)(d) of this rule to persons served by the water system. Public notice must be provided as soon as practical but no later than 12 months from the day the water system learns of the exceedance. The public water system must repeat the notice at least annually for as long as the exceedance persists. The Authority may require an initial notice sooner than 12 months and repeat notices more frequently than annually on a case-by-case basis;

(b) A copy of the notice must also be sent to all new billing units and new customers at the time service begins and to the Authority. If the public notice is posted, the notice must remain in place for as long as the secondary MCL is exceeded, but in no case less than seven days, even if the exceedance is eliminated;

(c) The form and manner of the public notice, including repeat notices must follow the requirements for tier 3 public notice;

(d) The notice must contain the following language, including the language necessary to fill in the blanks:

This is an alert about your drinking water and a cosmetic dental problem that might affect children under nine years of age. At low levels, fluoride can help prevent cavities, but children drinking water containing more than 2 mg/l of fluoride may develop cosmetic discoloration of their permanent teeth (dental fluorosis). The drinking water provided by your community water system {name} has a fluoride concentration of {insert value} mg/l.

Dental fluorosis, in its moderate or severe forms, may result in a brown staining or pitting of the permanent teeth. This problem occurs only in developing teeth, before they erupt from the gums. Children under nine should be provided with alternative sources of drinking water or water that has been treated to remove the fluoride to avoid the possibility of staining and pitting of their permanent teeth. You may also want to contact your dentist about proper use by young children of fluoride-containing products. Older children and adults may safely drink the water.

Drinking water containing more than 4 mg/l of fluoride (the U.S. EPA's drinking water standard) can increase your risk of developing bone disease. Your drinking water does not contain more than 4 mg/l of fluoride, but we're required to notify you when we discover that the fluoride levels in your drinking water exceed 2 mg/l because of this cosmetic dental problem.

For more information, please call {name of water system contact} of {name of community water system} at {phone number}. Some home water treatment units are also available to remove fluoride from drinking water. To learn more about available home water treatment units, you may call NSF International at 1-877-8-NSF-HELP.

(8) Special notice to the public for significant deficiencies or source water fecal contamination.

(a) A community water system that uses groundwater and that receives notification from the Authority of a significant deficiency or of an E. coli-positive groundwater source sample, that is not invalidated in accordance with OAR 333-061-0036(6)(l), must inform the public served by the water system of the E. coli-positive source sample or the significant deficiency that has not been corrected as prescribed by OAR 333-061-0043(5). The water system must continue to inform the public annually until the significant deficiency is corrected, or the fecal contamination in the groundwater source is determined by the Authority to be corrected in accordance with OAR 333-061-0032(6).

(b) A non-community groundwater system that receives notice from the Authority of a significant deficiency must inform the public served by the water system in a manner approved by the Authority of the significant deficiency if it has not been corrected within 12 months of the notification by the Authority. The water system must continue to inform the public annually until the significant deficiency is corrected. The information must include:

(A) The nature of the significant deficiency and the date the significant deficiency was identified by the Authority;

(B) The Authority-approved plan and schedule for correction of the significant deficiency, including any interim measures, progress to date, and any interim measures completed; and

(C) For water systems with a large proportion of non-English speaking consumers as determined by the Authority, information must be distributed in the appropriate language(s) regarding the importance of the notice or a telephone number or address where consumers may contact the system to obtain a translated copy of the notice or assistance in the appropriate language.

(c) If directed by the Authority, a non-community water system with significant deficiencies that have been corrected must inform its customers of the significant deficiencies, how the deficiencies were corrected, and the dates of correction under subsection (8)(b) of this rule.

(9) Special notice for repeated failure to conduct monitoring of the source water for Cryptosporidium and for failure to determine bin classification or mean Cryptosporidium level.

(a) Special notice for repeated failure to monitor. The owner or operator of a community or non-community water system that is required to monitor source water in accordance with OAR 333-061-0036(5)(e) must notify persons served by the water system that monitoring has not been completed as required no later than 30 days after the system has failed to collect any three months of monitoring as specified in Table 33. The notice must be repeated as specified in subsection (3)(b) of this rule. [Table not included. See ED. NOTE.]

(b) Special notice for failure to determine bin classification or mean Cryptosporidium level. The owner or operator of a community or non-community water system that is required to determine a bin

classification in accordance with OAR 333-061-0032(4)(f), or to determine a mean Cryptosporidium level as prescribed by OAR 333-061-0032(2)(c), must notify persons served by the water system that the determination has not been made as required no later than 30 days after the system has failed to report the determination in accordance with OAR 333-061-0032(2)(c)(A) through (D) or OAR 333-061-0032(4)(f)(G) and (H).

(A) The notice must be repeated as specified in subsection (3)(b) of this rule.

(B) The notice is not required if the system is complying with an Authority approved schedule to address the violation.

(c) The form and manner of the special notice must follow the requirements for a Tier 2 public notice as prescribed in subsection (3)(b) of this rule. The special notice must be presented as required by subsection (4)(c) of this rule.

(d) The special notice must contain the following language, including system specific language for the text within the braces.

(A) The special notice for repeated failure to conduct monitoring must contain:

{Water system name} is required to monitor the source of your drinking water for Cryptosporidium. Results of the monitoring are to be used to determine whether water treatment at the {treatment plant name} is sufficient to adequately remove Cryptosporidium from your drinking water. We are required to complete this monitoring and make this determination by {required bin determination date}. We ``did not monitor or test'' or ``did not complete all monitoring or testing'' on schedule and, therefore, we may not be able to determine by the required date what treatment modifications, if any, must be made to ensure adequate Cryptosporidium removal. Missing this deadline may, in turn, jeopardize our ability to have the required treatment modifications, if any, completed by the deadline required, {date}. For more information, please call {name of water system contact} of { water system name} at {phone number}.

(B) The special notice for failure to determine bin classification or mean Cryptosporidium level must contain the following language:

{Water system name} is required to monitor the source of your drinking water for Cryptosporidium in order to determine by {date} whether water treatment at the {treatment plant name} is sufficient to adequately remove Cryptosporidium from your drinking water. We have not made this determination by the required date. Our failure to do this may jeopardize our ability to have the required treatment modifications, if any, completed by the required deadline of {date}. For more information, please call {name of water system contact} of {water system name} at {phone number}.

(C) Each special notice must also include a description of what the system is doing to correct the violation and when the system expects to return to compliance or resolve the situation.

(10) Public notification by the Authority. The Authority may give notice to the public required by this section on behalf of the owner or operator of the public water system. However, the owner or operator of the public water system remains legally responsible for ensuring that the requirements of this section are met.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 448.131

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333-061-0043
Consumer Confidence Reports

This rule establishes the minimum requirements for the content of annual reports that community water systems must deliver to their customers. These reports must contain information on the quality of the water delivered by the systems and characterize the risks (if any) from exposure to contaminants detected in the drinking water in an accurate and understandable manner. For the purpose of this rule, customers are defined as billing units or service connections to which water is delivered by a Community Water System.

(1) Delivery deadlines:

(a) Community water systems must deliver their reports by July 1, annually. The report must contain data collected during, or prior to, the previous calendar year;

(b) A new community water system must deliver its first report by July 1 of the year after its first full calendar year in operation and annually thereafter;

(c) A community water system that sells water to another community water system must deliver the applicable information to the buyer system:

(A) No later than April 1, annually; or

(B) On a date mutually agreed upon by the seller and the purchaser, and specifically included in a contract between the parties.

(2) Content of the Reports:

(a) Each community water system must provide to its customers an annual report that contains the information specified in sections (2), (3), (4), and (5) of this rule;

(b) Each report must identify the source(s) of the water delivered by the community water system by providing information on:

(A) The type of water: for example, surface water, ground water; and

(B) The commonly used name (if any) and location of the body (or bodies) of water.

(c) If a source water assessment has been completed, the report must notify consumers of the availability of this information and the means to obtain it. In addition, systems are encouraged to highlight in the report significant potential sources of contamination in the drinking water protection area if they have readily available information. Where a system has received a source water assessment from the Authority, the report must include a brief summary of the system's susceptibility to potential sources of contamination, using language provided by the Authority or written by the operator;

(d) Each report must contain the following definitions:

(A) Maximum Contaminant Level Goal or MCLG: The level of a contaminant in drinking water below which there is no known or expected risk to health. MCLGs allow for a margin of safety;

(B) Maximum Contaminant Level or MCL: The highest level of a contaminant that is allowed in drinking water. MCLs are set as close to the MCLGs as feasible using the best available treatment technology.

(C) Variance: A system operating under a variance as prescribed in OAR 333-061-0045 must include the following definition in its report: Variances: State permission not to meet an MCL or a treatment technique under certain conditions;

(D) Treatment Technique or Action Level: A system which has a detection for a contaminant for which EPA has set a treatment technique or an action level must include one or both of the following definitions as applicable:

(i) Treatment Technique: A required process intended to reduce the level of a contaminant in drinking water;

(ii) Action Level: The concentration of a contaminant which, if exceeded, triggers treatment or other requirements which a water system must follow.

(E) Maximum Residual Disinfectant Level Goal or MRDLG: The level of a drinking water disinfectant below which there is no known or expected risk to health. MRDLGs do not reflect the benefits of the use of disinfectants to control microbial contaminants.

(F) Maximum Residual Disinfectant Level or MRDL: The highest level of disinfectant allowed in drinking water. There is convincing evidence that addition of a disinfectant is necessary for control of microbial contaminants.

(3) Detected Contaminants:

(a) The following information must be included in each report for contaminants subject to mandatory monitoring (except Cryptosporidium). Detected means at or above the detection level prescribed by each EPA approved analytical method set forth in 40 CFR 141:

(A) Contaminants and disinfection by-products subject to an MCL, action level, MRDL, or treatment technique (regulated contaminants); and

(B) Unregulated contaminants for which monitoring is required.

(b) The data relating to these contaminants must be displayed in one table or in several adjacent tables. Any additional monitoring results which a community water system chooses to include in its report must be displayed separately.

(c) The data must be derived from data collected to comply with state monitoring and analytical requirements during the calendar year except that where a system is allowed to monitor for regulated contaminants less often than once a year, the table(s) must include the date and results of the most recent sampling and the report must include a brief statement indicating that the data presented in the report are from the most recent testing done in accordance with the regulation. No data older than five years need be included.

(d) For detected regulated contaminants (listed in Table 39 of this rule), the table(s) in the report must contain: [Table not included. See ED. NOTE.]

(A) The MCL for that contaminant expressed as a number equal to or greater than 1.0 (as provided in Table 39); [Table not included. See ED. NOTE.]

(B) The MCLG for that contaminant expressed in the same units as the MCL;

(C) If there is no MCL for a detected contaminant, the table must indicate that there is a treatment technique, or specify the action level, applicable to that contaminant, and the report must include the definitions for treatment technique or action level, as appropriate, specified in paragraph (2)(d)(D) of this rule;

(D) For contaminants subject to an MCL, except turbidity and total coliforms and E. coli, the highest contaminant level used to determine compliance with these rules and the range of detected levels, as follows:

(i) When compliance with the MCL is determined annually or less frequently: the highest detected level at any sampling point and the range of detected levels expressed in the same units as the MCL;

(ii) When compliance with the MCL is determined by calculating a running annual average of all samples taken at a monitoring location: the highest average at any of the monitoring locations and the range of all monitoring locations must be expressed in the same unit of measure as the MCL. For the MCL for TTHM and HAA5 as specified by OAR 333-061-0030(2)(b), water systems must include the highest locational running annual average for TTHM and HAA5 and the range of individual sample results for all monitoring locations expressed in the same unit of measure as the MCL. If more than one location exceeds the MCL for TTHM or HAA5, the water system must include the locational running annual averages for all locations that exceed the MCL;

(iii) When compliance with the MCL is determined on a system wide basis by calculating a running annual average of all samples at all monitoring locations: the average and range of detections must be expressed in the same units as the MCL. The water system is required to include individual sample results for an IDSE conducted in accordance with OAR 333-061-0036(4)(b) of this rule when determining the range of TTHM and HAA5 results to be reported in the annual consumer confidence report for the calendar year that the IDSE samples were taken;

(iv) When rounding of results to determine compliance with the MCL is allowed by the regulations, rounding should be done prior to multiplying the results by the factor listed in Table 39 of this rule. [Table not included. See ED. NOTE.]

(e) Turbidity:

(A) When it is reported pursuant to OAR 333-061-0030(3)(a), 333-061-0032(2), and 333-061-0036(5)(a): the highest monthly value. The report should include an explanation of the reasons for measuring turbidity. This includes water systems currently without filtration treatment, but required to install filtration through a Notice of Violation and Remedial Order.

(B) When it is reported pursuant to OAR 333-061-0030(3): The highest single measurement and the lowest monthly percentage of samples meeting the turbidity limits specified in OAR 333-061-0030(3) for the filtration technology being used. The report should include an explanation of the reasons for measuring turbidity.

(f) Lead and copper: the 90th percentile value of the most recent round of sampling and the number of sampling sites exceeding the action level and the lead-specific information as prescribed in subsection (4)(c) of this rule.

(g) For total coliform until March 31, 2016:

(A) The highest monthly number of positive samples for systems collecting fewer than 40 samples per month; or

(B) The highest monthly percentage of positive samples for systems collecting at least 40 samples per month.

(h) For E. coli: the total number of positive samples.

(i) Reports that contain information regarding level 1 or level 2 coliform investigations required as specified in OAR 333-061-0078 must include the following definitions as applicable:

(A) "Level 1 Coliform Investigation" means a study of the water system to identify potential problems and determine (if possible) why total coliform bacteria have been found in our water system.

(B) "Level 2 Coliform Investigation" means a very detailed study of the water system to identify potential problems and determine (if possible) why an E. coli MCL violation has occurred or why total coliform bacteria have been found in our water system on multiple occasions.

(j) The likely source(s) of detected contaminants to the best of the operator's knowledge. Specific information regarding contaminants may be available in sanitary surveys and source water assessments, and should be used when available to the operator. If the operator lacks specific information on the likely source, the report must include one or more of the typical sources for that contaminant listed in Table 40 which are most applicable to the system. [Table not included. See ED. NOTE.]

(k) If a community water system distributes water to its customers from multiple hydraulically independent distribution systems that are fed by different raw water sources, the table should contain a separate column for each service area and the report should identify each separate distribution system. Alternatively, systems could produce separate reports tailored to include data for each service area.

(l) The table(s) must clearly identify any data indicating violations of MCLs, MRDLs, or treatment techniques and the report must contain a clear and readily understandable explanation of the violation, the length of the violation, the potential adverse health effects, and actions taken by the system to address the violation. To describe the potential health effects, the system must use the relevant language in Table 40 of this rule. [Table not included. See ED. NOTE.]

(m) For detected unregulated contaminants for which monitoring is required (except Cryptosporidium), the table(s) must contain the average and range at which the contaminant was detected. The report may include a brief explanation of the reasons for monitoring for unregulated contaminants.

(n) Information on Cryptosporidium, radon, and other contaminants:

(A) If the system has performed any monitoring for Cryptosporidium, which indicates that Cryptosporidium may be present in the source water or the finished water, the report must include:

(i) A summary of the results of the monitoring, and

(ii) An explanation of the significance of the results.

(B) If the system has performed any monitoring for radon which indicates that radon may be present in the finished water, the report must include:

(i) The results of the monitoring; and

(ii) An explanation of the significance of the results.

(C) If the system has performed additional monitoring which indicates the presence of other contaminants in the finished water, the system is strongly encouraged to report any results which may indicate a health concern. To determine if results may indicate a

health concern, EPA recommends that systems find out if EPA has proposed a National Primary Drinking Water Regulation or issued a health advisory for that contaminant by calling the Safe Drinking Water Hotline (800-426-4791). EPA considers detects above a proposed MCL or health advisory level to indicate possible health concerns. For such contaminants, EPA recommends that the report include:

(i) The results of the monitoring; and

(ii) An explanation of the significance of the results noting the existence of a health advisory or a proposed regulation.

(o) Compliance with OAR 333-061: In addition to subsection (3)(k) of this rule, the report must note any violation that occurred during the year covered by the report of a requirement listed below, and include a clear and readily understandable explanation of the violation, any potential adverse health effects, and the steps the system has taken to correct the violation.

(A) Monitoring and reporting of compliance data;

(B) Filtration and disinfection prescribed by OAR 333-061-0032: For systems which have failed to install adequate filtration or disinfection equipment or processes which constitutes a violation or have an equipment failure constituting a violation, the report must include the following language as part of the explanation of potential adverse health effects: Inadequately treated water may contain disease-causing organisms. These organisms include bacteria, viruses, and parasites which can cause symptoms such as nausea, cramps, diarrhea, and associated headaches;

(C) Lead and copper control requirements: For systems which fail to take one or more actions prescribed by OAR 333-061-0034 the report must include the applicable language in Table 40 of this rule for lead, copper, or both; [Table not included. See ED. NOTE.]

(D) Treatment techniques for Acrylamide and Epichlorohydrin: For systems which violate the requirements of OAR 333-061-0030(7), the report must include the relevant health effects language in Table 40 of this rule. [Table not included. See ED. NOTE.]

(E) Recordkeeping of compliance data;

(F) Special monitoring requirements prescribed by OAR 333-061-0036(2)(f) and for unregulated contaminants as required by EPA;

(G) Violation of the terms of a variance, administrative order or judicial order.

(p) Variances: If a system is operating under the terms of a variance as prescribed in OAR 333-061-0045, the report must contain:

(A) An explanation of the reasons for the variance;

(B) The date on which the variance was issued;

(C) A brief status report on the steps the system is taking to install treatment, find alternative sources of water, or otherwise comply with the terms and schedules of the variance; and

(D) A notice of any opportunity for public input in the review, or renewal, of the variance.

(q) Additional information:

(A) The report must contain a brief explanation regarding contaminants which may reasonably be expected to be found in drinking water including bottled water. This explanation may include the language in subparagraphs (3)(q)(A)(i), (ii) and (iii) of this rule, or systems may use their own comparable language. The report also must include the language of subparagraph (3)(q)(A)(iv) of this rule.

(i) The sources of drinking water (both tap water and bottled water) include rivers, lakes, streams, ponds, reservoirs, springs, and wells. As water travels over the surface of the land or through the ground, it dissolves naturally-occurring minerals and, in some cases, radioactive material, and can pick up substances resulting from the presence of animals or from human activity;

(ii) Contaminants that may be present in source water include:

(I) Microbial contaminants, such as viruses and bacteria, which may come from sewage treatment plants, septic systems, agricultural livestock operations, and wildlife;

(II) Inorganic contaminants, such as salts and metals, which can be naturally-occurring or result from urban stormwater runoff, industrial or domestic wastewater discharges, oil and gas production, mining, or farming;

(III) Pesticides and herbicides, which may come from a variety of sources such as agriculture, urban stormwater runoff, and residential uses;

(IV) Organic chemical contaminants, including synthetic and volatile organic chemicals, which are by-products of industrial processes and petroleum production, and can also come from gas stations, urban stormwater runoff, and septic systems;

(V) Radioactive contaminants, which can be naturally-occurring or be the result of oil and gas production and mining activities.

(iii) In order to ensure that tap water is safe to drink, EPA prescribes regulations which limit the amount of certain contaminants in water provided by public water systems. FDA regulations establish limits for contaminants in bottled water which must provide the same protection for public health;

(iv) Drinking water, including bottled water, may reasonably be expected to contain at least small amounts of some contaminants. The presence of contaminants does not necessarily indicate that water poses a health risk. More information about contaminants and potential health effects can be obtained by calling the Environmental Protection Agency's Safe Drinking Water Hotline (800-426-4791).

(B) The report must include the telephone number of the owner, operator, or designee of the community water system as a source of additional information concerning the report;

(C) In communities with a large proportion of non-English speaking residents the report must contain information in the appropriate language(s) regarding the importance of the report or contain a telephone number or address where such residents may contact the system to obtain a translated copy of the report or assistance in the appropriate language;

(D) The report must include information (for example, time and place of regularly scheduled board meetings) about opportunities for public participation in decisions that may affect the quality of the water;

(E) The systems may include such additional information as they deem necessary for public education consistent with, and not detracting from, the purpose of the report.

(4) Required additional health information:

(a) All reports must prominently display the following language: Some people may be more vulnerable to contaminants in drinking water than the general population. Immuno-compromised persons such as persons with cancer undergoing chemotherapy, persons who have undergone organ transplants, people with HIV/AIDS or other immune system disorders, some elderly, and infants can be particularly at risk from infections. These people should seek advice about drinking water from their health care providers. EPA/CDC guidelines on appropriate means to lessen the risk of infection by Cryptosporidium and other microbial contaminants are available from the Safe Drinking Water Hotline (800-426-4791).

(b) A system which detects nitrate at levels above 5 mg/l, but does not exceed the MCL:

(A) Must include a short informational statement about the impacts of nitrate on children using language such as: Nitrate in drinking water at levels above 10 mg/l is a health risk for infants of less than six months of age. High nitrate levels in drinking water can cause blue baby syndrome. Nitrate levels may rise quickly for short periods of time because of rainfall or agricultural activity. If you are caring for an infant you should ask advice from your health care provider.

(B) May write its own educational statement, but only in consultation with the Authority.

(c) Every report must include the following lead-specific information:

(A) A short informational statement about the lead in drinking water and its effects on children. The statement must include the following information: If present, elevated levels of lead can cause serious health problems, especially for pregnant women and young children. Lead in drinking water is primarily from materials and

components associated with service lines and home plumbing. {NAME OF WATER UTILITY} is responsible for providing high quality drinking water, but cannot control the variety of materials used in plumbing components. When your water has been sitting for several hours, you can minimize the potential for lead exposure by flushing your tap for 30 seconds to 2 minutes before using water for drinking or cooking. If you are concerned about lead in your water, you may wish to have your water tested. Information on lead in drinking water, testing methods, and steps you can take to minimize exposure is available from the Safe Drinking Water Hotline or at http://www.epa.gov/safewater/lead.

(B) The water system may write its own educational statement, but only in consultation with the Authority.

(d) Requirements related to coliform investigations as specified in OAR 333-061-0078.

(A) A water supplier required to comply with any requirement related to level one or level two coliform investigations that are not due to an exceedance of the MCL for E. coli must include in the report the text found in subparagraphs (4)(d)(A)(i) through (iii) of this rule as appropriate, replacing the language in brackets with system specific information as appropriate.

(i) Coliforms are bacteria that are naturally present in the environment and are used as an indicator that other, potentially harmful, waterborne pathogens may be present or that a potential pathway exists through which contamination may enter the drinking water distribution system. We found coliforms indicating the need to look for potential problems in water treatment or distribution. When this occurs, we are required to conduct investigation(s) to identify problems and to correct any problems that were found during these investigation(s).

(ii) During the past year we were required to conduct [INSERT NUMBER OF LEVEL 1 COLIFORM INVESTIGATIONS] level 1 coliform investigation(s). [INSERT NUMBER OF LEVEL 1 COLIFORM INVESTIGATIONS] level 1 coliform investigation (s) were completed. In addition, we were required to take [INSERT NUMBER OF CORRECTIVE ACTIONS] corrective actions and we completed [INSERT NUMBER OF CORRECTIVE ACTIONS] of these actions.

(iii) During the past year [INSERT NUMBER OF LEVEL 2 COLIFORM INVESTIGATIONS] level 2 coliform investigations were required to be completed for our water system. [INSERT NUMBER OF LEVEL 2 COLIFORM INVESTIGATIONS] level 2 coliform investigations were completed. In addition, we were required to take [INSERT NUMBER OF CORRECTIVE ACTIONS] corrective actions and we completed [INSERT NUMBER OF CORRECTIVE ACTIONS] of these actions.

(B) A water supplier required to comply with any requirements related to a level 2 coliform investigation due to an exceedance of the MCL for E. coli must include in the report the text found in subparagraphs (4)(d)(B)(i) and (ii) of this rule as appropriate, replacing the language in brackets with system specific information as appropriate.

(i) E. coli are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Human pathogens in these wastes can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a greater health risk for infants, young children, the elderly, and people with severely compromised immune systems. We found E. coli bacteria, indicating the need to look for potential problems in water treatment or distribution. When this occurs, we are required to conduct investigation(s) to identify problems and to correct any problems that were found during these investigations.

(ii) We were required to complete a level 2 coliform investigation because we found E. coli in our water system. In addition, we were required to take [INSERT NUMBER OF CORRECTIVE ACTIONS] corrective actions and we completed [INSERT NUMBER OF CORRECTIVE ACTIONS] of these actions.

(C) A water supplier that has failed to complete a required coliform investigation or correct all identified sanitary defects must include one or both of the following statements, as appropriate:

(i) During the past year, we failed to conduct the required coliform investigation(s).

(ii) During the past year, we failed to correct all sanitary defects that were identified during a coliform investigation as required.

(D) If E. coli is detected at a water system and the MCL for E. coli was exceeded, in addition to including the information as required by section (3) of this rule, the water supplier must include one or more of the statements specified in subparagraphs (4)(d)(D)(i) through (iv) of this rule as appropriate to describe any noncompliance:

(i) We had an E. coli-positive repeat sample following a total coliform-positive routine sample.

(ii) We had a total coliform-positive repeat sample following an E. coli-positive routine sample.

(iii) We failed to collect all required repeat samples following an E. coli-positive routine sample.

(iv) We failed to test for E. coli when a repeat sample tested positive for total coliform.

(E) If E. coli is detected at a water system but the MCL for E. coli was not exceeded, in addition to completing the table(s) as specified in section (3) of this rule, a water supplier may include a statement that explains that although E. coli was detected, the MCL for E. coli was not exceeded at the water system.

(5) Special requirements for groundwater systems:

(a) Any groundwater system that receives notification of a significant deficiency that is not corrected at the time of the next report, or of an E. coli-positive groundwater source sample that was not invalidated in accordance OAR 333-061-0036(6)(l) must inform its customers in the next report. The water system must continue to inform the public annually until the Authority determines that the particular significant deficiency is corrected or that the fecal contamination in the groundwater source is addressed in accordance with OAR 333-061-0032(6). Each report must include the following elements:

(A) The nature of the particular significant deficiency or the source of the fecal contamination (if the source is known), and the date the significant deficiency was identified by the Authority or the dates of the E. coli-positive groundwater source samples;

(B) If the fecal contamination in the groundwater source has been addressed as prescribed by OAR 333-061-0032(6) and the date of such action;

(C) The Authority-approved plan and schedule for correction, including interim measures, progress to date, and any interim measures completed for any significant deficiency or fecal contamination in the groundwater source that has not been addressed as prescribed by OAR 333-061-0032(6); and

(D) The potential health effects language specified in OAR 333-061-0097(4)(a) if the system received notice of a E. coli-positive groundwater source sample that was not invalidated by the Authority in accordance with OAR 333-061-0036(6)(l).

(b) The Authority may require a water system with significant deficiencies that have been corrected before the next report is issued to inform its customers of the significant deficiency, how the deficiency was corrected, and the date of correction in accordance with subsection (5)(a) of this rule.

(6) Report delivery and recordkeeping:

(a) Except as provided in subsection (6)(g) of this rule, each community water system must mail or otherwise directly deliver one copy of the report to each customer.

(b) The system must make a good faith effort to reach consumers who do not get water bills, using means recommended by the Authority. EPA expects that an adequate good faith effort will be tailored to the consumers who are served by the system but are not bill-paying customers, such as renters or workers. A good faith effort to reach consumers would include a mix of methods appropriate to the particular system such as: Posting the reports on the Internet; mailing to postal patrons in metropolitan areas; advertising the availability of the report in the news media; publication in a local newspaper; posting in public places such as cafeterias or lunch rooms of public buildings; delivery of multiple copies for

distribution by singularly-billed customers such as apartment buildings or large private employers; delivery to community organizations.

(c) No later than the date the system is required to distribute the report to its customers, each community water system must mail a copy of the report to the Authority, followed within three months by a certification that the report has been distributed to customers, and that the information is correct and consistent with the compliance monitoring data previously submitted to the Authority.

(d) No later than the date the system is required to distribute the report to its customers, each community water system must deliver the report to any other agency or clearinghouse identified by the Authority.

(e) Each community water system must make its reports available to the public upon request.

(f) Each community water system serving 100,000 or more persons must post its current year's report to a publicly-accessible site on the Internet.

(g) The Governor of a State or his designee, can waive the requirement of subsection (6)(a) of this rule for community water systems serving fewer than 10,000 persons.

(A) Such systems must:

(i) Publish the reports in one or more local newspapers serving the area in which the system is located;

(ii) Inform the customers that the reports will not be mailed, either in the newspapers in which the reports are published or by other means approved by the State; and

(iii) Make the reports available to the public upon request.

(B) Systems serving 500 or fewer persons may forego the requirements of subparagraphs (6)(g)(A)(i) and (ii) of this rule if they provide notice at least once per year to their customers by mail, door-to-door delivery or by posting in an appropriate location that the report is available upon request.

(h) Any system subject to this rule must retain copies of its consumer confidence report for no less than five years.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 431.110, 431.150

Hist.: OHD 4-1999, f. 7-14-99, cert. ef. 7-15-99; OHD 7-2000, f. 7-11-00, cert. ef. 7-15-00; OHD 23-2001, f. & cert. ef. 10-31-01; OHD 17-2002, f. & cert. ef. 10-25-02; PH 12-2003, f. & cert. ef. 8-15-03; PH 33-2004, f. & cert. ef. 10-21-04; PH 2-2006, f. & cert. ef. 1-31-06; PH 2-2008, f. & cert. ef. 2-15-08; PH 4-2009, f. & cert. ef. 5-18-09; PH 7-2010, f. & cert. ef. 4-19-10; PH 3-2013, f. & cert. ef. 1-25-13; PH 5-2016, f. 2-10-16, cert. ef. 4-1-16

333-061-0045
Variances

(1) Variances from the maximum contaminant levels may be granted by the Authority to public water systems under the following circumstances where:

(a) An evaluation satisfactory to the Authority indicates that alternative sources of water are not reasonably available to the system;

(b) There will be no unreasonable risk to health;

(c) The water supplier has provided sufficient evidence to confirm that the best available treatment techniques which are generally available are unable to treat the water in question so that it meets maximum contaminant levels;

(d) The water supplier agrees to notify the water users at least once every three months, or more frequently if determined by the Authority, that the water system is not in compliance;

(e) A compliance schedule is submitted which outlines how the water supplier intends to achieve compliance, and the water supplier agrees to review this schedule once every three years to determine whether changes have occurred in the conditions which formed the basis for the schedule; and

(f) A plan is submitted which outlines interim control measures including application of the best technology treatment technique to be implemented during the period that the variance is in effect.

(2) The Authority shall document all findings of its determinations and if the Authority prescribes a schedule requiring compliance with a contaminant level for which the variance is granted later than five years from the date of issuance of the variance the Authority shall:

(a) Document the rationale for the extended compliance schedule;

(b) Discuss the rationale for the extended compliance schedule in the required public notice and opportunity for public hearing; and

(c) Provide the shortest practicable time schedule feasible under the circumstances.

(3) Before denying a request for a variance, the Authority shall advise the water supplier of the reasons for the denial and shall give the supplier an opportunity to present additional information. If the additional information is not sufficient to justify granting the variance, the variance shall be denied.

(4) If the Authority determines that the variance should be granted, it shall announce its intention to either hold a public hearing in the affected area prior to granting the variance; or serve notice of intent to grant the variance either personally, or by registered or certified mail to all customers connected to the water system, or by publication in a newspaper in general circulation in the area. If no hearing is requested within 10 days of the date that notice is given, the Authority may grant the variance.

(5) When a variance has been granted, and a water supplier fails to meet the compliance schedule, or fails to implement the interim control measures, or fails to undertake the monitoring required under the conditions of the variance, the Authority may initiate enforcement action authorized by these rules.

(6) Variances from the maximum contaminant levels for volatile organic chemicals, organic chemicals and inorganic chemicals shall be issued by the Authority as follows:

(a) The Authority shall require Community water systems and Non-Transient Non-Community water systems to install or use any treatment method identified in OAR 333-061-0050(4)(b)(B), (E) and (F) as a condition for granting a variance except as provided in subsection (6)(b) of this rule. If, after the system's installation of the treatment method, the system cannot meet the MCL, that system shall be eligible for a variance.

(b) If a system can demonstrate through comprehensive engineering assessments, which may include pilot plant studies, that the treatment methods identified in OAR 333-061-0050(4)(b)(B), (E) and (F) would only achieve an insignificant reduction in contaminants, the Authority may issue a schedule of compliance that requires the system being granted the variance to examine other treatment methods as a condition of obtaining the variance.

(c) If the Authority determines that a treatment method identified in subsection (6)(b) of this rule is technically feasible, the Authority may require the system to install or use that treatment method in connection with a compliance schedule. The Authority's determination shall be based upon studies by the system and other relevant information.

(d) The Authority may require a public water system to use bottled water, point-of-use devices, point-of-entry devices or other means as a condition of granting a variance to avoid an unreasonable risk to health.

(7) The variances from the maximum contaminant level for fluoride shall be granted by the Authority as follows:

(a) The Authority shall require a Community water system to install or use any treatment method identified in OAR 333-061-0050(4)(b)(C) as a condition for granting a variance unless the Authority determines that such treatment method is not available and effective for fluoride control for the system. A treatment method shall not be considered to be "available and effective" for an individual system if the treatment method would not be technically appropriate and technically feasible for that system. If, upon application by a system for a variance, the Authority determines that none of the treatment methods identified in OAR 333-061-0050(4)(b)(C) are available and effective for the system, that system shall be entitled to a variance. The Authority's determination as to the availability and effectiveness of such treatment methods shall be based upon studies by the system and other relevant information. If a system submits information to demonstrate that a treat-

ment method is not available and effective for fluoride control for that system, the Authority shall make a finding whether this information supports a decision that such treatment method is not available and effective for that system before requiring installation or use of such treatment method.

(b) The Authority shall issue a schedule of compliance that may require the system being granted the variance to examine the following treatment methods to determine the probability that any of the following methods will significantly reduce the level of fluoride for that system, and if such probability exists, to determine whether any of these methods are technically feasible and economically reasonable, and that the fluoride reductions obtained will be commensurate with the costs incurred with the installation and use of such treatment methods for that system: Modification of lime softening; Alum coagulation; Electrodialysis; Anion exchange resins; Well field management; Alternate source; or Regionalization.

(c) If the Authority determines that a treatment method identified in subsection (6)(b) of this rule or any other treatment method is technically feasible, economically reasonable, and will achieve fluoride reductions commensurate with the costs incurred with the installation or use of such treatment method for the system, the Authority shall require the system to install or use that treatment method in connection with a compliance schedule. The Authority's determination shall be based upon studies by the system and other relevant information.

(8) Public water systems that use bottled water as a condition for receiving a variance must meet the following requirements.

(a) The public water system must develop and put in place a monitoring program approved by the Authority that provides reasonable assurances that the bottled water meets all MCLs. The public water system must monitor a representative sample of the bottled water for all applicable contaminants under OAR 333-061-0036 the first quarter that it supplies the bottled water to the public, and annually thereafter. Results of the monitoring program shall be provided to the Authority annually.

(b) As an alternative to subsection (7)(a) of this rule, the public water system must receive a certification from the bottled water company that the bottled water supplied has been taken from an "approved source" as defined in 21 CFR 129.3(a); the bottled water company has conducted monitoring in accordance with 21 CFR 129.80(g)(1) through (3); and the bottled water does not exceed any MCLs or quality limits as set out in 21 CFR 103.35, 110, and 129. The public water system shall provide the certification to the Authority the first quarter after it supplies bottled water and annually thereafter.

(c) The public water system is fully responsible for the provision of sufficient quantities of bottled water to every person supplied by the public water system, via door-to-door bottled water delivery.

(9) Public water systems that use point-of-use devices as a condition for obtaining a variance must meet the following requirements:

(a) It is the responsibility of the public water system to operate and maintain the point-of-use treatment system.

(b) The public water system must develop a monitoring plan and obtain Authority approval for the plan before point-of-use devices are installed for compliance. This monitoring plan must provide health protection equivalent to a monitoring plan for central water treatment.

(c) Effective technology must be properly applied under a plan approved by the Authority and the microbiological safety of the water must be maintained.

(d) The water system must submit adequate certification of performance, field testing and, if not included in the certification process, a rigorous engineering design review to the Authority for approval prior to installation.

(e) The design and application of the point-of-use devices must consider the tendency for increase in heterotrophic bacteria concentrations in water treated with activated carbon. It may be necessary to use frequent backwashing, post-contractor disinfection, and Heterotrophic Plate Count monitoring to ensure that the microbiological safety of the water is not compromised.

(f) All consumers shall be protected. Every building connected to the system must have a point-of-use device installed, maintained, and adequately monitored. The Authority must be assured that every building is subject to treatment and monitoring, and that the rights and responsibilities of the public water system customer convey with title upon sale of property.

(10) Public water systems shall not use bottled water to achieve compliance with an MCL. Bottled water or point-of-use devices may be used on a temporary basis to avoid an unreasonable risk to health.

(11) The Authority will not grant a variance or exemption to the requirements of OAR 333-061-0030(3), OAR 333-061-0030(4) or OAR 333-061-0034. Variances to OAR 333-061-0032 will only be granted as provided by section (12) of this rule. The Authority will not grant any variances to the requirements of OAR 333-061-0036 pertaining to the treatment of surface water and groundwater under the direct influence of surface water. No permits will be granted for OAR 333-061-0030(4), 333-061-0032(3)(c) or 333-061-0032(5)(b).

(12) The Authority may grant variances from the standards specified in OAR 333-061-0032(3)(e) through (g) requiring the use of a specified water treatment technique if the Authority determines that the use of a specified water treatment technique is not necessary to protect public health based on the nature of the raw water source for a public water system. A variance granted under this section shall be conditioned on such monitoring and other requirements as the Administrator of the U.S. Environmental Protection Agency or the Director of the Oregon Health Authority may prescribe.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 448.115, 448.135
Hist.: HD 9-1981(Temp), f. & ef. 6-30-81; HD 17-1981(Temp), f. & ef. 8-28-81; HD 4-1982, f. & ef. 2-26-82; Renumbered from 333-042-0213, HD 2-1983, f. & ef. 2-23-83; HD 11-1985, f. & ef. 7-2-85; HD 30-1985, f. & ef. 12-4-85; HD 9-1989, f. & cert. ef. 11-13-89; HD 26-1990, f. 12-26-90, cert. ef. 12-29-90; HD 9-1991(Temp), f. & cert. ef. 6-24-91; HD 1-1992, f. & cert. ef. 3-5-92; HD 12-1992, f. & cert. ef. 12-7-92; HD 3-1994, f. & cert. ef. 1-14-94; HD 1-1996, f. 1-2-96, cert. ef. 1-5-96; OHD 17-2002, f. & cert. ef. 10-25-02; PH 12-2003, f. & cert. ef. 8-15-03; PH 2-2008, f. & cert. ef. 2-15-08; PH 4-2009, f. & cert. ef. 5-18-09; PH 7-2010, f. & cert. ef. 4-19-10; PH 3-2013, f. & cert. ef. 1-25-13; PH 5-2016, f. 2-10-16, cert. ef. 4-1-16

333-061-0046
Permits

(1) Permits may be issued by the Authority under the following circumstances:

(a) The water system is existing and in operation on the date the MCL or treatment technique requirement became effective; and

(b) The water supplier is unable to comply with the maximum contaminant levels or a treatment requirement due to economic or other compelling factors and;

(c) The water system has not been granted a variance.

(2) Permits may be issued only when the following conditions are met:

(a) The system is unable to implement measures to develop an alternative source of water supply; and

(b) The system cannot reasonably make management or restructuring changes that will result in compliance or improve the quality of the drinking water; and

(c) The system cannot meet the standard without capital improvements which cannot be completed prior to the effective date of the standard; and

(d) In the case of a system which needs financial assistance for the necessary improvement, the system has entered into an agreement to obtain such financial assistance through Federal and State funding programs available to the water system; and

(e) If applicable, the system has entered into an enforceable agreement to become a part of a regional public water system, and the system is taking all practicable steps to meet the standard; and

(f) There will be no unreasonable risk to health; and

(g) The water supplier agrees to notify the water users at least once every three months that the water system is out of compliance; and

(h) The water supplier agrees to a compliance schedule prescribed by the Authority which includes interim measures to eliminate the risks to health and which sets a specific time limit for the water supplier to install the water treatment facilities or comply with the maximum contaminant levels. The compliance schedule shall not exceed 3 years from date of issuance. Bottled water, point-of-use devices or point-of-entry devices may be used as interim health protection measures as prescribed in OAR 333-061-0045(8) and (9) and 333-061-0050(4)(d), except that point-of-entry devices are not allowed as a condition for issuing a permit for corrosion control treatment requirements for lead and copper. Point-of-entry devices may be used as a condition for issuing a permit for source water treatment.

(3) The procedures for processing requests for permits shall be the same as indicated for variances in OAR 333-061-0045(3) and (4).

(4) After a permit has been issued, the water supplier shall be subject to the same requirements as those indicated for variances in OAR 333-061-0045(5).

(5) The Authority is not permitted to issue any permits for alternate requirements other than those required by OAR 333-061-0030(3) and (4), as well as the requirements of 333-061-0032, 333-061-0034 and 333-061-0036.

(6) The Authority shall document all findings of determinations and consider the following:

(a) Before finding that management and restructuring changes cannot be made, the Authority shall consider the following measures, and the availability of State Revolving Loan Fund assistance, or any other Federal or State program, that is reasonably likely to be available within the period of the permit to implement these measures:

(A) Consideration of the rate increases, accounting changes, the appointment of a State-certified operator under the State's Operator Certification program, contractual agreements for joint operation with one or more public water systems;

(B) Activities consistent with the State's Capacity Development Strategy to help the public water system acquire and maintain technical, financial and managerial capacity to come into compliance with the Safe Drinking Water Act; and

(C) Ownership changes, physical consolidation with another public water system, or other feasible and appropriate means of consolidation which would result in compliance with the Safe Drinking Water Act.

(b) The Authority must consider the availability of an alternative source of water, including the feasibility of partnerships with neighboring public water systems, as identified by the public water system or by the Authority consistent with the Capacity Development Strategy.

(7) In the case of a public water system serving a population of not more than 3,300 persons and which needs financial assistance for the necessary improvements under the initial compliance schedule, a permit granted by the Authority may be renewed for one or more additional 2-year periods, but not to exceed a total of six additional years, only if the Authority establishes that the public water system is taking all practicable steps to meet the requirements and the established compliance schedule to achieve full compliance with the contaminant level or treatment technique for which the permit was granted. The Authority shall document its findings in granting a permit under this rule.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 448.115 & 448.145
Hist.: HD 9-1989, f. & cert. ef. 11-13-89; HD 26-1990, f. 12-26-90, cert. ef. 12-29-90; HD 12-1992, f. & cert. ef. 12-7-92; HD 3-1994, f. & cert. ef. 1-14-94; OHD 17-2002, f. & cert. ef. 10-25-02; PH 12-2003, f. & cert. ef. 8-15-03

333-061-0050
Construction Standards

(1) General:

(a) These standards shall apply to the construction of new public water systems and to major additions or modifications to existing public water systems and are intended to assure that the system facilities, when constructed, will be free of public health hazards and will be capable of producing water which consistently complies with the maximum contaminant levels;

(b) Facilities at public water systems must comply with the construction standards in place at the time the facility was constructed or installed for use at a public water system. A public water system shall not be required to undertake alterations to existing facilities, unless the standard is listed as a significant deficiency as prescribed in OAR 333-061-0076(4) or if maximum contaminant levels are being exceeded.

(c) Non-public water systems that are converted to public water systems shall be modified as necessary to conform to the requirements of this rule.

(d) Facilities at public water systems shall be designed and constructed in a manner such that contamination will be effectively excluded, and the structures and piping will be capable of safely withstanding external and internal forces acting upon them;

(e) Only materials designed for potable water service and meeting NSF Standard 61 - Drinking Water System Components or equivalent shall be used in those elements of the water system which are in contact with potable water;

(f) New tanks, pumps, equipment, pipe valves and fittings shall be used in the construction of new public water systems, major additions or major modifications to existing water systems. The Authority may permit the use of used items when it can be demonstrated that they have been renovated and are suitable for use in public water systems;

(g) Prior to construction of new facilities, the water supplier shall submit plans to the Authority for approval as specified in OAR 333-061-0060(1)(a).

(h) Construction may deviate from the requirements of this section provided that documentation is submitted, to the satisfaction of the Authority, that the deviation is equal to or superior to the requirements of this section as specified in OAR 333-061-0055 (variances from construction standards).

(i) A public water system or other Responsible Management Authority using groundwater, or groundwater under the direct influence of surface water, derived from springs, confined or unconfined wells that wish to have a state certified wellhead protection program shall comply with the requirements as specified in OAR 333-061-0057, 0060, and 0065, as well as OAR 340-040-0140 through 0200. Additional technical information is available in the Oregon Wellhead Protection Guidance Manual.

(j) All new groundwater sources are subject to consideration for potential direct influence of surface water as prescribed in OAR 333-061-0032(8).

(2) Groundwater:

(a) Wells:

(A) For the purpose of this rule, wells are defined as holes or other excavations that are drilled, dug or otherwise constructed for the purpose of capturing groundwater or groundwater in hydraulic connection with surface water as a source of public drinking water.

(B) The area within 100 feet of the well shall be owned by the water supplier, or a perpetual restrictive easement shall be obtained by the water supplier for all land (with the exception of public rights-of-way) within 100 feet of the well. The easement shall be recorded with the county in which the well is located and with the recorded deed to the property. A certified true copy shall be filed with the Authority;

(C) Not withstanding paragraph (2)(a)(A) of this rule, wells located on land owned by a public entity, (Federal, State, County, Municipality) which is not the water supplier, a permit issued by the public entity to the water supplier shall suffice in lieu of an easement. Said permit shall state that no existing or potential public health hazard shall be permitted within a minimum of 100 feet of a well site;

(D) Public or private roadways may be allowed within 100 feet of a confined well, provided the well is protected against con-

tamination from surface runoff or hazardous liquids which may be spilled on the roadway and is protected from unauthorized access;

(E) The following sanitary hazards are not allowed within 100 feet of a well which serves a public water system unless waived by the Authority: any existing or proposed pit privy, subsurface sewage disposal drain field; cesspool; solid waste disposal site; pressure sewer line; buried fuel storage tank; animal yard, feedlot or animal waste storage; untreated storm water or gray water disposal; chemical (including solvents, pesticides and fertilizers) storage, usage or application; fuel transfer or storage; mineral resource extraction, vehicle or machinery maintenance or long term storage; junk/auto/scrap yard; cemetery; unapproved well; well that has not been properly abandoned or of unknown or suspect construction; source of pathogenic organisms or any other similar public health hazards. No gravity sewer line or septic tank shall be permitted within 50 feet of a well which serves a public water system. Clearances greater than indicated above shall be provided when it is determined by the Authority that the aquifer sensitivity and degree of hazard require a greater degree of protection. Above-ground fuel storage tanks provided for emergency water pumping equipment may be exempted from this requirement by the Authority provided that a secondary containment system is in place that will accommodate 125 percent of the fuel tank storage;

(F) Except as in paragraph (2)(a)(A) and (2)(a)(E) of this rule, in those areas served by community gravity sanitary sewers, the area of ownership or control may be reduced to 50 feet;

(G) Wells shall not be located at sites which are prone to flooding. In cases where the site is subject to flooding, the area around the well shall be mounded, and the top of the well casing shall be extended at least two feet above the anticipated 100-year (1 percent) flood level;

(H) Except as otherwise provided herein, wells shall be constructed in accordance with the general standards for the construction and maintenance of water wells in Oregon as prescribed in OAR chapter 690, divisions 200 through 220;

(I) Wells as defined in paragraph (2)(a)(A) of this rule that are less than 12 feet in depth must be constructed so as to be cased and sealed from the surface to a minimum of three feet above the bottom of the well. The casing may consist of concrete or metal culvert pipe or other pre-approved materials. The seal shall be watertight, be a minimum of four inches in thickness and may consist of cement, bentonite or concrete (see concrete requirements prescribed in OAR 690-210-315). The construction and placement of these wells must comply with all requirements of this rule.

(J) Before a well is placed into operation as the source of supply at a public water system, laboratory reports as required by OAR 333-061-0036 shall be submitted by the water supplier;

(K) Water obtained from wells which exceed the maximum contaminant levels shall be treated as outlined in section (4) of this rule;

(L) The pump installation, piping arrangements, other appurtenances, and well house details at wells which serve as the source of supply for a public water system, shall meet the following requirements:

(i) The line shaft bearings of turbine pumps shall be water-lubricated, except that bearings lubricated with non-toxic approved food-grade lubricants may be permitted in wells where water-lubricated bearings are not feasible due to depth to the water;

(ii) Where turbine pumps are installed, the top of the casing shall be sealed into the pump motor. Where submersible pumps are installed, the top of the casing shall be provided with a watertight sanitary seal;

(iii) A casing vent shall be provided and shall be fitted with a screened return bend;

(iv) Provisions shall be made for determining the depth to water surface in the well under pumping and static conditions;

(v) A sampling tap shall be provided on the pump discharge line;

(vi) Piping arrangements shall include provisions for pumping the total flow from the well to waste;

(vii) A method of determining the total output of each well shall be provided. This requirement may be waived by the Authority at confined wells which serve as the source of supply for Transient Non-Community water systems;

(viii) A reinforced concrete slab shall be poured around the well casing at ground surface. The slab shall be sloped to drain away from the casing;

(ix) The ground surface around the well slab shall be graded so that drainage is away from the well;

(x) The top of the well casing shall extend at least 12 inches above the concrete slab;

(xi) Provisions shall be made for protecting pump controls and other above-ground appurtenances at the well head. Where a wellhouse is installed for this purpose, it shall meet applicable building codes and shall be insulated, heated and provided with lights, except that where the wellhouse consists of a small removable box-like structure the requirement for lights may be waived by the Authority;

(xii) The wellhouse shall be constructed so that the well pump can be removed.

(xiii) Wells equipped with pitless adaptors or units are not required to meet the requirements of subparagraphs (2)(a)(L)(iii) and (viii) of this rule.

(M) The area in the vicinity of a well, particularly the area uphill or upstream, shall be surveyed by the water supplier to determine the location and nature of any existing or potential public health hazards;

(N) The requirements with respect to land ownership, clearances from public health hazards, and protection against flooding for wells in an unconfined aquifer shall be the same or more restrictive than those prescribed for wells in confined aquifers, as determined by the Authority.

(O) Before a well is placed into operation as the source of supply for a public water system, the following documents shall be submitted by the water supplier:

(i) Reports on pumping tests for yield and drawdown for unconfined wells;

(ii) Reports of laboratory analyses on contaminants in the water as required by OAR 333-061-0036;

(iii) Performance data on the pumps and other equipment;

(iv) Proposals for disinfection as required by section (5) of this rule, if applicable.

(v) Reports on determination of potential direct influence by surface water into groundwater source as prescribed in section (3) of this rule.

(b) Springs:

(A) In addition to those requirements under subsection (2)(a) of this rule, construction of spring supplies shall meet the following requirements:

(i) An intercepting ditch shall be provided above the spring to effectively divert surface water;

(ii) A fence shall be installed around the spring area unless other provisions are made to effectively prevent access by animals and unauthorized persons;

(iii) The springbox shall be constructed of concrete or other impervious durable material and shall be installed so that surface water is excluded;

(iv) The springbox shall be provided with a screened overflow which discharges to daylight, an outlet pipe provided with a shutoff valve, a bottom drain, an access manhole with a tightly fitting cover, and a curb around the manhole.

(v) Spring collection facilities that meet the definition of a well in paragraph (2)(a)(A) of this rule must comply with construction requirements specified in paragraph (2)(a)(I) of this rule.

(B) Reports on flow tests shall be provided to establish the yield of springs.

(3) Surface water and groundwater under direct surface water influence source facilities:

(a) In selecting a site for an infiltration gallery, or for a direct intake from a stream, lake, or impounding reservoir, consideration shall be given to land use in the watershed. A sanitary survey of the

watershed shall be made by the water supplier to evaluate natural and man-made factors which may affect water quality and investigations shall also be made of seasonal variations in water quality and quantity. A report giving the results of this survey shall be submitted for review and approval by the Authority.

(b) A determination shall be made as to the status of water rights, and this information shall be submitted to the Authority for review.

(c) Impounding reservoirs shall be designed and constructed so that they include the following features:

(A) The capacity shall be sufficient to meet projected demands during drought conditions;

(B) Outlet piping shall be arranged so that water can be withdrawn from various depths;

(C) Facilities shall be provided for releasing undesirable water.

(d) Direct intake structures shall be designed and constructed so that they include the following features:

(A) Screens shall be provided to prevent fish, leaves and debris from entering the system;

(B) Provisions shall be made for cleaning the screens, or self-cleaning screens shall be installed;

(C) Motors and electrical controls shall be located above flood level;

(D) Provisions shall be made to restrict swimming and boating in the vicinity of the intake;

(E) Valves or sluice gates shall be installed at the intake to provide for the exclusion of undesirable water when required.

(4) Water treatment facilities (other than disinfection):

(a) General

(A) Water treatment facilities shall be capable of producing water which consistently does not exceed maximum contaminant levels. The type of treatment shall depend on the raw water quality. The Authority shall make determinations of treatment capabilities based upon recommendations in the US EPA Guidance Manual for Compliance with the Filtration and Disinfection Requirements for Public Water Systems Using Surface Water Sources.

(B) Investigations shall be undertaken by the water supplier prior to the selection or installation of treatment facilities to determine the physical, chemical and microbiological characteristics of the raw water as appropriate. These investigations shall include a determination of the seasonal variations in water quality, as well as a survey to identify potential sources of contamination which may affect the quality of the raw water.

(C) Water obtained from wells constructed in conformance with the requirements of these rules and which is found not to exceed the maximum contaminant levels, may be used without treatment at public water systems;

(D) Laboratory equipment shall be provided so that the water supplier can perform analyses necessary to monitor and control the treatment processes.

(E) A sampling tap shall be provided following the treatment process and before the first user when any form of water treatment is in use at a water system.

(b) Best Available Technology

(A) Pilot studies or other supporting data shall be used to demonstrate the effectiveness of any treatment method other than that defined as best available technology. Pilot study protocol shall be approved beforehand by the Authority. When point-of-use (POU) or point-of-entry (POE) devices are used for compliance, programs to ensure proper long-term operation, maintenance, and monitoring shall be provided by the water system to ensure adequate performance.

(B) The Authority identifies the following as the best available technology, treatment techniques, or other means available for achieving compliance with the maximum contaminant levels for volatile organic chemicals:

(i) Central treatment using packed tower aeration for all these chemicals.

(ii) Central treatment using granular activated carbon for all these chemicals except vinyl chloride.

(C) The Authority identifies the following as the best available technology, treatment techniques or other means generally available for achieving compliance with the Maximum Contaminant Level for fluoride.

(i) Activated alumina absorption, centrally applied.

(ii) Reverse osmosis, centrally applied.

(D) The Authority identifies the following as the best available technology, treatment techniques, or other means available for achieving compliance with the MCL for E. coli as specified in OAR 333-061-0030(4).

(i) Protection of wells from fecal contamination by appropriate placement and construction.

(ii) Maintenance of a disinfectant residual throughout the distribution system.

(iii) Proper maintenance of the distribution system including appropriate pipe replacement and repair procedures, main flushing programs, proper operation and maintenance of storage tanks and reservoirs, cross connection control and maintaining a minimum pressure of 20 psi at all service connections.

(iv) Filtration treatment or disinfection of surface water or GWUDI or disinfection of groundwater using strong oxidants such as chlorine, chlorine dioxide, or ozone.

(v) For systems using only groundwater, compliance with the requirements of an Authority approved wellhead protection program.

(E) The Authority identifies the following as the best available technology, treatment techniques, or other means available for achieving compliance with the maximum contaminant levels for organic chemicals.

(i) Central treatment using packed tower aeration for Dibromochloropropane, Ethylene Dibromide, Hexachlorocyclopentadiene and Di(2-ethylhexyl)adipate.

(ii) Central treatment using granular activated carbon for all these chemicals except Trihalomethanes and Glyphosate.

(iii) Central treatment using oxidation (chlorination or ozonation) for Glyphosate.

(F) The Authority identifies the following as the best available technology, treatment techniques, or other means available for achieving compliance with the maximum contaminant levels for inorganic chemicals. Preoxidation may be required to convert Arsenic III to Arsenic V.

(i) Central treatment using coagulation/filtration for systems with 500 or more service connections for Antimony, Arsenic V (for systems with populations 501-10,000), Asbestos, Beryllium, Cadmium, Chromium, Mercury (influent concentration ≥ 10ug/L), and Selenium (Selenium IV only).

(ii) Central treatment using direct and diatomite filtration for Asbestos.

(iii) Central treatment using granular activated carbon for Mercury.

(iv) Central treatment using activated alumina for Arsenic V (for systems with populations l0,000 or less), Beryllium, Selenium and Thallium.

(v) Central treatment using ion exchange for Arsenic V (for systems with populations 10,000 or less), Barium, Beryllium, Cadmium, Chromium, Cyanide, Nickel, Nitrate, Nitrite and Thallium.

(vi) Central treatment using lime softening for systems with 500 or more service connections for Arsenic V (for systems with populations of 501-10,000), Barium, Beryllium, Cadmium, Chromium (Chromium III only), Mercury (influent concentration ≥ 10ug/L), Nickel and Selenium.

(vii) Central treatment using reverse osmosis for Antimony, Arsenic V (for systems with populations of 501-10,000), Barium, Beryllium, Cadmium, Chromium, Cyanide, Mercury (influent concentration ≥ 10ug/L), Nickel, Nitrate, Nitrite, and Selenium.

(viii) Central treatment using corrosion control for Asbestos and Lead and Copper.

(ix) Central treatment using electrodialysis for Arsenic V (for systems with populations of 501-10,000), Barium, Nitrate, and Selenium.

(x) Central treatment using alkaline chlorination (pH≥8.5) for Cyanide.

(xi) Central treatment using coagulation-assisted microfiltration for Arsenic V (for systems with populations 501-10,000).

(xii) Central treatment using oxidation/filtration for Arsenic V (to obtain high removals, iron to Arsenic ratio must be at least 20:1).

(xiii) Point-of-use treatment using activated alumina for Arsenic V (for systems with populations 10,000 or less).

(xiv) Point-of-use treatment using reverse osmosis for Arsenic V (for systems with populations 10,000 or less).

(G) The Authority identifies the following as the best technology, treatment techniques, or other means available for achieving compliance with the maximum contaminant levels for disinfection byproducts:

(i) For bromate concentrations: control of ozone treatment process to reduce production of bromate.

(ii) For chlorite concentrations: control of treatment processes to reduce disinfectant demand and control of disinfection treatment processes to reduce disinfectant levels.

(iii) For TTHM and HAA5, for water systems that disinfect their source water and monitor in accordance with OAR 333-061-0036(4)(c) or (d): enhanced coagulation or enhanced softening plus GAC10; or nanofiltration with a molecular weight cutoff less than or equal to 1000 Daltons; or GAC20.

(iv) For TTHMs and HAA5, for purchasing water systems with populations greater than or equal to 10,000 and that monitor in accordance with OAR 333-061-0036(4)(c) or (d) improved distribution system and storage tank management to reduce residence time, plus the use of chloramines for disinfectant residual maintenance. This applies only to the disinfected water that purchasing water systems receive from a wholesale system.

(v) For TTHMs and HAA5, for purchasing water systems with populations less than 10,000 and that monitor in accordance with OAR 333-061-0036(4)(c) or (d): improved distribution system and storage tank management to reduce residence time. This applies only to the disinfected water that purchasing water systems receive from a wholesale system.

(H) The Authority identifies the following as the best technology, treatment techniques, or other means available for achieving compliance with the maximum residual disinfectant levels: Control of treatment processes to reduce disinfectant demand and control of disinfection treatment processes to reduce disinfectant levels.

(I) The Authority identifies the following as the best available technology, treatment techniques, or other means available for achieving compliance with the MCLs for radionuclides.

(i) Central treatment using ion exchange for combined radium-226/228, beta particle/photon activity and uranium.

(ii) Central treatment using reverse osmosis for combined radium-226/228, gross alpha particle activity, beta particle/photon activity, and uranium (for systems with populations 501-10,000).

(iii) Central treatment using lime softening for combined radium-226/228, and uranium (for systems with populations 501-10,000).

(iv) Central treatment using enhanced coagulation/filtration for uranium.

(v) Central treatment using activated alumina for uranium (for systems with populations of 10,000 or less).

(vi) Central treatment using greensand filtration for combined radium-226/228.

(vii) Central treatment using electrodialysis for combined radium-226/228.

(viii) Central treatment using pre-formed hydrous manganese oxide filtration for combined radium-226/228.

(ix) Central treatment using co-precipitation with barium for combined radium-226/228.

(x) Point-of-use treatment using ion exchange for combined radium-226/228, beta particle/photon activity, and uranium.

(xi) Point-of use treatment using reverse osmosis for combined radium-226/228, gross alpha particle activity, beta particle/ photon activity, and uranium (for systems with populations of 10,000 or less).

(c) Filtration of Surface Water Sources and Groundwater Sources Under the Direct Influence of Surface Water

(A) All water systems using surface water or groundwater sources under the direct influence of surface water that fail to meet the criteria for avoiding filtration prescribed in OAR 33-061-0032(2) and (3) must meet all requirements of this subsection for installing filtration treatment.

(B) There are four standard filtration methods: conventional filtration, direct filtration, slow sand, and diatomaceous earth. Other filtration technologies are only acceptable if their efficiency at removing target organisms and contaminants can be demonstrated to be equal to or more efficient than these. The assumed log removals credited to filtration of Giardia lamblia and viruses will be based on recommendations in the US EPA Guidance Manual for Compliance with the Filtration and Disinfection Requirements for Public Water Systems Using Surface Water Sources. In all cases, filtration processes must be designed and operated to achieve at least 2.0 log removal of Giardia lamblia. For membrane filtration, removal credits shall be verified by a challenge study according to paragraphs (4)(c)(H) and (I) of this rule. Bag and Cartridge Filtration must have removal credits demonstrated in a challenge study according to paragraph (4)(c)(J) of this rule. The combination of filtration and disinfection must meet the inactivation levels prescribed in OAR 333-061-0032(1). Any water system wishing to challenge the assumed log removal credits must conduct demonstration studies based on the recommendations in the USEPA SWTR Guidance Manual and have the study protocol approved by the Authority.

(C) Pilot studies shall be conducted by the water supplier to demonstrate the effectiveness of any filtration method other than conventional filtration. Pilot study protocol shall be approved in advance by the Authority. Results of the pilot study shall be submitted to the Authority for review and approval.

(D) Regardless of the filtration method used, the water system must achieve a minimum of 0.5-log reduction of Giardia lamblia and a 1.0-log reduction of viruses from disinfection alone after filtration treatment.

(E) All filtration systems shall be designed and operated so as to meet the requirements prescribed in OAR 333-061-0032(4) and (5). Design of the filtration system must be in keeping with accepted standard engineering references acknowledged by the Authority such as the Great Lakes Upper Mississippi River "Recommended Standards for Water Works" technical reports by the International Reference Center for Community Water Supply and Sanitation, or publications from the World Health Organization. A list of additional references is available from the Authority upon request.

(F) Requirements for water systems using conventional or direct filtration

(i) Systems that employ multiple filters shall be designed such that turbidity measurements are monitored for each filter independently of the other filter(s). Each filter shall have a provision to discharge effluent water as waste.

(ii) All water treatment plants shall have an auto-dial call out alarm or an automatic shut-off for high turbidity.

(G) Additional requirements for membrane filtration. Each membrane filter system must have a turbidimeter installed after each filter unit for continuous indirect integrity monitoring. Once operating, direct and indirect integrity testing must be conducted on each unit as described in OAR 333-061-0036(5)(d). The operation and maintenance manual must include a diagnosis and repair plan such that the ability to remove pathogens is not compromised.

(H) Challenge Study criteria for Membrane Filtration. Water systems receive Cryptosporidium treatment credit for membrane filtration, as defined in OAR 333-061-0020(77)(f), that meets the criteria of this paragraph. The level of treatment credit a water system receives is equal to the lower of the values determined in this paragraph.

(i) The removal efficiency demonstrated during challenge testing conducted under the conditions in accordance with paragraph (4)(c)(I) of this rule.

(ii) The maximum removal efficiency that can be verified through direct integrity testing of the membrane filtration process under the conditions prescribed by OAR 333-061-0036(5)(d)(B).

(I) Challenge Testing. The membrane filter used by the water system must undergo challenge testing to evaluate removal efficiency, and results of the challenge testing must be reported to the Authority. Challenge testing must be conducted according to the criteria specified in this paragraph. Water systems may use data from challenge testing conducted prior to June 1, 2009 if the prior testing was consistent with the criteria specified in this paragraph.

(i) Challenge testing must be conducted on a full-scale membrane module, identical in material and construction to the membrane modules used in the water system's treatment facility, or a smaller-scale membrane module, identical in material and similar in construction to the full-scale module. A module is defined as the smallest component of a membrane unit in which a specific membrane surface area is housed in a device with a filtrate outlet structure.

(ii) Challenge testing must be conducted using Cryptosporidium oocysts or a surrogate that is removed no more efficiently than Cryptosporidium oocysts. Cryptosporidium or the surrogate used during challenge testing is referred to as the challenge particulate. The concentration of the challenge particulate, in both the feed and filtrate water, must be determined using a method capable of discretely quantifying the specific challenge particulate used in the test; gross measurements such as turbidity may not be used.

(iii) The maximum feed water concentration that can be used during a challenge test is based on the detection limit of the challenge particulate in the filtrate and must be determined according to the following equation:

Maximum Feed Concentration = 3.16 x 106 x (Filtrate Detection Limit)

(iv) Challenge testing must be conducted according to representative hydraulic conditions at the maximum design flux and maximum design process recovery specified by the manufacturer for the membrane module. Flux is defined as the throughput of a pressure driven membrane process expressed as flow per unit of membrane area. Recovery is defined as the volumetric percent of feed water that is converted to filtrate over the course of an operating cycle uninterrupted by events such as chemical cleaning or a solids removal process (that is, backwashing).

(v) Removal efficiency of a membrane module must be calculated from the challenge test results and expressed as a log removal value according to the following equation:

LRV = LOG10(Cf) - LOG10(Cp)

Where:

LRV = log removal value demonstrated during the challenge test;

Cf = the feed concentration measured during the challenge test; and

Cp = the filtrate concentration measured during the challenge test. Equivalent units must be used for the feed and filtrate concentrations. If the challenge particulate is not detected in the filtrate, the term Cp is set equal to the detection limit for the purpose of calculating the LRV. An LRV must be calculated for each membrane module evaluated during the challenge test.

(vi) The removal efficiency of a membrane filtration process demonstrated during challenge testing must be expressed as a log removal value (LRVC-Test). If fewer than 20 modules are tested, then LRVC-Test is equal to the lowest of the representative LRVs among the modules tested. If 20 or more modules are tested, then LRVC-Test is equal to the 10th percentile of the representative LRVs among the modules tested. The percentile is defined by (i/(n+1))where i is the rank of n individual data points ordered lowest to highest. If necessary, the 10th percentile may be calculated using linear interpolation.

(vii) The challenge test must establish a quality control release value (QCRV) for a non-destructive performance test that demonstrates the Cryptosporidium removal capability of the membrane filtration module. This performance test must be applied to each production membrane module used by the system that was not directly challenge tested in order to verify Cryptosporidium removal capability. Production modules that do not meet the established QCRV are not eligible for the treatment credit demonstrated during the challenge test.

(viii) If a previously tested membrane is modified in a manner that could change the removal efficiency of the membrane or the applicability of the non-destructive performance test and associated QCRV, additional challenge testing to demonstrate the removal efficiency of, and determine a new QCRV for, the modified membrane must be conducted and submitted to the Authority.

(J) Challenge Study requirements for Bag and Cartridge Filtration.

(i) The Cryptosporidium treatment credit awarded to bag or cartridge filters must be based on the removal efficiency demonstrated during challenge testing that is conducted according to the criteria specified in this paragraph. A factor of safety equal to 1-log for individual bag or cartridge filters and 0.5-log for bag or cartridge filters in series must be applied to challenge testing results to determine removal credit. Water systems may use results from challenge testing conducted prior to June 1, 2009 if the prior testing was consistent with the criteria specified in this paragraph.

(ii) Challenge testing must be performed on full-scale bag or cartridge filters and the associated filter housing or pressure vessel, that are identical in material and construction to the filters and housings the water system will use for removal of Cryptosporidium. Bag or cartridge filters must be challenge tested in the same configuration that the system will use, either as individual filters or as a series configuration of filters.

(iii) Challenge testing must be conducted using Cryptosporidium or a surrogate that is removed no more efficiently than Cryptosporidium. The microorganism or surrogate used during challenge testing is referred to as the challenge particulate. The concentration of the challenge particulate must be determined using a method capable of discreetly quantifying the specific microorganism or surrogate used in the test; gross measurements such as turbidity may not be used.

(iv) The maximum feed water concentration that can be used during a challenge test must be based on the detection limit of the challenge particulate in the filtrate (that is, filtrate detection limit) and must be calculated using the following equation:Maximum Feed Concentration = 1 x 104 x (Filtrate Detection Limit)

(v) Challenge testing must be conducted at the maximum design flow rate for the filter as specified by the manufacturer.

(vi) Each filter evaluated must be tested for a duration sufficient to reach 100 percent of the terminal pressure drop, which establishes the maximum pressure drop under which the filter may be used to comply with the requirements of this paragraph.

(vii) Removal efficiency of a filter must be determined from the results of the challenge test and expressed in terms of log removal values using the following equation:

LRV = LOG10(Cf)-LOG10(Cp)

Where:

LRV = log removal value demonstrated during challenge testing;

Cf = the feed concentration measured during the challenge test; and

Cp = the filtrate concentration measured during the challenge test. In applying this equation, the same units must be used for the feed and filtrate concentrations. If the challenge particulate is not detected in the filtrate, then the term Cp must be set equal to the detection limit.

(viii) Each filter tested must be challenged with the challenge particulate during three periods over the filtration cycle: within two hours of start-up of a new filter; when the pressure drop is between 45 and 55 percent of the terminal pressure drop; and at the end of the cycle after the pressure drop has reached 100 percent of the terminal pressure drop. An LRV must be calculated for each of these challenge periods for each filter tested. The LRV for the filter (LRVfilter) must be assigned the value of the minimum LRV observed during the three challenge periods for that filter.

(ix) If fewer than 20 filters are tested, the overall removal efficiency for the filter product line must be set equal to the lowest LRVfilter among the filters tested. If 20 or more filters are tested, the overall removal efficiency for the filter product line must be set equal to the 10th percentile of the set of LRVfilter values for the various filters tested. The percentile is defined by (i/(n+1))where i

is the rank of n individual data points ordered lowest to highest. If necessary, the 10th percentile may be calculated using linear interpolation.

(x) If a previously tested filter is modified in a manner that could change the removal efficiency of the filter product line, challenge testing to demonstrate the removal efficiency of the modified filter must be conducted and submitted to the Authority.

(K) Water systems using cartridge filtration must have pressure gauges installed before and after each cartridge filter.

(L) Water systems using diatomaceous earth filtration must add the body feed with the influent flow.

(d) Criteria and procedures for public water systems using point-of-entry (POE) or point-of-use (POU) devices.

(A) Public water systems may use POE or POU devices to comply with maximum contaminant levels, where specified in subsection (4)(b) of this rule, only if they meet the requirements of this subsection.

(B) It is the responsibility of the public water system to operate and maintain the POE or POU treatment system.

(C) The public water system must develop and obtain Authority approval for a monitoring plan before POE or POU devices are installed for compliance. Under the plan approved by the Authority, POE or POU devices must provide health protection equivalent to central water treatment. "Equivalent" means that the water would meet all Maximum Contaminant Levels as prescribed in OAR 333-061-0030 and would be of acceptable quality similar to water distributed by a well-operated central treatment plant. Monitoring must include contaminant removal efficacy, physical measurements and observations such as total flow treated and mechanical condition of the treatment equipment.

(D) Effective technology must be properly applied under a plan approved by the Authority and the microbiological safety of the water must be maintained.

(i) The water supplier must submit adequate certification of performance, field testing, and, if not included in the certification process, a rigorous engineering design review of the POE or POU devices to the Authority for approval prior to installation.

(ii) The design and application of the POE or POU devices must consider the tendency for increase in heterotrophic bacteria concentrations in water treated with activated carbon. It may be necessary to use frequent backwashing, post-contractor disinfection, and Heterotrophic Plate Count monitoring to ensure that the microbiological safety of the water is not compromised.

(iii) The POE or POU device must be evaluated to assure that the device will not cause increased corrosion of lead and copper bearing materials located between the device and the tap that could increase contaminant levels of lead and copper at the tap.

(E) All consumers shall be protected. Every building connected to the system must have a POE or POU device installed, maintained, and adequately monitored. The Authority must be assured that every building is subject to treatment and monitoring, and that the rights and responsibilities of the public water system customer convey with title upon sale of property.

(5) Facilities for continuous disinfection and disinfectant residual maintenance:

(a) Water obtained from surface sources or groundwater sources under the direct influence of surface water shall, as a minimum, be provided with continuous disinfection before such water may be used as a source of supply for a public water system. Water obtained from wells constructed in conformance with the requirements of these rules and which is found not to exceed microbiological maximum contaminant levels, may be used without treatment at public water systems;

(b) Water obtained from wells and springs shall be considered groundwater unless determined otherwise by the Authority. Wells and springs may be utilized without continuous disinfection if the construction requirements of section (2) of this rule are met and analyses indicate that the water consistently meets microbiological standards. A well or spring that is inadequately constructed, shows a history of E coli. contamination, and where the Authority determines that reconstruction will add a significant measure of public health protection, must be upgraded to meet current construction standards or disconnected from the water system.

(c) In public water systems where continuous disinfection is required as the sole form of treatment, or as one component of more extensive treatment to meet the requirements prescribed in OAR 333-061-0032(1), the facilities shall be designed so that:

(A) The disinfectant applied shall be capable of effectively destroying pathogenic organisms;

(B) The disinfectant is applied in proportion to water flow; and

(C) Disinfectants, other than ultraviolet light and ozone disinfection treatment, shall be capable of leaving a residual in the water which can be readily measured and which continues to serve as an active disinfectant; and

(D) Sufficient contact time shall be provided to achieve "CT" values capable of the inactivation required by OAR 333-061-0032(1). For ultraviolet light disinfection treatment, sufficient irradiance expressed in milliwatts per square centimeter (mWs/cm2) and exposure time expressed in seconds shall be provided to achieve UV dose levels expressed as (mWs/cm2) or millijoules per square centimeter (mJ/cm2) capable of the inactivation required by OAR 333-061-0032(1).

(d) When continuous disinfection, other than ultraviolet light disinfection, is required for reasons other than the treatment of surface water sources or groundwater sources under the direct influence of surface water, in addition to the requirements of paragraphs (5)(c)(A) through (C) of this rule, the facilities shall be designed so that:

(A) The primary disinfection treatment is sufficient to ensure at least 99.99 percent (4-log) inactivation or removal of viruses as determined by the Authority, or;

(B) There is sufficient contact time provided to achieve disinfection under all flow conditions between the point of disinfectant application and the point of first water use:

(i) When chlorine is used as the primary disinfectant, the system shall be constructed to achieve a free chlorine residual of 0.2 mg/l after 30 minutes contact time under all flow conditions before first water use;

(ii) When ammonia is added to the water with the chlorine to form a chloramine as the disinfectant, the system shall be constructed to achieve a combined chlorine residual of at least 2.0 mg/l after three hours contact time under all flow conditions before first water use;

(e) Provisions shall be made to alert the water supplier before the chlorine supply is exhausted. Water systems serving more than 3,300 people shall have an auto-dial call out alarm or an automatic shut-off for low chlorine residual when chlorine is used as a disinfectant.

(f) For continuous disinfection only, provisions shall be made for sampling the water before and after chlorination;

(g) Testing equipment shall be provided to determine the chlorine residual;

(h) Chlorinator piping shall be designed to prevent the contamination of the potable water system by backflow of untreated water or water having excessive concentrations of chlorine;

(i) The disinfectant must be applied in proportion to water flow;

(j) Chlorine gas feeders and chlorine gas storage areas shall:

(A) Be enclosed and separated from other operating areas;

(B) Chlorine cylinders shall be restrained in position to prevent upset by chaining 100 and 150 pound cylinders two-thirds of their height up from the floor and by double chocking one ton cylinders;

(C) The room housing the feeders and cylinders shall be above ground surface, shall have doors which open outward and to the outside and shall be ventilated by mechanical means at floor level and shall have an air intake located higher than the exhaust ventilation;

(D) Be located so that chlorine gas, if released, will not flow into the building ventilation systems;

(E) Have corrosion resistant lighting and ventilation switches located outside the enclosure, adjacent to the door;

(F) Be provided with a platform or hydraulic scale for measuring the weight of the chlorine cylinders;

(G) Be provided with a gas mask or self contained breathing apparatus approved by the National Institute of Occupational Safety and Health (NIOSH) for protection against chlorine gas and kept in good working condition. Storage of such equipment shall be in an area adjoining the chlorine room and shall be readily available. (Also see the Oregon Occupational Health and Safety regulations contained in OAR chapter 437.)

(k) When continuous disinfection treatment is provided through ultraviolet light (UV) disinfection, the facilities shall be designed to meet the requirements of this subsection:

(A) The UV unit must achieve the dosage indicated in Table 32 for the required pathogen inactivation. [Table not included. See ED. NOTE.]

(B) Ultraviolet lamps are insulated from direct contact with the influent water and are removable from the lamp housing;

(C) The treatment unit must have an upstream valve or device that prevents flows from exceeding the manufacturer's maximum rated flow rate, an ultraviolet light sensor that monitors light intensity through the water during operation, and a visual and audible alarm;

(D) There must be a visual means to verify operation of all ultraviolet lamps;

(E) The lamps, lamp sleeves, housings and other equipment must be able to withstand the working pressures applied through the unit;

(F) The treatment facility must be sheltered from the weather and accessible for routine maintenance as well as routine cleaning and replacement of the lamp sleeves and cleaning of the sensor windows/lenses;

(G) The lamps must be changed as per the manufacturer's recommendation; and

(H) The treatment unit must have shut-off valves at both the inlet side and the outlet side of the treatment unit. There shall be no bypass piping around the treatment unit.

(I) Reactor validation testing. All water systems, except those specified in paragraph (5)(k)(J) of this rule, must use UV reactors that have undergone validation testing to determine the operating conditions under which the reactor delivers the UV dose required in OAR 333-061-0036(5)(c) (that is, validated operating conditions). These operating conditions must include flow rate, UV intensity as measured by a UV sensor, UV Transmittance, and UV lamp status.

(i) When determining validated operating conditions, water systems must account for the following factors: UV absorbance by the water; lamp fouling and aging; measurement uncertainty of online sensors; UV dose distributions arising from the velocity profiles through the reactor; failure of UV lamps or other critical system components; and inlet and outlet piping or channel configurations of the UV reactor.

(ii) Validation testing must include the following: full scale testing of a reactor that conforms uniformly to the UV reactors used by the water system and inactivation of a test microorganism whose dose response characteristics have been quantified with a low pressure mercury vapor lamp.

(iii) The Authority may approve an alternative approach to validation testing.

(J) Non-Community water systems using only groundwater sources, and having minimal distribution systems as determined by the Authority, may use ultraviolet light as the only disinfectant when total coliforms but no E. coli have been detected in the source water. UV units must meet the specifications of a Class A UV system under the NSF Standard 55. The minimum ultraviolet light failsafe dosage set point shall be equivalent to 40 mW-s/cm2 (40 mJ/cm2) with a wavelength between 200 and 300 nanometers. The UV unit must automatically shut-off water flow if dosage drops below this failsafe set point.

(6) Finished water storage:

(a) Distribution reservoirs and treatment plant storage facilities for finished water shall be constructed to meet the following requirements:

(A) They shall be constructed of concrete, steel, wood or other durable material capable of withstanding external and internal forces which may act upon the structure;

(B) Ground-level reservoirs shall be constructed on undisturbed soil, bedrock or other stable foundation material capable of supporting the structure when full;

(C) Steel reservoirs, standpipes and elevated tanks shall be constructed in conformance with the AWWA Standards D100 and D103;

(D) Concrete reservoirs shall be provided with sufficient reinforcing to prevent the formation of cracks, and waterstops and dowels shall be placed at construction joints. Poured-in-place wall castings shall be provided where pipes pass through the concrete;

(E) Wooden reservoirs shall be redwood or other equally durable wood and shall be installed on a reinforced concrete base. Where redwood reservoirs are used, separate inlet and outlet pipes are required and the water entering the reservoir must be have a disinfectant continuously applied so as to result in a detectable residual in the water leaving the reservoir;

(F) Start-up procedures for new redwood tanks shall consist of filling the tank with a solution of water containing a minimum of two pounds of sodium carbonate per 1,000 gallons of water and retaining this solution in the tank a minimum of seven days before flushing;

(G) Where ground-level reservoirs are located partially below ground, the bottom shall be above the ground water table and footing drains discharging to daylight shall be provided to carry away ground water which may accumulate around the perimeter of the structure;

(H) The finished water storage capacity shall be increased to accommodate fire flows when fire hydrants are provided;

(I) Finished water storage facilities shall have watertight roofs;

(J) An access manhole shall be provided to permit entry to the interior for cleaning and maintenance. When the access manhole is on the roof of the reservoir there shall be a curbing around the opening and a lockable watertight cover that overlaps the curbing;

(K) Internal ladders of durable material, shall be provided where the only access manhole is located on the roof;

(L) Screened vents shall be provided above the highest water level to permit circulation of air above the water in finished water storage facilities;

(M) A drain shall be provided at the lowest point in the bottom, and an overflow of sufficient diameter to handle the maximum flow into the tank shall be provided at or near the top of the sidewall. The outlet ends of the drain and overflow shall be fitted with angle-flap valves or equivalent protection and shall discharge with an airgap to a watercourse or storm drain capable of accommodating the flow;

(N) A silt stop shall be provided at the outlet pipe;

(O) Where a single inlet/outlet pipe is installed and the reservoir floats on the system, provisions shall be made to insure an adequate exchange of water and to prevent degradation of the water quality and to assure the disinfection levels required in subparagraph (5)(c)(D) of this rule;

(P) A fence or other method of vandal deterrence shall be provided around distribution reservoirs;

(Q) When interior surfaces of finished water storage tanks are provided with a protective coating, the coating shall meet the requirements of NSF Standard 61 — Drinking Water System Components or equivalent.

(R) Reservoirs and clearwells that are to be used for disinfection contact time to treat surface water shall use a tracer study to determine the actual contact time. The Authority must approve procedures and protocols for the tracer study prior to the initiation of the study. The Authority recommends the US EPA Guidance Manual for Compliance with the Filtration and Disinfec-

tion Requirements for Public Water Systems Using Surface Water Sources for a tracer study procedure and protocol.

(S) Reservoirs and clearwells that are to be used for disinfection contact time to treat surface water shall have a means to adequately determine the flow rate on the effluent line.

(b) Pressure tanks for finished water shall meet the following requirements:

(A) Pressure tanks shall be installed above normal ground surface;

(B) Bypass piping around the pressure tank shall be provided to permit operation of the system while the tank is being maintained or repaired;

(C) Pressure tanks greater than 1,000 gallons shall be provided with an access manhole and a water sight-glass.

(D) All pressure tanks shall be provided with a drain, a pressure gauge, an air blow-off valve, means for adding air and pressure switches for controlling the operation of the pump(s);

(E) Pressure tanks shall be constructed of steel or an alternative material provided the tank is NSF 61 certified and shall be designed for pressure at least 50 percent greater than the maximum system pressure anticipated.

(7) Pumping facilities:

(a) Wherever possible, booster pumps shall take suction from tanks and reservoirs to avoid the potential for negative pressures on the suction line which result when the pump suction is directly connected to a distribution main;

(b) Pumps which take suction from distribution mains for the purpose of serving areas of higher elevation shall be provided with a low pressure cut-off switch on the suction side set at no less than 20 psi;

(c) Suction lift at pumping stations shall be avoided as far as possible, and pumps shall be installed so that the suction line is under a positive head. If suction lift cannot be avoided, provision shall be made for priming with water which does not exceed maximum contaminant levels;

(d) Pumping stations shall be located above maximum anticipated 100-year (1 percent) flood level, and the area around the pumping station shall be graded so that surface drainage is away from the station;

(e) Pumping stations shall be of durable construction so as to protect the equipment from the elements. The door to the pumping station shall be lockable, and facilities for heating and lighting shall be provided. The floor of the pumping station shall be sloped to provide adequate drainage.

(8) Distribution systems:

(a) Wherever possible, distribution pipelines shall be located on public property. Where pipelines are required to pass through private property, easements shall be obtained from the property owner and shall be recorded with the county clerk;

(b) Pipe, pipe fittings, valves and other appurtenances utilized at Community water systems shall be manufactured, installed and tested in conformance with the latest standards of the American Water Works Association, NSF International or other equivalent standards acceptable to the Authority;

(c) In Community water systems, distribution mains located in public roadways or easements, and the portion of the service connections from the distribution main to the customer's property line or service meter where provided are subject to the requirements of these rules. The piping from the customer's property line, or the meter where provided, to the point of water use (the building supply line) is subject to the requirements of the State Plumbing Code;

(d) In all Public Water Systems where the system facilities and the premises being served are both on the same parcel of property, requirements relating to pipe materials and pipe installation shall comply with the State Plumbing Code;

(e) Distribution piping shall be designed and installed so that the pressure measured at the property line in the case of Community water systems, or at the furthest point of water use, in the case of a Transient Non-Community water system of the type described in subsection (d) of this section, shall not be reduced below 20 psi;

(f) Distribution piping shall be carefully bedded and fully supported in material free from rocks and shall be provided with a cover of at least 30 inches. Select backfill material shall be tamped in layers around and over the pipe to support and protect it. Large rocks or boulders shall not be used as backfill over the pipe;

(g) Provision shall be made at all bends, tees, plugs, and hydrants to prevent movement of the pipe or fitting;

(h) Wherever possible, dead ends shall be minimized by looping. Where dead ends are installed, or low points exist, blow-offs of adequate size shall be provided for flushing;

(i) Air-relief valves shall be installed at high points where air can accumulate. The breather tube on air-relief valves shall be extended above ground surface and provided with a screened, downward facing elbow;

(j) Yarn, oakum, lead or other material which may impair water quality shall not be used where it will be in contact with potable water;

(k) Nonconductive water pipe (plastic or other material) that is not encased in conductive pipe or casing must have an electrically conductive wire or other approved conductor for locating the pipe when the pipeline is underground. The wire shall be No. 18 AWG (minimum) solid copper with blue colored insulation. Ends of wire shall be accessible in water meter boxes, valve boxes or casings, or outside the foundation of buildings where the pipeline enters the building. The distance between tracer lead access locations shall not be more than 1,000 feet. Joints or splices in wire shall be waterproof.

(l) Piping that is to be used for disinfection contact time shall be verified by plug flow calculations under maximum flow conditions.

(9) Crossings-Sanitary sewers and water lines:

(a) All reference to sewers in this section shall mean sanitary sewers;

(b) In situations involving a water line parallel to a sewer main or sewer lateral, the separation between the two shall be as indicated in Figure 1; [Figure not included. See ED NOTE.]

(c) In situations where a water line and a sewer main or sewer lateral cross, the separation between the two shall be as follows:

(A) Wherever possible, the bottom of the water line shall be 1.5 feet or more above the top of the sewer line and one full length of the water line shall be centered at the crossing;

(B) Where the water line crosses over the sewer line but with a clearance of less than 1.5 feet, the sewer line shall be exposed to the sewer line joints on both sides of the crossing to permit examination of the sewer pipe. If the sewer pipe is in good condition and there is no evidence of leakage from the sewer line, the 1.5-foot separation may be reduced. However, in this situation, the water supplier must center one length of the water line at the crossing and must prepare a written report of the findings and indicating the reasons for reducing the separation. If the water supplier determines that the conditions are not favorable or finds evidence of leakage from the sewer line, the sewer line shall be replaced with a full length of pipe centered at the crossing point, of PVC pressure pipe (ASTM D-2241, SDR 32.5), high-density PE pipe (Drisco pipe 1000), ductile-iron Class 50 (AWWA C-51), or other acceptable pipe; or the sewer shall be encased in a reinforced concrete jacket for a distance of 10 feet on both sides of the crossing.

(C) Where the water line crosses under the sewer line, the water supplier shall expose the sewer line and examine it as indicated in paragraph (9)(c)(B) of this rule. If conditions are favorable and there is no evidence of leakage from the sewer line, the sewer line may be left in place, but special precautions must be taken to assure that the backfill material over the water line in the vicinity of the crossing is thoroughly tamped in order to prevent settlement which could result in the leakage of sewage. In this situation, the water supplier must center one length of the water line at the crossing and must prepare a written report recording the manner in which the sewer line was supported at the crossing and the material and methods used in backfilling and tamping to prevent settlement of the sewer. If the water supplier determines that conditions are not favorable or finds evidence of leakage from

the sewer line, the provisions of paragraph (9)(c)(B) of this rule apply.

(d) When a water main is installed under a stream or other watercourse, a minimum cover of 30 inches shall be provided over the pipe. Where the watercourse is more than 15 feet wide, the pipe shall be of special construction with flexible watertight joints, valves shall be provided on both sides of the crossing so that the section can be isolated for testing or repair, and test cocks shall be provided at the valves.

(10) Disinfection of facilities:

(a) Following construction or installation of new facilities and repairs to existing facilities, those portions of the facilities which will be in contact with water delivered to users must be cleaned and flushed with potable water and disinfected according to AWWA Standards C651 through C654 before they are placed into service. Disinfection must be by chlorine unless another disinfectant can be demonstrated to be equally effective.

(b) For construction of new distribution pipelines (with any associated service connections and other appurtenances installed at the time of construction), disinfection by chlorination must be conducted as specified in paragraphs (A) through (C) of this subsection unless another method from AWWA Standard C651 is used.

(A) A solution with a free chlorine residual of 25 mg/l must be introduced to the pipe such that the solution will contact all surfaces and trapped air will be eliminated. The solution must remain in place for at least 24 hours.

(B) After 24 hours, if the free chlorine residual is 10 mg/l or greater, the chlorine solution must be drained and the pipe flushed with potable water. If the free chlorine residual is less than 10 mg/l after 24-hours, the pipe must be flushed and rechlorinated until a free chlorine residual of 10 mg/l or more is present after a 24 hour period.

(C) After the pipe is disinfected, flushed and filled with potable water, bacteriological samples must be collected to determine the procedures' effectiveness. At least two samples must be collected from the new pipe at least 16 hours apart and analyzed for coliform bacteria. If the pipe has held potable water for at least 16 hours before sample collection, two samples may be collected at least 15 minutes apart while the sample tap is left running. If the results of both analyses indicate the water is free of coliform bacteria, the pipe may be put into service. If the either sample indicates the presence of coliform bacteria, the disinfection and flushing process must be repeated until samples are free of coliform.

(c) For repaired pipelines that were depressurized and wholly or partly dewatered during repair or that likely experienced contamination during repair, disinfection according to the procedure specified in paragraphs (10)(b)(A) through (C) of this rule must be followed except that bacteriological samples must be collected downstream of the repair site. If the direction of flow is unknown, samples must be collected on each side of the repair site.

(d) A water line may be returned to service, following repairs or routine maintenance, prior to receiving a report on the bacteriological analysis if the following procedures have been completed:

(A) Customer meters were shut off prior to placing the water line out of service;

(B) The area below the water line to be repaired was excavated and dewatered;

(C) The exposed pipe was treated with a hypochlorite solution;

(D) The water line was flushed thoroughly, and a concentration of residual chlorine has been re-established that is comparable to the level normally maintained by the water system, if applicable; and

(E) Bacteriological analysis has been conducted as a record of repair effectiveness.

(e) For reservoirs and tanks, disinfection by chlorination shall be accomplished according to AWWA Standard C652 which includes, but is not limited to, the following methods:

(A) Filling the reservoir or tank and maintaining a free chlorine residual of not less than 10 mg/l for the appropriate 6 or 24 hour retention period; or

(B) Filling the reservoir or tank with a 50 mg/l chlorine solution and leaving for six hours; or

(C) Directly applying by spraying or brushing a 200 mg/l solution to all surfaces of the storage facility in contact with water if the facility were full to the overflow elevation.

(f) When the procedures described in paragraphs (10)(e)(A) and (B) of this rule are followed, the reservoir or tank shall be drained after the prescribed contact period and refilled with potable water, and a sample taken for microbiological analysis. If the results of the analysis indicate that the water is free of coliform organisms, the facility may be put into service. If not, the procedure shall be repeated until a sample free of coliform organisms is obtained;

(g) When the procedure described in paragraph (10)(e)(C) of this rule is followed, the reservoir or tank shall be filled with potable water and a sample taken for microbiological analysis. It will not be necessary to flush the reservoir or tank after the chlorine solution is applied by spraying or brushing. Microbiological analysis shall indicate that the water is free of coliform organisms before the facility can be put into service;

(h) When a reservoir is chlorinated following routine maintenance, inspection, or repair, it may be put back into service prior to receiving the report on the microbiological analysis provided the water leaving the reservoir has a free chlorine residual of at least 0.4 mg/l or a combined chlorine residual of at least 2.0 mg/l.

(i) Underwater divers used for routine maintenance, inspection, or repair of reservoirs shall use a full body dry suit with hardhat scuba and an external air supply. The diver shall be disinfected by spraying a 200 mg/l solution of chlorine on all surfaces that will come into contact with drinking water.

[ED. NOTE: Tables & Figures referenced are available from the agency.]

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 431.110, 431.150, 448.131, 448.150, 448.273, 448.279

Hist.: HD 106, f. & ef. 2-6-76; HD 12-1979, f. & ef. 9-11-79; HD 10-1981, f. & ef. 6-30-81; HD 17-1981(Temp), f. & ef. 8-28-81; HD 4-1982, f. & ef. 2-26-82; Renumbered from 333-042-0215, HD 2-1983, f. & ef. 2-23-83; HD 21-1983, f. 10-20-83, ef. 11-1-83; HD 11-1985, f. & ef. 7-2-85; HD 30-1985, f. & ef. 12-4-85 HD 3-1987, f. & ef. 2-17-87; HD 9-1989, f. & cert. ef. 11-13-89; HD 26-1990, f. 12-26-90, cert. ef. 12-29-90; HD 7-1992, f. & cert. ef. 6-9-92; HD 12-1992, f. & cert. ef. 12-7-92; HD 3-1994, f. & cert. ef. 1-14-94; HD 11-1994, f. & cert. ef. 4-11-94; HD 1-1996, f. 1-2-96, cert. ef. 1-5-96; HD 14-1997, f. & cert. ef. 10-31-97; OHD 4-1999, f. 7-14-99, cert. ef. 7-15-99; OHD 7-2000, f. 7-11-00, cert. ef. 7-15-00; OHD 17-2002, f. & cert. ef. 10-25-02; PH 12-2003, f. & cert. ef. 8-15-03; PH 33-2004, f. & cert. ef. 10-21-04; PH 2-2008, f. & cert. ef. 2-15-08; PH 4-2009, f. & cert. ef. 5-18-09; PH 7-2010, f. & cert. ef. 4-19-10; PH 3-2013, f. & cert. ef. 1-25-13; PH 5-2016, f. 2-10-16, cert. ef. 4-1-16

333-061-0055
Waivers from Construction Standards

The Authority may grant waivers from the construction standards prescribed by these rules:

(1) When it is demonstrated to the satisfaction of the Authority that strict compliance with the rule would be highly burdensome or impractical due to special conditions or causes; and

(2) When the public or private interest in the granting of the waiver is found by the Authority to clearly outweigh the interest of the application of uniform rules; and

(3) When alternate measures are provided which, in the opinion of the Authority, will provide adequate protection to the health and safety of the public including the ability to produce water which does not exceed the maximum contaminant levels listed in OAR 333-061-0030.

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 448.131 & 448.135

Hist.: HD 4-1982, f. & ef. 2-26-82; Renumbered from 333-042-0216, HD 2-1983, f. & ef. 2-23-83; PH 7-2010, f. & cert. ef. 4-19-10

333-061-0057
Voluntary Drinking Water Protection Program

(1) In accordance with OAR 340-040-0140 through 0200, a public water system or other responsible management authority that wishes to have a state certified drinking water protection program shall comply with the requirements prescribed in this rule.

(2) Delineation of the drinking water protection area (DWPA):

(a) Delineations will be accomplished for all Community, Non-transient Non Community and Transient Non Community water systems as part of the Safe Drinking Water Act's Source Water Assessment Program. Water systems may choose to complete or upgrade the delineations themselves. If so, they must comply with subsection (2)(b) of this rule;

(b) Delineation requirements for all groundwater sources are as follow:

(A) Delineations will be accomplished using a minimum TOT criterion of 10 years unless a hydrogeologic boundary is encountered at a shorter time of travel or as specified in subsection (2)(c) of this rule;

(B) Delineations will be accomplished by a registered geologist, engineering geologist or other licensed professional with demonstrated experience and competence in hydrogeology in accordance with ORS 672.505 through 672.705;

(C) Except as noted in subsection (2)(c) of this rule, a conceptual ground water model shall be developed for all public water systems participating in the voluntary drinking water protection program. The model shall be based on available information including, but not limited to, well reports, published reports and available unpublished reports and theses, etc. Sources of this information include the Water Resources Department, U. S. Geological Survey, Department of Geology and Mineral Industries, Department of Environmental Quality, university libraries and the Authority. The model shall include, but not be limited to, the identification and characterization of hydrogeologic units, determination of hydrogeologic boundaries, if any, areas of discharge and recharge and distribution of hydraulic head for the aquifer(s) of concern. The model shall also evaluate whether or not the porous media assumption is valid;

(D) The delineated DWPA and supporting documentation shall be submitted to the Authority for review and certification;

(E) Within 60 days of the receipt of the delineated drinking water protection area and supporting documentation, the Authority shall send a written acknowledgment of that receipt and an estimated date for review and certification of the delineation;

(F) The delineation techniques stipulated in this rule represent the minimum acceptable effort required for a state certified program. The use of a more sophisticated technique is acceptable.

(c) Springs. For water systems served by springs, hydrogeologic mapping shall be used to delineate the recharge area to the spring(s).

(d) Wells.

(A) All delineations for groundwater derived from wells shall use an adjusted pump rate (Qa) that allows for potential growth using one of the methods described below, whichever yields the smallest value for Qa:

(i) 125 percent of average pump rate as determined from the three months representing the highest usage; or

(ii) 125 percent of average pump rate as determined using a comparable community; or

(iii) The design capacity of the pump; or

(iv) 90 percent of the safe yield of the well.

(v) The water system's population times 200 gallons per day.

(B) For water systems serving a population ≤500 and using a single well, the minimum acceptable delineation method is a calculated fixed radius. Parameters considered in this technique include Qa, effective porosity, open (screened or perforated) interval or thickness of the water-bearing zone(s), whichever is less, and a TOT of 15 years.

(C) For water systems serving a population of 501 to 3,300 or systems serving ≤500 with multiple wells, the DWPA(s) shall be delineated using a combination of an analytical technique and hydrogeologic mapping.

(D) For water systems serving a population >3,300, the conceptual model shall be refined using site-specific collected data. Data collected shall include, but not be limited to, measured static water levels for the purpose of generating a map of the appropriate potentiometric-or water table surface, and at a minimum a 24-hour constant-rate aquifer test. The well to be tested should remain idle for a period of 24 hours prior to the test. Water levels in the well should be monitored at appropriate intervals during the pre-pumping, pumping and recovery phases. Additional technical information is given in the Oregon Wellhead Protection Guidance Manual and the 1996 Oregon Source Water Assessment Guidance.

(E) For water systems serving a population of 3,301 to 50,000, the DWPA(s) shall be delineated as provided in subsection (2)(c) of this rule, with the exception of using the site specific data collected in accordance with subsection (2)(c) of this rule.

(F) For water systems serving a population >50,000 and using wells, the DWPA(s) shall be delineated using numerical models or comparable analytical methods. The model must be calibrated using field observations and measurements of appropriate hydrogeologic parameters.

(e) Susceptibility Analysis. To guide the development of management strategies, the aquifer's susceptibility within the DWPA may be determined using the methods described in the Use and Susceptibility Waiver Guidance Document, the 1996 Oregon Source Water Assessment Guidance or another pre-approved process. Additional technical information is available in the Oregon Wellhead Protection Guidance Manual.

(f) Delineation Update. The water system's DWPA delineation shall be re-examined every five years or during the sanitary survey for that system for potential revisions (OAR 340-040-0190). Factors that may require revision of a DWPA boundary include, but are not limited to the following:

(A) A significant change in the pumping rate;

(B) A significant change in recharge to the aquifer;

(C) Wells outside the control of the water system placed in a manner that could significantly modify the shape and/or orientation of the original DWPA.

(3) New and Future Groundwater Sources:

(a) New sources. With regard to the voluntary wellhead protection program, a new source is defined as an additional or modified well(s) and/or spring(s) that will be used by the water system.

(A) For new wells or springs outside an existing DWPA or deriving water from a different aquifer than that supplying other already delineated DWPAs, the following steps shall be completed:

(i) If more than one potential site is available, the water system or other responsible management authority shall conduct a provisional delineation and a preliminary potential contaminant source inventory for each site being considered in order to evaluate the long-term viability of each of the sites available; and

(ii) Delineate the chosen site as prescribed in section (2) of this rule. Further technical information is provided in the Oregon Wellhead Protection Guidance Manual.

(B) For new wells or springs inside an existing DWPA or potentially influencing an existing DWPA, the following steps shall be completed:

(i) Evaluate sites and delineate DWPA(s) as prescribed in subparagraphs (3)(a)(A)(i) and (ii) of this rule; and

(ii) Modify the existing wellhead protection plan to encompass modifications resulting from the new delineation.

(C) New wells or springs as defined in subsection (3)(a) of this rule shall comply with all appropriate construction standards as prescribed in OAR 333-061-0050 and shall comply with plan submission requirements as prescribed in 333-061-0060.

(b) Future sources. A public water system or other responsible management authority that has recognized the need for future groundwater supplies beyond their current capacity may choose to identify the area where this future supply will be obtained in accordance with subparagraph (3)(a)(A)(i) of this rule.

(4) Contingency Planning:

(a) Public water systems shall develop or revise contingency plans for response to potential loss or reduction of their drinking water source(s). Key elements of the plan shall include, but not be limited to, the following:

(A) Inventory/prioritize all threats to the drinking water supply;

(B) Prioritize water usage;

(C) Anticipate responses to potential incidents;

(D) Identify key personnel and development of notification roster;

(E) Identify short-term and long-term replacement potable water supplies;

(F) Identify short-term and long-term conservation measures;

(G) Provide for plan testing, review and update;

(H) Provide for new and on-going training of appropriate individuals;

(I) Provide for education of the public; and

(J) Identify logistical and financial resources.

(b) Public water systems shall coordinate their contingency plan with the emergency response plans of the appropriate county and/or city and with the contingency plans developed by industries using hazardous materials within the wellhead protection area.

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 431.110, 431.150, 448.131, 448.150 & 448.273

Hist.: HD 1-1996, f. 1-2-96, cert. ef. 1-5-96; OHD 17-2002, f. & cert. ef. 10-25-02; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 2-2006, f. & cert. ef. 1-31-06; PH 7-2010, f. & cert. ef. 4-19-10

333-061-0058
Wellfield Determination

(1) Water systems possessing two or more wells that separately supply water to the distribution system may be eligible to have those wells considered as a wellfield source for monitoring purposes provided the requirements of this rule are met. Information pertinent to determining whether the wellfield designation is appropriate can be found in the water system's Source Water Assessment Report.

(2) To be classified as a wellfield, the wells must meet the following criteria:

(a) The wells must be within 2,500 feet of one another or as determined in a state approved hydrogeological study to minimize inter-well interference drawdowns. For wells located in a low-impact land use area, this criterion may be waived at the discretion of the Authority.

(b) The wells must produce from the same and no other aquifer. This criterion is determined using source water assessment results, based on well reports, maps and other hydrogeological information.

(3) To be considered for wellfield designation, the water supplier is asked to submit the following to the Authority:

(a) A schematic drawing showing all sources, entry points and relevant sample taps;

(b) A map and description of the land use activities within the respective wellhead protection areas (using the inventory section of the Source Water Assessment Report); and

(c) A description of the pumping patterns.

(4) If a water system's wells are considered to comprise a wellfield, the susceptibility analysis conducted during the source water assessment is utilized to determine the sampling point(s). Table 46 summarizes the alternatives: [Table not included. See ED. NOTE.]

(5) To determine the most susceptible well, the area within the two-year time-of-travel is considered. The Authority will consider the potential contaminant source inventory determined during the source water assessment, the aquifer sensitivity, pumping patterns and other pertinent hydrogeological information.

(6) The Authority may still designate more than one entry point within the wellfield as a sampling point if well construction and/or land use practices warrant. For a large area containing numerous wells, sub-wellfields may be identified, each with its own sample site designation.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 448.131 & 448.268

Hist.: OHD 17-2002, f. & cert. ef. 10-25-02; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 33-2004, f. & cert. ef. 10-21-04; PH 4-2009, f. & cert. ef. 5-18-09; PH 7-2010, f. & cert. ef. 4-19-10

333-061-0060
Plan Submission and Review Requirements

(1) Plan Submission:

(a) Construction and installation plans shall be submitted to and approved by the Authority before construction begins on new systems or major additions or modifications, as determined by the Authority, are made to existing systems. Plans shall be drawn to scale;

(b) Preliminary plans, pilot studies, master plans and construction plans shall be prepared by a Professional Engineer registered in Oregon, and submitted to the Authority unless exempted by the Authority (See OAR 333-061-0060(4));

(c) Plans shall set forth the following:

(A) Sufficient detail, including specifications, to completely and clearly illustrate what is to be constructed and how those facilities will meet the construction standards set forth in these regulations. Elevation or section views shall be provided where required for clarity;

(B) Supporting information attesting to the quality of the proposed source of water;

(C) Vicinity map of the proposed project relative to the existing system or established landmarks of the area;

(D) Name of the owner of the water system facilities during construction and the name of the owner and operator of the facilities after completion of the project;

(E) Procedures for cleaning and disinfecting those facilities which will be in contact with the potable water.

(d) Prior to drilling a well, a site plan shall be submitted which shows the site location, topography, drainage, surface water sources, specifications for well drilling, location of the well relative to sanitary hazards, dimensions of the area reserved to be kept free of potential sources of contamination, evidence of ownership or control of the reserve area and the anticipated depth of the aquifer from which the water is to be derived. The Authority will review well reports from the area and in consultation with the local watermaster and the well constructor as appropriate will recommend the depth of placement of the casing seal. After the well is drilled, the following documents shall be submitted to the Authority for review and approval: Well driller's report, report of the pump test which indicates that the well has been pumped for a sufficient length of time to establish the reliable yield of the well on a sustained basis, including data on the static water level, the pumping rate(s), the changes in drawdown over the duration of the test, the rate of recovery after the pump was turned off, reports on physical, chemical and microbiological quality of the well water, performance data on the well pump, a plan of the structure for protecting above-ground controls and appurtenances, and a plan showing how the well will be connected to the water system. (See OAR 333-061-0050(2)).

(e) Any community, non-transient non-community, or transient non-community water system that treats surface water or groundwater under the influence of surface water and that desires to make a significant change to its disinfection treatment process as defined by paragraphs (1)(e)(A) through (1)(e)(D) of this rule, is required to develop a disinfection profile and calculate a disinfection benchmark according to OAR 333-061-0036(4)(e). The water system must consult with and provide any additional information requested by the Authority prior to making such a change. The water system must develop a disinfection profile for Giardia lamblia and viruses, calculate a disinfection benchmark, describe the proposed change in the disinfection process, and analyze the effect(s) of the proposed change on current levels of disinfection according to the USEPA Disinfection Profiling and Benchmarking Guidance Manual

or the USEPA LT1-ESWTR Disinfection Profiling and Benchmarking Technical Guidance Manual and submit the information to the Authority for review and approval. Significant changes to the disinfection treatment process include:

(A) Changes to the point of application:

(B) Changes to the disinfectants used in the treatment process;

(C) Changes to the disinfection process;

(D) Any other modification identified by the Authority.

(f) A water system that uses either chloramines, chlorine dioxide, or ozone for primary disinfection, and that is required to prepare a disinfection profile for Giardia lamblia as prescribed by subsection (1)(e) of this rule, must also prepare a disinfection profile for viruses and calculate the logs of inactivation for viruses using the methods specified in OAR 333-061-0036(4)(l).

(2) Plan review:

(a) Upon receipt of plans, the Authority shall review the plans and either approve them or advise that correction or clarification is required. When the correction or clarification is received, and the item(s) in question are resolved, the Authority shall then approve the plans;

(b) Upon completion of a project, a professional engineer registered in Oregon shall submit to the Authority a statement certifying that the project has been constructed in compliance with the approved plans and specifications. When substantial deviations from the approved plans are made, as-built plans showing compliance with these rules shall be submitted to the Authority;

(c) Plans shall not be required for emergency repair of existing facilities. In lieu of plans, written notice shall be submitted to the Authority immediately after the emergency work is completed stating the nature of the emergency, the extent of the work and whether or not any threats to the water quality exists or existed during the emergency.

(3) Plan review fees: Plans submitted to the Authority shall be accompanied by a fee as indicated in Table 41. Those plans not accompanied by a fee will not be reviewed. [Table not included. See ED. NOTE.]

(4) Plan review exemptions:

(a) Water suppliers may be exempted from submitting plans of main extensions, providing they:

(A) Have provided the Authority with a current master plan; and

(B) Certify that the work will be carried out in conformance with the construction standards of these rules; and

(C) Submit to the Authority an annual summary of the projects completed; and

(D) Certify that they have staff qualified to effectively supervise the projects.

(b) Those water suppliers certifying that they have staff qualified to effectively plan, design and supervise their projects, may request the Authority for further exemption from this rule. Such requests must be accompanied by a listing of staff proposed to accomplish the work and a current master plan. To maintain the exemption, the foregoing must be annually updated;

(c) At the discretion of the Authority, Community, Transient and Non-Transient Non-Community and State Regulated water systems may be exempted from submitting engineered plans. They shall, however, submit adequate plans indicating that the project meets the minimum construction standards of these rules.

(5) Master plans:

(a) Community water systems with 300 or more service connections shall maintain a current master plan. Master plans shall be prepared by a professional engineer registered in Oregon and submitted to the Authority for review and approval.

(b) Each master plan shall evaluate the needs of the water system for at least a twenty year period and shall include but is not limited to the following elements:

(A) A summary of the overall plan that includes the water quality and service goals, identified present and future water system deficiencies, the engineer's recommended alternative for achieving the goals and correcting the deficiencies, and the recommended implementation schedule and financing program for constructing improvements.

(B) A description of the existing water system which includes the service area, source(s) of supply, status of water rights, current status of drinking water quality and compliance with regulatory standards, maps or schematics of the water system showing size and location of facilities, estimates of water use, and operation and maintenance requirements.

(C) A description of water quality and level of service goals for the water system, considering, as appropriate, existing and future regulatory requirements, nonregulatory water quality needs of water users, flow and pressure requirements, and capacity needs related to water use and fire flow needs.

(D) An estimate of the projected growth of the water system during the master plan period and the impacts on the service area boundaries, water supply source(s) and availability, and customer water use.

(E) An engineering evaluation of the ability of the existing water system facilities to meet the water quality and level of service goals, identification of any existing water system deficiencies, and deficiencies likely to develop within the master plan period. The evaluation shall include the water supply source, water treatment, storage, distribution facilities, and operation and maintenance requirements. The evaluation shall also include a description of the water rights with a determination of additional water availability, and the impacts of present and probable future drinking water quality regulations.

(F) Identification of alternative engineering solutions, environmental impacts, and associated capital and operation and maintenance costs, to correct water system deficiencies and achieve system expansion to meet anticipated growth, including identification of available options for cooperative or coordinated water system improvements with other local water suppliers.

(G) A description of alternatives to finance water system improvements including local financing (such as user rates and system development charges) and financing assistance programs.

(H) A recommended water system improvement program including the recommended engineering alternative and associated costs, maps or schematics showing size and location of proposed facilities, the recommended financing alternative, and a recommended schedule for water system design and construction.

(I) If required as a condition of a water use permit issued by the Water Resources Department, the Master Plan shall address the requirements of OAR 690-086-0120 (Water Management and Conservation Plans).

(c) The implementation of any portion of a water system master plan must be consistent with OAR 333-061 (Public Drinking Water Systems, Oregon Health Authority), OAR 660-011 (Public Facilities Planning, Department of Land Conservation and Development) and OAR 690-086 (Water Management and Conservation Plans, Water Resources Department).

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 448.131

Hist.: HD 106, f. & ef. 2-6-76; HD 4-1980, f. & ef. 3-21-80; HD 17-1981(Temp), f. & ef. 8-28-81; HD 4-1982, f. & ef. 2-26-82; Renumbered from 333-042-0220, HD 2-1983, f. & ef. 2-23-83; HD 13-1985, f. & ef. 8-1-85; HD 9-1989, f. & cert. ef. 11-13-89; HD 3-1994, f. & cert. ef. 1-14-94; HD 11-1994, f. & cert. ef. 4-11-94; HD 1-1996, f. 1-2-96, cert. ef. 1-5-96; HD 14-1997, f. & cert. ef. 10-31-97; OHD 4-1999, f. 7-14-99, cert. ef. 7-15-99; OHD 7-2000, f. 7-11-00, cert. ef. 7-15-00; OHD 23-2001, f. & cert. ef. 10-31-01; OHD 17-2002, f. & cert. ef. 10-25-02; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 33-2004, f. & cert. ef. 10-21-04; PH 2-2006, f. & cert. ef. 1-31-06; PH 4-2009, f. & cert. ef. 5-18-09; PH 7-2010, f. & cert. ef. 4-19-10; PH 23-2015, f. 12-8-15, cert. ef. 1-1-16; PH 5-2016, f. 2-10-16, cert. ef. 4-1-16

333-061-0061
Capacity Requirements for Public Water Systems

(1) Water system capacity is defined as the technical, managerial, and financial capability of the water system necessary to plan for, achieve, and maintain compliance with applicable drinking water standards.

(2) Capacity requirements for new public water systems.

(a) Any new community, non-transient non-community, or transient non-community public water system commencing operations on or after October 1, 1999, must meet the applicable requirements in this rule prior to serving drinking water to the public. The owner of such water system shall submit evidence of meeting all applicable requirements to the Authority for review and shall commence operation only after Authority approval. This rule does not apply to water systems that were built and operating prior to October 1, 1999.

(b) Requirements for Technical Capacity

(A) The water system must comply with the local land use requirements of OAR 333-061-0062, including submission to the Authority of evidence of approval by the local land use authority.

(B) The water system must comply with plan submission and review requirements of OAR 333-061-0060, and plans submitted must comply with construction standards in 333-061-0050.

(C) The owner of a new water system must demonstrate a valid water right permit as required and prescribed by the Oregon Water Resources Department (ORS Chapter 537).

(D) The water system must submit initial water quality test results demonstrating compliance with applicable Maximum Contaminant Levels (OAR 333-061-0030), and applicable treatment requirements and performance standards (OAR 333-061-0032 and 0034).

(E) Community water systems shall have water use meters installed at all service connections.

(F) Community water systems with 300 or more service connections shall have a master plan meeting the requirements of OAR 333-061-0060.

(c) Requirements for Managerial Capacity

(A) Community and non-transient non-community water systems must employ or contract for the services of a certified operator as required by OAR 333-061-0225.

(B) Community water systems within areas of Oregon where State or Federally listed sensitive, threatened or endangered fish species are located, shall consult with the Oregon Water Resources Department. If required by the Oregon Water Resources Department, community water systems shall have water management and conservation plans meeting the requirements of Oregon Water Resources Department OAR 690-086-0010 through 0920.

(d) Requirements for Financial Capacity. The water system must establish a water rate structure and billing procedure, or alternate financial plan, to assure that funds are collected and available to meet the anticipated operation, maintenance, and replacement costs of the water system.

(3) Capacity requirements for public water systems applying for a loan from the Drinking Water State Revolving Loan Fund.

(a) All public water systems qualifying for a Drinking Water State Revolving Fund loan must receive a capacity assessment for technical and managerial capacity from the Authority, and financial capacity from the Oregon Economic & Community Development Department through the loan application process, prior to contract execution.

(b) All deficiencies identified in the capacity assessment must be corrected such that:

(A) Those deficiencies identified in the capacity assessment as major deficiencies must be corrected prior to contract execution. Major deficiencies include but are not limited to the following:

(i) Under technical capacity, major infrastructure deficiencies identified in the sanitary survey and not corrected as a part of this project or identified as a deficiency under paragraph (E) of this subsection; or

(ii) Under managerial capacity, no certified operator and no contract or agreement for operator services from another water system or management agency; or

(iii) Under financial capacity, inappropriate financial statements, lack of a capital financing program, or an inadequate rate structure to cover necessary system operation, debt service, or capital replacement.

(B) Those deficiencies identified in the capacity assessment as loan conditions must be corrected as a part of the contract prior to contract completion or on a schedule set and/or approved and tracked by the Authority or its designee. Loan condition deficiencies are deficiencies which may take considerable staff or contractor time and possibly some funding to correct. Loan condition deficiencies include but are not limited to the following:

(i) Under technical capacity, inadequate or no water rights, incomplete installation of water use meters, incomplete or no engineering drawings of the water system, out-of-date or no master plan, or incomplete or no plan review on prior construction projects; or

(ii) Under managerial capacity, having an operator at a lower level than required in responsible charge of the water system, no written emergency response plan, no written water conservation program if required by the Water Resources Department under OAR 690-086-0010 through 690-086-0920, no written water system operations manual, or no cross connection program.

(C) Those deficiencies identified in the capacity assessment as short term deficiencies must be corrected prior to contract completion and will be tracked by the Authority. Short term deficiencies are deficiencies which can be quickly corrected with additional staff attention. Short term deficiencies include but are not limited to the following:

(i) Under technical capacity, water quality monitoring is incomplete, no coliform sample plan or site map, or no written water quality monitoring plan; or

(ii) Under managerial capacity, no annual cross connection summary report if required, or no consumer confidence report if required.

(D) Those deficiencies identified in the capacity assessment as corrected with the project will be considered by the Authority as corrected with contract completion.

(E) All other deficiencies identified in the capacity assessment must be identified and established as a future construction project in the water system master plan, feasibility study, or other such document in order to be considered by the Authority as corrected in the future.

(c) Funding to correct a deficiency identified as a loan condition under paragraph (b)(B) of this section may be included as part of the project contract under the Drinking Water State Revolving Fund, if that part of the project to correct the deficiency qualifies under the terms of the Drinking Water State Revolving Fund.

(4) Capacity requirements for other public water systems.

(a) All community, non-transient non-community, and transient non-community public water systems will receive capacity assessments conducted by or with the assistance of the Authority.

(A) The capacity assessment consists of a written report identifying deficiencies in technical, managerial, and financial capacity, and a letter listing recommendations to correct the deficiencies. The findings of the capacity assessment and recommendations for correction will be presented to the management of the water system at a regular or special meeting.

(B) The frequency of capacity assessments for a public water system, as described in this subsection, is dependent on the risk to human health as determined by the Authority.

(C) The recommendations for correction of deficiencies identified in capacity assessments are, or, become requirements for any public water system, as described in this subsection, with multiple violations of the drinking water standards, in significant non-compliance with the drinking water standards, or an Administrative Order issued by the Authority.

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 431.110, 431.150, 448.131, 448.150, 448.268, 448.273

Hist.: OHD 4-1999, f. 7-14-99, cert. ef. 7-15-99; OHD 17-2002, f. & cert. ef. 10-25-02; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 2-2008, f. & cert. ef. 2-15-08; PH 7-2010, f. & cert. ef. 4-19-10

333-061-0062
Land Use Coordination

(1) The purpose of this rule is to assure that Oregon Health Authority's actions taken pursuant to ORS 448.131 and OAR

chapter 333, division 61, comply with state land use coordination requirements in ORS 197.180 and OAR chapter 660, divisions 30 and 31. This rule also implements applicable portions of the Authority's state agency coordination program concerning the review and approval of plans and projects pursuant to ORS 448.131.

(2) The requirements of OAR 333-061, shall apply to Authority approval of plans or projects submitted under ORS 448.131 for:

(a) New public water systems;

(b) Major additions, alterations, and extensions of water transmission mains;

(c) Development of new water sources; and

(d) Relocation of water treatment or storage facilities.

(3) In order to approve a plan or project listed under subsections (2)(a) through (d) of this rule, the Authority shall find that it complies with the Statewide Planning Goals and is compatible with applicable acknowledged city and county comprehensive plan and land use regulations. To make its goal compliance and plan compatibility findings, the Authority shall comply with sections (1) through (9) of this rule and shall also adhere to the procedures in the Authority's state agency coordination program which is hereby adopted by reference.

(4) Except where the Authority is required to directly address the Statewide Planning Goals, the Authority shall make its goal compliance findings for each plan or project listed in subsections (2)(a) through (d) of this rule based on the land use compatibility information provided to the Authority by the project applicant.

(5) An applicant seeking approval of a plan or project listed in subsections (2)(a) through (d) of this rule shall provide the Authority with information documenting the plan or project's compatibility with the applicable acknowledged comprehensive plans and land use regulations. Such documentation shall be submitted in a manner as established by the Authority and shall include one of the following:

(a) A copy of the local land use permit (e.g., conditional use permit, subdivision approval, zoning clearance, etc.) demonstrating that the plan or project has received land use approval from the jurisdiction; or

(b) Written information from an authorized representative of the affected city or county affirming that the proposed plan or project is compatible with the acknowledged comprehensive plan(s) for the area, but does not require specific land use approval by the jurisdiction; or

(c) Other written information acceptable to the Authority equivalent to subsection (5)(a) or (b) of this rule demonstrating the plan or project's land use compatibility.

(6) The Authority shall adopt findings directly against the Statewide Planning Goals if a situation ever arises where the Authority must approve a plan or project, but is unable to rely upon or is not provided with the appropriate land use compatibility information by the applicant. In this instance, the Authority shall comply with OAR 660-030-0065 and the corresponding procedures in the Authority's state agency coordination program to adopt the necessary findings demonstrating the plan or project's compliance with the Statewide Goals.

(7) Where more than one unit of local government has land use approval authority over the plan or site of the proposed project, written information from the applicant must be submitted to the Authority as provided in section (5) of this rule documenting the plan or project's compatibility with each of the affected jurisdiction's comprehensive plans.

(8) Information documenting land use compatibility in accordance with section (5) of this rule may be submitted to the Authority for public water system master plans or portions thereof. In this section, no subsequent land use compatibility determination will be required for an individual project where the applicant demonstrated that the project is contemplated by and consistent with the previously approved master plan.

(9) The meaning of land use terms used in this rule shall be as defined in OAR 660-030-0005.

Stat. Auth.: ORS 197.180 & 448.131

Stats. Implemented: ORS 197.180 & 448.131

Hist.: HD 11-1982(Temp), f. & ef. 6-1-82; HD 23-1982, f. & ef. 11-15-82; HD 2-1983, f. & ef. 2-23-83; HD 21-1984, f. & ef. 10-23-84; HD 1-1985(Temp), f. & ef. 1-28-85; HD 19-1990, f. 6-28-90, cert. ef. 7-2-90; PH 7-2010, f. & cert. ef. 4-19-10

333-061-0063

Environmental Review Process for The Safe Drinking Water Revolving Loan Fund Program

(1) This rule provides for environmental review of actions that are funded through the Safe Drinking Water Revolving Loan Fund (SDWRLF). This rule is applied in a manner that is consistent with 40 CFR Part 6, Subpart E and related subparts (July 1, 1997). An applicant for funding from the SDWRLF shall consult with the Authority at an early stage in the preparation of an application to determine the required level of environmental review. Based on review of existing information, the Authority shall assess the potential environmental effects of the proposed action and shall instruct the applicant either to:

(a) Submit a request for a categorical exclusion in a format specified by the Authority;

(b) Prepare and submit an environmental information document (EID) in a format specified by the Authority; or

(c) Prepare and submit an environmental impact report (EIR) in a format specified by the Authority.

(2) Categorical exclusions:

(a) Categorical exclusions are categories of actions proposed for funding from the SDWRLF, which do not individually, cumulatively over time, or in conjunction with other actions, have a significant effect on the quality of the human environment, and have been identified by the Authority as having no such effect. Such actions may be excluded by the Authority from further environmental review requirements if the information provided by the water supplier and any additional information before the Authority does not identify any environmental effects of the action that warrant additional environmental review by the Authority. The following actions may be categorically excluded by the Authority:

(A) Actions solely directed toward minor rehabilitation of existing facilities, functional replacement of equipment, or toward the construction of new ancillary facilities adjacent or appurtenant to existing facilities;

(B) Actions in sewered communities with a population of 10,000, or less, which are for minor upgrading or minor expansion of existing drinking water systems. This category does not include actions that directly or indirectly involve new drinking water sources, or the extension of new water distribution systems;

(C) Actions in unsewered communities with a population of 10,000 or less, that do not include the development of new drinking water sources, and that will not result in any increase in or change to the rate, nature or location of water diversion or discharge to surface water.

(b) In addition to the criteria set forth in subsection (a) of this rule, categorical exclusions will not be granted if the proposed action meets the criteria for not granting such exclusions in 40 CFR 6.107(e) or 6.505(c) (July 1, 1997). In addition, in order to qualify for a categorical exclusion, the action must be compatible with applicable acknowledged comprehensive plans and land use regulations, which must be documented according to the requirements of OAR 333-061-0062(5) and (7).

(c) A categorical exclusion may be revoked by the Authority and an environmental review required if the proposed action no longer meets the requirements for a categorical exclusion due to changes in the proposed action, or if the Authority determines from new information that significant environmental effects may result from the proposed action.

(d) If a categorical exclusion is granted, and a notice of the exclusion has been published in a newspaper of general circulation in the geographical area of the proposed action, the action can proceed.

(3) Environmental review process:

(a) When issuance of a categorical exclusion is not appropriate, the applicant shall prepare an EID or an EIR, as required by the

Authority. The EID or EIR shall consider practicable alternatives to the proposed action (including a no-action alternative), as well as the proposed action.

(b) The EIR or EID shall contain an evaluation of applicable laws relating to significant environmental resources that may be affected by the proposed action and alternatives to the proposed action. The applicant shall consult with appropriate federal, state and local agencies regarding such laws.

(c) The EIR or EID shall consider a full range of relevant impacts (both direct and indirect, and current and future impacts) of the proposed action and alternatives to the proposed action, including measures to mitigate adverse impacts, cumulative impacts, and impacts that cause irreversible or irretrievable commitment of resources.

(d) If the Authority requires an EID, the applicant shall prepare and the Authority shall review a draft EID. Following its review, the Authority shall either request additional information regarding potential impacts of the proposed action, or shall accept the EID as final. Once the Authority accepts the EID, the Authority shall prepare an environment assessment (EA) of the proposed action based on the EID and any other supplemental information deemed necessary by the Authority. Based on the EA and any measures to mitigate or eliminate adverse effects of the proposed action on the environment (which measures shall be included as a condition of any loan award as set forth in section (4) of this rule), the Authority will either prepare and issue a Finding of No Significant Impact (FNSI) or require the preparation of an EIR under subsection (3)(e) of this rule. In determining whether to issue a FNSI, the Authority shall apply the criteria set forth in 40 CFR 6.509, 6.108(a) and 6.108 (c through g) (July 1, 1997). If the Authority determines to issue a FNSI, notice of the FNSI shall be published in a newspaper of general circulation in the geographical area of the proposed action. Following a period of at least thirty (30) days after publication of the notice, and after any public concerns about the impacts of the proposed action are resolved to the extent determined to be appropriate by the Authority, the Authority may issue a final FNSI, and the action can proceed.

(e) If the Authority requires an EIR:

(A) The applicant shall conduct a duly noticed public meeting regarding the proposed action, which may be combined with other public hearings or meetings regarding the proposed action;

(B) The applicant shall prepare and submit a draft EIR to all interested agencies and persons, for review and comment;

(C) The applicant shall prepare and submit a final EIR that responds to agency and public comments for Authority review and decision;

(D) The Authority, following its review of the EIR, shall determine whether the action may proceed. In the event the Authority determines the action may proceed following completion of an EIR, it shall specify in writing what mitigation measures, if any, are to be required.

(4) In the event the Authority determines the action may proceed following preparation of an EID or an EIR, the Authority shall ensure that mitigation measures identified in its review as required for the issuance of a FNSI or otherwise, are implemented. This may be done by incorporating such measures as conditions of any loan agreement, or otherwise as the Authority determines will best ensure their completion in a timely manner.

(5) Under appropriate circumstances, the Authority may allow the partitioning of environmental review such that the environmental review will be required for only a component/portion of a planned system instead of completing an environmental review for the remainder of the system(s). In determining whether to approve partitioning of environmental review, the Authority shall consider 40 CFR Section 6.507 (July 1, 1997).

(6) Waiver; validity:

(a) If environmental review for the proposed action has already been conducted by another government agency, the Authority may, in its discretion, waive the requirements of this rule.

(b) Environmental reviews may be valid for up to five years. If a loan application is received for an action with an environmental review that is more than five years old, the Authority shall require a new or supplemental environmental review in accordance with these rules.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 448.273(4)
Hist.: OHD 9-1998, f. & cert. ef. 9-23-98; PH 7-2010, f. & cert. ef. 4-19-10; PH 5-2016, f. 2-10-16, cert. ef. 4-1-16

333-061-0064
Emergency Response Plan Requirements

All public water systems shall maintain a current emergency response plan.

(1) The emergency response plan shall be completed according to the following schedule and shall be reviewed and updated at least every five years.

(a) Completed by September 30, 2003 for public water systems serving 100,000 population or more.

(b) Completed by June 30, 2004 for public water systems serving a population of 50,000 or more but less than 100,000.

(c) Completed by December 31, 2004 for public water systems serving a population greater than 3,300 but less than 50,000.

(d) Completed by June 30, 2005 for public water systems serving a population of 3,300 or less.

(e) If a public water system applying for funds from the Safe Drinking Water Revolving Loan Fund Program is required to develop an emergency response plan as a part of a capacity assessment, then the emergency response plan is required to be completed before final payout of the loan.

(2) All public water systems shall complete a security vulnerability assessment and develop a prioritized plan for risk reduction.

(3) As evidence of completion, all public water systems shall submit a statement to the Authority certifying that the Emergency Response Plan and vulnerability assessment have been completed according to the requirements of this rule and that staff have been instructed in the use of the emergency response plan. The emergency response plan/vulnerability assessment shall be made available for review by the Authority and/or the County Health Department. All Community water systems >3,300 population are required to submit a copy of their Vulnerability Assessment and certification of completion for their Emergency Response Plan and Vulnerability Assessment to EPA as required in the federal Bioterrorism Preparedness and Response Act of 2002.

(4) Community water systems shall coordinate with the lead County Emergency Coordinator when preparing or revising an emergency response plan.

(5) The emergency response plan shall include but is not limited to the following elements:

(a) Communications and authority.

(A) Develop an emergency contacts list, and review and update this list at least annually.

(B) Decision-making authorities and responsibilities of water system personnel shall be determined and detailed in the emergency response plan.

(C) Procedure for notification of agencies, the water users, and the local media.

(b) Water system security. Public water systems shall develop a security program. The security program shall include, but is not limited to, the following components: security management, physical activity, physical security, chemical storage and use, personnel, computer system, and program evaluation as defined in the State Model Emergency Response Plan.

(c) Water system hazard review.

(A) Public water systems shall conduct an inspection of the water system annually to identify the hazards that could affect the water system.

(B) Public water systems shall correct construction deficiencies to eliminate hazards or potential hazards, correct major sanitary

survey deficiencies as determined by the Authority, and perform regular maintenance.

(d) Emergency equipment and water supplies.

(A) Public water systems shall make provisions for an auxiliary power supply if not a gravity system, and redundant equipment for critical components. Community water systems shall identify equipment that can be utilized in the event of an intentional attack which can render harmless or significantly lessen the impact of the attack on the public health and safety and supply of public drinking water.

(B) Public water systems shall develop a plan for emergency water to include the rationing of drinking water, identifying and utilizing alternative drinking water sources and supplies, and alternative distribution of drinking water.

(e) Emergency response procedures

(A) Public water systems shall develop procedures for responding to emergencies most likely to strike the water system. Community water systems shall develop plans and procedures that can be implemented in the event of a terrorist or other intentional attack on the water system.

(B) The emergency response plan shall describe procedures to isolate all parts of the water system. Community water systems shall develop actions and procedures which can render harmless or significantly lessen the impact of terrorist attacks or other intentional actions on public health and safety and supply of public drinking water.

(C) The emergency response plan shall describe the emergency disinfection procedure, process for issuing a boil water advisory, and process for handling a waterborne disease outbreak.

(6) Water system staff shall be instructed and trained in the use of the emergency response plan.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 448.131, 448.160
Hist.: OHD 17-2002, f. & cert. ef. 10-25-02; PH 12-2003, f. & cert. ef. 8-15-03; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 33-2004, f. & cert. ef. 10-21-04; PH 4-2009, f. & cert. ef. 5-18-09; PH 7-2010, f. & cert. ef. 4-19-10

333-061-0065
Operation and Maintenance

(1) Public water systems shall be operated and maintained in a manner that assures continuous production and delivery of potable water by:

(a) Operating all phases and components of the system effectively in the manner for which they were designed;

(b) Assuring that all leaks are promptly repaired and, broken or malfunctioning equipment is promptly repaired or replaced;

(c) Making readily available and in good condition the proper equipment, tools and parts to make repairs to the system. When possible, notice shall be given to the water users of impending repairs that will affect the quality of the water or the continuity of the water service. All repairs must meet the construction standards of these rules and comply with disinfection requirements of OAR 333-061-0050 prior to reestablishing use of the repaired portion of the system;

(d) Implementing actions to assure safe drinking water during emergencies. Water suppliers seeking a state certified wellhead protection program for their water system shall comply with the contingency planning requirements as prescribed in OAR 333-061-0057(4).

(2) Personnel:

(a) Personnel responsible for maintenance and operation of public water systems shall be competent, knowledgeable of all the functions of that particular facility and shall have the training and experience necessary to assure continuous delivery of water which does not exceed the maximum contaminant levels;

(b) Certification as prescribed by OAR 333-061-0210 through 333-061-0272 is required for personnel in direct responsible charge of operations for all community and non-transient non-community water systems.

(c) Personnel responsible for operating water treatment plants at transient non-community water systems using water sources classified as surface water or groundwater under the direct influence of surface water must attend the Authority's "Essentials of Surface Water Treatment" training course or an equivalent training.

(3) The identity of ownership of a water system shall be filed with the Authority. Notification of changes in ownership shall be filed immediately with the Authority upon completion of the transaction.

(4) All public water systems must maintain a current water system operations manual.

(a) The water system operations manual shall be completed according to the requirements of the capacity assessment or sanitary survey and shall be reviewed and updated at least every five years. If a public water system applying for funds from the Safe Drinking Water Revolving Loan Fund Program is required to develop a water system operations manual as a part of a capacity assessment, then the water system operations manual is required to be completed before final payout of the loan.

(b) As evidence of completion, public water systems shall submit a statement to the Authority certifying that the water system operations manual has been completed according to the requirements in this rule, and that staff have been instructed in the use of the water system operations manual.

(c) The water system operations manual shall include, but is not limited to, the following elements if they are applicable:

(A) Source operation and maintenance;

(B) Water treatment operation and maintenance;

(C) Reservoir operation and maintenance;

(D) Distribution system operation and maintenance; and

(E) Written protocols for on-site operators describing the operational decisions the operator is allowed to make under OAR 333-061-0225.

(d) Water system staff shall be instructed and trained in the use of the water system operations manual.

(5) Documents and records:

(a) The following documents and records shall be retained by the water supplier at community water systems and shall be available when the system is inspected or upon request by the Authority:

(A) Complete and current as-built plans and specifications of the entire system and such other documents as are necessary for the maintenance and operation of the system;

(B) Current operating manuals covering the general operation of each phase of the water system;

(C) A current master plan and revisions thereof;

(D) Data showing production capabilities of each water source and system component;

(E) Current records of the number, type and location of service connections;

(F) Current records of raw water quality, both chemical and microbiological;

(G) Current records of all chemicals and dosage rates used in the treatment of water;

(H) Reports on maintenance work performed on water treatment and delivery facilities;

(I) Records relating to the sampling and analysis undertaken to assure compliance with the maximum contaminant levels;

(J) Record of residual disinfectant measurements, where applicable;

(K) Records of cross connection control and backflow prevention device testing, where applicable;

(L) Records of customer complaints pertaining to water quality and follow-up action undertaken;

(M) Fluoridation records, where applicable;

(N) Other records as may be required by these rules.

(6) Water Treatment Operations:

(a) Chlorinators and other equipment used to apply chemicals at a public water system shall be operated and maintained in accordance with the manufacturers' specifications and recommendations for efficient operation and safety.

(b) When chlorine is used as the disinfectant, the procedures shall be as follows:

(A) Chlorine shall be applied in proportion to the flow;

(B) For reasons other than the treatment of surface water sources or groundwater sources under the direct influence of surface water, the rate of application shall be sufficient to result in a free chlorine residual of at least 0.2 mg/l after a 30-minute contact time and throughout the distribution system;

(c) When ammonia is added to the water with the chlorine to form a chloramine as the disinfectant, for reasons other than the treatment of surface water sources or groundwater sources under the direct influences of surface water, the rate of application shall result in a combined chlorine residual of at least 2.0 mg/l after a three-hour contact time;

(d) When corrosion control chemicals are applied to achieve compliance with the action levels for lead and copper, the point of application shall be after all other treatment processes, unless determined otherwise by the Authority.

(e) At water systems where cartridge filters are used, the filters must be changed according to the manufacturer's recommended pressure differential.

(7) When an emergency arises within a water system which affects the quality of water produced by the system, the water supplier shall notify the Authority immediately.

(8) Water suppliers must complete an Authority approved start-up procedure prior to serving water to the public at all seasonal water systems as defined in OAR 333-061-0020(168). The start-up procedure may include a requirement to conduct additional monitoring at the discretion of the Authority. A water supplier may be exempted from some or all of the requirements related to start-up of a seasonal water system if the entire distribution system remains pressurized during the entire period that the water system is not operating. Failing to complete an Authority-approved start-up procedure at a seasonal water system prior to serving water to the public is a violation of treatment technique requirements and of this rule.

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 431.110, 431.150, 448.131, 448.150, 448.273 & 448.279

Hist.: HD 106, f. & ef. 2-6-76; HD 17-1981(Temp), f. & ef. 8-28-81; HD 4-1982, f. & ef. 2-26-82; Renumbered from 333-042-0225, HD 2-1983, f. & ef. 2-23-83; HD 20-1983, f. 10-20-83, ef. 11-1-83; HD 1-1988, f. & cert. ef. 1-6-88; HD 9-1989, f. & cert. ef. 11-13-89; HD 26-1990, f. 12-26-90, cert. ef. 12-29-90; HD 7-1992, f. & cert. ef. 6-9-92; HD 1-1996, f. 1-2-96, cert. ef. 1-5-96; OHD 17-2002, f. & cert. ef. 10-25-02; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 4-2009, f. & cert. ef. 5-18-09; PH 7-2010, f. & cert. ef. 4-19-10; PH 3-2013, f. & cert. ef. 1-25-13; PH 14-2014, f. & cert. ef. 5-8-14; PH 5-2016, f. 2-10-16, cert. ef. 4-1-16

333-061-0070
Cross Connection Control Requirements

(1) Water suppliers shall undertake cross connection control programs to protect the public water systems from pollution and contamination.

(2) The water supplier's responsibility for cross connection control shall begin at the water supply source, include all public treatment, storage, and distribution facilities under the water supplier's control, and end at the point of delivery to the water user's premises.

(3) Water suppliers shall develop and implement cross connection control programs that meet the minimum requirements set forth in these rules.

(4) Water suppliers shall develop a procedure to coordinate cross connection control requirements with the appropriate local administrative authority having jurisdiction.

(5) The water supplier shall ensure that inspections of approved air gaps, approved devices, and inspections and tests of approved backflow prevention assemblies protecting the public water system are conducted:

(a) At the time of installation, any repair or relocation;

(b) At least annually;

(c) More frequently than annually for approved backflow prevention assemblies that repeatedly fail, or are protecting health hazard cross connections, as determined by the water supplier;

(d) After a backflow incident; or

(e) After an approved air gap is re-plumbed.

(6) Approved air gaps, approved devices, or approved backflow prevention assemblies, found not to be functioning properly shall be repaired, replaced or re-plumbed by the water user or premises owner, as defined in the water supplier's local ordinance or enabling authority, or the water supplier may take action in accordance with subsection (9)(a) of these rules.

(7) A water user or premises owner who obtains water from a water supplier must notify the water supplier if they add any chemicals or substance to the water.

(8) Premises isolation requirements:

(a) For service connections to premises listed or defined in Table 42 (Premises Requiring Isolation), the water supplier shall ensure an approved backflow prevention assembly or an approved air gap is installed; [Table not included. See ED. NOTE.]

(A) Premises with cross connections not listed or defined in Table 42 (Premises Requiring Isolation), shall be individually evaluated. The water supplier shall require the installation of an approved backflow prevention assembly or an approved air gap commensurate with the degree of hazard on the premises, as defined in Table 43 (Backflow Prevention Methods); [Table not included. See ED. NOTE.]

(B) In lieu of premise isolation, the water supplier may accept an in-premises approved backflow prevention assembly as protection for the public water system when the approved backflow prevention assembly is installed, maintained and tested in accordance with these rules.

(b) Where premises isolation is used to protect against a cross connection, the following requirements apply;

(A) The water supplier shall:

(i) Ensure the approved backflow prevention assembly is installed at a location adjacent to the service connection or point of delivery;

(ii) Ensure any alternate location used must be with the approval of the water supplier and must meet the water supplier's cross connection control requirements; and

(iii) Notify the premises owner and water user, in writing, of thermal expansion concerns.

(B) The premises owner shall:

(i) Ensure no cross connections exist between the point of delivery from the public water system and the approved backflow prevention assemblies, when these are installed in an alternate location; and

(ii) Assume responsibility for testing, maintenance, and repair of the installed approved backflow prevention assembly to protect against the hazard.

(c) Where unique conditions exist, but not limited to, extreme terrain or pipe elevation changes, or structures greater than three stories in height, even with no actual or potential health hazard, an approved backflow prevention assembly may be installed at the point of delivery; and

(d) Where the water supplier chooses to use premises isolation by the installation of an approved backflow prevention assembly on a one- or two-family dwelling under the jurisdiction of the Oregon Plumbing Specialty Code and there is no actual or potential cross connection, the water supplier shall:

(A) Install the approved backflow prevention assembly at the point of delivery;

(B) Notify the premises owner and water user in writing of thermal expansion concerns; and

(C) Take responsibility for testing, maintenance and repair of the installed approved backflow prevention assembly.

(9) In community water systems, water suppliers shall implement a cross connection control program directly, or by written agreement with another agency experienced in cross connection control. The local cross connection program shall consist of the following elements:

(a) Local ordinance or enabling authority that authorizes discontinuing water service to premises for:

(A) Failure to remove or eliminate an existing unprotected or potential cross connection;

(B) Failure to install a required approved backflow prevention assembly;

(C) Failure to maintain an approved backflow prevention assembly; or

(D) Failure to conduct the required testing of an approved backflow prevention assembly.

(b) A written program plan for community water systems with 300 or more service connections shall include the following:

(A) A list of premises where health hazard cross connections exist, including, but not limited to, those listed in Table 42 (Premises Requiring Isolation); [Table not included. See ED. NOTE.]

(B) A current list of certified cross connection control staff members;

(C) Procedures for evaluating the degree of hazard posed by a water user's premises;

(D) A procedure for notifying the water user if a non-health hazard or health hazard is identified, and for informing the water user of any corrective action required;

(E) The type of protection required to prevent backflow into the public water supply, commensurate with the degree of hazard that exists on the water user's premises, as defined in Table 43 (Backflow Prevention Methods); [Table not included. See ED. NOTE.]

(F) A description of what corrective actions will be taken if a water user fails to comply with the water supplier's cross connection control requirements;

(G) Current records of approved backflow prevention assemblies installed, inspections completed, backflow prevention assembly test results on backflow prevention assemblies and verification of current Backflow Assembly Tester certification; and

(H) A public education program about cross connection control.

(c) The water supplier shall prepare and submit a cross connection control Annual Summary Report to the Authority, on forms provided by the Authority, before the last working day of March each year.

(d) In community water systems having 300 or more service connections, water suppliers shall ensure at least one person is certified as a Cross Connection Control Specialist, unless specifically exempted from this requirement by the Authority.

(10) Fees: Community water systems shall submit to the Authority an annual cross connection program implementation fee, based on the number of service connections, as follows:

Service Connections — Fee:
15-99 — $30.
100-999 — $75.
1,000-9,999 — $200.
10,000 or more — $350.

(a) Billing invoices will be mailed to water systems in the first week of November each year and are due by January first of the following year;

(b) Fees are payable to Oregon Health Authority by check or money order;

(c) A late fee of 50 percent of the original amount will be added to the total amount due and will be assessed after January 31 of each year.

(11) In transient or non-transient non-community water systems, the water supplier that owns or operates the system shall:

(a) Ensure no cross connections exist, or are isolated from the potable water system with an approved backflow prevention assembly, as required in section (12) of this rule;

(b) Ensure approved backflow prevention assemblies are installed at, or near, the cross connection; and

(c) Conduct an annual cross connection survey and inspection to ensure compliance with these rules, and test all backflow assemblies annually. All building permits and related inspections are to be made by the Department of Consumer and Business Services, Building Codes Division, as required by ORS 447.020.

(12) Approved backflow prevention assemblies and devices required under these rules shall be approved by the University of Southern California, Foundation for Cross-Connection Control and Hydraulic Research, or other equivalent testing laboratories approved by the Authority.

(13) Backflow prevention assemblies installed before the effective date of these rules that were approved at the time of installation, but are not currently approved, shall be permitted to remain in service provided the assemblies are not moved, the piping systems are not significantly remodeled or modified, the assemblies are properly maintained, and they are commensurate with the degree of hazard they were installed to protect. The assemblies must be tested at least annually and perform satisfactorily to the testing procedures set forth in these rules.

(14) Tests performed by Authority-certified Backflow Assembly Testers shall be in conformance with procedures established by the University of Southern California, Foundation for Cross Connection Control and Hydraulic Research, Manual of Cross-Connection Control, 10th Edition, or other equivalent testing procedures approved by the Authority.

(15) Backflow prevention assemblies shall be tested by Authority-certified Backflow Assembly Testers, except as otherwise provided for journeyman plumbers or apprentice plumbers in OAR 333-061-0072 of these rules (Backflow Assembly Tester Certification). The Backflow Assembly Tester must produce three copies of all test reports. One copy must be maintained in the Tester's permanent records, one copy must be provided to the water user or property owner, and one copy must be provided to the water supplier.

(a) Test reports must be provided within 10 working days; and

(b) The test reports must be in a manner and form acceptable to the water supplier.

(16) All approved backflow prevention assemblies subject to these rules shall be installed in accordance with OAR 333-061-0071 and the Oregon Plumbing Specialty Code.

(17) The Authority shall establish an advisory board for cross connection control issues consisting of not more than nine members, and including representation from the following:

(a) Oregon licensed Plumbers;

(b) Authority certified Backflow Assembly Testers;

(c) Authority certified Cross Connection Specialists;

(d) Water Suppliers;

(e) The general public;

(f) Authority certified Instructors of Backflow Assembly Testers or Cross Connection Specialists;

(g) Backflow assembly manufacturers or authorized representatives;

(h) Engineers experienced in water systems, cross connection control or backflow prevention; and

(i) Oregon certified Plumbing Inspectors.

[ED. NOTE: Tables referenced are available from the agency.]

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 431.110, 431.150, 448.131, 448.150, 448.268, 448.271, 448.273, 448.278, 448.279, 448.295 & 448.300

Hist.: HD 106, f. & ef. 2-6-76; HD 17-1981(Temp), f. & ef. 8-28-81; HD 4-1982, f. & ef. 2-26-82; Renumbered from 333-042-0230, HD 2-1983, f. & ef. 2-23-83; HD 20-1983, f. 10-20-83, ef. 11-1-83; HD 30-1985, f. & ef. 12-4-85; HD 3-1987, f. & ef. 2-17-87; HD 1-1988, f. & cert. ef. 1-6-88; HD 9-1989, f. & cert. ef. 11-13-89; HD 26-1990, f. 12-26-90, cert. ef. 12-29-90; HD 1-1994, f. & cert. ef. 1-7-94; HD 1-1996, f. 1-2-96, cert. ef. 1-2-96; OHD 4-1999, f. 7-14-99, cert. ef. 7-15-99; PH 34-2004, f. & cert. ef. 11-2-04; PH 2-2006, f. & cert. ef. 1-31-06; PH 2-2008, f. & cert. ef. 2-15-08; PH 4-2009, f. & cert. ef. 5-18-09; PH 7-2010, f. & cert. ef. 4-19-10; PH 3-2013, f. & cert. ef. 1-25-13; PH 5-2016, f. 2-10-16, cert. ef. 4-1-16

333-061-0071
Backflow Prevention Assembly Installation and Operation Standards

(1) Any approved backflow prevention assembly required by OAR 333-061-0070 shall be installed in a manner that:

(a) Facilitates its proper operation, maintenance, inspection, and in-line testing using standard installation procedures approved by the Authority, such as, but not limited to, University of Southern California, Manual of Cross-Connection Control, 10th Edition, the Pacific Northwest Section American Water Works Association,

Cross Connection Control Manual, 7th Edition, or the local administrative authority having jurisdiction;

(b) Precludes the possibility of continuous submersion of an approved backflow prevention assembly, and precludes the possibility of any submersion of the relief valve on a reduced pressure principle backflow prevention assembly; and

(c) Maintains compliance with all applicable safety regulations and the Oregon Plumbing Specialty Code.

(2) For premises isolation installation:

(a) The approved backflow prevention assembly shall be installed at a location adjacent to the service connection or point of delivery; or

(b) Any alternate location must be with the advance approval of the water supplier and must meet the water supplier's cross connection control requirements; and

(c) The premises owner shall ensure no cross connections exist between the point of delivery from the public water system and the approved backflow prevention assembly.

(3) Bypass piping installed around any approved backflow prevention assembly must be equipped with an approved backflow prevention assembly to:

(a) Afford at least the same level of protection as the approved backflow prevention assembly being bypassed; and

(b) Comply with all requirements of these rules.

(4) All Oregon Plumbing Specialty Code approved residential multi-purpose fire suppression systems constructed of potable water piping and materials do not require a backflow prevention assembly.

(5) Stand-alone fire suppression systems shall be protected commensurate with the degree of hazard, as defined in Table 43 (Backflow Prevention Methods). [Table not included. See ED. NOTE.]

(6) Stand-alone irrigation systems shall be protected commensurate with the degree of hazard, as defined in Table 43 (Backflow Prevention Methods). [Table not included. See ED. NOTE.]

(7) A Reduced Pressure Principle Backflow Prevention Assembly (RP) or Reduced Pressure Principle-Detector Backflow Prevention Assembly (RPDA): [Figure 1 not included. See ED. NOTE.]

(a) Shall conform to bottom and side clearances when the assembly is installed inside a building. Access doors may be provided on the top or sides of an above-ground vault;

(b) Shall always be installed horizontally, never vertically, unless they are specifically approved for vertical installation;

(c) Shall always be installed above the 100 year (1 percent) flood level unless approved by the appropriate local administrative authority having jurisdiction;

(d) Shall never have extended or plugged relief valves;

(e) Shall be protected from freezing when necessary;

(f) Shall be provided with an approved air gap drain;

(g) Shall not be installed in an enclosed vault or box unless a bore-sighted drain to daylight is provided;

(h) May be installed with reduced clearances if the pipes are two inches in diameter or smaller, are accessible for testing and repairing, and approved by the appropriate local administrative authority having jurisdiction;

(i) Shall not be installed at a height greater than five feet unless there is a permanently installed platform meeting Oregon Occupational Safety and Health Administration (OR-OSHA) standards to facilitate servicing the assembly; and

(j) Be used to protect against a non-health hazard or health hazard for backsiphonage or backpressure conditions.

(8) A Double Check Valve Backflow Prevention Assembly (DC) or Double Check Detector Backflow Prevention Assembly (DCDA): [Figure 2 not included. See ED. NOTE.]

(a) Shall conform to bottom and side clearances when the assembly is installed inside a building;

(b) May be installed vertically as well as horizontally provided the assembly is specifically listed for that orientation in the Authority's Approved Backflow Prevention Assembly List.

(c) May be installed below grade in a vault, provided that water-tight fitted plugs or caps are installed in the test cocks, and the assembly shall not be subject to continuous immersion;

(d) Shall not be installed at a height greater than five feet unless there is a permanently installed platform meeting Oregon Occupational Safety and Health Administration (OR-OSHA) standards to facilitate servicing the assembly;

(e) May be installed with reduced clearances if the pipes are two inches in diameter or smaller, provided that they are accessible for testing and repairing, and approved by the appropriate local administrative authority having jurisdiction;

(f) Shall have adequate drainage provided except that the drain shall not be directly connected to a sanitary or storm water drain. Installers shall check with the water supplier and appropriate local administrative authority having jurisdiction for additional requirements;

(g) Shall be protected from freezing when necessary; and

(h) Be used to protect against non-health hazards under backsiphonage and backpressure conditions.

(9) A Pressure Vacuum Breaker Backsiphonage Prevention Assembly (PVB) or Spill-Resistant Pressure Vacuum Breaker Backsiphonage Prevention Assembly (SVB) shall: [Figure 3 not included. See ED. NOTE.]

(a) Be installed where occasional water discharge from the assembly caused by pressure fluctuations will not be objectionable;

(b) Have adequate spacing available for maintenance and testing;

(c) Not be subject to flooding;

(d) Be installed a minimum of 12 inches above the highest downstream piping and outlets;

(e) Have absolutely no means of imposing backpressure by a pump or other means. The downstream side of the pressure vacuum breaker backsiphonage prevention assembly or spill-resistant pressure vacuum breaker backsiphonage prevention assembly may be maintained under pressure by a valve; and

(f) Be used to protect against backsiphonage only, not backpressure.

(10) An Atmospheric Vacuum Breaker (AVB) shall: [Figure 4 not included. See ED. NOTE.]

(a) Have absolutely no means of shut-off on the downstream or discharge side of the atmospheric vacuum breaker;

(b) Not be installed in dusty or corrosive atmospheres;

(c) Not be installed where subject to flooding;

(d) Be installed a minimum of six inches above the highest downstream piping and outlets;

(e) Be used intermittently;

(f) Have product and material approval under the Oregon Plumbing Specialty Code for non-testable devices.

(g) Not be pressurized for more than 12 hours in any 24-hour period; and

(h) Be used to protect against backsiphonage only, not backpressure.

[ED. NOTE: Tables, Figures & Publications referenced are available from the agency.]

Stat. Auth.: ORS 448.131

Stats. Implemented:: ORS 431.110, 431.150, 448.131, 448.150, 448.268, 448.273, & 448.279

Hist.: HD 9-1989, f. & cert. ef. 11-13-89; HD 1-1994, f. & cert. ef. 1-7-94, Renumbered from 333-061-0099; HD 1-1996, f. 1-2-96, cer.t. ef. 1-5-96; HD 14-1997, f. & cert. ef. 10-31-97; OHD 4-1999, f. 7-14-99, cert. ef. 7-15-99; PH 34-2004, f. & cert. ef. 11-2-04; PH 2-2006, f. & cert. ef. 1-31-06; PH 4-2009, f. & cert. ef. 5-18-09; PH 7-2010, f. & cert. ef. 4-19-10; PH 3-2013, f. & cert. ef. 1-25-13; PH 5-2016, f. 2-10-16, cert. ef. 4-1-16

333-061-0072
Backflow Assembly Tester Certification

(1) In order to be certified as a backflow assembly tester, individuals must successfully complete all the requirements of this rule for testing backflow prevention assemblies. Only the following individuals may perform the field-testing on backflow prevention assemblies required by these rules:

(a) Individuals certified by the Authority to test backflow prevention assemblies; and

(b) Journeyman plumbers defined as those who hold a certificate of competency issued under ORS Chapter 693 or apprentice plumbers, as defined under ORS 693.010.

(2) Journeyman plumbers or apprentice plumbers who test backflow prevention assemblies shall satisfactorily complete an Authority approved backflow assembly tester training course, according to rules adopted by the Director of Consumer and Business Services.

(3) Individuals certified as a backflow assembly tester must comply with ORS 448.279(2).

(4) All backflow assembly tester training courses must be approved by the Authority and taken at an Authority approved training facility.

(5) Satisfactory completion of an approved backflow assembly tester training course means:

(a) Completing the course;

(b) Scoring at least 70 percent on the written examination; and

(c) Scoring at least 90 percent on the physical-performance examination.

(6) In order to apply for initial backflow assembly tester certification, individuals must submit:

(a) A completed initial application with all required documentation as specified on the initial application form and in this rule, including but not limited to:

(A) Proof of high school graduation, GED, associate's degree, bachelor's degree, master's degree, or PhD; and

(B) Proof of satisfactory completion, as described in section (5) of this rule, of a backflow assembly tester initial training course within the 12 months prior to the Authority receiving the completed application; and

(b) The initial certification fee as specified in section (9) of this rule.

(7) Backflow assembly tester certification expires on December 31 every two years based upon the first letter in the last name of the individual. Certification for individuals with names beginning in the letters A–K expire in even numbered years, and certification for individuals with names beginning in the letters L–Z expire in odd-numbered years. Certification renewal fees may be prorated if individuals are required to renew their certification prior to the end of the most recent two-year certification period.

(a) Backflow assembly testers may only perform tests if they possess current, valid certification.

(b) In order to apply to renew backflow assembly tester certification, individuals must submit:

(A) A completed renewal application with all required documentation as specified on the renewal application form and in this rule, including but not limited to:

(i) Proof of satisfactory completion, as described in section (5) of this rule, of either a backflow assembly tester renewal course or a backflow tester initial training course within the two year period prior to the expiration date of the certification; and

(ii) Yearly test gauge accuracy verification or calibration reports performed in the same month every year, as determined by the backflow assembly tester; and

(B) The certification renewal fee, as specified in section (9) of this rule.

(c) The Authority may grant certification renewal without a reinstatement fee until January 31 in the year following the expiration date of the certification. A reinstatement fee as prescribed by section (9) of this rule is required in addition to the renewal fee for all renewal applications received after the grace period ending on January 31 following the expiration date of the certification.

(d) Backflow assembly testers that fail to renew their certification for one year following the expiration date of their certification must meet the requirements established for applicants as prescribed by sections (6) or (8) of this rule as applicable.

(8) In order to apply for backflow assembly tester certification based on reciprocity, individuals must submit:

(a) A completed reciprocity application form with all required documentation as specified on the application form and in these rules, including but not limited to:

(A) Proof of current certification from a state or entity having substantially equivalent certification training and testing standards to those set forth in these rules, as determined by the Authority;

(B) Proof of satisfactory completion, as described in section (5) of this rule, of a backflow assembly tester initial training course or a backflow tester renewal course within the 12 months prior to the Authority receiving the completed application;

(C) Proof of high school graduation, GED, associate's degree, bachelor's degree, master's degree, or PhD; and

(D) Yearly test gauge accuracy verification or calibration reports performed in the same month every year, as determined by the backflow assembly tester; and

(b) The reciprocity review and initial certification fees as specified in section (9) of this rule.

(9) Fees related to backflow assembly tester certification.

(a) Payments shall be made to the Oregon Health Authority, Public Health Division.

(b) The Authority will not refund any fees once it has initiated processing an application.

(c) Fees are:

(A) Initial Certification (2-years) $195;

(B) Certification Renewal (2-years) $195;

(C) Reciprocity Review $35;

(D) Reinstatement $50; and

(E) Combination Certification Renewal (2-years) $305.

(d) Initial certification fees may be prorated to the nearest year for the remainder of the 2-year certification period.

(e) The Combination Certification Renewal fee applies when applicants simultaneously renew their backflow assembly tester and cross connection specialist certifications.

(10) Enforcement related to Backflow Assembly Tester certification

(a) The Authority may deny an initial application for certification, an application for renewal of certification, an application for certification based on reciprocity, or revoke a certification if the Authority determines the applicant/backflow assembly tester:

(A) Provided false information to the Authority;

(B) Did not possess certification issued by another state or entity because it was revoked;

(C) Permitted another person to use their certificate number;

(D) Failed to properly perform backflow prevention assembly testing;

(E) Falsified a backflow assembly test report;

(F) Failed to comply with ORS 448.279(2);

(G) Failed to comply with these rules or other applicable federal, state or local laws or regulations; or

(H) Performed backflow assembly tests with a gauge that was not calibrated for accuracy within the 12-month period prior to testing the assembly.

(b) Applicants or backflow assembly testers who have been denied initial, renewal, or reciprocity certification or whose certifications have been revoked have the right to appeal according to the provisions of chapter 183, Oregon Revised Statutes.

(c) Applicants or backflow assembly testers who have been denied initial, renewal, or reciprocity certification or whose certifications have been revoked, may not reapply for certification for one year from the date of denial or revocation of certification.

(d) Applicants or backflow assembly testers may petition the Authority prior to one year from the date of denial or revocation and may be allowed to reapply at an earlier date, at the discretion of the Authority.

(e) Backflow assembly tester test reports shall be made available to the Authority upon request.

Stat. Auth.: ORS 448.131, 448.279

Stats. Implemented: ORS 448.131, 448.278, 448.279

Hist.: HD 1-1994, f. & cert. ef. 1-7-94; HD 1-1996, f. 1-2-96, cert. ef. 1-5-96; HD 14-1997, f. & cert. ef. 10-31-97; OHD 4-1999, f. 7-14-99, cert. ef. 7-15-99; PH 34-2004, f. & cert. ef. 11-2-04; PH 2-2006, f. & cert. ef. 1-31-06; PH 2-2008, f. & cert. ef. 2-15-08; PH 7-2010, f. & cert. ef. 4-19-10; PH 3-2013, f. & cert. ef. 1-25-13; PH 14-2014, f. & cert. ef. 5-8-140; PH 23-2015, f. 12-8-15, cert. ef. 1-1-16

333-061-0073
Cross Connection Specialist Certification

(1) In order to be certified as a cross connection specialist, individuals must successfully complete all the applicable requirements of this rule. Only individuals certified by the Authority may administer cross connection control programs.

(2) Individuals certified as a cross connection specialist must comply with ORS 448.279(2).

(3) All training courses must be taken at an Authority approved training facility or be an Oregon Environmental Services Advisory Council approved course.

(4) Satisfactory completion of an approved cross connection specialist training course means:

(a) Completing the course; and

(b) Scoring at least 70 percent on the written examination.

(5) In order to apply for initial cross connection specialist certification, individuals must submit:

(a) A completed initial application with all required documentation as specified on the initial application form and in this rule, including but not limited to:

(A) Proof of high school graduation, GED, associate's degree, bachelor's degree, master's degree, or PhD; and

(B) Proof of satisfactory completion, as described in section (4) of this rule, of a cross connection specialist initial training course within the 12 months prior to the Authority receiving the completed application;

(C) Proof of one-year of experience working with public water systems as defined in OAR 333-061-0020 or plumbing as defined in ORS 447.010; and

(b) The initial certification fee as specified in section (8) of this rule.

(6) Cross connection specialist certification expires on December 31 every two years based upon the first letter in the last name of the individual. Certification for individuals with names beginning in the letters A-K expires in even numbered years, and certification for individuals with names beginning in the letters L-Z expires in odd numbered years Certification renewal fees may be prorated if individuals are required to renew their certification prior to the end of the most recent two-year certification period.

(a) In order to apply to renew cross connection specialist certification, individuals must submit:

(A) A completed renewal application with all required documentation as specified on the application form and in this rule, including but not limited to, proof of satisfactory completion of a total of at least 0.6 continuing education units from cross connection-related training courses or meetings taken within the two year period immediately prior to the date of the Authority receiving the completed application. Training courses and meetings must be attended at an Authority approved training facility or be approved by the Oregon Environmental Services Advisory Council; and

(B) The certification renewal fee, as specified in section (8) of this rule.

(b) The Authority may grant certification renewal without a reinstatement fee until January 31 in the year following the expiration date of the certification. A reinstatement fee as prescribed by section (8) of this rule is required in addition to the renewal fee for all renewal applications received after the grace period ending on January 31 following the expiration date of the certification.

(c) Cross connection specialists that fail to renew their certification for one year following the expiration date of their certification must meet the requirements established for applicants as prescribed by sections (5) or (7) of this rule.

(7) In order to apply for cross connection specialist certification based on reciprocity, individuals must submit:

(a) A completed reciprocity application form with all required documentation as specified on the application form and in this rule, including but not limited to:

(A) Proof of current certification from a state or entity having substantially equivalent certification training and testing standards to those set forth in these rules, as determined by the Authority;

(B) Proof of satisfactory completion, as described in section (4) of this rule, of a cross connection specialist initial training course or cross connection specialist renewal course within the 12 months prior to the Authority receiving the completed application;

(C) Proof of high school graduation, GED, associate's degree, bachelor's degree, master's degree, or PhD; and

(b) The reciprocity application fee as specified in section (8) of this rule.

(8) Fees related to Cross Connection Specialist certification.

(a) Payments shall be made to the Oregon Health Authority, Public Health Division.

(b) The Authority will not refund any fees once it has initiated processing an application.

(c) Fees are:

(A) Initial Certification (2-years) $195;

(B) Certification Renewal (2-years) $195;

(C) Reciprocity Review $35;

(D) Reinstatement $50; and

(E) Combination Certification Renewal (2-years) $305.

(d) Initial certification fees may be prorated to the nearest year for the remainder of the 2-year certification period.

(e) The Combination Certification Renewal fee applies when applicants simultaneously renew their backflow assembly tester and cross connection specialist certifications.

(9) Enforcement related to cross connection specialist certification.

(a) The Authority may deny an initial application for certification, an application for renewal of certification, an application for certification based on reciprocity, or revoke a certification if the Authority determines the applicant/cross connection specialist:

(A) Provided false information to the Authority;

(B) Did not possess certification issued by another state or entity because it was revoked;

(C) Permitted another person to use their certificate number;

(D) Falsified a survey/inspection/Annual Summary Report;

(E) Failed to comply with ORS 448.279(2); or

(F) Failed to comply with these rules or other applicable federal, state or local laws or regulations.

(b) Applicants or cross connection specialists who have been denied initial, renewal, or reciprocity certification or who have had their certification revoked have the right to appeal according to the provisions of Chapter 183, Oregon Revised Statutes.

(c) Applicants or cross connection specialists who have been denied initial, renewal, or reciprocity certification or who have had their certification revoked may not reapply for certification for one year from the date of denial or revocation of certification.

(d) Applicants or cross connection specialists may petition the Authority prior to one year from the date of denial or revocation and may be allowed to reapply at an earlier date, at the discretion of the Authority.

Stat. Auth.: ORS 448.131, 448.279
Stats. Implemented: ORS 448.131, 448.278, & 448.279
Hist.: OHD 4-1999, f. 7-14-99, cert. ef. 7-15-99; PH 34-2004, f. & cert. ef. 11-2-04; PH 7-2010, f. & cert. ef. 4-19-10; PH 3-2013, f. & cert. ef. 1-25-13; PH 14-2014, f. & cert. ef. 5-8-140; PH 23-2015, f. 12-8-15, cert. ef. 1-1-16

333-061-0074
Cross Connection Training Programs, Course, and Instructor Requirements

(1) In order to qualify as an Authority approved Cross Connection Specialist training program or facility or Backflow Assembly Tester training program or facility, the following requirements must be met:

(a) The training program must keep permanent records on attendance and performance of each student that enrolls in a course;

(b) The training program must submit the names of students who have successfully completed the training course to the Authority upon completion of the training course;

(c) The training schedule must be set in advance and the schedule must be submitted to the Authority quarterly for review and publication;

(d) The backflow training program must maintain a proper ratio of student-to-training equipment. A maximum ratio of three students for each backflow assembly test station is allowed for the Backflow Assembly Tester-training course;

(e) The training program must provide uniform training at all course locations;

(f) The training program shall provide the training materials necessary to complete the course. The training materials must be updated annually and submitted to the Authority for approval; and

(g) The training program must have the following minimum training equipment available for each course:

(A) Each test station for Backflow Assembly Tester initial training and certification renewal courses shall include:

(i) An operating pressure vacuum breaker backsiphonage prevention assembly, spill resistant pressure vacuum breaker backsiphonage prevention assembly, double check valve backflow prevention assembly, and a reduced pressure principle backflow prevention assembly, with appropriate test gauges for each assembly; and

(ii) A backflow prevention assembly failure simulator shall also be provided that is capable of simulating leaking check valves, shutoff valves, and relief valve failures.

(B) The training aids for the Backflow Assembly Tester training program or facility and Cross Connection Specialist training program or facility shall include the atmospheric vacuum breaker, pressure vacuum breaker backsiphonage prevention assembly, spill resistant pressure vacuum breaker backsiphonage prevention assembly, double check valve backflow prevention assembly, reduced pressure principle backflow prevention assembly, and a variety of test gauges.

(h) The training program must maintain uniform course curriculum according to sections (2), (3), (4) and (5) of this rule section, and maintain uniform instructor requirements according to section (6) of this rule section, subject to approval by the Authority.

(2) Requirements for the Cross Connection Specialist initial training course shall include:

(a) A minimum of 30 hours of training;

(b) The course content shall contain, but is not limited to, the following topics:

(A) Definitions, identification of cross connection hazards, and the hydraulics of backflow;

(B) Approved cross connection control methods, backflow prevention assembly specifications, and testing methods used for Authority-approved backflow prevention assemblies;

(C) Cross connection control requirements for public water systems, implementation of a cross connection control program, and writing a local cross connection control ordinance;

(D) Public education and record keeping requirements for an effective cross connection control program;

(E) Facility water use inspection techniques and hands on inspection of local facilities to identify actual or potential cross connections;

(F) Cross connection control program enforcement and managing a Backflow Assembly Tester program; and

(G) Review and discussion of Cross Connection Specialist safety issues.

(c) A minimum score of 85 percent is required to pass the Authority approved Cross Connection Specialist written examination.

(3) Requirements for the Backflow Assembly Tester initial training course shall include:

(a) A minimum of 40 hours of training;

(b) The course content shall contain, but is not limited to, the following topics:

(A) Definitions, identification of cross connections, and the hydraulics of backflow;

(B) Hazards associated with backflow pollution and contamination of potable water, approved cross connection control methods, and cross connection control program requirements for public water systems;

(C) Backflow prevention assembly approval requirements, specifications and installation requirements for approved backflow prevention assemblies, and backflow prevention assembly repair techniques;

(D) Complete disassembly and reassembly of each type of backflow prevention assembly;

(E) Hands-on demonstration of the correct test procedures, troubleshooting for each type of backflow prevention assembly, and diagnosis of two failure and/or abnormal conditions during the hands- on backflow assembly test of each type of backflow prevention assembly;

(F) Test gauge calibration and gauge accuracy verification methods; and

(G) Review and discussion of Backflow Assembly Tester safety issues.

(c) A minimum score of 75 percent is required to pass the Authority-approved Backflow Assembly Tester written examination; and

(d) A minimum score of 90 percent is required to pass the Authority-approved Backflow Assembly Tester physical performance examination.

(4) Requirements for Cross Connection Specialist certification renewal shall include:

(a) A minimum of 0.6 CEU of training;

(b) The course content shall contain, but is not limited to, the following topics:

(A) Review of cross connection control regulations OAR 333-061-0070 through 0073;

(B) Review and discussion of recent backflow incidents and identification of cross connections; and

(C) Review and discussion of Cross Connection Specialist safety issues.

(5) Requirements for Backflow Assembly Tester certification renewal shall include:

(a) A minimum of 0.5 CEU of training, excluding examination time;

(b) The course content shall contain, but is not limited to, the following topics:

(A) Review of cross connection control regulations OAR 333-061-0070 through 0073;

(B) Review of approved test procedures for backflow prevention assemblies;

(C) Hands-on demonstration of the correct test procedures for each type of backflow prevention assembly;

(D) The correct student diagnosis and explanation of two failure and/or abnormal conditions during the hands-on backflow prevention assembly test of each type of backflow prevention assembly;

(E) Review and discussion of Backflow Assembly Tester safety issues; and

(F) Written examination that includes questions on cross connection control regulations OAR 333-061-0070 through 0073.

(c) A minimum score of 75 percent is required to pass the Authority approved Backflow Assembly Tester written examination; and

(d) A minimum score of 90 percent is required to pass the Authority approved Backflow Assembly Tester physical performance examination.

(6) Instructor qualification requirements shall include:

(a) To be eligible as an instructor for Cross Connection Specialist initial training or certification renewal course, the following experience in the cross connection control field is required:

(A) Must be currently certified as a Cross Connection Specialist in Oregon;

(B) Must have 2 years experience in enforcement of cross connection control requirements, or as a certified Cross Connection Specialist, or have related experience, subject to approval by the Authority;

(C) Must participate in two complete Cross Connection Specialist training courses as a student instructor assigned to teach a portion of the curriculum. A student instructor training program

schedule must be submitted to the Authority for approval before training begins;

(D) Must receive a recommendation from the instructor of record for approval as an instructor. An unfavorable recommendation must be documented by supporting information and may be challenged by the trainee or by the Authority; and

(E) Must attend at least one instructor update meeting provided by the Authority each year.

(b) To be eligible as an instructor for the Backflow Assembly Tester initial training or certification renewal course, the following experience in the backflow prevention field is required:

(A) Must be currently certified as a Backflow Assembly Tester in Oregon;

(B) Must have 2 years experience as a certified Backflow Assembly Tester and experience installing, testing backflow prevention assemblies, or as a vocational instructor, or have related experience, subject to approval by the Authority;

(C) Must participate in two complete Backflow Assembly Tester training courses as a student instructor assigned to teach a portion of the text curriculum and the physical performance portion of the curriculum. A student instructor training program schedule must be submitted to the Authority for approval before training begins;

(D) Must receive a recommendation from the instructor of record for approval as an instructor. An unfavorable recommendation must be documented by supporting information and may be challenged by the trainee or by the Authority; and

(E) Must attend at least one instructor update meeting provided by the Authority each year.

(c) The Authority shall maintain a list of qualified instructors.

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 431.110, 431.150, 448.131, 448.150, 448.268, 448.273, 448.278 & 448.279

Hist.: OHD 4-1999, f. 7-14-99, cert. ef. 7-15-99; PH 34-2004, f. & cert. ef. 11-2-04; PH 3-2013, f. & cert. ef. 1-25-13

333-061-0075
Sanitary Surveys of Watersheds

(1) In water systems utilizing surface water sources or groundwater sources under the direct influence of surface water that do not provide filtration treatment, the water supplier shall conduct sanitary surveys of the watershed as deemed necessary by the water system to meet the requirements of OAR 333-061-0032(2)(b)(B). The results of the watershed survey will be reviewed by the Authority during the annual on-site inspection required by OAR 333-061-0032(2)(b)(C). The Authority recommends that systems which do provide filtration treatment for surface water sources or groundwater sources under the direct influence of surface water also conduct annual sanitary surveys of the watershed.

(2) The survey shall include but not be limited to, an evaluation of the following man made and natural features in the watershed and their effect on water quality:

(a) Nature of and condition of dams, impoundments, intake facilities, diversion works, screens, disinfection equipment, perimeter fences, signs, gates;

(b) Nature of surface geology, character of soils, presence of slides, character of vegetation and forests, animal population, amounts of precipitation;

(c) Nature of human activities, extent of cultivated and grazing land, zoning restrictions, extent of human habitation, logging activities, method of sewage disposal, proximity of fecal contamination to intake, recreational activities and measures to control activities in the watershed;

(d) Nature of raw water, level of coliform organisms, vulnerability assessments of potential contaminants, algae, turbidity, color, mineral constituents, detention time in reservoir, time required for flow from sources of contamination to intake;

(e) Type and effectiveness of measures to control contamination, and algae, disinfection applications and residuals carried, monitoring practices, patrol of borders.

(3) A report on the findings of the survey shall be submitted annually to the Authority as required by OAR 333-061-0040(1).

(4) The Authority recommends using the guidelines in the US EPA Guidance Manual for Compliance with the Filtration and Disinfection Requirements for Public Water Systems Using Surface Water Sources to construct an effective watershed control management plan. A list of additional references recommended by the Authority is available upon request.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 431.110, 448.115, 448.131 & 448.150

Hist.: HD 106, f. & ef. 2-6-76; HD 137(Temp), f. & ef. 3-9-77; HD 140, f. & ef. 6-28-77; HD 17-1981(Temp), f. & ef. 8-28-81; HD 4-1982, f. & ef. 2-26-82; Renumbered from 333-042-0233, HD 2-1983, f. & ef. 2-23-83; HD 26-1990, f. 12-26-90, cert. ef. 12-29-90; PH 5-2016, f. 2-10-16, cert. ef. 4-1-16

333-061-0076
Sanitary Surveys

(1) All sanitary surveys as defined by OAR 333-061-0020(167) and this rule shall be conducted by the Authority.

(2) Every water system must undergo a sanitary survey at least every five years at a frequency determined by the Authority. Water suppliers must provide the Authority, upon request, any existing information that will enable the Authority to conduct the sanitary survey.

(3) The sanitary survey report shall be completed by staff and sent to the water system following the site visit. The content of the sanitary survey report shall address, at a minimum, the following components of a water system: source of supply; treatment; distribution system; finished water storage; pumps, pump facilities and controls; monitoring, reporting and data verification; system management and operations; and operator certification compliance.

(4) The sanitary survey report must identify any significant deficiency prescribed in this section, or any violation of drinking water regulations, discovered in the on-site visit. For the purposes of sanitary surveys, significant deficiencies for all water systems are:

(a) Surface Water Treatment:

(A) Incorrect location for compliance turbidity monitoring;

(B) For systems serving more than 3,300 people, no auto-dial, call-out alarm or auto-plant shutoff for low chlorine residual;

(C) For conventional or direct filtration, no auto-dial, call-out alarm or auto-plant shutoff for high turbidity when no operator is on-site;

(D) For conventional filtration, settled water turbidity not measured daily;

(E) For conventional or direct filtration, turbidity profile not conducted on individual filters at least quarterly;

(F) For cartridge filtration, no pressure gauges before and after cartridge filter;

(G) For cartridge filtration, filters not changed according to manufacturer's recommended pressure differential; and

(H) For diatomaceous earth filtration, body feed not added with influent flow.

(b) Groundwater Well Construction:

(A) Sanitary seal and casing not watertight;

(B) Does not meet setbacks from hazards;

(C) Wellhead not protected from flooding;

(D) No raw water sample tap;

(E) No treated sample tap, if applicable; and

(F) If well vent exists, not screened.

(c) Groundwater Springbox Construction:

(A) Not constructed of impervious, durable material;

(B) No watertight access hatch/entry;

(C) No screened overflow;

(D) Does not meet setbacks from hazards;

(E) No raw water sample tap; and

(F) No treated sample tap, if applicable.

(d) Disinfection:

(A) No means to adequately determine flow rate on contact chamber effluent line;

(B) Failure to calculate CT values correctly; and

(C) No means to adequately determine disinfection contact time under peak flow and minimum storage conditions.

(e) Finished water storage:

(A) Hatch not locked;

(B) Roof and hatch not watertight;

(C) No flap-valve or equivalent over drain/overflow; and

(D) No screened vent.

(5) Sanitary survey fees. All water suppliers are subject to a fee payable to the Authority for sanitary surveys conducted according to this rule on or before the due date specified on the invoice sent to the water supplier.

(a) For community water systems, the sanitary survey fee is based upon either the number of connections or the population served.

(A) For community water systems with more than 250 service connections, the sanitary survey fee shall be based upon the number of connections served by the system.

(B) For community water systems with 250 service connections or less, but serving more than 1,000 people, the sanitary survey fee shall be based upon the population served by the system. For wholesale community water systems in this category, the sanitary survey fee will be assessed as a community water system without water treatment (WT) as specified in the table below.

(b) Transient non-community water systems identified as campgrounds with multiple handpumps will be considered one water system and assessed a single fee for the purposes of this rule.

(c) Late fees. A late fee will be assessed to any water system which fails to pay its sanitary survey fee within 10 days of the due date in the invoice sent to the water system. The late fee may be waived at the discretion of the Authority. Fees for sanitary surveys are listed in Table 44 below: [Table not included. See ED. NOTE.]

(6) Response required to address sanitary survey deficiencies:

(a) For water systems that use surface water sources or GWUDI sources, water suppliers must respond in writing to the Authority within 45 days of receiving the sanitary survey report.

(A) The response of the water system must include:

(i) The plan the water system will follow to resolve or correct the identified significant deficiencies;

(ii) The plan the water system will follow to resolve or correct any violations of drinking water regulations identified during the sanitary survey or at any other time; and

(iii) The schedule the water system will follow to execute the plan.

(B) The plans and schedules identified above in subparagraphs (6)(a)(A)(i) through (iii) of this rule must be approved by the Authority.

(b) For water systems that use only groundwater sources, water suppliers must consult with the Authority within 30 days of receiving written notice of a significant deficiency or a violation of a drinking water regulation identified during the sanitary survey. Within 120 days of receiving written notice of a significant deficiency or violation of a drinking water regulation, water suppliers must:

(A) Have corrected the significant deficiency or rule violation; or

(B) Be in compliance with an Authority approved corrective action plan.

(7) Public water systems that fail to respond to the Authority within the timeframe specified, are required to issue a tier 2 public notice as prescribed in OAR 333-061-0042(2)(b)(D).

(8) Public water systems must correct the deficiencies or violations identified in the sanitary survey according to the Authority-approved schedule identified in section (6) of this rule. Failure to do so constitutes a violation of these rules.

[ED. NOTE: Tables, Figures & Publications referenced are available from the agency.]

Stat. Auth.: ORS 448.131, 448.150

Stats. Implemented: ORS 448.131, 448.150

Hist.: OHD 23-2001, f. & cert. ef. 10-31-01; OHD 17-2002, f. & cert. ef. 10-25-02; PH 12-2003, f. & cert. ef. 8-15-03; PH 2-2008, f. & cert. ef. 2-15-08; PH 4-2009, f. & cert. ef. 5-18-09; PH 7-2010, f. & cert. ef. 4-19-10; PH 23-2015, f. 12-8-15, cert. ef. 1-1-16; PH 5-2016, f. 2-10-16, cert. ef. 4-1-16

333-061-0077

Composite Correction Program & Comprehensive Performance Evaluations

(1) All Comprehensive Performance Evaluation Reports (CPEs) as defined by OAR 333-061-0020(36) and this rule shall be conducted by the Authority.

(2) Any public water system using surface water or groundwater under direct surface water influence which treats the water using conventional or direct filtration treatment is subject to the Composite Correction Program, including CPEs, as determined necessary or appropriate by the Authority.

(3) Any public water system using surface water or groundwater under direct surface water influence which treats the water using conventional or direct filtration treatment that has a measured filtered water turbidity level greater than 2.0 NTU from any individual filter in two consecutive measurements taken 15 minutes apart in each of two consecutive months as stated in OAR 333-061-0040(1)(d)(B) (ii)(IV) is required to have a CPE conducted on that public water system's water treatment facility.

(4) The CPE report shall be completed by staff and sent to the water system following the site visit. The content of the CPE report shall include, at a minimum, the following components: An assessment of the water treatment plant performance from current and historical water quality data, an evaluation of each major (treatment) unit process, an identification and prioritization of the water treatment plant performance limiting factors, and an assessment by the Authority if additional comprehensive technical assistance would be beneficial to the water system. The CPE results must be written into a report and submitted to the public water system by the Authority.

(5) The public water system receiving the CPE report must respond in writing to the Authority within 45 days (for systems serving at least 10,000 people) or 120 days (for systems serving less than 10,000 people) of receiving the report as required by OAR 333-061-0040(1)(k). The response of the public water system must include:

(a) The plan the public water system will follow to resolve or correct the identified performance limiting factors that are within the water system's (and its governing body) ability to control; and

(b) The schedule the public water system will follow to execute the plan.

(6) The public water system must take corrective action through the CCP according to the schedule identified in subsection (5)(b) of this rule to resolve the performance limiting factors identified. Failure by the water system to take corrective action to resolve the performance limiting factors constitutes a violation of these rules.

Stat. Auth.: ORS 448.150

Stats. Implemented: ORS 448.131, 448.150

Hist.: OHD 23-2001, f. & cert. ef. 10-31-01; PH 12-2003, f. & cert. ef. 8-15-03; PH 4-2009, f. & cert. ef. 5-18-09; PH 7-2010, f. & cert. ef. 4-19-10; PH 3-2013, f. & cert. ef. 1-25-13; PH 5-2016, f. 2-10-16, cert. ef. 4-1-16

333-061-0078

Coliform Investigations

(1) A coliform investigation, as defined in OAR 333-061-0020(30), is an evaluation to identify the possible presence of sanitary defects, defects in distribution system coliform monitoring practices, and the likely reason that the coliform investigation was triggered at the public water system. Coliform investigations are separated into two levels as described in this section.

(a) A level 1 coliform investigation is conducted by the water supplier or a representative thereof. Minimum elements of the investigation include review and identification of atypical events that could affect distributed water quality or indicate that distributed water quality was impaired; changes in distribution system maintenance and operation that could affect distributed water quality (including water storage); source and treatment considerations that bear on distributed water quality, where appropriate (for example, whether a ground water system is disinfected); existing water quality monitoring data; and inadequacies in sample sites, sampling protocol, and sample processing.

(b) A level 2 coliform investigation is conducted by the Authority or a party approved by the Authority and is a more detailed and comprehensive examination of a water system (including the system's monitoring and operational practices) than a level 1 investigation. Minimum elements include those that are part of a level 1 investigation and additional review of available information, internal and external resources, and other relevant practices. Water suppliers must comply with any expedited actions or additional actions required by the Authority in the case of an exceedance of the MCL for E. coli.

(2) Coliform investigations must be conducted according to section (3) of this rule after a coliform investigation trigger identified in this section is exceeded at a water system.

(a) Level 1 coliform investigation triggers include, but are not limited to:

(A) Exceeding 5.0 percent total coliform-positive samples for the month at water systems where 40 or more samples per month are collected;

(B) Having two or more total coliform-positive samples in the same month at water systems where fewer than 40 samples per month are collected; or

(C) Failing to collect every required repeat sample after any single total coliform-positive sample.

(b) Level 2 coliform investigation triggers include, but are not limited to:

(A) An exceedance of the MCL for E. coli as specified in OAR 333-061-0030(4); or

(B) A second level 1 trigger as specified in subsection (2)(a) of this rule within a rolling 12-month period, unless the Authority has determined a likely cause for the total coliform-positive samples responsible for the first level 1 investigation trigger and established that the water supplier corrected the problem.

(c) The results of all routine and repeat samples collected according to OAR 333-061-0036(6)(b) through (g) not invalidated by the Authority must be used to determine whether a coliform investigation trigger as specified in this section has been exceeded.

(d) Special purpose samples, such as those collected to determine whether disinfection practices are sufficient following pipe placement, replacement, or repair, may not be used to determine whether a coliform investigation trigger has been exceeded.

(3) Water suppliers must ensure that coliform investigations are conducted in order to identify the possible presence of sanitary defects and defects in distribution system coliform monitoring practices.

(a) Water suppliers must ensure that investigators evaluate at least the minimum elements as specified in subsection (1)(a) or (1)(b) of this rule and must conduct the investigation consistent with any Authority directives that tailor specific investigation elements with respect to the size and type of the system and the size, type, and characteristics of the distribution system.

(b) Water suppliers must conduct level 1 coliform investigations consistent with Authority requirements if any of the investigation triggers specified in subsection (2)(a) of this rule are exceeded.

(A) The coliform investigation must be completed as soon as practical after exceeding the trigger, and must include a report summarizing the investigation.

(B) In the completed investigation report, water suppliers must describe sanitary defects detected, corrective actions completed, and a proposed timetable for any corrective actions not already completed. The investigation report may also note that no sanitary defects were identified.

(C) If the Authority reviews the completed coliform investigation report and determines that the investigation is not sufficient (including any proposed timetable for any corrective actions not already completed), the Authority will consult with the water supplier. If the Authority requires revisions after consultation, the water supplier must submit a revised investigation report to the Authority on an agreed-upon schedule not to exceed 30 days from the date of the consultation.

(c) Water suppliers must submit to and ensure a level 2 coliform investigation is conducted as soon as practical after a coliform investigation trigger specified in subsection (2)(b) of this rule is exceeded. Water suppliers must ensure a completed investigation report is submitted to the Authority as specified in OAR 333-061-0040(1)(l).

(A) Water suppliers must communicate with the Authority to ensure the investigation is completed within 30 days after learning that a coliform investigation trigger was exceeded.

(B) Completed investigation reports must describe sanitary defects detected, corrective actions completed, and a proposed timetable for any corrective actions not already completed. The investigation report may also note that no sanitary defects were identified.

(C) Water suppliers must comply with any expedited actions or additional actions required by the Authority in the case of an exceedance of the MCL for E. coli.

(D) If the Authority reviews a completed level 2 coliform investigation report and determines that the investigation is not sufficient (including any proposed timetable for any corrective actions not already completed), the Authority will consult with the water supplier. If the Authority requires revisions after consultation, the water supplier must ensure a revised investigation report is submitted to the Authority on an agreed-upon schedule not to exceed 30 days.

(d) Upon completion and submission of a level 1 or level 2 coliform investigation report, the Authority must determine if a likely cause for the level 1 trigger or level 2 trigger was identified and determine whether the water supplier corrected the problem, or agreed to a schedule acceptable to the Authority for correcting the problem.

(4) Water suppliers must correct sanitary defects discovered during level 1 or level 2 coliform investigations as soon as practical. For corrections not completed by the time an investigation report is submitted to the Authority, the water supplier must complete the corrective action(s) in compliance with a timetable approved by the Authority in consultation with the water supplier. The water supplier must notify the Authority when each scheduled corrective action is completed. At any time during the investigation or corrective action phase, either the water supplier or the Authority may request a consultation with the other party to determine the appropriate actions to be taken. The water supplier may consult with the Authority regarding all relevant information that may impact its ability to comply with a requirement of this rule, including the method of accomplishment, an appropriate timeframe, and other relevant information.

(5) Failing to conduct the required coliform investigation after a trigger is exceeded or failure to complete corrective actions according to an Authority approved timetable is a violation of this rule.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 448.131, 448.150
Hist.: PH 5-2016, f. 2-10-16, cert. ef. 4-1-16

333-061-0080
Role of Counties

(1) Counties may develop water service plans to encourage small water systems to consolidate where possible.

(2) Prior to issuing building permits, the issuing agency must certify that the Authority has approved construction and installation plans for water system developments proposed after August 21, 1981. They must additionally certify that the water system development plan does not violate the water service plans for the city or county where the building permit will be issued.

(3) Counties or boundary commissions are authorized to approve the formation, dissolution, consolidation and expansion of water systems not owned by cities. In doing so, counties or boundary commissions should consider whether water service is extended in a logical fashion and whether water systems have a financial base sufficient for operation and maintenance.

(4) The Authority may delegate upon request any of its duties as set forth in these rules to counties. In doing so, the Authority shall require assurances that the county shall:

(a) Employ sufficient qualified personnel to perform the duties involved;

(b) Perform the duties involved continuously for the duration of the delegation;

(c) Report periodically on the nature and status of the activities being performed.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 448.165 & 448.170
Hist.: HD 4-1982, f. & ef. 2-26-82; Renumbered from 333-042-0238, HD 2-1983, f. & ef. 2-23-83

333-061-0085
Supplemental Fluoridation

(1) When fluoride compounds are added at public water systems for the prevention of dental caries, it shall be done in accordance with the following:

(a) The chemical feed apparatus shall be of a type specifically designed for metering fluoride compounds in proportion to the flow of water being treated. The apparatus shall possess an accuracy tolerance of no more than plus or minus five percent and shall be designed and installed in a manner such that the injection of fluoride compounds is terminated when the water being treated ceases to flow;

(b) The specifications for the fluoride compounds shall conform with the most current AWWA standards as follows:

(A) Sodium fluoride — AWWA B701.

(B) Sodium fluorosilicate — AWWA B702.

(C) Fluorosilicic acid — AWWA B703.

(c) Respirators, replacement units and other safety equipment shall be stored in approved, dust-proof containers or cabinets when not in use.

(2) Prior to the application of fluoride compounds at public water systems, the water supplier shall submit to the Authority and receive approval for:

(a) Plans and specifications for the equipment with information on the testing instruments and protective devices for the operating personnel;

(b) Specifications of the fluoride compound to be used;

(c) Qualifications and training record of the person in responsible charge of the fluoridation operation;

(d) Current chemical analysis of the unfluoridated water.

(3) During operation of the fluoridation equipment, the operator shall:

(a) Not exceed 2.0 mg/l of fluoride in the finished water;

(b) Maintain all equipment in good working order;

(c) Make determinations of the fluoride content by approved methods on:

(A) The unfluoridated water as required by the Authority;

(B) The fluoridated water daily.

(d) Record daily the amount of fluoride added to the water, the quantity of water treated and the fluoride levels of the treated water. These records shall be submitted to the Authority monthly;

(e) Submit a split sample of the fluoridated water to the Authority for analysis as the Authority may require;

(f) Maintain and use safety equipment as required in this section.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 431.110, 431.150, 448.131, 448.150 & 448.273
Hist.: HD 106, f. & ef. 2-6-76; HD 17-1981(Temp), f. & ef. 8-28-81; HD 4-1982, f. & ef. 2-26-82; Renumbered from 333-042-0240, HD 2-1983, f. & ef. 2-23-83; HD 11-1985, f. & ef. 7-2-85; HD 9-1989, f. & cert. ef. 11-13-89; HD 14-1997, f. & cert. ef. 10-31-97; OHD 17-2002, f. & cert. ef. 10-25-02; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04

333-061-0087
Product Acceptability Criteria

(1) Any pipe, solder, or flux which is used in the installation or repair of:

(a) Any public water system, or

(b) Any plumbing in a residential or nonresidential facility providing water for human consumption shall be lead free. This subsection shall not apply to leaded joints necessary for the repair of cast iron pipes.

(2) Labeling of Solders. No solder containing more than 0.20 percent lead shall be sold in Oregon after July 1, 1985, unless said solder contains a warning label, prominently displayed, which states, "Contains Lead. Oregon Law prohibits the use of this solder in making up joints and fittings in any private or public potable water supply system or any individual water user's line". Solder to be used in making up joints and fittings in any private or public potable water supply system or any individual water user's line shall meet ASTM Specification B32-76.

(3) Plumbing piping shall not be used for electrical grounding in any new construction.

(4) Use of lead pipe prohibited. No lead pipe shall be used in any potable water system. Persons who own or operate a public water system shall submit a compliance schedule, acceptable to the Authority, for the identification and removal of all lead service pipes or they shall certify to the Authority that no lead service piping exists in the system. The compliance schedule or the certification shall be submitted for approval by July 1, 1985.

(5) Materials and products which come into contact with drinking water supplied by public water systems or which come into contact with drinking water treatment chemicals used by public water systems shall meet the requirements of NSF Standard 61 Drinking Water System Components — Health Effects (Revised October 1988) or equivalent. These materials and products include but are not limited to process media, protective materials, joining and sealing materials, pipes and related products, and mechanical devices used in treatment, transmission, and distribution systems.

(6) Products added to public water systems for treatment, purposes including but not limited to disinfection, oxidation, filtration, scale control, corrosion control, pH adjustment, softening, precipitation, sequestering, fluoridation, coagulation, flocculation, and water well treatment shall meet the requirements of NSF Standard 60 - Drinking Water Treatment Chemicals — Health Effects (Revised October 1988) or equivalent.

(7) Point-of-use reverse osmosis drinking water treatment systems and materials and components used in these systems designed to be used for the reduction of specific contaminants from public water supplies shall meet the requirements of NSF Standard 58 — Reverse Osmosis Drinking Water Treatment Systems — or equivalent.

(8) Point-of-use and point-of-entry drinking water treatment units, other than reverse osmosis units, designed to be used for the reduction of specific contaminants from public water supplies shall meet the requirements of NSF Standards 53 — Drinking Water Treatment Units -Health Effects — or equivalent.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 448.115 & 448.131
Hist.: HD 18-1984, f. & ef. 9-4-84; HD 3-1988(Temp), f. & cert. ef. 2-12-88; HD 17-1988, f. & cert. ef. 7-27-88; HD 9-1989, f. & cert. ef. 11-13-89; OHD 17-2002, f. & cert. ef. 10-25-02; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 3-2013, f. & cert. ef. 1-25-13

333-061-0090
Penalties

(1) Violation of these rules shall be punishable as set forth in ORS 448.990 which stipulates that violation of any section of these rules is a Class A misdemeanor.

(2) Pursuant to ORS 448.280, 448.285 and 448.290, any person who violates these rules shall be subject to a civil penalty. Each and every violation is a separate and distinct offense, and each day's violation is a separate and distinct violation.

(3) The civil penalty for the following violations shall not exceed $1,000 per day for each violation:

(a) Failure to obtain approval of plans prior to the construction of water system facilities;

(b) Failure to construct water system facilities in compliance with approved plans;

(c) Failure to take immediate action to correct maximum contaminant level violations;

(d) Failure to comply with sampling and analytical requirements;

(e) Failure to comply with reporting and public notification requirements;

(f) Failure to meet the conditions of a compliance schedule developed under a variance or permit;

(g) Failure to comply with cross connection control requirements;

(h) Failure to comply with the operation and maintenance requirements;

(i) Failure to comply with an order issued by the Authority; and

(j) Failure to utilize an operator in direct responsible charge of a water system.

(4) Civil penalties shall be based on the population served by public water systems and shall be in accordance with Table 45 below: [Table not included. See ED. NOTE.]

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 448.131, 448.280, 448.285, 448.290, & 448.990

Hist.: HD 106, f. & ef. 2-6-76; HD 17-1981(Temp), f. & ef. 8-28-81; HD 4-1982, f. & ef. 2-26-82; Renumbered from 333-042-0245, HD 2-1983, f. & ef. 2-23-83; HD 3-1987, f. & ef. 2-17-87; HD 9-1989, f. & cert. ef. 11-13-89; HD 26-1990, f. 12-26-90, cert. ef. 12-29-90; OHD 4-1999, f. 7-14-99, cert. ef. 7-15-99; OHD 3-2000, f. 3-8-00, cert. ef. 3-15-00; OHD 17-2002, f. & cert. ef. 10-25-02; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 33-2004, f. & cert. ef. 10-21-04; PH 2-2006, f. & cert. ef. 1-31-06; PH 4-2009, f. & cert. ef. 5-18-09; PH 7-2010, f. & cert. ef. 4-19-10; PH 3-2013, f. & cert. ef. 1-25-13; PH 14-2014, f. & cert. ef. 5-8-14; PH 5-2016, f. 2-10-16, cert. ef. 4-1-16

333-061-0095
Severability

These rules are severable, if any rule or part thereof or the application of such rule to any person or circumstance is declared invalid, that invalidity shall not affect the validity of any remaining portion of these rules.

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 448.131

Hist.: HD 17-1981(Temp), f. & ef. 8-28-81; HD 4-1982, f. & ef. 2-26-82; Renumbered from 333-042-0250, HD 2-1983, f. & ef. 2-23-83

333-061-0097
Adverse Health Effects Language

When providing the information on potential adverse health effects required by these rules in notices of violations of maximum contaminant levels, maximum residual disinfectant levels, treatment technique requirements, or notices of the granting or the continued existence of variances or permits, or notices of failure to comply with a variance or permit schedule, the owner or operator of a public water system shall include the language specified below for each contaminant.

(1) Adverse Health Effects for Organic Chemicals:

(a) Volatile Organic Chemicals (VOCs):

(A) Benzene. Some people who drink water containing benzene in excess of the MCL over many years could experience anemia or a decrease in blood platelets, and may have an increased risk of getting cancer.

(B) Carbon tetrachloride. Some people who drink water containing carbon tetrachloride in excess of the MCL over many years could experience problems with their liver and may have an increased risk of getting cancer.

(C) Chlorobenzene. Some people who drink water containing chlorobenzene in excess of the MCL over many years could experience problems with their liver or kidneys.

(D) o-Dichlorobenzene. Some people who drink water containing o-dichlorobenzene well in excess of the MCL over many years could experience problems with their liver, kidneys, or circulatory systems.

(E) p-Dichlorobenzene. Some people who drink water containing p-dichlorobenzene in excess of the MCL over many years could experience anemia, damage to their liver, kidneys, or spleen, or changes in their blood.

(F) 1,2-Dichloroethane. Some people who drink water containing 1,2-dichloroethane in excess of the MCL over many years may have an increased risk of getting cancer.

(G) 1,1-Dichloroethylene. Some people who drink water containing 1,1-dichloroethylene in excess of the MCL over many years could experience problems with their liver.

(H) cis-1,2-Dichloroethylene. Some people who drink water containing cis-1,2-dichloroethylene in excess of the MCL over many years could experience problems with their liver.

(I) trans-1,2-Dichloroethylene. Some people who drink water containing trans-1,2- dichloroethylene well in excess of the MCL over many years could experience problems with their liver.

(J) Dichloromethane(methylene chloride). Some people who drink water containing dichloromethane in excess of the MCL over many years could have liver problems and may have an increased risk of getting cancer.

(K) 1,2-Dichloropropane. Some people who drink water containing 1,2-dichloropropane in excess of the MCL over many years may have an increased risk of getting cancer.

(L) Ethylbenzene. Some people who drink water containing ethylbenzene well in excess of the MCL over many years could experience problems with their liver or kidneys.

(M) Styrene. Some people who drink water containing styrene well in excess of the MCL over many years could have problems with their liver, kidneys, or circulatory system.

(N) Tetrachloroethylene(PCE). Some people who drink water containing tetrachloroethylene in excess of the MCL over many years could have problems with their liver, and may have an increased risk of getting cancer.

(O) 1,2,4-trichlorobenzene. Some people who drink water containing 1,2,4-trichlorobenzene well in excess of the MCL over many years could experience changes in their adrenal glands.

(P) 1,1,1-Trichloroethane. Some people who drink water containing 1,1,1- trichloroethane in excess of the MCL over many years could experience problems with their liver, nervous system, or circulatory system.

(Q) 1,1,2-Trichloroethane. Some people who drink water containing 1,1,2-trichloroethane well in excess of the MCL over many years could have problems with their liver, kidneys, or immune systems.

(R) Trichloroethylene. Some people who drink water containing trichloroethylene in excess of the MCL over many years could experience problems with their liver and may have an increased risk of getting cancer.

(S) Toluene. Some people who drink water containing toluene well in excess of the MCL over many years could have problems with their nervous system, kidneys, or liver.

(T) Vinyl chloride. Some people who drink water containing vinyl chloride in excess of the MCL over many years may have an increased risk of getting cancer.

(U) Xylenes. Some people who drink water containing xylenes in excess of the MCL over many years could experience damage to their nervous system.

(b) Synthetic Organic Chemicals (SOCs):

(A) 2,4-D. Some people who drink water containing the weed killer 2,4-D well in excess of the MCL over many years could experience problems with their kidneys, liver, or adrenal glands.

(B) 2,4,5-TP(Silvex). Some people who drink water containing 2,4,5-TP in excess of the MCL over many years could experience liver problems.

(C) Alachlor. Some people who drink water containing alachlor in excess of the MCL over many years could have problems with their eyes, liver, kidneys, or spleen, or experience anemia, and may have an increased risk of getting cancer.

(D) Atrazine. Some people who drink water containing atrazine well in excess of the MCL over many years could experience problems with their cardiovascular system or reproductive difficulties.

(E) Benzo(a)pyrene. Some people who drink water containing benzo(a)pyrene in excess of the MCL over many years may experience reproductive difficulties and may have an increased risk of getting cancer.

(F) Carbofuran. Some people who drink water containing carbofuran in excess of the MCL over many years could experience problems with their blood, or nervous or reproductive systems.

(G) Chlordane. Some people who drink water containing chlordane in excess of the MCL over many years could experience problems with their liver or nervous system, and may have an increased risk of getting cancer.

(H) Dalapon. Some people who drink water containing dalapon well in excess of the MCL over many years could experience minor kidney changes.

(I) Di(2-ethylhexyl)adipate. Some people who drink water containing di(2-ethylhexyl)adipate well in excess of the MCL over many years could experience toxic effects such as weight loss, liver enlargement or possible reproductive difficulties.

(J) Di(2-ethylhexyl)phthalate. Some people who drink water containing di(2-ethylhexyl)phthalate well in excess of the MCL over many years may have problems with their liver or experience reproductive difficulties, and may have an increased risk of getting cancer.

(K) Dibromochloropropane (DBCP). Some people who drink water containing DBCP in excess of the MCL over many years could experience reproductive difficulties and may have an increased risk of getting cancer.

(L) Dinoseb. Some people who drink water containing dinoseb well in excess of the MCL over many years could experience reproductive difficulties.

(M) Diquat. Some people who drink water containing diquat in excess of the MCL over many years could get cataracts.

(N) Dioxin (2,3,7,8-TCDD). Some people who drink water containing dioxin in excess of the MCL over many years could experience reproductive difficulties and may have an increased risk of getting cancer.

(O) Endothall. Some people who drink water containing endothall in excess of the MCL over many years could experience problems with their stomach or intestines.

(P) Endrin. Some people who drink water containing endrin in excess of the MCL over many years could experience liver problems.

(Q) Ethylene dibromide (EDB). Some people who drink water containing ethylene dibromide in excess of the MCL over many years could experience problems with their liver, stomach, reproductive system, or kidneys, and may have an increased risk of getting cancer.

(R) Glyphosate. Some people who drink water containing glyphosate in excess of the MCL over many years could experience problems with their kidneys or reproductive difficulties.

(S) Heptachlor. Some people who drink water containing heptachlor in excess of the MCL over many years could experience liver damage and may have an increased risk of getting cancer.

(T) Heptachlor epoxide. Some people who drink water containing heptachlor epoxide in excess of the MCL over many years could experience liver damage and may have an increased risk of getting cancer.

(U) Hexachlorobenzene. Some people who drink water containing hexachlorobenzene in excess of the MCL over many years could experience problems with their liver or kidneys or adverse reproductive effects, and may have an increased risk of getting cancer.

(V) Hexachlorocyclopentadiene. Some people who drink water containing hexachlorocyclopentadiene well in excess of the MCL over many years could experience problems with their kidneys or stomach.

(W) Lindane. Some people who drink water containing lindane in excess of the MCL over many years could experience problems with their kidneys or liver.

(X) Methoxychlor. Some people who drink water containing methoxychlor in excess of the MCL over many years could experience reproductive difficulties.

(Y) Oxamyl. Some people who drink water containing oxamyl in excess of the MCL over many years could experience slight nervous system effects.

(Z) Polychlorinated biphenyls (PCBs). Some people who drink water containing polychlorinated biphenyls in excess of the MCL over many years could experience changes in their skin, problems with their thymus gland, immune deficiencies or reproductive or nervous system difficulties, and may have an increased risk of getting cancer.

(AA) Pentachlorophenol. Some people who drink water containing pentachlorophenol in excess of the MCL over many years could experience problems with their liver or kidneys, and may have an increased risk of getting cancer.

(BB) Picloram. Some people who drink water containing picloram in excess of the MCL over many years could experience problems with their liver.

(CC) Simazine. Some people who drink water containing simazine in excess of the MCL over many years could experience problems with their blood.

(DD) Toxaphene. Some people who drink water containing toxaphene in excess of the MCL over many years could have problems with their kidneys, liver, or thyroid, and may have an increased risk of getting cancer.

(2) Special Notice for Lead and Copper.

(a) Mandatory health effects information. When providing the information in public notices on the potential adverse health effects of lead in drinking water, the owner or operator of the water system shall include the following specific language in the notice:

"Infants and children who drink water containing lead in excess of the action level could experience delays in their physical or mental development. Children could show slight deficits in attention span and learning abilities. Adults who drink this water over many years could develop kidney problems or high blood pressure."

(b) Mandatory health effects information. When providing information on the potential adverse health effects of copper in drinking water, the owner or operator of the water system shall include the following specific language in the notice:

"Copper is an essential nutrient, but some people who drink water containing copper in excess of the action level over a relatively short amount of time could experience gastrointestinal distress. Some people who drink water containing copper in excess of the action level over many years could suffer liver or kidney damage. People with Wilson's Disease should consult their personal doctor."

(3) Inorganics — public notice language.

(a) Antimony. Some people who drink water containing antimony well in excess of the MCL over many years could experience increases in blood cholesterol and decreases in blood sugar.

(b) Arsenic. Some people who drink water containing arsenic in excess of the MCL over many years could experience skin damage or problems with their circulatory system, and may have an increased risk of getting cancer.

(c) Asbestos. Some people who drink water containing asbestos in excess of the MCL over many years may have an increased risk of developing benign intestinal polyps.

(d) Barium. Some people who drink water containing barium in excess of the MCL over many years could experience an increase in their blood pressure.

(e) Beryllium. Some people who drink water containing beryllium well in excess of the MCL over many years could develop intestinal lesions.

(f) Cadmium. Some people who drink water containing cadmium in excess of the MCL over many years could experience kidney damage.

(g) Chromium. Some people who use water containing chromium well in excess of the MCL over many years could experience allergic dermatitis.

(h) Cyanide. Some people who drink water containing cyanide well in excess of the MCL over many years could experience nerve damage or problems with their thyroid.

(i) Fluoride. Some people who drink water containing fluoride in excess of the MCL (4.0 mg/l) over many years could get bone disease, including pain and tenderness of the bones. Fluoride in

drinking water at half the MCL (2.0mg/l) or more may cause mottling of children's teeth, usually in children less than nine years old. Mottling, also known as dental fluorosis, may include brown staining or pitting of the teeth, and occurs only in developing teeth before they erupt from the gums.

(j) Mercury. Some people who drink water containing inorganic mercury well in excess of the MCL over many years could experience kidney damage.

(k) Nitrate (as nitrogen). Infants below the age of 6 months who drink water containing nitrate in excess of the MCL could become seriously ill and, if untreated, may die. Symptoms include shortness of breath and blue baby syndrome.

(l) Nitrite. Infants below the age of 6 months who drink water containing nitrite in excess of the MCL could become seriously ill and, if untreated, may die. Symptoms include shortness of breath and blue baby syndrome.

(m) Total Nitrate and Nitrite. Infants below the age of 6 months who drink water containing nitrate and nitrite in excess of the MCL could become seriously ill and, if untreated, may die. Symptoms include shortness of breath and blue baby syndrome.

(n) Selenium. Selenium is an essential nutrient. However, some people who drink water containing selenium in excess of the MCL over many years could experience hair or fingernail losses, numbness in fingers or toes, or problems with their circulation.

(o) Thallium. Some people who drink water containing thallium in excess of the MCL over many years could experience hair loss, changes in their blood, or problems with their kidneys, intestines, or liver.

(4) Microbiological contaminants

(a) When providing information in public notices required under OAR 333-061-0042(2)(b) for exceeding the MCL for total coliform bacteria as specified in 40 CFR 141.63, the water supplier must include the following specific language in the notice:

"Coliforms are bacteria that are naturally present in the environment and are used as an indicator that other, potentially harmful, bacteria may be present. Coliforms were found in more samples than allowed and this was a warning of potential problems."

(b) When providing information in public notices for an exceedance of the MCL for E. coli bacteria as prescribed by OAR 333-061-0030(4), the language within quotation marks must be included, exactly as written:

"E. coli are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Human pathogens in these wastes can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a greater health risk for infants, young children, the elderly, and people with severely compromised immune systems."

(c) When providing information in public notices for failing to complete a coliform investigation or corrective action as required by OAR 333-061-0078, the language specified in paragraphs (4)(c)(A) or (4)(c)(B) must be included, exactly as written except for the language within brackets. The language in paragraph (4)(c)(A) must be used when total coliform was detected at a water system and the language in (4)(c)(B) must be used when E. coli was detected regardless of whether the MCL for E. coli was exceeded.

(A) Coliforms are bacteria that are naturally present in the environment and are used as an indicator that other, potentially harmful, waterborne pathogens may be present or that a potential pathway exists through which contamination may enter the drinking water distribution system. We found coliforms indicating the need to look for potential problems in water treatment or distribution. When this occurs, we are required to conduct investigations to identify problems and to correct any problems that are found.

[THE WATER SUPPLIER MUST USE THE FOLLOWING APPLICABLE SENTENCES.]

We failed to conduct the required coliform investigation.

We failed to correct all identified sanitary defects that were found during the coliform investigation(s).

(B) E. coli are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Human pathogens in these wastes can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a greater health risk for infants, young children, the elderly, and people with severely compromised immune systems. We violated the standard for E. coli, indicating the need to look for potential problems in water treatment or distribution. When this occurs, we are required to conduct a detailed investigation to identify problems and to correct any problems that are found.

[THE WATER SUPPLIER MUST USE THE FOLLOWING APPLICABLE SENTENCES.]

We failed to conduct the required coliform investigation.

We failed to correct all identified sanitary defects that were found during the coliform investigation that we conducted.

(d) When providing information in public notices for failing to complete an Authority approved start-up procedure at a seasonal water system, the water supplier must include specific information about the situation as prescribed by OAR 333-061-0042(4)(a). Additionally, if monitoring was required as part of the Authority approved start-up procedure the following language in quotation marks must be included, exactly as written except for the language in brackets where water system specific information must be included: "We are required to monitor your drinking water for specific contaminants on a regular basis. Results of regular monitoring are an indicator of whether or not your drinking water meets health standards. During [compliance period], we did not complete [any or all] required monitoring or testing for coliform bacteria, and therefore cannot be sure of the quality of your drinking water during that time."

(e) Turbidity. Turbidity has no health effects. However, turbidity can interfere with disinfection and provide a medium for microbial growth. Turbidity may indicate the presence of disease-causing organisms. These organisms include, bacteria, viruses, and parasites that can cause symptoms such as nausea, cramps, diarrhea and associated headaches.

(5) Treatment Techniques -- Public Notice Language.

(a) Acrylamide. Some people who drink water containing high levels of acrylamide over a long period of time could have problems with their nervous system or blood, and may have an increased risk of getting cancer.

(b) Epichlorohydrin. Some people who drink water containing high levels of epichlorohydrin over a long period of time could experience stomach problems, and may have an increased risk of getting cancer.

(c) Surface Water Treatment Rule (Giardia, viruses, heterotrophic plate count bacteria, Legionella), Interim Enhanced Surface Water Treatment Rule (Giardia, viruses, heterotrophic plate count bacteria, Legionella and Cryptosporidium), Long Term 1 Enhanced Surface Water Treatment Rule (Giardia, viruses, heterotrophic plate count bacteria, Legionella and Cryptosporidium) and Filter Backwash Recycling Rule (Cryptosporidium). Inadequately treated water may contain disease-causing organisms. These organisms include bacteria, viruses, and parasites which can cause symptoms such as nausea, cramps, diarrhea, and associated headaches.

(d) Groundwater. Inadequately treated or inadequately protected water may contain disease-causing organisms. These organisms can cause symptoms such as diarrhea, nausea, cramps, and associated headaches.

(e) Use of an emergency groundwater source that has been identified as potentially groundwater under direct influence of surface water, but has not been fully evaluated. This type of source may not be treated sufficiently to inactivate pathogens such as Giardia lamblia and Cryptosporidium.

(6) Disinfectant and Disinfection Byproducts -- Special Adverse Health Effects Language.

(a) Total Trihalomethanes (TTHMs). Some people who drink water containing trihalomethanes in excess of the MCL over many years may experience problems with their liver, kidneys, or central nervous system, and may have an increased risk of getting cancer.

(b) Haloacetic Acids (HAA). Some people who drink water containing haloacetic acids in excess of the MCL over many years may have an increased risk of getting cancer.

(c) Chlorine. Some people who use water containing chlorine well in excess of the MRDL could experience irritating effects to their eyes and nose. Some people who drink water containing chlo-

rine well in excess of the MRDL could experience stomach discomfort.

(d) Chloramines. Some people who use water containing chloramines well in excess of the MRDL could experience irritating effects to their eyes and nose. Some people who drink water containing chloramines well in excess of the MRDL could experience stomach discomfort or anemia.

(e) Chlorine dioxide. (where any 2 consecutive daily samples taken at the entrance to the distribution system are above the MRDL). Some infants and young children who drink water containing chlorine dioxide in excess of the MRDL could experience nervous system effects. Similar effects may occur in fetuses of pregnant women who drink water containing chlorine dioxide in excess of the MRDL. Some people may experience anemia.

NOTE: In addition to the language in this introductory text of subsection (6)(e) of this rule, water systems must include either the language in paragraphs (6)(e)(A) or (6)(e)(B) of this rule. Water systems with a violation at the treatment plant, but not in the distribution system, are required to use the language in paragraph (6)(e)(A) of this rule and treat the violation as a non-acute violation. Water systems with a violation in the distribution system are required to use the language in paragraph (6)(e)(B) of this rule and treat the violation as an acute violation.

(A) The chlorine dioxide violations reported today are the result of exceedances at the treatment facility only, and do not include violations within the distribution system serving users of this water supply. Continued compliance with chlorine dioxide levels within the distribution system minimizes the potential risk of these violations to present consumers.

(B) The chlorine dioxide violations reported today include exceedances of the EPA standard within the distribution system serving water users. Violations of the chlorine dioxide standard within the distribution system may harm human health based on short-term exposures. Certain groups, including fetuses, infants, and young children, may be especially susceptible to nervous system effects of excessive exposure to chlorine dioxide-treated water. The purpose of this notice is to advise that such persons should consider reducing their risk of adverse effects from these chlorine dioxide violations by seeking alternate sources of water for human consumption until such exceedances are rectified. Local and State health authorities are the best sources for information concerning alternate drinking water.

(f) Bromate. Some people who drink water containing bromate in excess of the MCL over many years may have an increased risk of getting cancer.

(g) Chlorite. Some infants and young children who drink water containing chlorite in excess of the MCL could experience nervous system effects. Similar effects may occur in fetuses of pregnant women who drink water containing chlorite in excess of the MCL. Some people may experience anemia.

(h) Total Organic Carbon (TOC). Total Organic Carbon (TOC) has no health effects. However, TOC provides a medium for the formation of disinfection byproducts (DBPs). These byproducts include trihalomethanes and haloacetic acids. Drinking water containing these byproducts in excess of the MCL may lead to adverse health effects, liver or kidney problems, or nervous system effects, and may lead to an increased risk of getting cancer.

(7) Adverse health effects for radionuclides:

(a) Beta/photon emitters. Certain minerals are radioactive and may emit forms of radiation known as photons and beta radiation. Some people who drink water containing beta and photon emitters in excess of the MCL over many years may have an increased risk of getting cancer.

(b) Alpha emitters. Certain minerals are radioactive and may emit a form of radiation known as alpha radiation. Some people who drink water containing alpha emitters in excess of the MCL over many years may have an increased risk of getting cancer.

(c) Combined Radium-226/228. Some people who drink water containing radium-226 or -228 in excess of the MCL over many years may have an increased risk of getting cancer.

(d) Uranium. Some people who drink water containing uranium in excess of the MCL over many years may have an increased risk of getting cancer and kidney toxicity.

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 448.131. 448.150

Hist.: HD 9-1989, f. & cert. ef. 11-13-89; HD 26-1990, f. 12-26-90, cert. ef. 12-29-90; HD 9-1991(Temp), f. & cert. ef. 6-24-91; HD 1-1992, f. & cert. ef. 3-5-92; HD 7-1992, f. & cert. ef. 6-9-92; HD 12-1992, f. & cert. ef. 12-7-92; HD 3-1994, f. & cert. ef. 1-14-94; HD 11-1994, f. & cert. ef. 4-11-94; HD 1-1996, f. 1-2-96, cert. ef. 1-5-96; OHD 7-2000, f. 7-11-00, cert. ef. 7-15-00; OHD 23-2001, f. & cert. ef. 10-31-01; OHD 17-2002, f. & cert. ef. 10-25-02; PH 12-2003, f. & cert. ef. 8-15-03; PH 33-2004, f. & cert. ef. 10-21-04; PH 2-2006, f. & cert. ef. 1-31-06; PH 4-2009, f. & cert. ef. 5-18-09; PH 5-2016, f. 2-10-16, cert. ef. 4-1-16

333-061-0098
References

All standards, listings and publications referred to in these rules are by those references made a part of these rules as though fully set forth. Copies are available from Oregon Health Authority, Public Health Division.

(1) American Society for testing and materials (ASTM) specification B32-83 (solder)

(2) American Water Works Association (AWWA) Standards

(3) Clean Water Act (EPA)

(4) Code of Federal Regulations (40 CFR: 141.21-.25, 141.30 — Inorganics, etc.)

(5) Code of Federal Regulations (21 CFR: 103, 110 and 129 — Bottled water)

(6) Federal Insecticide, Fungicide and Rodenticide ACT (FIFRA-EPA)

(7) Manual of Cross Connection Control, USC 10th Edition, October 2009

(8) National Bureau of Standards (NBS) Handbook 69, — Maximum Permissible Body Burdens and Maximum Permissible Concentrations of Radionuclides in Air and Water for Occupational Exposure

(9) National Primary Drinking Water Regulations (40 CFR 141 and 142)

(10) NSF Standard 53 — Drinking Water Treatment Units — Health Effects

(11) NSF Standard 58 — Reverse Osmosis Drinking Water Treatment Systems

(12) NSF Standard 60 — Drinking Water Treatment Chemicals — Health Effects

(13) NSF Standard 61, Section 9 — Drinking Water System Components — Health Effects

(14) National Secondary Drinking Water Regulations (40 CFR 143)

(15) Oregon Administrative Rules chapter 437 (Oregon OSHA)

(16) Oregon Administrative Rules chapter 660, division 011 (Public Facilities Planning)

(17) Oregon Administrative Rules chapter 660, division 031 (Land Conservation & Development)

(18) Oregon Administrative Rules chapter 690, divisions 200 through 220 (General standards for the construction and maintenance of water wells in Oregon, Water Resources Department)

(19) Oregon Revised Statutes 197 (Land Conservation & Development)

(20) Oregon Revised Statutes 215 and 227 (Land Use Planning)

(21) Oregon Revised Statutes 448 (Public Water Systems)

(22) Oregon Revised Statutes 468.700 to 468.990 (DEQ)

(23) Oregon Revised Statutes 527.610 to 527.990 (Dept. of Forestry)

(24) Oregon Revised Statutes 536.220 to 536.360 (Water Resources)

(25) Oregon Revised Statutes 634.992 (Dept. of Agriculture)

(26) Oregon State Plumbing Code

(27) Standard Methods for the Examination of Water and Wastewater, 22nd Edition, 2012.

(28) Supplement to the 19th Edition of Standard Methods for the Examination of Water and Wastewater, 1996.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 431.110, 431.150, 448.131, 448.150, 448.273 & 448.279

Hist.: HD 9-1989, f. & cert. ef. 11-13-89; HD 12-1992, f. & cert. ef. 12-7-92; HD 3-1994, f. & cert. ef. 1-14-94; HD 1-1996, f. 1-2-96, cert. ef. 1-5-96; OHD 7-2000, f. 7-11-00, cert. ef. 7-15-00; PH 3-2013, f. & cert. ef. 1-25-13

Public Water Systems/Certification

333-061-0210
Scope

OAR 333-061-0210 through 333-061-0272 apply to community and non-transient non-community public water systems, water suppliers responsible for these types of water systems, and the operators of water treatment plants and distribution systems at community and non-transient non-community public water systems.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 448.450, 448.455, 448.460, 448.465 & 448.994
Hist.: HD 2-1988(Temp), f. & cert. ef. 2-10-88; HD 18-1988, f. & cert. ef. 7-27-88; OHD 7-2002, f. & cert. ef. 5-2-02; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 33-2004, f. & cert. ef. 10-21-04; PH 14-2014, f. & cert. ef. 5-8-14

333-061-0220
Classification of Water Treatment Plants and Water Distribution Systems

Water treatment plants and distribution systems at community and non-transient non-community public water systems are classified based on the size and complexity of the water system facility. Classification of a water system or water system facility determines the level of certification required for operators in direct responsible charge of a water system or water system facility as prescribed by OAR 333-061-0225.

(1) Small water system classification applies when a water system serves 150 service connections or less and:

(a) Uses only groundwater as its source; or

(b) Purchases finished water from another public water system.

(2) Water distribution classification applies when a water system is not classified as small in accordance with section (1) of this rule, and is based on the population served by the water system as follows:

Classification: — Population Served:
Water Distribution 1 — 1 to 1,500.
Water Distribution 2 — 1,501 to 15,000.
Water Distribution 3 — 15,001 to 50,000.
Water Distribution 4 — 50,001 or more

(3) Water treatment classification applies to water treatment plants when:

(a) A water system is not classified as small in accordance with section (1) of this rule; and

(b) Treatment is provided for contaminants identified in OAR 333-061-0030(1) through (5) and (7) by that water treatment plant.

(c) Water treatment classification is based on a point system that reflects the complexity of water treatment present. Points are assigned as follows:

Item — Points.
Treatment system size: (population served or flow whichever is greater).
Population served — 1/10,000 (max 30).
Average daily flow — 1/1 mgd (max 30).
Treatment system water source:
Groundwater: — 3.
Surface Water or Groundwater Under the Influence of Surface Water — 5.
Chemical Treatment/Addition Process:
Fluoridation — 5.
Disinfection:
Ultraviolet (UV) — 2.
UV with Chlorine Residual — 5.
Ammonia/Chloramination — 3.
Chlorine — 5.
Mixed Oxidants — 7.
Ozonation (on-site generation) — 10.
Residual Maintenance — 0.
pH adjustment:
Slaked-Quicklime (Calcium Oxide) — 5.
Hydrated Lime (Calcium Hydroxide) — 4.
All others — 1.
(hydrochloric acid, sodium hydroxide, sulfuric acid, sodium carbonate).
Coagulation & Flocculation processes:
Chemical addition — 1–5.
(1 point for each type of chemical coagulant or polymer added, maximum 5 points).
Rapid mix units:
Mechanical mixers — 3.
Injection mixers — 2.
In-line blender mixers — 2.
Flocculation units:
Hydraulic flocculators — 2.
Mechanical flocculators — 3.
Clarification and Sedimentation Processes:
Adsorption Clarifier — 10.
Horizontal-flow (rectangular basins) — 5.
Horizontal-flow (round basins) — 7.
Up-flow solid contact sedimentation — 15.
Inclined-plate sedimentation — 10.
Tube sedimentation — 10.
Dissolved air flotation — 10.
Filtration Processes:
Single/mono media filtration — 3.
Dual or mixed media filtration — 5.
Membrane Filtration/Microscreens — 5.
Direct — 5.
Diatomaceous earth — 12.
Slow sand filtration — 5.
Cartridge/bag filters — 5.
Pressure or greensand filtration — 10.
Stability or Corrosion Control:
Slaked-Quicklime (calcium oxide) — 10.
Hydrated Lime (calcium hydroxide) — 8.
Caustic soda (sodium hydroxide) — 6.
Orthophosphate — 5.
Soda ash (sodium carbonate) — 4.
Aeration: Packed tower, Diffusers — 3.
Calcite — 2.
Others: sodium bicarbonate, silicates — 4.
Other Treatment Processes:
Aeration — 3.
Packed tower aeration — 5.
Ion exchange/softening — 5.
Lime-soda ash softening — 20.
Copper sulfate treatment — 5.
Powdered activated carbon — 5.
Potassium permanganate — 5.
Special Processes (reverse osmosis, activated alumina, other) — 15.
Sequestering (polyphosphates) — 3.
Residuals Disposal:
Discharge to lagoons — 5.
Discharge to lagoons and then raw water source — 8.
Discharge to raw water — 10.
Disposal to sanitary sewer — 3.
Mechanical dewatering — 5.
On-site disposal — 5.
Land application — 5.
Solids composting — 5.
Facility characteristics Instrumentation:
The use of SCADA or similar instrumentation systems to provide data with no process control — 1.
The use of SCADA or similar instrumentation systems to provide data with partial process control — 3.
The use of SCADA or similar instrumentation systems to provide data with complete process control — 5
Clear well size less than average day design flow — 5.
Classification of Water Treatment Plants.
Classification — Points:
Water Treatment 1 — 1 to 30.
Water Treatment 2 — 31 to 55.
Water Treatment 3 — 56 to 75.
Water Treatment 4 — 76 or more.

(4) Filtration endorsement is an additional classification that applies when a water treatment plant is classified as Water Treatment 2 and uses conventional or direct filtration treatment to treat surface water or groundwater under the influence of surface water. Filtration endorsement certification, as prescribed by OAR 333-061-0235, is required for operators designated in direct responsible charge of a water treatment plant receiving the filtration endorsement classification, except for those operators already certified at Water Treatment Level 3 or higher.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 448.450, 448.455, 448.460, 448.465 & 448.994
Hist.: HD 2-1988(Temp), f. & cert. ef. 2-10-88; HD 18-1988, f. & cert. ef. 7-27-88; HD 11-1989(Temp), f. & cert. ef. 12-29-89; HD 19-1990, f. 6-28-90, cert. ef. 7-2-90; HD 14-1997, f. & cert. ef. 10-31-97; OHD 7-2002, f. & cert. ef. 5-2-

02; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 33-2004, f. & cert. ef. 10-21-04; PH 2-2006, f. & cert. ef. 1-31-06; PH 4-2009, f. & cert. ef. 5-18-09; PH 3-2013, f. & cert. ef. 1-25-13; PH 14-2014, f. & cert. ef. 5-8-14

333-061-0225
General Requirements Applying to Water Suppliers and Water Systems

(1) Water suppliers responsible for community and non-transient non-community water systems must at all times employ, contract with, or otherwise utilize an operator to be in direct responsible charge of every distribution system and water treatment plant. An operator designated in direct responsible charge of a distribution system or water treatment plant must be available during those periods of time when decisions relating to treatment processes, water quality, and water quantity that may affect public health are made.

(a) The operator(s) described in this section must be certified as prescribed by OAR 333-061-0228 or 333-061-0235 through 0265, at a level equal to or greater than the classification of the distribution system or water treatment plant as prescribed by 333-061-0220, for which they are responsible.

(b) A water supplier subject to this rule must report to the Authority, the name(s) of the operator(s) that has been designated to be in direct responsible charge of the distribution system and water treatment plant as applicable, and must notify the Authority within 30 days of any change of operator.

(2) A water supplier may employ, contract with, or utilize other operators in addition to those required by section (1) of this rule. For operators certified at less than the Authority-required level(s) for distribution or treatment, the water supplier must establish a written protocol for each of the other operators that:

(a) Describes the operational decisions the operator is allowed to make;

(b) Requires the operator to notify the operator in direct responsible charge when they make decisions related to process control, water quality or water quantity that may affect public health;

(c) Describes the specific conditions under which the operator must consult with the operator in direct responsible charge, and when and how consultation is to be made;

(d) Takes into account the certification level of the operator; their knowledge, skills, and abilities, and the range of expected operating conditions of the water system; and

(e) Is signed and dated by the operator in direct responsible charge and the operator to which the protocol applies, and is available for inspection by the Authority.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 448.450, 448.455, 448.460, 448.465 & 448.994
Hist.: HD 2-1988(Temp), f. & cert. ef. 2-10-88; HD 18-1988, f. & cert. ef. 7-27-88; HD 11-1989(Temp), f. & cert. ef. 12-29-89; HD 19-1990, f. 6-28-90, cert. ef. 7-2-90; HD 1-1996, f. 1-2-96, cert. ef. 1-5-96; HD 14-1997, f. & cert. ef. 10-31-97; OHD 16-2001(Temp), f. 7-31-01, cert. ef. 8-1-01 thru 1-28-02; Administrative correction 3-14-02; OHD 7-2002, f. & cert. ef. 5-2-02; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 33-2004, f. & cert. ef. 10-21-04; PH 4-2009, f. & cert. ef. 5-18-09; PH 3-2013, f. & cert. ef. 1-25-13; PH 14-2014, f. & cert. ef. 5-8-14

333-061-0228
Certification Requirements For Small Water System Operators

(1) In order to apply for certification as the operator of a water system classified as small as prescribed by OAR 333-061-0220(1), individuals must:

(a) Have graduated from high school or completed an approved GED program; and

(A) Complete an Authority approved training for small water system operations and water treatment processes; or

(B) Pass an Authority approved written examination relating to small water system operations and water treatment; and

(b) Submit a certificate demonstrating the completion of the required training or examination specified in paragraphs (1)(a)(A) or (B) of this rule.

(2) Certification at the small water system level expires on July 31 three years after the training or examination as specified in paragraphs (1)(a)(A) or (B) was completed.

(3) Individuals certified as prescribed by OAR 333-061-0235 through 333-061-0265 at levels 1 through 4 for water distribution or water treatment are qualified to be designated in direct responsible charge of a water system classified as small as prescribed by 333-061-0220(1).

(4) Small water system certification as prescribed by this rule is exempt from fees.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 448.450, 448.455, 448.460, 448.465 & 448.994
Hist.: OHD 7-2002, f. & cert. ef. 5-2-02; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 33-2004, f. & cert. ef. 10-21-04; PH 7-2010, f. & cert. ef. 4-19-10; PH 3-2013, f. & cert. ef. 1-25-13; PH 14-2014, f. & cert. ef. 5-8-14

333-061-0230
Contracting For Services

(1) Water suppliers responsible for community and non-transient non-community water systems may establish contracts with an individual certified operator, another water supplier, or an organization with certified operators available for contract to obtain operational services at a public water system.

(2) Operators contracted to be in direct responsible charge of a water system, distribution system or a water treatment plant, as prescribed by OAR 333-061-0225 must be certified at or greater than the level of the classification of the water system or facility for which they will be responsible.

(3) Written contracts for operators designated in direct responsible charge of a water system must:

(a) Require the operator to be available on call 24 hours every day and able to respond on-site, to the water system, upon request; and

(b) Specify that the operator will take corrective action when the results of analyses or measurements indicate maximum contaminant levels have been exceeded or minimum treatment levels are not maintained.

(4) Water suppliers must submit to the Authority, a copy of any contract established for certified operators serving at a water system for which the water supplier is responsible.

(a) Contracts must be signed by the operator and the water supplier, or an authorized representative of the water supplier, before the operator may provide any services to the water supplier.

(b) Contracts must be submitted to the Authority within 30 days of the contract being signed by all parties.

(5) Contracts are only valid for individuals that possess current certification.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 448.450, 448.455, 448.460, 448.465 & 448.994
Hist.: HD 2-1988(Temp), f. & cert. ef. 2-10-88; HD 18-1988, f. & cert. ef. 7-27-88; HD 19-1990, f. 6-28-90, cert. ef. 7-2-90; HD 14-1997, f. & cert. ef. 10-31-97; OHD 7-2002, f. & cert. ef. 5-2-02; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 33-2004, f. & cert. ef. 10-21-04; PH 2-2006, f. & cert. ef. 1-31-06; PH 7-2010, f. & cert. ef. 4-19-10; PH 14-2014, f. & cert. ef. 5-8-14

333-061-0232
General Requirements Applying to Water System Operators

Operators serving at water systems and water system facilities as specified in OAR 333-061-0210 are responsible for ensuring the safe operation of the water system facilities for which they are responsible, and the production of safe drinking water at that water system. All operators serving at water treatment plants and distribution systems must:

(1) Comply with any Authority order or investigation;

(2) Ensure every application, record, or other document filed with or reported to the Authority by the operator is true and accurate; and

(3) Immediately notify the Authority when a violation of these rules is observed that may result in a public health hazard.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 448.450, 448.455 & 448.994
Hist.: PH 14-2014, f. & cert. ef. 5-8-14

333-061-0235
Operator Certification Requirements, Levels 1–4

Operator certification, as specified in this rule, applies to each of the levels of water system facility classification specified in OAR 333-061-0220(2) through (4), and does not apply to small water system classification as specified in OAR 333-061-0220(1).

(1) In order to receive certification as specified in this rule, applicants must:

(a) Provide proof of, including the date of graduation or completion, a high school diploma, GED, associate's degree, bachelor's degree, master's degree, or PhD; and

(b) Successfully complete an examination for the level and type of certification sought by the applicant.

(2) Minimum qualifications for water treatment (WT) or water distribution (WD) operator certification are identified in Table 46. Experience or a combination of experience and education is required depending on the certification and level sought. [Table not included. See ED. NOTE.]

(a) Operating experience must have been gained through direct, "hands-on" operation of water system facilities and includes, but is not limited to, decisions related to water quality or quantity that may affect public health. Knowledge gained from the performance of duties as an official, inspector, manager, engineer, or director of public works, and that does not include the actual operation or supervision of water system facilities, does not qualify an individual for certification as prescribed by these rules.

(A) For water distribution certification, experience in one of the following fields may be accepted, not to exceed one-half of the total experience required: wastewater collection; water treatment; cross connection control; and industrial or commercial process water treatment.

(B) For water treatment certification, experience in one of the following fields may be accepted, not to exceed one-half of the total experience required: wastewater treatment; wastewater treatment laboratory; water distribution; and industrial or commercial process water treatment.

(C) One year of experience is equivalent to 12 months of full-time employment with one hundred percent of the individual's time dedicated to activities directly related to the certification for which they are applying.

(D) Operating experience earned at a water treatment plant or distribution system is considered qualifying experience for certification up to one classification level higher than that of the water system facility where the experience was earned.

(b) The Authority may, at its discretion, permit the substitution of post high school education for experience. Acceptable fields of study include, but are not limited to: allied sciences, chemistry, engineering, industrial or commercial water processing, wastewater collection, wastewater treatment plant operations, wastewater laboratory analysis, water distribution, and water treatment plant operations.

(A) Substituted education may not exceed one-half of the experience required for the certification and level sought.

(B) Any degree or accumulation of college credit hours must be from an educational institution accredited through an agency recognized by the U.S. Department of Education to be acceptable.

(C) The following are considered equivalent to 12 months of post high school education:

(i) One year of college education;

(ii) Thirty semester hours of college education;

(iii) Forty-five quarter hours of college education; or

(iv) Forty-five continuing education units (CEU).

(D) College credits and post high school education from other sources may be combined to total 45 CEU.

(3) Individuals may request credit for on-the-job training as either experience or education, but not both.

(4) Individuals seeking certification at water distribution and water treatment levels 3 and 4 must possess experience in operational decision making as defined in OAR 333-061-0020(126). Any work experience as specified in subsection (2)(a) of this rule qualifies as operational decision making experience if it meets the criteria specified in OAR 333-061-0020(126).

(5) To qualify for filtration endorsement certification, as prescribed by OAR 333-061-0220(4), individuals must:

(a) Possess WT Level 2 certification;

(b) Have one year of operational decision making experience at a water treatment plant utilizing conventional or direct filtration treatment; and

(c) Successfully pass a filtration endorsement examination.

Stat. Auth.: ORS 448.131, 448.150
Stats. Implemented: ORS 448.450, 448.455
Hist.: HD 2-1988(Temp), f. & cert. ef. 2-10-88; HD 18-1988, f. & cert. ef. 7-27-88; HD 19-1990, f. 6-28-90, cert. ef. 7-2-90; HD 1-1996, f. 1-2-96, cert. ef. 1-5-96; HD 14-1997, f. & cert. ef. 10-31-97; OHD 7-2002, f. & cert. ef. 5-2-02; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 33-2004, f. & cert. ef. 10-21-04; PH 2-2006, f. & cert. ef. 1-31-06; PH 7-2010, f. & cert. ef. 4-19-10; PH 3-2013, f. & cert. ef. 1-25-13; PH 14-2014, f. & cert. ef. 5-8-14; PH 5-2016, f. 2-10-16, cert. ef. 4-1-16

333-061-0245
Applications For Certification Levels 1–4

(1) An applicant for certification must submit documentation with any application demonstrating that their qualifying experience and education meets the minimum requirements as specified in OAR 333-061-0235.

(2) To obtain initial certification or certification at a higher level by examination, individuals must:

(a) Submit complete, original, signed copies of their application for the examination, and affidavit of experience;

(b) Meet the minimum qualifications for the certification sought as prescribed by OAR 333-061-0235;

(c) Pay the applicable examination fee as prescribed by OAR 333-061-0265 for the certification sought and examination applied for; and

(d) Successfully pass the examination for the certification sought.

(3) To obtain certification by reciprocity, individuals must:

(a) Possess current, valid certification in another state or province which has a recognized certification program substantially equivalent to the requirements set forth in these rules;

(b) Submit a complete, original, signed reciprocity application and an affidavit of experience;

(c) Pay the applicable reciprocity application fee as prescribed by OAR 333-061-0265 for each certificate desired; and

(d) Pay the exam fee as prescribed by OAR 333-061-0265, for any examination as prescribed by OAR 333-061-0250, if required by the Authority.

(4) All applications for exams must be accompanied by the appropriate fee(s) and documentation, and must be submitted to the Authority 60 days prior to the desired examination date.

(5) Operating experience earned at a water treatment plant or distribution system is considered qualifying experience for examinations up to one classification level higher than that of the water system where the applicant gained their experience.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 448.450, 448.455, 448.460, 448.465 & 448.994
Hist.: HD 2-1988(Temp), f. & cert. ef. 2-10-88; HD 18-1988, f. & cert. ef. 7-27-88; HD 11-1989(Temp), f. & cert. ef. 12-29-89; HD 19-1990, f. 6-28-90, cert. ef. 7-2-90; HD 1-1996, f. 1-2-96, cert. ef. 1-5-96; HD 14-1997, f. & cert. ef. 10-31-97; OHD 7-2002, f. & cert. ef. 5-2-02; OHD 17-2002, f. & cert. ef. 10-25-02; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 33-2004, f. & cert. ef. 10-21-04; PH 2-2006, f. & cert. ef. 1-31-06; PH 2-2008, f. & cert. ef. 2-15-08; PH 7-2010, f. & cert. ef. 4-19-10; PH 3-2013, f. & cert. ef. 1-25-13; PH 14-2014, f. & cert. ef. 5-8-14

333-061-0250
Examinations for Certification, Levels 1–4

(1) Examinations will be provided at locations and at times designated by the Authority or its designee.

(2) Applicants must obtain a minimum score of 70 percent in order to pass the examination.

(3) Individuals may not take the same examination more than twice in a 12 month period unless they can demonstrate, to the satisfaction of the Authority, that they have completed specific educa-

tion related to the examination since taking the second examination.

(4) The Authority or its designee will score all examinations and notify applicants of the results. Examinations will not be returned to the applicant.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 448.450, 448.455, 448.460, 448.465 & 448.994
Hist.: HD 2-1988(Temp), f. & cert. ef. 2-10-88; HD 18-1988, f. & cert. ef. 7-27-88; HD 19-1990, f. 6-28-90, cert. ef. 7-2-90; HD 14-1997, f. & cert. ef. 10-31-97; OHD 7-2002, f. & cert. ef. 5-2-02; PH 4-2003, f. & cert. ef. 3-28-03; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 33-2004, f. & cert. ef. 10-21-04; PH 2-2006, f. & cert. ef. 1-31-06; PH 2-2008, f. & cert. ef. 2-15-08; PH 3-2013, f. & cert. ef. 1-25-13; PH 14-2014, f. & cert. ef. 5-8-14

333-061-0260
Certificate Renewal Levels 1–4

(1) Certification expires December 31 every two years based upon the first letter in the last name of the individual. Certification for individuals with names beginning in the letters A–K expires in even numbered years, and certification for individuals with names beginning in the letters L–Z expires in odd numbered years. Certification renewal fees may be prorated if an individual's current certification expires one year prior to the beginning of the next two-year certification period.

(2) Operators must earn two continuing education units (CEU) every two years in areas of relevant subject matter as described below.

(a) CEU for specialized operator training will be accepted from the following categories at the discretion of the Authority.

(A) Technical capacity: water treatment facilities construction and performance, source construction and protection, capacity, storage, pumping and distribution facility construction and protection, water distribution integrity/leakage and water quality issues related to public/user health.

(B) Managerial capacity: water system operation, planning, system governance, development and implementation of system policies, professional support, record keeping, drinking water and related regulations to insure protection of public health, communication and involvement with water users.

(C) Financial capacity: adequacy of revenues to meet expenses, revenue sources, affordability of user charges, rate setting process, budgeting, production and utilization of a capital improvement plan, periodic financial audits, bond ratings, debt and borrowing.

(b) Two college credits in the fields of engineering, chemistry, water/wastewater technology, or allied sciences satisfy continuing education requirements.

(c) CEU from other states having standards equal to or greater than these rules may be accepted by the Authority.

(d) Maintaining CEU records is the responsibility of the operator.

(e) CEU credit will be awarded for the same course or training only once every two year period.

(3) An operator who fails to renew their certification as prescribed by section (1) of this rule by the expiration date cannot be in direct responsible charge of a water system.

(4) The Authority may grant certification renewal without a reinstatement fee until January 31 in the year following the expiration date of the certification. A reinstatement fee as prescribed by OAR 333-061-0265 is required in addition to any renewal fees for all renewal applications received after the grace period ending on January 31 immediately following the expiration date of the certification.

(5) Any certified operator who fails to renew their certification for one year following the expiration date of the certification must meet the requirements established for initial applicants for certification as specified in OAR 333-061-0245.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 448.450, 448.455, 448.460, 448.465 & 448.994
Hist.: HD 2-1988(Temp), f. & cert. ef. 2-10-88; HD 18-1988, f. & cert. ef. 7-27-88; HD 19-1990, f. 6-28-90, cert. ef. 7-2-90; HD 14-1997, f. & cert. ef. 10-31-97; OHD 7-2002, f. & cert. ef. 5-2-02; PH 4-2003, f. & cert. ef. 3-28-03; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 33-2004, f. & cert. ef. 10-21-04; PH 2-2006, f. & cert. ef. 1-31-06; PH 2-2008, f. & cert. ef. 2-15-08; PH 14-2014, f. & cert. ef. 5-8-14

333-061-0265
Fees

(1) All fees must be paid to the Oregon Health Authority or its designee.

(2) Application fees are not refundable unless:

(a) The Authority has taken no action on a certification application; or

(b) The Authority determines the wrong application has been filed.

(3) Applicants for certification by exam must submit the exam fee and application fee, along with an original signed and complete application. Examination fees may be refunded if:

(a) The application is denied, or

(b) The applicant notifies the Authority no less than one week in advance of the exam that the applicant is unable to sit for the exam.

(4) Applications will be accepted for processing only when accompanied by the appropriate fees as indicated in the fee schedule below:

(a) Certification Renewal — $140.
(b) Combination Certification-each additional — $70.
(c) Application Fee:
(A) Level 1 Distribution or Treatment — $90.
(B) Level 2 Distribution or Treatment — $125.
(C) Level 3 Distribution or Treatment — $160.
(D) Level 4 Distribution or Treatment — $195.
(E) Filtration Endorsement — $90.
(d) Reciprocity Review (each certification) — $100.
(e) Reinstatement — $50 + Certificate Renewal Fee.
(f) Document Replacement Fee — $25.

(5) Filtration endorsement certification is an extension of an operator's water treatment certification, and no additional annual fee is required to maintain the endorsement.

(6) A document replacement fee must be paid at the time of request for a replacement document.

Stat. Auth.: ORS 448.131, 448.450
Stats. Implemented: ORS 448.131, 448.450, 448.465
Hist.: HD 2-1988(Temp), f. & cert. ef. 2-10-88; HD 18-1988, f. & cert. ef. 7-27-88; HD 11-1989(Temp), f. & cert. ef. 12-29-89; HD 19-1990, f. 6-28-90, cert. ef. 7-2-90; OHD 3-2000, f. 3-8-00, cert. ef. 3-15-00; OHD 7-2002, f. & cert. ef. 5-2-02; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 33-2004, f. & cert. ef. 10-21-04; PH 2-2006, f. & cert. ef. 1-31-06; PH 2-2008, f. & cert. ef. 2-15-08; PH 7-2010, f. & cert. ef. 4-19-10; PH 14-2014, f. & cert. ef. 5-8-14; PH 23-2015, f. 12-8-15, cert. ef. 1-1-16

333-061-0270
Refusal, Suspension, or Revocation of Certification

(1) The Authority may deny an individual's initial or renewal application for operator certification, or suspend or revoke an operator's certification if the applicant or operator:

(a) Obtained the certificate by fraud, deceit, or misrepresentation;

(b) Has been grossly negligent, incompetent or has demonstrated misconduct in the performance of the duties of an operator or supervisor of a distribution system or water treatment plant in Oregon or any other state, province or country;

(c) Has violated or failed to comply with any Authority rule or order;

(d) Fails to comply with any Authority investigation; or

(e) Knowingly makes any false statement or misrepresentation in any application, record, or other document filed with the Authority.

(2) An individual whose application or certification is proposed to be denied, suspended, or revoked has the right to a hearing pursuant to ORS Chapter 183.

(3) No person whose certificate has been revoked under this rule is eligible to apply for certification for one year from the effective date of the final order of revocation. Any such person who applies for certification must meet all the requirements established for initial applicants.

Stat. Auth.: ORS 448.131

Stats. Implemented: ORS 431.110, 431.150, 448.450, 448.455, 448.460, 448.465 & 448.994
Hist.: HD 2-1988(Temp), f. & cert. ef. 2-10-88; HD 18-1988, f. & cert. ef. 7-27-88; HD 11-1989(Temp), f. & cert. ef. 12-29-89; HD 19-1990, f. 6-28-90, cert. ef. 7-2-90; OHD 7-2002, f. & cert. ef. 5-2-02; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 33-2004, f. & cert. ef. 10-21-04; PH 2-2006, f. & cert. ef. 1-31-06; PH 4-2009, f. & cert. ef. 5-18-09; PH 14-2014, f. & cert. ef. 5-8-14

333-061-0272
Suspension of Certification

(1) The Authority may immediately suspend an operator's certification for violation of any portion of OAR 333-061-0005 to 333-061-0270 if the Authority finds that such violation(s) constitute a serious danger to the public health or safety. The Authority shall set forth specific reasons for such findings.

(2) An operator has 90 days from the date of notice to the operator to request a hearing. The hearing shall be held as soon as practicable if a request for hearing is received by the Authority.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 431.110, 431.150, 448.450, 448.455 & 448.994
Hist.: OHD 7-2002, f. & cert. ef. 5-2-02; PH 16-2004(Temp), f. & cert. ef. 4-9-04 thru 10-5-04; PH 20-2004, f. & cert. ef. 6-18-04; PH 6-2010(Temp), f. & cert. ef. 3-16-10 thru 9-10-10; PH 18-2010, f. & cert. ef. 8-12-10; PH 14-2014, f. & cert. ef. 5-8-14

Domestic Well Program

333-061-0305
Purpose

The purpose of these rules is to provide a basis for implementing ORS 448.271. This law became effective on July 24, 1989, and establishes a program to provide water quality monitoring of underground aquifers that are used for domestic purposes.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 448.271
Hist.: HD 24-1990, f. & cert. ef. 11-16-90; PH 7-2010, f. & cert. ef. 4-19-10

333-061-0310
Scope

These rules apply to sellers in any transaction for the sale or exchange of real estate that includes a dug, drilled or driven well that supplies ground water for domestic purposes. Properties with springs that are used for domestic purposes are exempt from these rules. The seller is required to have certain tests done on the well water and send the results to the Authority. Failure of seller to test will not interfere with the sale of the property. The Authority may require tests for other contaminants under certain conditions.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 448.271
Hist.: HD 24-1990, f. & cert. ef. 11-16-90; PH 7-2010, f. & cert. ef. 4-19-10

333-061-0324
Area of Public Health Concern

If the Authority confirms, as a result of monitoring required by OAR 333-061-0036, monitoring or assessment activities conducted by the Department of Environmental Quality, or any other scientifically valid data approved by the Authority, the presence of contaminants likely to cause adverse human health effects in groundwater supplies, then the Authority may declare an area of public health concern. The declaration shall specify the following:

(1) The specific aquifer(s) or geographic boundaries subject to the contamination;

(2) The detected contaminant(s);

(3) The human health risks attributed to the contaminant;

(4) The expected duration of the contamination; and

(5) The suspected or confirmed source of the contamination.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 448.271
Hist.: PH 7-2010, f. & cert. ef. 4-19-10

333-061-0325
Domestic Well Tests

(1) In any transaction for the sale or exchange of real estate that includes a well that supplies ground water for domestic purposes, the seller of the real estate shall, upon accepting an offer to purchase that real estate, have the well water tested for arsenic, nitrate, and total coliform bacteria. If the well is in a designated area of public health concern, the Authority may require additional testing.

(2) The seller, or seller's designee, must submit the results of the required tests to the Authority and to the buyer within 90 days of receiving the results of the tests.

(3) If the seller, or seller's designee, fails to comply with sections (1) and (2) of this rule, this does not invalidate any of the documents needed to complete the sale of the real estate.

(4) The seller, or seller's designee, is responsible for making sure that the Authority's Water Systems Data Sheet is completed and submitted to the Authority with copies of the arsenic, nitrate, and total coliform bacteria lab slips.

(5) The Water Resources Department well identification number and a description of the property shall be entered on the water system data sheet for the seller to be considered in compliance with ORS 448.271. The description shall include township, range, section, street address, city, state and zip code.

(6) The lab tests required by ORS 448.271 cannot be waived even if the buyer agrees not to have the well tested.

(7) The lab tests for arsenic, nitrate, and coliform bacteria are considered valid for one year if they are associated with the sale of the property.

(8) If the well is not on the property being sold, but the real property includes an interest to a well on adjacent property, including an easement, that interest would be considered part of the real property. Therefore the tests would be required.

(9) ORS 448.271 only applies to wells that have been made operational to supply groundwater for domestic purposes. Capped domestic wells on unimproved lots are not required to be tested.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 431.110, 431.150, 448.131 & 448.271
Hist.: HD 24-1990, f. & cert. ef. 11-16-90; HD 14-1997, f. & cert. ef. 10-31-97; PH 7-2010, f. & cert. ef. 4-19-10

333-061-0330
Accredited Laboratories

Only laboratories accredited according to Oregon Environmental Laboratory Accreditation Program (ORELAP) standards, as prescribed by OAR 333-064-0005 through 0065, shall be used to conduct the water tests required by these rules.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 431.110, 431.150, 448.131 & 448.271
Hist.: HD 24-1990, f. & cert. ef. 11-16-90; HD 14-1997, f. & cert. ef. 10-31-97; PH 7-2010, f. & cert. ef. 4-19-10

333-061-0335
Sample Collection

(1) Only persons who have knowledge of the appropriate procedures for the collection and handling of the water samples for arsenic, nitrate, and total coliform bacteria and who have experience in this area shall collect the samples. These persons include Registered Sanitarians, certified water system operators, well drillers, pump installers, and lab technicians. Specific instructions for the collection, preservation, handling and transport of the samples may be obtained from certified laboratories, county health departments or the Authority and must be strictly adhered to.

(2) The samples must be drawn from the source prior to any form of water treatment. Samples may be collected after treatment injection points where water treatment has been bypassed or temporarily disabled.

(3) In the event that the well has been shock chlorinated, no follow up samples shall be taken until five days have elapsed.

Stat. Auth.: ORS 448.131
Stats. Implemented: ORS 431.110, 431.150, 448.131 & 448.271
Hist.: HD 24-1990, f. & cert. ef. 11-16-90; HD 14-1997, f. & cert. ef. 10-31-97; PH 7-2010, f. & cert. ef. 4-19-10; PH 3-2013, f. & cert. ef. 1-25-13

DIVISION 62

PUBLIC SPA POOL RULES

333-062-0005
Purpose

These rules adopted pursuant to the provisions of ORS 448.011, prescribe the requirements for the construction and operation of public spa pools and bathhouses. They are for the purpose of protecting the health and welfare of persons using these facilities.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0300

333-062-0010
Adoption by Reference

Outside standards, listings and publications referred to in these rules are by reference made a part of these rules.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 183.355
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0305

333-062-0015
Definitions

As used in these rules unless otherwise required by context:

(1) "Administrator" means the Assistant Director of the Oregon Health Authority, Public Health Division.

(2) "Approved" means approved in writing by the Division.

(3) "Bathhouse" means a structure which contains dressing rooms, showers and toilet facilities for use with an adjacent public spa pool or public swimming pool.

(4) "Builder" means a person who, in the pursuit of an independent business, undertakes, or offers to undertake, or submits a bid, to construct, alter, repair, or improve any public swimming pool, spa pool or bathhouse and the appurtenances.

(5) "Cross Connection" means an unprotected connection between the piping carrying potable water and the piping or fixtures which carry other water or other substances.

(6) "Division" means the Oregon Health Authority, Public Health Division.

(7) "General-Use Public Spa Pool" means any public spa pool other than limited-use public spa pool. Public spa pools operated in conjunction with a companion facility but not limited to use of the residents, patrons, or members of the companion facility are general-use spa pools.

(8) "Horseplay" means any unsafe activity which in the opinion of the Division or the spa operator endangers the spa users and bystanders.

(9) "Lifeguard" means a person with current American Red Cross lifeguard, National Pool and Waterpark Lifeguard, YMCA lifeguard (or equivalent as determined by the Public Health Division) certification or license.

(10) "Limited-use Public Spa Pool" means any public spa pool located at and operated in connection with a companion facility such as a residential housing facility having five or more living units, traveler's accommodations, mobile home park, recreation park, boarding school, organizational camp, dude ranch, club or association where use of the pool is limited to residents, patrons or members of the companion facility.

(11) "Oxidized" means a process of chemically removing organic debris, using a product used to reduce combined chlorine and for the purposes of these rules is an alternative to superchlorination.

(12) "Person" includes, in addition to the definition in ORS 174.100, municipalities, recreation districts, counties and state agencies or instrumentalities.

(13) "Private Swimming Pool" means any swimming pool, wading pool or spa pool owned by no more than four individuals, either jointly, individually or through association, incorporation or otherwise and operated and maintained in conjunction with a companion residential housing facility and having no more than four living units, for the use of the occupants thereof and their personal friends only. Private pools shall not be subject to the provisions of these rules.

(14) "Public Spa Pool" means any public swimming pool or wading pool designed primarily to direct water or air-enriched water under pressure onto the bather's body with the intent of producing a relaxing or therapeutic effect.

(15) "Public Swimming Pool" means an artificial structure and its appurtenances, which contains water more than two feet deep which is expressly designated or which is used with the knowledge and consent of the owner or operator for swimming or recreational bathing and which is for the use of any segment of the public. "Public swimming pool" includes, but is not limited to, swimming pools owned or operated by:

(a) Traveler's accommodations;
(b) Recreation parks;
(c) Colleges;
(d) Schools;
(e) Organizational camps as defined in ORS 446.310;
(f) Clubs;
(g) Associations;
(h) Business establishments for their patrons or employees;
(i) Private persons and that are open to the public;
(j) Recreation districts;
(k) Municipalities;
(l) Counties; or
(m) A state agency.

(16) "Public Wading Pool" means an artificial structure, and its appurtenances, which contains water less than two feet deep which is expressly designated or which is used with the knowledge and consent of the owner or operator for wading or recreational bathing and which is for the use of any segment of the public, whether limited to patrons of a companion facility or not.

(17) "Supplemental Disinfectant" means a disinfectant which is intended to augment water quality in a public swimming pool or spa and will provide disinfection in conjunction with the approved primary disinfectant.

(18) "These rules" mean OAR 333-062-0005 through 333-062-0185.

(19) "Variance" means written permission from the division for a public swimming pool, public spa pool or public wading pool to be operated when it does not comply with all the applicable rules for public swimming pools, public spa pools or public wading pools.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0310; HD 24-1983(Temp), f. & ef. 12-16-83; HD 18-1991, f. & cert. ef. 10-15-91; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94

333-062-0020
Compliance

(1) Public spa pools built prior to June 23, 1981, are exempt from the following requirements of these rules, provided such pools are constructed and maintained in accordance with the plans approved by the Division for the construction of the spa pool, and provided the exemption does not present a health or safety hazard:

(a) OAR 333-062-0065(3);
(b) OAR 333-062-0085(1), (2), and (10);
(c) OAR 333-062-0090(2)(a);
(d) OAR 333-062-0095(3) and (4);
(e) OAR 333-062-0100(2);
(f) OAR 333-062-0115(2)(a), (b), (c);
(g) OAR 333-062-0140(1).

(2) The above exemptions do not apply to any alteration or replacement of the affected components.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0315; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94

333-062-0025
Permit to Construct

(1) No person shall construct a public spa pool or bathhouse adjacent thereto, or alter any such structures without:

(a) Submitting complete plans and specifications to the Division;

(b) Paying the stipulated plan review fee to the Division;

(c) Receiving a written plan approval or conditional approval from the Division;

(d) Paying the stipulated construction permit fee (unless fee exempt) to the Division;

(e) Receiving a permit to construct from the Division.

(2) Plans, specifications, and fees required herein shall be submitted at the time of filing application for a construction permit.

(3) No person shall deviate from the approved or conditionally approved plans and specifications during the construction or alteration of a facility described in section (1) of this rule without the written approval of the Division.

(4) Construction permits will be issued only to the owner or authorized agent of the owner.

(5)(a) The Division may issue a conditional construction permit where the plans and specifications for the proposed public spa pool demonstrate a new technology or alternative mode of operation not contemplated in these rules. Such a permit may be issued only when the proponent of the facility has provided information to the Division from which the Division determines that the spa pool may be reasonably expected to:

(A) Operate continuously in a clean and sanitary manner;

(B) Not constitute a menace to public health or safety; and

(C) Provide health and safety protection equal to or greater than that required by these rules.

(b) The conditional permit may impose conditions which will be set forth in a license for operation. These conditions may include but not be limited to submission of monitoring reports, sampling requirements, use restrictions, and such other conditions as the Division may deem necessary to protect the public health and safety or to further establish the Division's expectancy of such protection. Furthermore, any license issued subject to a conditional construction permit shall carry the condition that by its acceptance the holder understands that a conditional license may not be renewed, may be revoked or suspended, or a permanent license not issued in the future, if the Division determines that the provisions of subsections (5)(a), (b) and (c) of this rule are not met. Such conditional construction permit authority is not conferred upon any county notwithstanding any delegated or contractual authority in administration and enforcement of the public spa pool statutes and rules.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.020
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0320; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94

333-062-0030
Plans

(1) Plans and specifications shall be prepared by a professional engineer or architect registered in the State of Oregon. Specific exemptions to this requirement may be granted by the Division, where in the judgment of the Division no architectural or engineering problems are presented and the plans accurately depict the proposed spa pool and address all requirements of these rules.

(2) Plans shall be submitted in duplicate, drawn to scale and in sufficient detail to completely and clearly illustrate what is to be constructed and shall include:

(a) One plan view;

(b) One cross section through the main drain;

(c) One overall plan showing the pool in relation to other facilities in the area. (This plan may be combined with subsection (2)(a) of this rule);

(d) One detailed view of the equipment room layout;

(e) One vicinity map;

(f) One piping schematic showing piping, pipe size, inlets, main drains, skimmers, gutter outlets, vacuum fittings, and all other appurtenances connected to the pool piping system. (This plan may be combined with subsection (2)(a) of this rule);

(g) One cross section of the step treads and risers.

(3) Plans must show all required components of the spa pool and its appurtenances and plan notes such as "fence by owner" or "deck to be under separate contract" shall not be acceptable as a substitute for scale drawings.

(4) Plans shall include the following information in tabulated form:

(a) Legal address of the facility;

(b) Location of the facility if different from legal address;

(c) Owner's or authorized agent's name, address and telephone number;

(d) Surface area of pool;

(e) Pool volume, turn over time, flow rate, filter rate/unit area, type of filter and total system head loss;

(f) Manufacturer, make and model numbers of the pump, filter, and automatic chemical feed apparatus, filter head loss (clean and dirty), and pump curve showing design flow rate and head;

(g) Source of water used at the pool;

(h) Means of disposing of backwash water and/or drained water from the spa;

(i) Specifications of materials relating to the spa pool, piping, inlets and outlets, skimmers.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.030
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0325; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94

333-062-0035
Licenses

No person shall operate a public spa pool, without:

(1) The pool having received a final construction inspection and approval from the Division;

(2) Making application for a license to operate such a pool;

(3) Paying the license fee; and

(4) Securing a license from the Division;

(5) Such license terminates and is renewable on December 31 of each year.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.035
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0330; HD 24-1983(Temp), f. & ef. 12-16-83; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94

333-062-0040
Conditional Licenses

(1) Conditional licenses may be issued by the Division in circumstances in which:

(a) There is substantial compliance with these rules;

(b) In which a written schedule for total compliance approved by the Division is instituted and maintained; and

(c) Where in the judgment of the Division, there will be no immediate threat to health and safety during the time in which to meet complete compliance. The Division may also require special safeguards to be instituted and maintained as a condition of the conditional license.

(2) Conditional licenses may also be issued by the Division as provided in OAR 333-062-0025(5).

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0335; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94

333-062-0045
Maintenance and Modification

(1) All equipment of public spa pools shall be operational and shall be kept in good repair. Such equipment shall be maintained in conformance with the original design or better.

(2) The structural components of all public spa pools and their appurtenances shall be maintained in good repair.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011

Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0340

333-062-0050
Size

Public spa pools shall be sized according to and shall not exceed the design limit of the bather load function shown below. Bather loads are specific in-tank loads only.

Maximum Load = A divided by 10

Where A equals the surface area of the public spa pool in square feet.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0345

333-062-0055
Dimensions

(1) Public spa pools shall not have sharp edges or protrusions where walls meet at an acute angle. Public spa pools shall be shaped so as to provide for complete water circulation and mixing.

(2) Public spa pools shall be no deeper than 4' (1.22 m) measured from the water line.

(3) The maximum depth of any seat or sitting bench shall be 2'0" (61 cm) measured from the water line.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0350

333-062-0060
Finishes and Markings

(1) Wall and floor finishes shall be of non-toxic materials, shall be impervious and enduring. Such finishes shall be smooth and easily cleanable.

(2) Public spa pools shall have permanent depth markings plainly and conspicuously posted and located as follows:

(a) The maximum water depth shall be clearly marked;

(b) Depth markings shall be at least 4" (10 cm) in height and of a contrasting color with the background;

(c) Depth markings shall be placed within 18" (46 cm) of the water's edge and shall be positioned to be read while standing on the deck facing the water;

(d) Depth markings shall be spaced at no more than 25' (7.62 m) intervals and shall be uniformly located around the perimeter of the spa.

(3) Spas with wooden interior surfaces are not allowed.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0355

333-062-0065
Illumination

(1) Where underwater lighting is used, the electrical circuit to the underwater light shall be equipped with a ground fault interrupter.

(2) Where underwater lighting is not employed, and night or indoor bathing is permitted, the combined area and pool lighting shall be not less than two watts per square foot (0.93 m2) of deck area.

(3) Where underwater lighting is used, and night or indoor bathing is permitted, area lighting shall be provided for the deck areas and directed away from the spa pool surface. No less than 0.6 watts incandescent or the equivalent per square foot of deck area shall be used.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0360; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94

333-062-0070
Ventilation

(1) A public spa pool license holder must ensure that there is sufficient ventilation to prevent build-up of harmful amounts of moisture or chemical byproducts in the air of buildings enclosing spa pools.

(2) New and public spa pool ventilation systems renovated after September 1, 2014 must comply with the requirements of the Oregon Structural Specialty Code, 2014 Edition, and the Oregon Mechanical Specialty Code, 2014 Edition.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0365; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94; PH 23-2014, f. 8-15-14, cert. ef. 9-1-14

333-062-0075
Ladders, Recessed Steps and Stairways

(1) Spa ladders, recessed steps or stairways shall be provided where spa depth exceed 24."

(2) There shall be at least one ladder, set of recessed steps or stairway for each 50 feet of spa pool perimeter or fraction thereof.

(3) Ladder treads, recessed step surfaces and stairs shall have slip-resistant surfaces.

(4)(a) Ladders and recessed steps shall be provided with two handrails;

(b) Stairs shall be provided with at least one handrail.

(5) Recessed steps shall drain into the pool.

(6) Stairway treads shall have a minimum unobstructed horizontal tread depth of 10" (25 cm) and a minimum unobstructed surface area of 240 square inches (154 cm2).

(7) Risers at the centerline of the stairway treads shall have a maximum uniform height of 12" (30 cm). The vertical riser height from deck surface down to the top of the first tread shall not exceed 12" (30 cm). When the bottom tread serves as a bench or seat, the bottom riser shall be a maximum of 14" (35 cm).

(8) Ladders and handrails shall be securely mounted.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0370; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94

333-062-0080
Spa Pool Enclosure

A public spa pool license holder must ensure that:

(1) A public spa pool is protected by an enclosure such as a fence, wall, or building without private entrances to the pool area; and

(2) Spa pool enclosures including windows, gates and doors are constructed in such a manner so as to discourage or prevent access to the pool by unsupervised children and domestic animals and incorporate the following construction standards:

(a) Enclosures shall not be less than four feet (1.2 m) in height measured from the outside ground at a point one foot (300 mm) horizontal from the base of the enclosure;

(b) There shall be not more than four inches (100 mm) of space between the bottom of the enclosure and the ground's surface or pool deck;

(c) Separation between vertical sections and bars shall be a maximum of four inches (100mm);

(d) Horizontal rails shall be spaced with a minimum 42 inches (1065mm) separation;

(e) All exterior projections or recessions shall be 42 inches (1065mm) from either the top or bottom of the fence;

(f) Gates and doors in spa enclosures shall be self-closing and shall be equipped with a lockable and self-latching device. The operating controls for the self-latching device shall be located at least 42 inches (1065 mm) above the exterior ground or pool deck. Gates and doors on new pools must swing "out" of the pool enclosure, or away from the pool. If an existing pool's gates or door does not swing away from the pool, it must be changed when the change is not highly burdensome or impractical due to special conditions or cause

(g) Entrances with self-closing and self-locking devices requiring the use of a key, keycard or combination code to gain access may have controls located at a minimum of 36 inches to 54

inches (0.9 m to 1.35 m) above the exterior ground surface. The gates or doors cannot require a key, keycard or combination code to exit the pool area;

(h) Construction methods and materials shall be used that provide a durable and low maintenance structure;

(i) Buildings enclosing public spa pools constructed on or after September 1, 2014 and buildings enclosing spa pools that are remodeled or renovated on or after September 1, 2014 shall be constructed in accordance with the requirements of the Oregon Structural Specialty Code 2014 Edition.

(3) When a pool is closed to patrons, all entry/exit points are to be properly maintained and secured against unauthorized entry.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 448.011

Stats. Implemented: ORS 448.011

Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0375; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94; PH 23-2014, f. 8-15-14, cert. ef. 9-1-14

333-062-0085
Decks

(1) A 6' x 8' continuous unobstructed deck shall be provided on at least one side of all public spa pools with less than 100 square feet of water surface. Public spa pools with 100 square feet of water surface area or more shall provide additional deck area at least four feet wide around at least 50 percent of the spa.

(2) Walkways and decks shall be constructed of concrete, non-slip tile or equally impervious material with a smooth, but non-slip, easily cleanable surface.

(3) Decks shall slope no less than 1/4" (6 mm) per foot (30 cm).

(4) Deck surfaces shall be slip-resistant.

(5) Joints between concrete deck slabs shall be water tight and shall be designed so as to protect the pool, coping and its mortar bed from movement of the deck.

(6) Decks shall be provided with expansion joints. New and replacement expansion joints shall not be constructed of wood.

(7) Voids between adjoining concrete deck slabs shall be no greater than 3/16" (5 mm).

(8) Adjoining deck surface elevations shall vary no more than 1/4" (6 mm).

(9) Decks shall be drained to perimeter drains.

(10) Wood decking around public spa pools is prohibited.

Stat. Auth.: ORS 448.011

Stats. Implemented: ORS 448.011

Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0380; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94

333-062-0090
Overflow Systems

(1) All public spa pools shall be operated with a continuous overflow.

(2)(a) Where surface skimmers are used, the flow rate through the skimmer shall be designed to provide 50 percent of the total turnover rate with a maximum flow through any single skimmer of 30 gpm;

(b) The minimum acceptable width for the intake throat of a skimmer, measured at the wider location, shall be 5";

(c) Where surface skimmers are used as the sole overflow system, one surface skimmer shall be provided for each 100 square feet (9.3 m^2) or fraction thereof of the spa's surface area. If a conflict arises between subsection (a) of this section and this subsection, the subsection requiring the greatest number of skimmers shall apply;

(d) When two or more skimmers are used in a spa, they shall be located so as to maintain effective skimming action over the entire surface area of the spa.

Stat. Auth.: ORS 448.011

Stats. Implemented: ORS 448.011

Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0385

333-062-0095
Recirculation Systems

(1) Public spa pools shall have recirculation systems and filtration systems with piping, pumps, filters, disinfection and other equipment which maintain spa pool water quality in accordance with OAR 333-062-0165(1).

(2) The system of pumps, filters, disinfection facilities and other equipment shall be of adequate size to recirculate, filter and disinfect the entire volume of spa water within 30 minutes.

(3) The recirculation system shall be a two pump system. One pump will provide the required turnover rate, filtration and disinfection for the spa water. The second pump shall provide the water for the hydrotherapy turbulence of the water.

(4) Public spa pool recirculation systems shall be separate from companion swimming pools.

(5) Recirculation and filtration systems shall be in operation continuously while the facility is in use.

Stat. Auth.: ORS 448.011

Stats. Implemented: ORS 448.011

Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0390; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94

333-062-0100
Inlets

(1) Pool inlets must be provided, sized, and arranged to produce a uniform circulation of water so as to maintain a uniform disinfectant residual throughout the pool.

(2) There must be at least one inlet per 400 square feet of pool area or 10,000 gallons of water, whichever is greater, with a minimum of two inlets.

(3) Grates must be designed so as to prevent entrapment of fingers.

(4) All recirculation inlet fittings must be adjustable for rate of flow. Wall inlet fittings must be directional.

(5) Inlet fittings must have tamper-proof screws that cannot be removed except with tools. Grates, vortex plates and inlet fittings must be in place whenever the spa is in use.

(6) Direct potable water pool inlets must:

(a) Be over-the-rim spouts with an air-gap located beside grab rails;

(b) Be through-the-wall fill lines located above the water level and equipped with an appropriate backflow prevention device installed per OAR 333-061-0071; or

(c) Be directly connected to the recirculation water supply and equipped with reduced pressure device installed per OAR 333-061-0071 on the potable water supply adjacent to the connection with the spa pool recirculation water.

Stat. Auth.: ORS 448.011

Stats. Implemented: ORS 448.005 - 448.100 & 448.990

Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0395; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94; PH 6-2009(Temp), f. 6-16-09, cert. ef. 6-17-09 thru 12-13-09; Administrative correction 12-23-09; PH 16-2009, f. & cert. ef. 12-23-09

333-062-0103
Submerged Suction Fittings and Drains

(1) The requirement in section (3) of this rule applies to:

(a) A spa pool constructed after December 25, 2009;

(b) A spa pool constructed before December 25, 2009, that on or after July 1, 2015, has its submerged suction fittings renovated or remodeled.

(2)(a) Every spa pool must have an easy and effective means of draining the pool.

(b) Main drain and submerged suction outlets must be designed with sufficient open area that the maximum velocity through the cover does not exceed the cover's listed flowrate. Drains and suction fittings must be installed to minimize tripping, toe stubbing and scrape hazards.

(c) All hardware and fittings must be supplied by the manufacturer and installed according to the manufacturer's directions.

(d) Broken or missing grate fittings. If the pool operator finds that a suction fitting is broken or missing, the operator must close

the pool immediately, shut down the recirculation system and remain closed until the fitting has been replaced.

(3) New construction. Main drain and submerged suction fitting systems must provide entrapment, hair entanglement and evisceration protection.

(a) Main drains and submerged suction fittings and sumps must be compliant with the requirements of ANSI/APSP-16 Suction Fittings for Use in Swimming Pools, Wading Pools, Spas, and Hot Tubs (2011). The cover must be labeled and include; "VGB 2008," the logo of the third party listing agency, the standard for which it was tested, the gallons per minute flow for which it was approved and the location it is to be placed.

(b) The spa licensee must maintain any documentation concerning the main drain or submerged suction fitting.

(c) All submerged suction fittings must be installed with a sump designed and approved by the manufacturer for that outlet cover.

(d) All field built sumps must be designed by an Oregon registered engineer and must be built so the opening of the suction pipe is no closer than 1.5 times the pipe's inside diameter from the bottom of the listed suction cover/plate.

(e) Main drains and submerged suction fittings must be separated by at least three feet (915mm)(measured from the main drain connector pipe centerlines) between the furthest fittings, or be on separate planes, placed so the floor and wall suction fittings cannot be easily blocked at the same time.

(A) The outlets must be sized to handle an equal portion of at least 200 percent of the recirculation flow.

(B) The outlets must be installed so that they cannot be isolated from one another; no intervening valves.

(C) The piping going back to the pump must be located in the hydraulic middle of the connector piping, and must be the same size as the connector piping.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.005 - 448.100 & 448.990
Hist.: PH 16-2009, f. & cert. ef. 12-23-09; PH 23-2014, f. 8-15-14, cert. ef. 9-1-14

333-062-0105
Piping

(1) Spa pool recirculation piping shall be sized to carry the following maximum design flows:

(a) Discharge piping (except copper) — 10 ft./sec. (3.05 m/sec.);

(b) Discharge piping (copper) — 8 ft./sec. (2.44 m/sec.);

(c) Suction velocity — 6 ft./sec. (1.83 m/sec.).

(2) Pool recirculation piping, if plastic, shall comply with **National Sanitation Foundation Standard Number 14 for Plastic Piping System Components and Related Materials**.

(3) Spa pool backwash and/or drain lines shall be permanently piped with an air break. For all spa pools built after May 1, 1986, the pool backwash and/or drain line shall be permanently piped with an air break to discharge into an approved sewerage system.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0400; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94

333-062-0110
Pumps

(1) A pump and motor shall be provided for recirculation of pool water:

(a) All pumps shall be provided with a strainer on the suction side of the pump. The strainer shall be at least equal in size to the pump suction line;

(b) Strainers installed below water level shall be provided with a valve on each side to facilitate cleaning.

(2) Performance of pumps shall meet the conditions of flow required for filtering and backwashing the filters against the total dynamic head developed by the complete system. Pumps shall be capable of providing design flow rates at no less than 60 feet (1.83 kg/cm2) of total dynamic head.

(3) Pumps shall be capable of pumping at a rate sufficient to turn over the total pool volume within 30 minutes.

(4) Pumps on public spa pools built or remodeled after the effective date of these rules shall comply with National Sanitation Foundation Standard Number 50 on centrifugal pumps.

(5) Pumps shall be sized so as to pump the flow required in section (3) of this rule under filter soil conditions such as to create pressures or vacuums at which manufacturers recommend filter cleaning.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0405; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94

333-062-0115
Filters

(1) Filters shall be capable of maintaining pool water clarity as described in OAR 333-062-0165(1)(i) under conditions of maximum user load.

(2) Public spa pool filter rates shall not exceed the following:

(a) High rate sand filter — 18 gpm per square foot (.093 m^2) of filter media or that rate approved by the manufacturer for that particular filter, whichever is less;

(b) Diatomaceous earth filters — 1.5 gpm (5.7 1pm) per square foot (.09 m^2) of filter media;

(c) Cartridge filters — 0.375 gpm per square foot of effective filter area. Effective filter area shall be that as determined by a testing laboratory recognized by the Division to make such tests.

(3) A means shall be provided to permit release of air which enters the filter tank.

(4) Filter components which require servicing shall be accessible and available for inspection and repair.

(5) Filters shall meet the safety performance standards of the **National Sanitation Foundation Number 50 for Circulation System Components for Swimming Pools**.

(6) Separation tanks or settling sumps are required with DE filters. Separation tanks shall:

(a) Be provided with a manual means of air release or a lid which provides a slow and safe release of pressures;

(b) Have a precautionary statement affixed warning the user that the air release must be opened before starting the circulation pump.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0410; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94

333-062-0120
Heaters

(1) Fired water heaters installed after September 1, 1994, used exclusively for heating water for spa pools are considered pool boilers and are exempt from the requirements of ORS 480.510 to 480.665 (Boiler and Pressure Vessel Law) if:

(a) Units are equipped with a flow switch or pressure switch set at a minimum of 1-1/2 psig;

(b) No intervening stop valves are installed on the discharge side of the unit;

(c) Discharge piping is not reduced from the engineering sizing of the fired heater;

(d) All units are equipped with an ASME-approved pressure and temperature relieving device set at 50 psig;

(e) The unit has a maximum of 10 gallons capacity contained within the unit; and

(f) The burner is wired in series with the recirculation pump.

(2) Where fuel-burning swimming pool heaters are provided for public spa pools, they shall:

(a) Be situated so that the pilot light, if present, is readily accessible;

(b) Be provided with an adequate supply of combustion air;

(c) Be equipped with metal or chlorinated polyvinyl chloride pipe (CPVC) for a minimum of 18 inches upstream and downstream of the heating equipment. However, where manufacturer's recom-

mended installation allows shorter lengths of CPVC, installation according to the manufacturer's recommendation is allowed in lieu of 18 inches of CPVC if documentation of manufacturer's recommendations is provided.

(3) Where electrical heaters are provided, they shall be installed in accordance with the **Oregon Electrical Specialty Code, 2014 Edition.**

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0415; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94; PH 23-2014, f. 8-15-14, cert. ef. 9-1-14

333-062-0125
Disinfectant and Chemical Feeders

(1) A means of disinfecting the public spa pool water shall be provided which provides a disinfecting residual in the pool waters at all times as described in OAR 333-062-0165(1)(a).

(2) Automatic disinfection equipment for introducing a disinfectant shall be provided.

(3) Disinfection equipment shall be equipped with suitable controls capable of fine feed rate adjustment.

(4) Hypochlorinators, erosion (flow-through) feeders, or other adjustable output rate chemical feeding equipment shall conform to **National Sanitation Foundation Number 50 for Circulation System Components for Swimming Pools**.

(5) Where chlorine gas is used as the disinfectant:

(a) Such chlorine gas, its feeders, and other containers shall be housed in a room or compart-ment separate from other pool equipment. Such room or compartment shall:

(A) Be at or above ground level;

(B) Have adequate ventilation to the outside air;

(C) Have a door which opens to the outside of the building of which the room or compartment is a part. Doors installed after the effective date of these rules shall have a shatter-proof gas tight inspection window for viewing the enclosed area. Such a door must open away from public access area;

(D) Be located so that chlorine gas, if accidentally released will not flow into the pool room or into the building ventilation systems;

(E) Have lighting and ventilation switches located outside the enclosure, adjacent to the door;

(F) Shall have a fail-safe mechanism which ceases chlorination in case of malfunction;

(G) Gas chlorinators shall be equipped with an anti-siphon chlorine injection device.

(b) A platform scale for measuring the weight of the chlorine cylinders shall be provided;

(c) A full face negative pressure respirator with a chlorine cartridge approved by the National Institute of Occupational Safety and Health (NIOSH) for protection against chlorine gas or a U.S. approved self-contained breathing apparatus approved by the U.S. Bureau of Mines shall be supplied, kept in good working condition and mounted outside the chlorine enclosure.

NOTE: Storage of such equipment in rooms adjoining the chlorine room is permissible provided such equipment is readily available.

(6) Where disinfectants other than chlorine or bromine are used, such disinfectants shall:

(a) Achieve water disinfection equal to that which free chlorine or bromine provides at the concentration specified in OAR 333-062-0165(1)(a);

(b) Be approved by the Division;

(c) Pose no adverse physiological hazards to the users and have a proven record of effectiveness.

(7) Ozone disinfection may be used only under conditional approval by the Division as a supplemental system. Interim guidelines governing the installation and operation of ozone equipment may be requested from the Division.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0420; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94

333-062-0130
Air Induction Systems

(1) Air induction systems, when provided, shall totally prevent water back-up that would cause electrical shock hazards.

(2) Air intake sources shall be positioned and/or designed to minimize contaminants (such as deck water, dirt, etc.) from being introduced into the spa pool.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0425

333-062-0135
Valves, Meters, and Gauges

(1) Flow meters shall be installed in all recirculation systems. Such meters shall:

(a) Measure flow in gallons per minute;

(b) Be mounted as recommended by the manufacturer; and

(c) Be located so as to be easily read.

(2) Pressure gauges shall be installed on the inlet and outlet of the filter.

(3) When the pump is below the overflow rim of the spa, valves shall be installed on permanently connected suction and discharge lines and located in an accessible place outside the walls of the spa. All valves shall be located where they will be readily and easily accessible for maintenance and removal.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0430

333-062-0140
Equipment Room

(1) Spa pool equipment rooms shall be large enough to permit ready access to all equipment for both operation and maintenance with a minimum floor area of 50 square feet with a floor drain.

(2) Spa pool equipment rooms shall be adequately ventilated.

(3) Spa pool equipment rooms shall protect the equipment from the elements and be locked permitting access only to authorized personnel.

(4) Equipment rooms shall be lighted to properly operate and maintain equipment.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0435; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94

333-062-0145
Ground Fault Interrupter

A certified ground fault interrupter shall be provided in all branch circuits involved in lighting or receptacle outlets according to Article 680 of the Oregon Electrical Specialty Code, 2014 Edition.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0440; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94; PH 23-2014, f. 8-15-14, cert. ef. 9-1-14

333-062-0150
Bathhouses and Sanitary Facilities

(1) Where a spa pool is operated in conjunction with a companion facility, a bathhouse common to both facilities shall be acceptable, provided the minimum facility ratios and locations described in sections (2) through (5) of this rule are followed.

(2) Bathhouses must be maintained in good repair and kept clean. Bathhouses for all spa pools built after September 1, 2014 must:

(a)(A) Meet the requirements of:

(i) The Oregon Structural Specialty Code, 2014 Edition;

(ii) The Oregon Mechanical Specialty Code, 2014 Edition;

(iii) The Oregon Electrical Specialty Code, 2014 Edition;

(iv) The Oregon Plumbing Specialty Code, 2014 Edition.

(B) Including all permit and inspection requirements of the aforementioned codes.

(b) Provide toilets and lavatories within 1,000 feet (305 m) of the spa;

(c) Contain dressing room(s) and sanitary facilities, separate for each sex;

(d) Have floors which are slip resistant, easily cleanable, and coved to a height of four inches (100 mm);

(e) Have shower compartments with walls which are impervious to water to a height of six feet (1.8 m) above the floor. An effective water-tight joint between the wall and the floor shall be maintained. (Wooden racks or duck boards over shower floors are prohibited);

(f) Have interior wall and ceiling finishes which are smooth, easily cleanable, and impervious to water;

(g) Where rubber or impervious mats are used, have such mats clean and dry between usages;

(h) Have shower stall floors that are finished with non-slip impervious surfaces;

(i) Where glass bath or glass shower doors are used, have such doors made of safety glass.

(3) Sanitary facilities, based upon the following maximum user load and equal distribution of sexes, shall be provided:

(a) Toilets:

(A) Women, one per 40 spa users or fraction thereof, with a minimum of two;

(B) Men, one per 60 spa users or a fraction thereof with a minimum of two. Urinals shall be an acceptable substitute for no more than one-half of the toilets.

(b) Lavatories adjacent to toilets, one per 60 spa users or fraction thereof.

(c) Showers — One shower head per 40 pool users of fraction thereof, with a minimum of two.

(4) Hot and cold or tempered water only shall be provided at all shower heads.

(5) Soap shall be provided at all shower heads and lavatories.

(6) Hose bibs shall be provided for washing down the bathhouse interior.

(7) Floors shall slope a minimum of one-quarter inch per foot (2.1 percent slope) and shall drain to floor drains.

(8) The bathhouse shall be located within 1,000 feet (305 m) of the spa pool.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0445; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94; PH 23-2014, f. 8-15-14, cert. ef. 9-1-14

333-062-0155
Food Service

No food or drink shall be permitted within a four foot area surrounding the spa pool. Glass containers are not permitted within the pool enclosure. Food and drink shall be permitted in the visitor and spectator areas or in separated snack areas for pool users. Trash containers shall be provided in the food service areas.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0450; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94

333-062-0160
Domestic Water Quality

(1) All water used in public spa pools and bathhouses shall comply with the rules of the Division for Domestic Water Supplies, OAR 333-061-0005 through 333-061-0099.

(2) There shall be no cross-connection between the public spa water recirculation system or backwash system and the domestic water supply.

(3) Public spa pool water recirculation and backwash systems shall comply with the Cross Connection Control Requirements of OAR 333-061-0070.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0455; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94

333-062-0165
Spa Water Quality

(1) Water in public spa pools shall be maintained with water quality parameters within limits set out in **Table 1**. [Table not included. See ED. NOTE.]

(2) Testing Equipment:

(a) All public swimming pools shall have functional test kit(s) or equipment for measuring the pH, free and combined chlorine concentration, or bromine, (or concentration of other approved disinfectant), total alkalinity, turbidity (water clarity) and cyanuric acid if stabilized chlorine is used;

(b) Functional test kits or testing systems shall be provided to test for total copper and silver concentrations when they are used as supplemental disinfectants;

(c) Test kits for measuring free chlorine or bromine shall use DPD as the reagent.

(3) Pool operators shall test and record the parameters described in section (1) of this rule with the following minimum frequencies during periods when the pool is open for use:

(a) pH — Every two hours;

(b) Chlorine (Non-stabilized) — Hourly; chlorine (stabilized) — Every two hours; continuous reading devices shall satisfy requirements of subsections (3)(a) and (b) of this rule if such devices record in pH units and ppm of free chlorine;

(c) Bromine — hourly; continuous reading devices shall record in units of ppm bromine;

(d) Total alkalinity — Daily;

(e) Total copper — Weekly, if used;

(f) Total silver:

(A) If ionizing technology is used, once per quarter for one year after equipment is installed; twice per year thereafter;

(B) Weekly if silver is dispensed without using ionizing technology.

(g) Turbidity — Daily;

(h) Cyanuric acid — Weekly (when using stabilized chlorine);

(i) Calcium hardness — Weekly (recommended).

(4) Spa pools shall be drained and refilled with fresh water at least once every 30 days.

(5) Spa pool water shall be oxidized or superchlorinated as needed when combined chlorine exceeds spa water quality parameters, **Table 1**. [Table not included. See ED. NOTE.]

(6) Notwithstanding the above, the Division may require any other testing frequency for a spa water parameter or a chemical added to the spa for the purpose of protecting public health.

[ED. NOTE: Tables referenced are available from the agency.]
Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0460; HD 18-1991, f. & cert. ef. 10-15-91; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94

333-062-0170
Operation and Maintenance

(1) Operators of public spa pools shall be thoroughly knowledgeable on good practices of the spa operation and with the laws and rules pertaining to public spa pools. If, at any time, the spa meets one of the spa pool closure criteria in OAR 333-062-0255 the spa pool license holder, operator, or responsible supervisor shall immediately close the spa to the public until the requirements are satisfied.

(2)(a) Operators of public spa pools shall keep records pertaining to the operation and maintenance of the pool which they operate;

(b) Such records shall be maintained daily during periods when the pool is open, shall be retained by the operator and made available to the Division on request. All such records shall be retained for a period of two years;

(c) Records shall include at least the following:

(A) Results of the tests described in OAR 333-062-0165(3);

(B) Date and time of filter backwash;

(C) Dates that the pool was emptied or cleaned;

(D) Periods of recirculation equipment operation or malfunction and repair.

(d) A recommended record keeping form is provided in Appendix A.

(3) All parts and facilities of public spa pools and bathhouses shall be kept clean, in good repair and free of safety hazards.

[ED. NOTE: Appendix referenced is available from the agency.]

Stat. Auth.: ORS 448.011

Stats. Implemented: ORS 448.011

Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0465; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94; PH 23-2014, f. 8-15-14, cert. ef. 9-1-14

333-062-0175
Safety

(1)(a) The operator of any public spa pool shall report in writing to the Division any drowning, other death or injury requiring medical treatment occurring on the spa pool's premises;

(b) Such reports shall be made on forms provided by the Division and shall be submitted within seven days of the occurrence.

(2) Operators or managers shall make visual observation of the spa pool during operating hours. Such visual observation shall be no less than once every two hours.

(3) Lifeguards, pool operators and managers shall enforce the following rules at all public spa pools:

(a) Non-swimmers and children under 14 years of age shall not use the spa pool unless a lifeguard or a responsible adult observer is present;

(b) Bathers shall take a cleansing shower;

(c) No person suffering from a communicable disease transmissible via water or under the influence of an intoxicating liquor or drug shall use the pool;

(d) No person shall take food or drink inside the pool enclosure except in areas specifically designated for such use as described in OAR 333-062-0155;

(e) No person shall bring, throw or carry food, drink, smoking material, trash, debris, or any other foreign substances into the pool;

(f) No person shall run or engage in horseplay in or around a public spa pool;

(g) Persons in street shoes shall not be permitted on the pool deck areas used by the bathers.

(4) The hydrotherapy pump and air blower shall be connected to a maximum 15 minute timer switch located no closer than ten feet from the spa water's edge.

(5) Recirculation pumps and heater thermostat switches shall be inaccessible to bathers.

Stat. Auth.: ORS 448.011

Stats. Implemented: ORS 448.011

Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0470; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94

333-062-0180
Signs

(1) All public spa pools shall post a sign at the entrance to the spa pool enclosure reading as follows:

STOP

All persons are required to take a cleansing shower before entering the spa pool.

CAUTION

Elderly persons and those suffering from heart disease, diabetes or high blood pressure should consult their physician before using the spa pool.

No person suffering from a communicable disease, transmissible via water, shall use the spa pool. Persons using prescription medications should consult their physician before using the spa pool.

Individuals under the influence of alcohol should not use the spa pool

No person shall use the spa pool alone

Pregnant women should not use the spa pool without consulting their physician.

Persons should spend no more than 15 minutes in the spa at any one session

All children under 14 years of age shall be accompanied by a responsible adult observer.

No person shall run or engage in horseplay in or around the spa pool.

(2) Signs shall be a minimum of 24" x 18" with letters at least 3/8" in height.

Stat. Auth.: ORS 448.011

Stats. Implemented: ORS 448.011

Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0475; HD 23-1994, f. 8-22-94, cert. ef. 9-1-94

333-062-0185
Variance

(1) The Division may grant a variance from requirements of these rules as follows:

(a) Where it is demonstrated to the satisfaction of the Division that strict compliance with the rule would be highly burdensome or impractical due to special conditions or cause;

(b) Where the public or private interest in the granting of the variance is found by the Division to clearly outweigh the interest of the application of uniform rules; and

(c) Where such alternative measures are provided which in the opinion of the Division will provide adequate public health and safety protection.

(2) Such variance authority is not conferred upon any county notwithstanding delegated or contractual authority in administration and enforcement of the swimming pool statutes and rules.

Stat. Auth.: ORS 448.011

Stats. Implemented: ORS 448.037

Hist.: HD 14-1980(Temp), f. & ef. 12-19-80; HD 8-1981, f. & ef. 6-23-81; Renumbered from 333-042-0480

333-062-0250
Enforcement

(1) ACCESS. The pool license holder, operator, or responsible supervisor must permit an authorized employee or agent of the Division to enter any public spa pool area, whenever the spa pool is open, or at any other reasonable time for the purpose of inspecting the spa pool. The inspection may include, but is not limited to, the bathhouse or toilet/shower facilities, chemical storage, pool enclosure and security provisions, recirculation equipment, piping, ventilation, supervision areas, operations, pool records and files, to determine compliance with these rules.

(2) NOTICE OF VIOLATIONS. If upon inspection of a public spa pool, the Division or its agent finds that the spa pool is not designed, constructed, equipped, maintained or operated as required by these rules, the Division or its agent must notify the license holder, operator, or responsible supervisor in writing of the violations. The inspection report must specify the changes required to make the spa pool and its operation conform to the standards established in these rules and the time period within which to comply. If the violations pose an immediate danger to the public's health, the Division or its agent may take action authorized under OAR 333-062-0255 prior to notifying the license holder, operator, or responsible supervisor in writing of the violations.

(3) SUSPENSION OR REVOCATION. If the license holder does not correct the violations listed in the notice issued under section (2) of this rule within the specified time period, the Division or its agent may issue a notice proposing to suspend or revoke the license to operate the spa pool in accordance with ORS Chapter 183. A license holder shall have 21 days to request a hearing.

Stat. Auth.: ORS 448.011

Stats. Implemented: ORS 448.011

Hist.: PH 23-2014, f. 8-15-14, cert. ef. 9-1-14

333-062-0255
Spa Pool Closure Criteria

(1) If one or more of the conditions outlined in subsection (3)(a) through (j) of this rule is present at the public spa pool facility, the spa pool license holder, operator or responsible supervisor must immediately close the pool until the situation is resolved.

(2) If a spa pool license holder, operator or responsible supervisor has not acted in accordance with section (1) of this rule, the Division or its agent may issue an emergency suspension order, and close a spa in accordance with ORS 183.430(2). The emergency suspension may be used if one or more of the conditions in subsec-

tion (3)(a) through (j) of this rule exist that present a serious and immediate danger to the public's health or safety.

(3) Conditions requiring immediate closure of the public spa pool, until they are resolved include:

(a) CHEMICAL PARAMETERS. Failure to comply with the disinfectant residual levels, high levels for cyanuric acid or out of range pH established in OAR 333-062-0170(1), and items (a) thru (i) of Table 1;

(b) WATER QUALITY. Failure to comply with the water quality standards for clarity and bacteria established in OAR 333-062-0165(1) and items (j) and (k) of Table 1;

(c) TEMPERATURE. Water temperature over 104 degrees Fahrenheit.

(d) TREATMENT EQUIPMENT. A non-operational circulation pump, filter, or disinfectant feeder. With the approval of the local public health authority, when the chemical feeder(s) is inoperative for no more than a few hours while repairs are made, the spa pool may remain open, if the water chemistry can be maintained manually.

(e) ELECTRICAL SAFETY.

(A) The presence of bare electrical wires or other obvious electrical deficiency; or

(B) The presence of lightning or severe storms within a minimum 10-mile (16 km) proximity of the pool at outdoor spa pools.

(f) SUPERVISION. The absence of a responsible supervisor or required lifeguard;

(g) ENCLOSURES. Enclosures such as fences, doors, gates or windows that are not in compliance with OAR 333-062-0080;

(h) SUBMERGED SUCTION FITTINGS. A broken, missing or improperly attached submerged suction fitting, as required by OAR 333-062-0103(1)(d);

(i) FECAL ACCIDENT. A fecal accident occurs or feces is found in the pool. Information related to proper fecal incident response can be found at http://public.health.oregon.gov/HealthyEnvironments/Recreation/PoolsLodging/Documents/cdcfecal.pdf; or

(j) OTHER CONDITIONS. The presence of a hazardous substance or object in the spa pool, or the existence of any condition creating an immediate danger to health or safety.

(4) In accordance with ORS 183.430(2), a license holder shall have 90 days after the date of notice of emergency suspension to request a hearing and if a hearing is requested a hearing must be granted to the licensee or permittee as soon as practicable after such demand.

Stat. Auth.: ORS 448.011
Stats. Implemented: ORS 448.011
Hist.: PH 23-2014, f. 8-15-14, cert. ef. 9-1-14

DIVISION 64

ACCREDITATION OF LABORATORIES

333-064-0005
Purpose

These rules are for the purpose of implementing Oregon Revised Statutes (ORS) 438.605 to 438.620, 448.280 and the Oregon Drinking Water Quality Act of 1981. ORS 438.610 states that the Oregon Health Authority shall by adopting standards in concurrence with the accrediting body, implement an environmental laboratory accreditation program hereafter referred to as the Oregon Environmental Laboratory Accreditation Program (ORELAP). These rules establish requirements for the accreditation of laboratories analyzing samples under the guidance of the Clean Air Act (CAA), Clean Water Act (CWA), Safe Drinking Water Act (SDWA), the Resource, Conservation and Recovery Act (RCRA) and cannabis testing under ORS 475B.550 to 475B.590. Testing of water samples under ORS 448.150, Oregon's Drinking Water Quality Act, must be conducted by an ORELAP accredited laboratory.

Stat. Auth.: ORS 448.150(1), 448.131, 448.280(1)(b) & (2), 438.605, 438.610, 438.615, 438.620 & 475B.565
Stats. Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615, 438.620 & 475B.565
Hist.: OHD 7-1999, f. & cert. ef. 10-26-99; OHD 16-2002, f. & cert. ef. 10-10-02; PH 13-2003(Temp), f. & cert. ef. 9-22-03 thru 3-20-04; PH 20-2003, f. 12-02-03, cert. ef. 12-08-03; PH 6-2011, f. & cert. ef. 8-9-11; PH 31-2015(Temp), f. 12-29-15, cert. ef. 1-1-16 thru 6-28-16; PH 17-2016, f. & cert. ef. 6-7-16

333-064-0010
Scope

(1) These rules apply to:

(a) Laboratories seeking accreditation to perform environmental or agricultural laboratory testing;

(b) Laboratories seeking accreditation to perform sampling and laboratory testing of marijuana items as required by ORS 475B.565; and

(c) Accredited laboratories performing:

(A) Environmental or agricultural testing; or

(B) Sampling and testing of marijuana items.

(2) Accreditation as described in these rules is required for all laboratories reporting drinking water analysis results to the Oregon Health Authority except for Oregon Department of Agriculture Laboratory, Oregon Department of Environmental Quality Laboratory and the Oregon State Public Health Laboratory which must be certified by the United States Environmental Protection Agency for drinking water analysis.

(3) Accreditation as described in these rules is required for all Oregon laboratories testing marijuana items.

Stat. Auth.: ORS 448.150(1), 448.131, 448.280(1)(b) & (2), 438.605, 438.610, 438.615, 438.620 & 475B.565
Stats. Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615, 438.620 & 475B.565
Hist.: OHD 7-1999, f. & cert. ef. 10-26-99; OHD 16-2002, f. & cert. ef. 10-10-02; PH 13-2003(Temp), f. & cert. ef. 9-22-03 thru 3-20-04; PH 20-2003, f. 12-02-03, cert. ef. 12-08-03; PH 6-2011, f. & cert. ef. 8-9-11; PH 31-2015(Temp), f. 12-29-15, cert. ef. 1-1-16 thru 6-28-16; PH 17-2016, f. & cert. ef. 6-7-16

333-064-0015
Adoption by Reference

All standards, listings and publications referred to in these rules are, by those references, made a part of these rules as though fully set forth. Copies are available through Oregon Health Authority, Oregon State Public Health Laboratory.

Stat. Auth.: ORS 448.150(1), 448.131, 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620
Stats. Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620
Hist.: OHD 7-1999, f. & cert. ef. 10-26-99; OHD 16-2002, f. & cert. ef. 10-10-02; PH 13-2003(Temp), f. & cert. ef. 9-22-03 thru 3-20-04; PH 20-2003, f. 12-02-03, cert. ef. 12-08-03; PH 6-2011, f. & cert. ef. 8-9-11

333-064-0020
Severability

These rules are severable. If any rule or part thereof or the application of such rule to any person or circumstance is declared invalid, that invalidity shall not affect the validity of any remaining portion of these rules.

Stat. Auth.: ORS 448.150(1) & 448.131, 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620
Stats. Implemented: ORS 448.280(1)(b)(2), 438.605, 438.610, 438.615 & 438.620
Hist.: OHD 7-1999, f. & cert. ef. 10-26-99

333-064-0025
Definitions

As used in these rules, unless the context indicates otherwise:

(1) "Accrediting Body" means the official accrediting authority for the Oregon Environmental Laboratory Accreditation Program comprised of the Administrator of the Oregon State Public Health Laboratory or designee, the Laboratory Administrator of the Department of Environmental Quality or designee and the Laboratory Administrator of the Department of Agriculture or designee.

(2) "Air" as a matrix means air samples, which are analyzed for possible contaminants under the guidance of the Clean Air Act.

(3) "Authority" means the Oregon Health Authority.

(4) "Biological Tissue" as a matrix means samples of biological tissue, excluding those of human origin.

(5) "Cannabis Sampling" means an activity related to obtaining a representative sample of a marijuana item for purposes of testing

in accordance with these rules and OAR 333-007-0300 to 333-007-0490.

(6) "Clean Air Act (CAA)" means the enabling legislation, 42 U.S.C. 7401 et seq. (1974), Public Law 91-604, 84 Stat. 1676 Public Law 95-95, 91 Stat., 685 and Public Law 95-190, 91 Stat., 1399, that empowers the EPA to promulgate air quality standards, monitor and enforce them.

(7) "Clean Water Act (CWA)" means the enabling legislation under 33 U.S.C. 1251 et seq., Public Law 92-50086, Stat. 816 that empowers the EPA to set discharge limitations, write discharge permits, monitor and bring enforcement action for non-compliance.

(8) "Drinking Water" as a matrix means samples of presumed potable water and source water, which are analyzed for possible contaminants under the guidance of the Safe Drinking Water Act.

(9) "Fields of Accreditation" means those matrix, technology/method, and analyte combinations for which ORELAP offers accreditation.

(10) "Laboratory" means a fixed location or mobile facility that collects or analyzes samples in a controlled and scientific manner with the appropriate equipment and instruments required by accredited sampling and testing methods.

(11) "Marijuana item" has the meaning given that term in ORS 475B.550.

(12) "Mobile Category 1 Laboratory" means any facility, deployed for no more than six consecutive months and no more than six months during a calendar year, that:

(a) Analyzes samples utilizing the staff and equipment from the parent fixed laboratory;

(b) Operates under the quality system of its parent fixed laboratory;

(c) Is capable of moving or being moved from site to site, such as but not limited to vans, trailers and motor coaches; and

(d) May operate under the fixed laboratory's accreditation.

(13) "Mobile Category 2 Laboratory" means any facility that:

(a) Analyzes samples;

(b) Operates under its own quality system;

(c) Is capable of moving or being moved from site to site, such as but not limited to vans, trailers and motor coaches; and

(d) Issues the final reports or is a mobile laboratory operating with a fixed laboratory's quality system, but is deployed for more than six consecutive months or more than six months in a calendar year.

(14) "National Environmental Laboratory Accreditation Program (NELAP)" means the program established to oversee the implementation of the TNI Standards.

(15) "NELAP approved accrediting body" means a state or federal department/agency that has been approved by NELAP as being an entity whose accreditation and assessment program meets all of the requirements of the TNI Standards.

(16) "Non-Potable Water" as a matrix means aqueous samples, which are analyzed under the guidance of the Clean Water Act or the Resource, Conservation and Recovery Act.

(17) "On-site assessment" means an on-site visit to the laboratory to verify items addressed in the ORELAP application and to evaluate the facility and analytical performance for conformance with the TNI Standards.

(18) "ORELAP approved assessor" means an assessor whose qualification has been evaluated by ORELAP and found to meet TNI Standards for laboratory on-site assessors.

(19) "Primary Accreditation" means accreditation by a NELAP approved accrediting body based on a laboratory's compliance to TNI Standards after a review of the laboratory's application, quality manual, PT results and on-site assessment results as described in the TNI Standards.

(20) "Proficiency testing (PT)" means the analysis of samples obtained from providers that meet the TNI standards for PT providers. The composition of the sample is unknown to the laboratory performing the analysis, and is used in part to evaluate the ability of the laboratory to produce precise and accurate results.

(21) "Public water system" means a water system as defined in OAR 333-061-0010.

(22) "Quality Manual (QM)" means a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of a laboratory to ensure the quality of its product and the utility of its product to its users.

(23) "Resource Conservation and Recovery Act (RCRA)" means the enabling legislation, 42 U.S.C. section 6901 et seq. (1976), that requires the EPA to protect human health and protecting and monitoring the environment by regulating hazardous waste disposal practices.

(24) "Safe Drinking Water Act (SDWA)" means the SDWA enacted in 1974 and the Safe Drinking Water Amendments of 1986, 42 U.S.C. 300f et seq., Public Law 93-523, that is the enabling legislation that requires the EPA to protect the quality of drinking water in the U.S. by setting maximum allowable contaminant levels, monitoring, and enforcing violations.

(25) "Secondary Accreditation" means the recognition by reciprocity for the fields of accreditation, methods and analytes for which the laboratory holds current primary accreditation by another NELAP approved accrediting body.

(26) "Solids" as a matrix means samples of soil, sludge and other non-aqueous compounds analyzed under the guidance of the Resource, Conservation and Recovery Act. Cannabinoid products and concentrates or extracts as defined in ORS 475B.550 shall be included in this matrix as solids.

(27) "TNI" means the NELAC Institute. TNI is a voluntary organization of state and federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories.

(28) "TNI Standards" means the adopted TNI Standards (© 2009 The NELAC Institute), which are documents describing the elements of laboratory accreditation that was developed and established by the consensus principles of TNI and meets the approval requirements of TNI procedures and policies.

(29) "These rules" means the Oregon Administrative Rules encompassed by OAR 333-064-0005 through 333-064-0065.

(30) "Third party assessor" means an ORELAP approved assessor who has a current contract with the Oregon Health Authority to perform on-site assessments of laboratories for ORELAP and is not employed by the state agencies comprising ORELAP's accrediting body.

(31) "United States Environmental Protection Agency (EPA)" means the federal government agency with the responsibility for protecting public health and safeguarding and improving the natural environment (that is air, water, and land) upon which human life depends.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 438.605, 438.610, 438.615, 438.620, 448.131, 448.150(1), 448.280(1)(b) & (2)

Stats. Implemented: ORS 438.605, 438.610, 438.615, 438.620, 448.280(1)(b) & (2)

Hist.: OHD 7-1999, f. & cert. ef. 10-26-99; OHD 1-2001, f. & cert. ef. 1-17-01; OHD 16-2002, f. & cert. ef. 10-10-02; PH 5-2003, f. 5-15-03, cert. ef. 7-1-03; PH 13-2003(Temp), f. & cert. ef. 9-22-03 thru 3-20-04; PH 20-2003, f. 12-02-03, cert. ef. 12-08-03; PH 23-2004, f. & cert. ef. 7-1-04; PH 8-2005, f. 6-1-05, cert. ef. 7-1-05; PH 6-2011, f. & cert. ef. 8-9-11; PH 31-2015(Temp), f. 12-29-15, cert. ef. 1-1-16 thru 6-28-16; PH 17-2016, f. & cert. ef. 6-7-16

333-064-0030

Schedule for Requesting Accreditation, Period of Accreditation

(1) Laboratories in Oregon will be considered to be accredited by ORELAP after the laboratory has requested accreditation, been evaluated by ORELAP and has met all criteria in accordance with OAR 333-064-0035.

(2) The accreditation period for each laboratory is for one year with subsequent accreditation periods beginning from the first day the laboratory is granted accreditation.

(3) Laboratories must reapply for ORELAP approval annually, with the application to be received by ORELAP 120 calendar days prior to the expiration of the current accreditation period and with all appropriate fees paid no less than 60 days prior to the expiration of their current certificate of accreditation.

(4) ORELAP-accredited laboratories may apply for accreditation of additional parameters (analytes, methods, matrices) at any time during their accreditation period with accreditation for such parameters expiring with the current accreditation period.

Stat. Auth.: ORS 448.150(1), 448.131, 448.280(1)(b) & (2), 438.610 & 438.615
Stats. Implemented: ORS 438.605, 438.610 & 438.615
Hist.: OHD 7-1999, f. & cert. ef. 10-26-99; OHD 1-2001, f. & cert. ef. 1-17-01; OHD 16-2002, f. & cert. ef. 10-10-02; PH 13-2003(Temp), f. & cert. ef. 9-22-03 thru 3-20-04; PH 20-2003, f. 12-02-03, cert. ef. 12-08-03; PH 6-2011, f. & cert. ef. 8-9-11

333-064-0035
Approval Requirements

(1) This rule and the TNI Standards describe the procedure for obtaining and maintaining accreditation.

(2) ORELAP accreditation can be granted, denied, suspended, or revoked in total or in part as described in the TNI Standards.

(3) In no case shall a laboratory be accredited that does not comply with the TNI Standards as specified in this rule.

(4) The elements for accreditation shall include but are not restricted to:

(a) Application for accreditation:

(A) ORELAP will make online, electronic applications available to all laboratories requesting an application.

(B) The laboratory must request ORELAP accreditation by completing and submitting to ORELAP an acceptable application that includes all elements as required by the TNI Standards. For primary accreditation this includes a completed application with all required documents. For secondary accreditation this includes a completed application with all of the required documents plus proof of accreditation from a primary accrediting body.

(b) Laboratory's participation in a biennial on-site assessment(s) as required by the TNI Standards. Environmental testing laboratories seeking initial, primary ORELAP accreditation shall not be granted accreditation prior to an acceptable on-site assessment;

(c) Laboratory's participation in proficiency testing (PT) and the obtaining of acceptable PT results according to the TNI Standards;

(d) A quality manual (QM) that includes all elements as set forth in the TNI Standards;

(e) Laboratory staff members that meet the TNI Standards for training and experience for their responsibilities within the environmental laboratory;

(f) Creation and retention of all records pertaining to samples and analyses, including chain of custody documents, log books, work sheets, raw data, calculations, quality assurance data, and reports according to TNI Standards;

(g) Laboratory's full payment of all appropriate fees as described in OAR 333-064-0060.

Stat. Auth.: ORS 448.150(1), 448.131, 448.280(1)(b)(2), 438.605, 438.610, 438.615 & 438.620
Stats. Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620
Hist.: OHD 7-1999, f. & cert. ef. 10-26-99; OHD 1-2001, f. & cert. ef. 1-17-01; OHD 16-2002, f. & cert. ef. 10-10-02; PH 13-2003(Temp), f. & cert. ef. 9-22-03 thru 3-20-04; PH 20-2003, f. 12-02-03, cert. ef. 12-08-03; PH 8-2005, f. 6-1-05, cert. ef. 7-1-05; PH 6-2011, f. & cert. ef. 8-9-11

333-064-0040
Action Response for Laboratory Drinking Water Analysis Results

(1) If an accredited laboratory is authorized by the water supplier to report results of analyses required by OAR 333-061-0036 and performed by the laboratory directly to the Oregon Health Authority (Authority), then it must do so within 10 days after the end of the month, or within 10 days after the end of the monitoring period.

(2) If a result exceeds the maximum contaminant level (MCL) specified in OAR 333-061-0030:

(a) The accredited lab that issues the final test report must:

(A) Validate the results of any sample analysis and report that analysis directly to the Authority and to the water supplier within 48 hours or two business days of completing the analytical run if the sample analysis:

(i) Exceeds the MCL for nitrate as specified in OAR 333-061-0030(1); or

(ii) Is positive for coliform bacteria.

(B) Report any sample analysis directly to the Authority and to the water supplier within 24 hours or on the next business day after validating a sample result that exceeds the MCL for any chemical analyte specified in OAR 333-061-0030 other than nitrate.

(C) Report any sample analysis directly to the Authority and to the water supplier within 24 hours or on the next business day after obtaining a sample result from a subcontracted laboratory, if the sample analysis:

(i) Exceeds the MCL for nitrate as specified in OAR 333-061-0030(1) or is positive for coliform bacteria; or

(ii) Exceeds the MCL for any chemical analyte specified in OAR 333-061-0030 other than nitrate upon validating the sample analysis.

(b) Accredited, subcontracted laboratories must:

(A) Validate the results of any sample analysis and report that analysis to their client laboratory within 48 hours or two business days of completing the analytical run if the analysis:

(i) Exceeds the MCL for nitrate as specified in OAR 333-061-0030(1); or

(ii) Is positive for coliform bacteria.

(B) Report any sample analysis to their client laboratory within 24 hours or on the next business day after validating a sample result that exceeds the MCL for any chemical analyte specified in OAR 333-061-0030 other than nitrate.

(3) The laboratory must notify the public water system and, if authorized by the water system, the Authority of all unregulated contaminants detected and their concentrations from each specific method used to measure the regulated contaminants.

(4) The laboratory must use report forms that have been approved by the Authority for reporting drinking water test results to the Authority.

Stat. Auth.: ORS 448.150(1) & 448.131
Stats. Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620
Hist.: OHD 7-1999, f. & cert. ef. 10-26-99; OHD 16-2002, f. & cert. ef. 10-10-02; PH 13-2003(Temp), f. & cert. ef. 9-22-03 thru 3-20-04; PH 20-2003, f. 12-02-03, cert. ef. 12-08-03; PH 3-2011, f. & cert. ef. 4-21-11

333-064-0045
Procedure for Contesting Actions of ORELAP

The procedure for contesting the actions of ORELAP regarding denial, suspension and revocation of accreditation, or other changes in accreditation status is in accordance with the Administrative Procedures Act, ORS 183.

Stat. Auth.: ORS 448.150(1) & 448.131, 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620
Stats. Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620
Hist.: OHD 7-1999, f. & cert. ef. 10-26-99

333-064-0050
Accreditation of Out-of-State and Mobile Category 2 Laboratories

(1) ORELAP shall accredit out-of-state laboratories that are eligible for reciprocal accreditation provided:

(a) The laboratory is accredited by a state recognized as a NELAP accrediting body for those fields of testing (analytes, methods, matrices) in which the laboratory is requesting accreditation pursuant to this rule.

(b) The laboratory submits to ORELAP an acceptable application as described in OAR 333-064-0035(4).

(c) The laboratory pays all appropriate fees as described in OAR 333-064-0060.

(2) ORELAP may accredit out-of-state laboratories that are located in states that do not have a NELAP approved accrediting body for the fields of testing and matrices in which the laboratory desires accreditation provided that the laboratory complies with all the requirements in OAR 333-064-0035.

(3) ORELAP may accredit mobile category 2 laboratories that do not operate as an entity of an Oregon fixed base facility as out-of-state laboratories. Such laboratories must meet all of the requirements for out-of-state laboratories pursuant to these rules.

Stat. Auth.: ORS 448.150(1) & 448.131, 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620
Stats. Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620
Hist.: OHD 7-1999, f. & cert. ef. 10-26-99; PH 6-2011, f. & cert. ef. 8-9-11

333-064-0055
Display of Certificate

Accredited environmental laboratories shall post or display their most recent ORELAP accreditation certificate and their ORELAP-accredited fields of testing in a prominent place in the laboratory facility.

Stat. Auth.: ORS 448.150(1) & 448.131, 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620
Stats. Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620
Hist.: OHD 7-1999, f. & cert. ef. 10-26-99

333-064-0060
Fee Schedule

Fees will be charged to Oregon and out-of-state laboratories according to the following schedule. A mobile category 2 laboratory that operates as an entity of an Oregon fixed base facility will be considered an in-state laboratory, and one that does not operate as an entity of an Oregon fixed base facility will be considered an out-of-state laboratory. Mobile category 1 laboratories are covered under the parent fixed laboratory's accreditation and are not required to pay an additional fee. Mobile category 2 laboratories require separate accreditation and are accredited to their vehicle identification numbers (VIN).

(1) A non-refundable application fee must be paid for each application requesting accreditation for methods.

(a) For laboratories located in Oregon, one of three levels of fees, Tier 1 at $450, Tier 2 at $900 and Tier 3 at $1,600 will be charged. The Tiers will be determined by the total number of points derived from the number of fields of accreditation requested for accreditation listed in subsections (2)(a) through (c) of this rule.

(A) Each Basic Field of Accreditation has a multiplier of 1.

(B) Each Moderate Field of Accreditation has a multiplier of 3.

(C) Each Complex Field of Accreditation has a multiplier of 5.

(D) Each Advanced Technology Field of Accreditation has a multiplier of 7.

(E) Cannabis Sampling only for application has a multiplier of 11.

(F) The total number of points is determined by first summing the number of fields of accreditation within each category (Basic, Moderate, Complex or Advanced Technology) and then multiplying the sums by their appropriate multiplier as given in this rule. The sum of these results determines the total number of points for each laboratory. Laboratories with a total of 1 to 10 points are to be considered Tier 1 laboratories, 11 to 25 points are Tier 2 laboratories and 26 or more points are Tier 3 laboratories.

(b) For each out-of-state laboratory requesting primary or secondary accreditation through ORELAP, one of three levels of fees, Tier 1 at $1,650, Tier 2 at $2,640 and Tier 3 at $3,960 will be charged with each Tier determined according to subsection (1)(a) of this rule.

(c) If a new owner acquires the laboratory and wishes the laboratory to remain accredited, the laboratory must submit a new owner application, and may be required to pay the application fee and be subject to a new on-site assessment and payment of on-site assessment fees as described in this rule.

(2) Upon ORELAP's review of a laboratory's application, each laboratory requesting primary accreditation through ORELAP, when ORELAP personnel will be used for the assessment, will be charged an assessment fee as follows:

(a) Oregon laboratories will be charged $90 and out-of-state laboratories will be charged $120 for each of the following Basic Fields of Accreditation requested for accreditation:

(A) Gravimetric;

(B) Physical;

(C) Probe.

(b) Oregon laboratories will be charged $350 and out-of-state laboratories will be charged $462 for each of the following Moderate Fields of Accreditation requested for accreditation:

(A) Inorganic Atomic absorption spectrometry;

(B) Inorganic Atomic fluorescence spectrometry;

(C) Inorganic-non-metals automated colorimetric;

(D) Inorganic-non-metals manual colorimetric;

(E) Inorganic-ion chromatography (IC);

(F) Organic-liquid chromatography (LC);

(G) General microbiology including but not limited to these three: 1) Chromofluorogenic; 2) Membrane Filter and /or Heterotrophic Plate Count (HPC); and 3) Multiple Tube Fermentation/Most Probable Number (MPN) (one fee applies for all);

(H) Asbestos (bulk);

(I) Asbestos — electron microscopy.

(c) Oregon laboratories will be charged $500 and out-of-state laboratories will be charged $660 for each of the following Complex Fields of Accreditation requested for accreditation:

(A) Organic — gas chromatography/mass spectrometry (GC/MS) — volatiles;

(B) Organic — gas chromatography/mass spectrometry (GC/MS) — extractables;

(C) Organic — liquid chromatography/mass spectrometry (LC/MS);

(D) Organic — gas chromatography (GC) volatiles, extractables;

(E) Inorganic — metals — inductively coupled plasma/atomic emission spectrometry (ICP/AES);

(F) Inorganic — metals — inductively coupled plasma/mass spectrometry (ICP/MS);

(G) Inorganic — ion chromatography/mass spectrometry (IC/MS);

(H) X-ray;

(I) Whole Effluent Toxicity (WET) immunoassay;

(J) Radiochemistry.

(d) Oregon laboratories will be charged $1,000 and out-of-state laboratories will be charged $1,440 for each of the following Advanced Technology Fields of Accreditation requested for accreditation:

(A) Organic — gas chromatography/tandem mass spectrometry (GC/MS/MS);

(B) Organic — high resolution gas chromatography/high resolution mass spectrometry (HiResGC/HiResMS);

(C) Organic — liquid chromatography/tandem mass spectrometry (LC/MS/MS);

(D) Microbiology — Polymerase chain reaction (PCR);

(E) Mycology and Parasitology — Filtration/Immunomagnetic Separation/Immunoflurorescence Assay microscopy (Filtration/IMS/FA);

(F) Cannabis Sampling.

(e) The following additional fees will be charged to Oregon laboratories for each additional matrix per field of accreditation for which the laboratory has requested accreditation:

(A) $10 for Basic Fields of Accreditation.

(B) $40 for Moderate Fields of Accreditation.

(C) $75 for Complex Fields of Accreditation.

(D) $150 for Advanced Technology Fields of Accreditation.

(f) The following additional fees will be charged to out-of-state laboratories for each additional matrix per field of accreditation for which the laboratory has requested accreditation:

(A) $13 for Basic Fields of Accreditation.

(B) $53 for Moderate Fields of Accreditation.

(C) $100 for Complex Fields of Accreditation.

(D) $198 for Advanced Technology Fields of Accreditation.

(3) For purposes of section (2) of this rule the matrices are:
(a) Air;
(b) Biological tissue;
(c) Drinking water;
(d) Non-potable water; and
(e) Solids.

(4) Assessment fees must be paid before a routine on-site assessment will be performed.

(5) All laboratories must pay the appropriate on-site assessment fee per on-site assessment performed due to just cause according to TNI Standards.

(6) All Oregon laboratories requesting primary accreditation through ORELAP where Oregon state assessor(s) will perform the on-site assessment must pay an on-site trip fee for each on-site assessment. For a mobile category 2 laboratory, the trip fees are waived if it is moved to the Oregon State Public Health Laboratory for the on-site assessment, and reduced to the amount in excess of its fixed base facility when moved to the fixed base facility if both are to be assessed at the same time.

(a) On-site trip fees are $350 for Tier 1, $500 for Tier 2 and $1,000 for Tier 3 laboratories with the Tiers determined according to subsection (1)(a) of this rule.

(b) All laboratories must pay the appropriate on-site trip fee for performing each required on-site assessment and additional assessments as requested by the laboratory for accreditation for additional fields of accreditation and matrices.

(c) All laboratories must pay the appropriate on-site trip fee per on-site assessment performed due to just cause according to TNI Standards.

(7) All laboratories located in Oregon requesting primary accreditation through ORELAP where ORELAP has determined that third party assessors will be used, must pay ORELAP application assessment fees plus all third party assessors costs. ORELAP may require the laboratory to pay the on-site assessment costs directly to the third party assessor according to the schedule of the assessor for all required on-site assessments.

(8) All out of-state laboratories must pay all on-site assessment costs incurred by ORELAP approved assessors to perform the on-site assessment including but not limited to transportation, per diem and wages during travel. For a mobile category 2 laboratory, the travel costs are waived if it is moved to the Oregon State Public Health Laboratory for the on-site assessment, and reduced to the amount in excess of its fixed base facility when moved to the fixed base facility if both are to be assessed at the same time. The excess amount is to be determined by those fields of accreditation and matrices requested for accreditation by the mobile lab that have not been requested by its fixed based facility. If third party assessors are used, ORELAP may require the lab to pay the on-site assessment costs directly to the assessor according to the schedule of the assessor for all required inspections.

(9) Accredited laboratories requesting additions to their fields of accreditation during the accreditation period must pay:

(a) The difference in cost of the application fee with a minimum fee of $200;

(b) The difference in cost of the assessment fee;

(c) An on-site trip fee, as described in subsection (6)(a) and section (8) of this rule, based only on the additional parameters if ORELAP determines that an on-site assessment is required.

Stat. Auth.: ORS 438.605 - 438.620 & 448.280(1)(b) & (2)
Stats. Implemented: ORS 438.605 - 438.620
Hist.: OHD 7-1999, f. & cert. ef. 10-26-99; OHD 1-2001, f. & cert. ef. 1-17-01; OHD 16-2002, f. & cert. ef. 10-10-02; PH 13-2003(Temp), f. & cert. ef. 9-22-03 thru 3-20-04; PH 20-2003, f. 12-02-03, cert. ef. 12-08-03; PH 3-2006(Temp), f. & cert. ef. 2-8-06 thru 7-30-06; PH 5-2006, f. & cert. ef. 4-6-06; PH 6-2011, f. & cert. ef. 8-9-111; PH 31-2015(Temp), f. 12-29-15, cert. ef. 1-1-16 thru 6-28-16; PH 17-2016, f. & cert. ef. 6-7-16

333-064-0065
Civil Penalties

(1) In addition to any other penalty provided by law, the Oregon Health Authority, in collaboration with the accrediting body, may impose a civil penalty not to exceed $500 per day per violation upon any and all laboratories that:

(a) Falsely purport to be ORELAP accredited;

(b) Improperly use their ORELAP accreditation status in order to mislead; or

(c) Use the TNI\NELAP logo in catalogs, advertisements, business solicitations, proposals, quotations, laboratory reports and other materials without proper authorization.

(2) The Oregon Health Authority reserves the right to pursue other remedies and may take any other disciplinary action against alleged violators.

(3) In establishing the amount of the penalty for each violation, the Oregon Health Authority will consider, but not be limited to the following factors:

(a) The gravity and magnitude of the violation;

(b) The laboratory's previous record of complying or failing to comply with this rule.

(c) The laboratory's history in taking all feasible steps or in following all procedures necessary or appropriate to correct the violation; and,

(d) Such other considerations as the Oregon Health Authority may consider appropriate.

(4) The Oregon Health Authority in collaboration the accrediting body may deny, suspend or revoke accreditation of any laboratory that fails to pay on demand a civil penalty that has become due and payable, provided that it first gives the laboratory an opportunity for a hearing as outlined in ORS chapter 183.

Stat. Auth.: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620
Stats. Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620
Hist.: OHD 7-1999, f. & cert. ef. 10-26-99; OHD 16-2002, f. & cert. ef. 10-10-02; PH 13-2003(Temp), f. & cert. ef. 9-22-03 thru 3-20-04; PH 20-2003, f. 12-02-03, cert. ef. 12-08-03; PH 3-2006(Temp), f. & cert. ef. 2-8-06 thru 7-30-06; PH 5-2006, f. & cert. ef. 4-6-06; PH 6-2011, f. & cert. ef. 8-9-11; PH 17-2016, f. & cert. ef. 6-7-16

Oregon Environmental Laboratory Accreditation Program (ORELAP)

333-064-0100
Marijuana Item Sampling Procedures and Testing

(1) For purposes of this rule the definitions in OAR 333-007-0310 apply unless the context indicates otherwise.

(2) Sampling.

(a) A laboratory must prepare marijuana item sampling policies and procedures that contain all of the information necessary for collecting and transporting samples from a marijuana item in a manner that does not endanger the integrity of the sample for any analysis required by this rule. These policies and procedures must be appropriate to the matrix being sampled.

(b) Sampling policies and procedures must be accredited by ORELAP prior to any marijuana samples being taken. The policies and procedures must be consistent with the following ORELAP sampling protocols approved by the accrediting body, incorporated by reference:

(A) Usable Marijuana: ORELAP-SOP-001 Rev 2.0;

(B) Concentrates and Extract: ORELAP-SOP-002 Rev 2.0; and

(C) Cannabis Products: ORELAP-SOP-003 Rev 2.0. [Sampling protocols may be found on the ORELAP and Cannabis Testing webpage, public.health.oregon.gov/LaboratoryServices/EnvironmentalLaboratoryAccreditation/Pages/cannabis-info.aspx]

(c) Care should be taken by laboratory personnel while sampling to avoid contamination of the non-sampled material. Sample containers must be free of analytes of interest and appropriate for the analyses requested.

(d) A sufficient sample size must be taken for analysis of all requested tests and the quality control performed by the testing laboratory for these tests.

(e) A laboratory must comply with any recording requirements for samples and subsamples in the accredited policies and procedures and at a minimum:

(A) Record the location of each sample and subsample taken.

(B) Assign a field identification number for each sample, subsample and field duplicate that have an unequivocal link to the laboratory analysis identification.

(C) Assign a unique identification number for the test batch in accordance with OAR 333-007-0370 and TNI EL standard requirements.

(D) Have a documented system for uniquely identifying the samples to be tested to ensure there can be no confusion regarding the identity of such samples at any time. This system must include identification for all samples, subsamples, preservations, sample containers, tests, and subsequent extracts or digestates.

(E) Place the laboratory identification code as a durable mark on each sample container.

(F) Enter a unique identification number into the laboratory records. This number must be the link that associates the sample with related laboratory activities such as sample preparation. In cases where the sample collector and analyst are the same individual, or the laboratory pre-assigns numbers to sample containers, the unique identification number may be the same as the field identification code.

(f) Combining subsamples.

(A) Subsamples collected from the same batch must be combined into a single sample by a laboratory prior to testing unless the batch is undergoing process validation or has not yet gone through process validation.

(B) Subsamples and samples collected from different batches may not be combined.

(C) Field duplicates may not be combined with the primary samples.

(3) THC and CBD testing validity. When testing a sample for THC and CBD a laboratory must comply with additional method validation as follows:

(a) Run a laboratory control standard in accordance with TNI standards requirements within acceptance criteria of 70 percent to 130 percent recovery.

(b) Analyze field duplicates of samples within precision control limits of plus or minus 20 percent RPD, if field duplicates are required.

(4) Calculating total THC and total CBD.

(a) Total THC must be calculated as follows, where M is the mass or mass fraction of delta-9 THC or delta-9 THCA:

$M_{\text{total delta-9 THC}} = M_{\text{delta-9 THC}} + 0.877 \times M_{\text{delta-9 THCA}}$.

(b) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA:

$M_{\text{total CBD}} = M_{\text{CBD}} + 0.877 \times M_{\text{CBDA}}$.

(c) Each test report must include the total THC and total CBD.

(5) Report total THC and total CBD as Dry Weight. A laboratory must report total THC and Total CBD content by dry weight calculated as follows:

$P_{\text{total THC(dry)}} = P_{\text{total THC(wet)}} / [1-(P_{\text{moisture}}/100)]$

$P_{\text{total CBD(dry)}} = P_{\text{total CBD(wet)}} / [1-(P_{\text{moisture}}/100)]$

(6) Calculating RPD and RSD.

(a) A laboratory must use the following calculation for determining RPD:

RPD= *(sample result–duplicate result)(sample result+duplicate result*2

(b) A laboratory must use the following calculation for determining RSD:

% RSD= sx x*100%*

s=i=0n(xi–x)2(n–1)

(c) For purposes of this section:

(A) S = standard deviation.

(B) n = total number of values.

(C) x_i = each individual value used to calculate mean.

(D) x = mean of n values.

(d) For calculating both RPD and RSD if any results are less than the LOQ the absolute value of the LOQ is used in the equation.

(7) Tentative Identification of Compounds (TIC).

(a) If a laboratory is using a gas chromatography mass spectrometry instrument for analysis when testing cannabinoid concentrates or extracts for solvents and determines that a sample may contain compounds that are not included in the list of analytes the laboratory is testing for the laboratory must attempt to achieve tentative identification.

(b) Tentative identification is achieved by searching NIST 2014 or an equivalent database (>250,000 compounds).

(c) A laboratory shall report to the licensee or registrant and the Authority or the Commission, depending on which agency has jurisdiction, up to five tentatively identified compounds (TICS) that have the greatest apparent concentration.

(d) Match scores for background subtracted or deconvoluted spectra should exceed 90 percent compared to library spectrum.

(A) The top five matches over 90 percent must be reported by the lab

(B) TIC quantitation is estimated by comparing analyte area to the closest internal standard area and assuming a response factor (RF) =1.

(8) A laboratory must provide:

(a) Any pesticide test result to the Department of Agriculture upon that agency's request.

(b) A sample or a portion of a sample to the Department of Agriculture upon that agency's request, document the chain of custody from the laboratory to the Department, and document that the sample or portion of the sample was provided to the Department in the Commission's seed to sale tracking system.

(9) A laboratory performing tests for a licensee must enter any information required by the Commission in the Commission's seed to sale tracking system.

(10) A laboratory performing tests for a registrant must comply with the documentation requirements in OAR 333-007-0370.

(11) The Authority may, in its discretion, deviate from TNI Standards in order to comply with OAR 333-007-0400 to 333-007-0490 and these rules based on the state's needs.

Stat. Auth.: ORS 438.605, 438.610, 438.615 & 438.620, ORS 475B.555.

Stats. Implemented: ORS 438.605, 438.610, 438.615 & 438.620, ORS 475B.555

Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

333-064-0110

Reporting Marijuana Test Results

(1) For purposes of this rule the definitions in OAR 333-007-0310 apply unless the context indicates otherwise.

(2) Within 24 hours of completion of the laboratory's data review and approval procedures a laboratory must report all failed tests for testing required under OAR 333-007-0300 to 333-007-0490 except for failed water activity, whether or not the lab is reanalyzing the sample under OAR 333-007-0450:

(a) Into the Commission's seed to sale tracking system if performing testing for a licensee; and

(b) To the Authority electronically at www.healthoregon.org/ommp if performing testing for a registrant.

(3) The laboratory must report all test results required under OAR 333-007-0300 to 333-007-0490 that have not been reported under section (2) of this rule into the Commission's seed to sale tracking system if performing testing for a licensee.

(4) A laboratory must determine and include on each test report its limit of quantification (LOQ) for each analyte listed in OAR 333-007-0400 Table 3 and OAR 333-007-0410 Table 4.

(5) When reporting pesticide testing results the laboratory must include in the report any target compound that falls below the LOQ that has a signal to noise ratio of greater than 3:1 and meets identification criteria with a result of "detected."

(6) A test report must include any associated test batch numbers and the date each test was completed.

(7) A laboratory that is reporting failed test results to the Commission or the Authority in accordance with section (2) of this rule must report the failed test at the same time or before reporting to the licensee or registrant.

(8) In addition to reporting failed test results in accordance with section (2) of this rule a laboratory conducting testing for a registrant must report to the Authority electronically at www.healthoregon.org/ommp any pesticide testing report with a "detected" as described in section (5) of this rule.

(9) Test results expire after one year.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555
Hist.: PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16; PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

DIVISION 68

ACCREDITATION OF TRAINING PROGRAMS FOR PROFESSIONALS ENGAGED IN LEAD-BASED PAINT ACTIVITES

333-068-0005
Authority, Purpose, Scope

(1) Authority. These rules are promulgated in accordance with and under the authority of ORS 431.920.

(2) Purpose. These rules prescribe the requirements for accredited training programs to ensure a properly trained workforce to perform inspection, risk assessment and abatement of hazards associated with lead-based paint. These rules are designed to ensure that good quality training is available to those who need or want to have training in lead-based paint inspection, assessment or abatement activities.

(3) Scope.

(a) A training program may seek accreditation to offer lead-based paint activity courses in any of the following disciplines: inspector, risk assessor, supervisor, project designer, and abatement worker. A training program accredited in a discipline may also seek accreditation to offer refresher courses for the discipline.

(b) These rules prescribe the requirements for training programs to provide, offer, or claim to provide Authority accredited lead-based paint activities courses.

(c) These rules prescribe those actions or circumstances that constitute failure to achieve or maintain competency, or that otherwise are contrary to the public interest, for which the Authority may deny, suspend, or revoke accreditation.

(d) These rules provide criteria for the certification by the Authority and licensure by the Construction Contractors Board (CCB) of persons and the firms employing persons who have completed accredited training.

(e) These rules establish fees to the extent necessary to defray costs of those activities prescribed herein.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 19-1997, f. & cert. ef. 12-12-97; PH 4-2011, f. & cert. ef. 6-16-11

333-068-0010
Adoption By Reference

All standards, listings and publications referred to in these rules are by those references made a part of these rules as though fully set forth.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 19-1997, f. & cert. ef. 12-12-97

333-068-0015
Definitions

As used in these rules unless otherwise required by context:

(1) "Abatement" means any measure or set of measures designed to permanently eliminate lead-based paint hazards including, but not limited to:

(a) The removal of lead-based paint and lead-contaminated dust, the permanent enclosure or encapsulation of lead-based paint, the replacement of lead-painted surfaces or fixtures, and the removal or covering of lead-contaminated soil; and

(b) All preparation, cleanup, disposal, and post-abatement clearance examination activities associated with such measures;

(c) Specifically, abatement includes, but is not limited to:

(A) Projects for which there is a written contract or other documentation, which provides that an individual or firm will be conducting activities in or to a residential dwelling or child-occupied facility that results in permanent elimination of lead-based paint hazards or designed to permanently eliminate lead-based paint hazards as described in subsections (1)(a) and (1)(b) above.

(B) Projects resulting in the permanent elimination of lead-based paint hazards, conducted by certified and licensed firms or individuals, unless such projects are covered under subsection (1)(d) of this definition.

(c) Projects resulting in the permanent elimination of lead-based paint hazards; conducted by firms or individuals who, through their company name or promotional literature, represent, advertise, or hold themselves out to be in the business of performing lead-based paint activities, unless such projects are covered under subsection (1)(d) of this section.

(d) Projects resulting in the permanent elimination of lead-based paint hazards that are conducted in response to state or local abatement orders.

(e) Abatement does not include renovation, remodeling, landscaping or other activities, when such activities are not designed to permanently eliminate lead-based paint hazards, but, instead, are designed to repair, restore, or remodel a given structure or dwelling, even though these activities may incidentally result in a reduction or elimination of lead-based paint hazards. Furthermore, abatement does not include interim controls, operations and maintenance activities, or other measures and activities designed to temporarily, but not permanently, reduce lead-based paint hazards.

(2) "Accreditation" means the process whereby the Authority has reviewed and approved a training program's written application with associated materials for accreditation, and has conducted an on-site audit finding the training program in compliance as specified in these rules.

(3) "Accredited Training Program" means an individual, corporation, partnership or other unincorporated association or public entity to which the Authority, the U.S. Environmental Protection Agency (EPA), or an EPA-authorized state or tribal program has received accreditation or provisional accreditation to provide training for individuals engaged in lead-based paint activities.

(4) "Approved" means approved in writing by the Authority.

(5) "Authority" means the Oregon Health Authority.

(6) "Certified" means successful completion of a training program accredited by the Authority, EPA or an EPA-authorized state or tribal program, passage of a certification examination administered by the Authority, satisfaction of any other requirements for the appropriate discipline, and submittal and approval of the appropriate application by the Authority for inspection, risk assessment or abatement activities in target housing and child-occupied facilities.

(7) "Certified firm" means a company, partnership, corporation, sole proprietorship, association, or other business entity that performs lead-based paint activities that the Authority has issued a certificate under OAR 333-069-0005 through 333-069-0090.

(8) "Clearance examination" means visual examination and clearance testing performed following abatement of lead-based paint or lead-based paint hazards using documented methodologies as defined in this section. Such examination shall be performed by a person certified to perform risk assessments or lead-based paint inspections.

(9) "Clearance examination standards" means values that indicate the maximum amount of lead permitted in dust on a surface or in soil following completion of an abatement activity. Standards for lead in dust are 40 micrograms per square foot ($\mu g/ft^2$) on floors, 250 $\mu g/ft^2$ on interior window sills, and 400 $\mu g/ft^2$ on window troughs. The values for lead in soil are 400 parts per million (ppm) in play areas and 1,200 ppm in the remainder of the yard.

(10) "Contact hour" means 60 minutes of lead-based paint related training which may include a break of not more than 10 minutes.

(11) "Course completion document" means documentation issued by an accredited training program to an individual as proof of successful completion of an Authority approved lead-based paint course or refresher training course.

(12) "Demonstration testing" means the observation and scoring of a student's job task and equipment use skills taught during a course or refresher training course.

(13) "Discipline" means a specific type or category of lead-based paint activity.

(14) "Guest instructor" means an individual who is responsible for providing less than 30 percent of training in any course.

(15) "Hands-on training" means training during which students practice skills that they will be expected to perform at the worksite.

(16) "Inspection" means a surface-by-surface investigation to determine the presence of lead-based paint and the provision of a report, in writing, explaining the results of the investigation.

(17) "Inspector" means an individual who is certified by the Authority to conduct in target housing and child-occupied facilities a surface-by-surface investigation to determine the presence of lead-based paint and the provision of a written report explaining the results of the investigation; and to collect dust-wipe and soil samples incidental to post-abatement clearance examination, in accordance with OAR 333-069-0070.

(18) "Instructor" means an individual who is responsible for providing 30 percent or more of training in any course.

(19) "Interactive/participatory teaching methods" means instruction which consists of active participation of the students, such as brainstorming, hands-on training, demonstration and practice, small group problem-solving, learning games, discussions, risk mapping, field visits, walk-throughs, problem-posing, group work assignments, homework review sessions, question-and-answer periods, skits, or role-playing sessions. Lecture is not considered an interactive/participatory teaching method.

(20) "Job tasks" mean the specific activities performed in the context of work.

(21) "Lead-based paint" means paint or other surface coatings that contain lead equal to or in excess of 1.0 milligram per square centimeter or 0.5 percent by weight.

(22) "Lead-based paint activities" means, in the case of target housing and child-occupied facilities, inspection, risk-assessment, and abatement.

(23) "Lead-based paint hazard" means any condition that causes exposure to lead from lead-contaminated dust, lead-contaminated soil, lead-contaminated paint that is deteriorated or present in accessible surfaces, friction surfaces or impact surfaces that would result in adverse human health effects.

(24) "Licensed" means a person who has been certified by the Authority in one or more disciplines and has completed the requirements of the CCB.

(25) "Person" means individuals, corporations, associations, firms, partnerships, joint stock companies, and public entities.

(26) "Principal instructor" means the individual who has the primary responsibility for organizing and teaching a particular course.

(27) "Proficiency test" means any alternative to a conventional written examination that is used to measure a trainee's mastery of course content. An oral examination offered to a trainee with a manual disability is an example of a proficiency test.

(28) "Provisional accreditation" means the Authority has reviewed and finds acceptable a training program's written application for accreditation, but has not conducted an on-site audit as specified in these rules.

(29) "Project designer" means an individual who is certified by the Authority and licensed by the CCB to interpret lead inspection or risk assessment reports and to develop plans, specifications, and project procedures for lead abatement projects in target housing and child-occupied facilities, including, occupant notification and protection, clean-up and clearance, and abatement reports.

(30) "Refresher training course" means a minimum seven hour training course (or four hours for project designer) accredited by the Authority to update an individual's knowledge and skills in the discipline in which training is offered.

(31) "Risk assessment" means an on-site investigation to determine the existence, nature, severity, and location of lead-based paint hazards, and the provision of a report by the individual or the firm conducting the risk assessment, explaining the results of the investigation and options for reducing lead-based hazards.

(32) "Risk assessor" means an individual who is certified by the Authority and licensed by the CCB to conduct, in target housing and child-occupied facilities, on-site investigations to determine the existence, nature, severity, and location of lead-based paint hazards, and to provide a report explaining the results of the investigation and options for reducing lead-based hazards; and who may conduct a lead-hazard investigation, in accordance with OAR 333-069-0070.

(33) "Sample quality control" means a plan or design which ensures the authenticity, integrity, and accuracy of samples, including dust, soil, and paint chip or film samples. Sample quality control also includes provisions for representative sampling and control samples.

(34) "Supervisor" means an individual who is certified by the Authority and licensed by the CCB to either conduct or oversee and direct the work-site conduct of lead-based paint abatement and clearance activities in target housing and child-occupied facilities, and to prepare occupant protection plans and abatement reports in accordance with OAR 333-069-0070.

(35) "These rules" means OAR 333-068-0005 through 333-068-0065.

(36) "Training manager" means the individual responsible for administering a training program and monitoring the performance of principal instructors and guest instructors.

(37) "Worker" means an individual who is certified by the Authority and licensed by the CCB to conduct work site lead-based paint abatement activities in target housing and child-occupied facilities in accordance with OAR 333-069-0070.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 19-1997, f. & cert. ef. 12-12-97; PH 4-2011, f. & cert. ef. 6-16-11

333-068-0020
Accreditation Required

(1) No person shall provide, offer, or claim to provide an accredited lead-based paint activities course unless the person has received accreditation or provisional accreditation from the Authority.

(2) Curriculums may be accredited for the initial and refresher training courses for inspector, risk assessor, abatement worker, supervisor, and project designer.

(3) Only Authority accredited or provisionally accredited training programs are eligible to offer refresher training courses for lead-based paint discipline courses.

(4) To qualify for and maintain accreditation, a training program shall:

(a) Propose and offer at least one accredited or provisionally accredited lead-based paint training course.

(b) Conform with personnel, operational and curriculum requirements.

(c) Comply with accreditation application and procedural requirements.

(5) The Authority shall review and approve or deny accreditation, provisional accreditation, or renewal of accreditation of any applicant.

(a) If approved, a written notice shall be sent to the applicant.

(b) If denied, the Authority shall state, in writing, the reasons for denial. An applicant may reapply for accreditation of the same course after a period of 30 days from the date the application was denied.

(6) Provisional status shall be removed upon an on-site audit stating that requirements for Authority approval are satisfied.

(a) A provisional accredited or accredited training program shall permit the Authority to conduct an audit without charge to the Authority.

(b) Advance notice shall not be required prior to conducting an audit.

(c) An audit shall be performed on-site and shall include, but not be limited to, a review of: records, including course completion forms and attendance records; facilities; instructional curriculum; examination design, administration and security procedures, and

results, including those of demonstration testing; classroom instruction; audio-visual materials; course content; and coverage.

(7) Accreditation must be obtained and maintained for each training course and refresher training course.

(8) Accreditation shall be valid for 1 year, must be renewed annually, and shall not be transferrable.

(9) Accreditation based on a valid lead-based paint accreditation issued by the EPA or by an EPA-authorized state or tribal program shall be issued with an expiration date not to exceed the date of expiration listed on the EPA or EPA-authorized state or tribal accreditation document.

(10) The provider of an accredited or provisionally accredited training course shall submit for review a written description of changes in method or content that affect one-half hour or more of contact instruction.

(11) A provider of an accredited training course may not implement changes in method or content that affect one-half hour or more of contact instruction without prior approval of the Authority.

(12) An accredited or provisionally accredited training program shall permit the Authority to conduct unannounced on-site audits at any time.

(13) An accredited or provisionally accredited training program shall notify the Authority within 30 days of any change to the current application.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 19-1997, f. & cert. ef. 12-12-97; PH 4-2011, f. & cert. ef. 6-16-11

333-068-0025
Application

(1) Submittal of a completed application for course accreditation or re-accreditation shall include:

(a) Name, address, and phone number of training program and training program manager.

(b) List of course(s) for which accreditation is being applied.

(c) Training program manager signed statement certifying each instructor meets qualifications under OAR 333-068-0030 in these rules, as well as, a list of the topics/skill areas to be taught by each instructor.

(d) A copy of the entire course or refresher course instruction curriculum, including, but not limited to: learning objectives; documentation of course agenda with time allocation for each course topic and sequence of topics to be covered during the course(s); student and instructor manuals, handouts, quizzes and homework.

(e) Copy of the test blueprint describing the portion of test questions devoted to each major course topic.

(f) Description of the classroom and field site training facilities, equipment for lecture and hands-on training and equipment storage.

(g) Description of the procedures for conducting the assessment of the hands-on skills and evaluation testing of trainees' ability to perform work practices.

(h) A copy of the quality control plan developed by the training manager. The plan shall be used to maintain and improve the training program and contain at least the following elements:

(A) Procedures for periodic revision of training materials and course test to be current with innovations in the field.

(B) Procedures for the training manager's annual review of principle instructor competency.

(i) An example of numbered certificates to be issued to students who successfully complete the training course.

(j) Description of record keeping procedures.

(k) Schedule of anticipated course dates and location(s).

(l) Description of the amount of time and type of hands-on training including student-to-instructor ratio during hands-on training.

(m) Description of the teaching methods to be used for each major topic and for hands-on training.

(n) Description of the audio/visual aids to be used for each major topic.

(2) The program application materials shall demonstrate that it meets the minimum requirements for each discipline for which the program is seeking accreditation.

(3) Documentation of compliance with Oregon Administrative Rules for radioactive lead detection devices in accordance with OAR chapter 333, divisions 102 and 103, which includes, but is not limited to, licensing, storage, and use requirements shall be provided.

(4) Documentation of accreditation issued by the EPA or an EPA-authorized state or tribal program, if applicable.

(5) Applicants for accreditation based on accreditation from the EPA or an EPA-authorized state or tribal program must document to the Authority that they have read and understand the accreditation standards as described in these rules.

(6) When re-accrediting, the training program shall submit a completed application form and required documentation, except for unchanged information and documentation that was submitted with the original application.

(7) When seeking accreditation to offer an additional course, the training program shall submit a completed application form and required documentation, except for unchanged information and documentation submitted with the original application for accreditation.

(8) The Authority may deny an application for accreditation or re-accreditation of a training course for any of the following reasons:

(a) Failure to complete application in accordance with Authority policy or instructions.

(b) Failure to meet minimum curriculum standards as set forth in these rules.

(c) Failure to meet minimum operational standards as set forth in these rules.

(d) Failure to pass a field audit conducted in accordance with Authority policy and procedures.

(9) An applicant whose application for accreditation or re-accreditation of a training course has been denied by the Authority may submit another application for accreditation or reaccreditation of the course after a period of 30 days from the date the application was denied.

(10) The Authority may withdraw provisional accreditation of a training program following the failure of a field audit of that course. If provisional accreditation is withdrawn by the Authority, the training program is required to receive written permission from the Authority before continuing to offer the course for which provisional accreditation has been withdrawn.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 19-1997, f. & cert. ef. 12-12-97; PH 4-2011, f. & cert. ef. 6-16-11

333-068-0030
Minimum Personnel Requirements

(1) The training program shall be administered by a training manager having the following minimum qualifications:

(a) Two years of experience administering training programs or two years of experience teaching or training adults;

(b) Successful completion of a course that provides instruction in the planning and teaching of an adult education course, or has obtained a bachelor's or graduate level degree in adult education from an accredited college or university;

(c) A bachelor's or graduate degree in building construction technology, engineering, industrial hygiene, safety, public health, education, business administration or program management including: lead or asbestos abatement, painting, carpentry, renovation, remodeling, occupational safety and health, or industrial hygiene;

(d) Successful completion of at least 16 contact hours of lead-based paint training from any of the required topics listed in OAR 333-068-0040.

(2) Each training program shall be taught by a principal instructor who shall be responsible for the organization of the course, teaching of all course material, may deliver course content and has the following minimum qualifications:

(a) Has completed a course that provides instruction in the planning and teaching of any adult education course, or has obtained a degree in adult education from an accredited college or university, or has at least two years of classroom experience in teaching workers or adults;

(b) Successful completion of at least 16 contact hours lead-based paint training from any of the required topics listed in OAR 333-068-0040;

(c) Demonstrated one year of experience, education, or training in lead or asbestos abatement, painting, carpentry, renovation, remodeling, occupational safety and health, or industrial hygiene. Except, that instructors of hands-on training must have two years of such experience; and

(d) Successful completion of seven contact hours of an Authority accredited refresher training instruction annually.

(3) Only a principal instructor receiving a satisfactory annual performance review by the training manager shall provide course or refresher training, unless the instructor is also the training manager.

(4) The training manager may designate guest instructors as needed for teaching particular skills specific to the lecture, hands-on activities, or work practice components of a course.

(a) Each qualified guest instructor shall have a minimum of one year of experience related to the subject matter that they teach.

(b) Except that, guest instructors of hands-on training shall have a minimum of two years of lead-based paint activities experience.

(5) The maximum student to instructor ratio shall be 30 to 1 for classroom training and 10 to 1 for hands-on instruction.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 19-1997, f. & cert. ef. 12-12-97; OHD 1-1999, f. & cert. ef. 1-19-99; PH 4-2011, f. & cert. ef. 6-16-11

333-068-0035
Minimum Operation Requirements

(1) The training program shall have available and provide adequate facilities for delivery of the lecture, hands-on training and assessment activities. This includes training equipment that reflects current work practices, and maintaining or updating the equipment and facilities as needed.

(2) For each course offered, the training program shall conduct at the completion of each course a course test composed of questions relevant to the objectives of the course and, if applicable, a hands-on skills assessment, or in the alternative, a proficiency test for that discipline.

(a) The written course examination shall contain a minimum of 50 questions, which shall be presented in multiple-choice format.

(b) A member of the training staff or a designated proctor must remain in the room where the examination is being administered until all trainees have completed the exam.

(c) Each trainee must successfully complete the hands-on skills assessment and receive a passing score on the written course test to pass any course, or successfully complete a proficiency test.

(d) The hands-on skill assessment is an evaluation of the effectiveness of the hands-on training which shall test the ability of the trainees to demonstrate satisfactory performance of work practices and procedures in OAR 333-069-0070, as well as any other skills demonstrated in the course.

(3) The training manager is responsible for maintaining the validity and integrity of the hands-on skills assessment or proficiency test to assure that it accurately evaluates the trainee's performance of the work practices and procedures associated with the course topics.

(4) The training manager is responsible for maintaining the validity and integrity of the course test to ensure that it accurately evaluates the trainee's knowledge and retention of the course topics.

(a) The course test is an evaluation of the overall effectiveness of the training which shall test the trainee's knowledge and retention of the topics covered during the course. A score of 70 percent is considered passing the course test.

(b) The course test shall be developed in accordance with the test blueprint submitted with the training course accreditation application.

(5) Training programs shall issue unique course completion certificates to each individual who successfully completes the course requirements. The course completion certificate shall include:

(a) The name, a unique identification number, and the individual's address;

(b) Name of particular course completed;

(c) Dates of course completion/test passage;

(d) Expiration date of certification, which shall be six months from date of course completion;

(e) Name, address, and telephone number of training program

(6) The training manager shall develop and implement a quality control plan to be used to maintain or improve the quality of the training program and contain at least:

(a) Procedures for periodic revision of training materials and course test to reflect innovations in the field; and

(b) Procedures for training manager's annual review of instructor competency.

(7) The training manager shall offer courses which teach the work practice standards, testing criteria and field measurements for conducting lead-based paint activities and other lead-based paint standards that are at least as protective of the environment and of public health as those developed by the EPA, and in accordance with worker safety requirements of the Oregon Occupational Safety and Health Administration (OR-OSHA), and based on principles and practices determined to protect the environment and human beings from exposure to lead contaminants. These standards shall be taught in the appropriate courses to provide trainees with the knowledge needed to perform the lead-based paint activities they are responsible for conducting

(8) The training manager shall be responsible for ensuring that the training program complies at all times with the accreditation regulations.

(9) The training manager shall provide the Authority with a current listing of training courses including the date, time and location of scheduled lead-based paint training courses.

(10) The training manager shall permit the Authority to conduct a course audit without charge to the Authority.

(a) Advance notice shall not be required prior to conducting a course audit to verify the contents of the application for accreditation.

(b) A course audit shall be performed on-site and shall include, but not be limited to, a review of: instructional curriculum; examination design, administration and security procedures, and results, including those of demonstration testing; classroom instruction; audio-visual materials; course content; coverage; teaching facilities, and equipment licensure.

(11) An accredited training program shall maintain at the principal place of business in Oregon, accurate records of attendance; examination results including demonstration testing; completed course forms; and training director, instructor and guest instructor qualifications, for at least seven years.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 19-1997, f. & cert. ef. 12-12-97; PH 4-2011, f. & cert. ef. 6-16-11

333-068-0040
Minimum Curriculum Requirements

(1) The inspector course shall consist of a minimum of 24 contact hours. At least 10 of the 24 required contact hours shall be taught using interactive/participatory teaching methods, which includes a minimum of eight hours hands-on training.

(a) Classroom instruction shall include, but not be limited to:

(A) Roles and responsibilities of lead-based paint inspector including qualifications and conflicts of interest.

(B) One contact hour of background information on lead, including but not limited to, identification of environmental lead

sources such as surface dust, soil, water, air and food; history of uses and locations of lead and leaded paint in buildings; lead dust and paint characteristics; and summary of abatement control options.

(C) One contact hour of adverse health effects of lead exposure, including but not limited to, nature of lead-related diseases; pathways of exposure and how exposure occurs; dose-response relationships; permissible exposure limit; blood lead levels in children and adults; effects on various body systems; different effects on children and adults including women and the fetus during pregnancy; symptoms and diagnosis of lead poisoning and reportable blood lead levels; how lead in the body is absorbed, distributed and eliminated; medical treatment for lead poisoning including but not limited to chelation therapy.

(D) One contact hour on regulatory review and background information of relevant federal, state, and local regulations including guidance that pertains to lead-based paint and lead-based paint activities.

(E) At least one contact hour on radiation information and safety training requirements including but not limited to:

(i) The Oregon radiation safety training requirements.

(ii) Ionization radiation including atomic structure, units of radiation, radioactivity, radioactive decay, ionization, radiation absorption in matter, and radiation detection.

(iii) Safe use of X-ray florescent (XRF) analyzers, including limitations, transportation, storage, records, record keeping and licensing requirements.

(F) At least two contact hours on lead-based paint respiratory protection and personal protective training that conforms with OAR 437-003-0001(4)(m).

(G) At least six contact hours on inspection work practice standard tasks including, but not limited to:

(i) Legal responsibilities and insurance issues including liabilities, errors and omissions, and bonding.

(ii) Formulation of a testing plan for multi-family dwellings and single family target housing and child-occupied facilities, including notification of property owner and occupants, building access, and use of warning signs.

(iii) Investigation protocol, sample collection including equipment, procedures, quality assurance, contamination factors before, during and after abatement as set forth in the U.S. Housing and Urban Development's (HUD's) " Guidelines for the Evaluation and Control of Lead-based Paint Hazards in Housing" and EPA's "Residential Sampling of Lead: Protocols for Dust and Soil Sampling".

(iv) Sample analysis and quality assurance procedures including National Lead Laboratory Accreditation Program (NLLAP) recognized laboratories to test paint, dust, soil and other media.

(b) Hands-on training shall include performance of tasks including but not limited to:

(A) Lead-based paint inspection methods including selection of rooms and components for sampling or testing.

(B) Paint, dust and soil sampling methodologies.

(C) Clearance standards and testing, including random sampling.

(D) Preparation of a final inspection report.

(2) The risk assessor course shall consist of a minimum of 40 contact hours, which includes a 24 contact hour inspector course. At least 16 of the 40 required contact hours shall be taught using interactive/participatory teaching methods, which includes a minimum of 12 hours of hands-on training.

(a) Classroom instruction shall include, but not be limited to:

(A) Role and responsibilities of a risk assessor including risk assessor qualifications, legal obligations, conflicts of interest, and insurance issues.

(B) Collection of background information to perform a risk assessment

(C) Sources of environmental lead contamination exposure sources including paint, surface dust and soil, water, air, packaging, and food.

(D) Risk assessment report form;

(E) Lead hazard screen protocol;

(F) Development of hazard control options, the role of interim controls, and operations and maintenance activities to reduce lead-based paint hazards.

(G) Preparation of a final risk assessment report;

(H) Record keeping;

(I) At least nine contact hours on lead hazard screen and risk assessment work practice standard tasks for target housing and child-occupied facilities.

(b) Hands-on training shall include performance of tasks including but not limited to:

(A) Visual inspections for the purposes of identifying potential lead-based paint hazard sources;

(B) Sampling for other sources of lead exposure;

(C) Interpretation of lead-based paint and other lead sampling results including all applicable state or federal guidance or regulations pertaining to lead-based paint hazards.

(3) The supervisor course shall consist of at least a minimum of 32 contact hours. At least 13 of the 32 required contact hours shall be taught using interactive/participatory teaching methods which includes a minimum of eight hours hands-on training.

(a) Classroom instruction shall include, but not be limited to:

(A) Roles and responsibilities of lead-based paint supervisor including supervisor qualifications, legal obligations, conflicts of interest, abatement liability, and insurance issues.

(B) Background information on lead, including but not limited to, identification of environmental lead sources such as surface dust, soil, water, air and food; history of uses and locations of lead and leaded paint in buildings; lead dust and paint characteristics; and summary of abatement control options.

(C) Adverse health effects of lead exposure, including but not limited to, nature of lead related diseases; pathways of exposure and how exposure occurs; dose-response relationships; permissible exposure limit; blood lead levels in children and adults; effects on various body systems; different effects on children and adults including women and the fetus during pregnancy; symptoms and diagnosis of poisoning and reportable blood lead levels; how lead in the body is absorbed, distributed and eliminated; medical treatment for lead poisoning including but not limited to chelation therapy.

(D) Regulatory review and background information of relevant federal, state, and local regulations including guidance that pertains to lead-based paint and lead-based paint activities.

(E) At least two contact hours on lead-based paint respiratory protection and personal protective training that conforms with OAR 437-003-0001(64)(m).

(F) Identification and prevention of hazards encountered during lead-based paint activities including potential lead hazard exposure; prevention of lead dust contamination; emergency procedures for sudden releases and electrical, heat stress, fire, explosion and other hazards, chemical air contaminants, and disturbance of friable asbestos.

(G) Record keeping.

(H) Personal hygiene, including entry and exit procedures for the work area, use of showers, avoidance of eating, drinking, smoking, chewing, and applying cosmetics in the work or changing area, avoidance of take-home exposures.

(I) Medical monitoring requirements discussion of need for medical monitoring of lead toxicity and disclosure of lead related medical history and treatment of lead poisoning cases including medical removal and issues involved in selecting medical services.

(J) Hazard communication with property owner, occupants and neighbors relative to the reduction or elimination of lead sources at the job site.

(K) Development and implementation of an occupant protection plan and abatement report.

(L) Clearance examination standards and testing.

(M) Clean-up and waste disposal.

(N) At least six contact hours on supervisor work practice standard tasks including but not limited to:

(i) Interior and exterior leaded paint, soil and dust abatement methods, including chemical, enclosure, manual, mechanical, blasting, and encapsulation; removal and demolition; ventilation and engineering controls; management in place; and clean-up techniques, including high efficiency particulate air (HEPA) vacuums and negative air machines, as described in HUD's "Guidelines for the Evaluation and Control of Lead-based Paint Hazards in Housing."

(ii) Construction and maintenance of containment barriers.

(iii) Warning signs and their placement.

(iv) Electrical and ventilation system lockout and hazardous and non-hazardous waste characterization and disposal.

(b) Hands-on training shall include performance of tasks including but not limited to:

(A) Risk assessment and inspection report interpretation;

(B) Hazard recognition and control;

(C) Respiratory protection and protective clothing;

(D) Lead paint abatement or lead hazard reduction including prohibited methods;

(E) Interior dust abatement/clean-up or lead hazard reduction;

(F) Soil and exterior dust abatement or lead hazard reduction.

(4) The project designer course shall consist of at least a minimum of 40 contact hours, which includes a 32 contact hours supervisor course. At least 16 of the 40 required contact hours shall be taught using interactive/participatory teaching methods, which includes a minimum of eight hours hands-on training and shall include, but not be limited to:

(a) Role and responsibilities of a project designer.

(b) Development and implementation of an occupant protection plan for large scale abatement projects.

(c) Lead-based paint abatement and lead-based paint hazard reduction methods, including restricted practices for large scale projects.

(d) Interior dust abatement/clean-up or lead hazard control and reduction methods for large scale projects.

(e) Clearance examination standards and testing for large scale projects.

(f) Integration of lead-based paint abatement methods with modernization and rehabilitation projects for large scale abatement projects.

(5) The abatement worker course shall consist of at least a minimum of 16 contact hours. At least eight of the 16 required contact hours shall be taught using interactive/participatory teaching methods, which includes a minimum of eight hours hands-on training.

(a) Classroom instruction shall include, but not be limited to:

(A) Role and responsibilities of an abatement worker.

(B) One contact hour of background information on lead, including but not limited to, identification of environmental lead sources such as surface dust, soil, water, air and food; history of uses and locations of lead and leaded paint in buildings; lead dust and paint characteristics; and summary of abatement control options.

(C) One contact hour of adverse health effects of lead exposure, including but not limited to, nature of lead related diseases; pathways of exposure and how exposure occurs; dose-response relationships; permissible exposure limit; blood lead levels in children and adults; effects on various body systems; different effects on children and adults including women and the fetus during pregnancy; symptoms and diagnosis of poisoning and reportable blood lead levels; how lead in the body is absorbed, distributed and eliminated; medical treatment for lead poisoning including but not limited to chelation therapy.

(D) One contact hour on regulatory review and background information of relevant federal, state, and local regulations including guidance that pertains to lead-based paint and lead-based paint activities.

(E) Identification and prevention of hazards encountered during lead-based paint activities including potential lead hazard exposure; prevention of lead dust contamination; emergency procedures for sudden releases and electrical, heat stress, fire, explosion and other hazards, chemical air contaminants, and disturbance of friable asbestos.

(F) At least six contact hours on lead-based paint abatement work practice standard tasks including, but not limited to:

(i) Interior and exterior leaded paint, soil and dust abatement methods, including chemical, enclosure, hand, mechanical, blasting, encapsulation, and management in place, and clean-up techniques, including high efficiency particulate air (HEPA) vacuums and negative air machines, as described in HUD's " Guidelines for the Evaluation and Control of Lead-based Paint Hazards in Housing."

(ii) Construction and maintenance of containment barriers.

(iii) Warning signs and their placement.

(iv) Electrical and ventilation system lockout and hazardous and non-hazardous waste characterization and disposal.

(G) Record keeping.

(H) At least two contact hours on lead-based paint respiratory protection and personal protective training that conforms with OAR 437-003-0001(4)(m).

(I) Personal hygiene, including entry and exit procedures for the work area, use of showers, avoidance of eating, drinking, smoking, chewing, and applying cosmetics in the work or changing area, avoidance of take-home exposures.

(J) Medical monitoring requirements discussion that shall include, but not be limited to, the need for medical monitoring of lead toxicity; the disclosure of lead-related medical history; and the treatment of lead poisoning cases, including issues of medical removal and of selecting medical services.

(K) Hazard communication with property owner, occupants and neighbors relative to the reduction or elimination of lead sources at the job site.

(b) Hands-on training shall include performance of tasks including but not limited to:

(A) Lead-based paint hazard recognition and control;

(B) Lead-based paint abatement and lead-based paint hazard reduction methods, including restricted practices;

(C) Interior dust abatement/clean-up methods or lead hazard reduction;

(D) Soil & exterior dust abatement methods or lead hazard reduction;

(E) Waste disposal.

(6) OR-OSHA respiratory protection and personal protective equipment training is required under these rules. Other OR-OSHA lead-based paint requirements may be included in the training, but are not required by the Authority.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 19-1997, f. & cert. ef. 12-12-97; PH 4-2011, f. & cert. ef. 6-16-11

333-068-0045
Minimum Requirements for Accreditation of Refresher Training Course

(1) Refresher training shall only be provided by an accredited training program for the same course discipline.

(2) Refresher training course shall consist of at least seven contact hours of training except for the project designer refresher course which shall consist of at least four contact hours of training.

(3) Each refresher training course shall review the curriculum topics of the respective accredited or provisionally accredited lead-based paint training course and include, but not be limited to:

(a) An overview of current lead-based paint safety practices in general, as well as, specific safety practices for the refresher discipline.

(b) An update on current federal, state, and local lead-based paint laws and regulations in general, as well as, specific laws and regulations applicable to the discipline.

(c) An update on current technologies relating to lead-based paint activities in general, as well as, specific information pertaining to the discipline.

(4) Each student shall be required to pass a course test and a hands-on assessment (if applicable) covering course topics and

upon passing the student shall be provided with a course completion certificate.

(5) The training program shall conduct a hands-on assessment, if applicable, and a course completion test for each course offered.

(6) At least 40 percent of refresher education instruction shall be taught using interactive/participatory teaching methods, except for refresher education instruction for lead abatement workers, which shall be taught using at least 50 percent interactive/participatory teaching methods.

(7) A training program seeking accreditation of a refresher course shall submit a written application including:

(a) Name, address, and telephone number;

(b) List of course(s) for which accreditation application is being made;

(c) A copy of student manuals and instructor manuals to be used for each course;

(d) A copy of the course agenda for each course;

(e) Also include with the application for accreditation documentation that complies with OAR 333-068-0030(1) through (4).

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 19-1997, f. & cert. ef. 12-12-97; PH 4-2011, f. & cert. ef. 6-16-11

333-068-0050
Renewal of Training Program

(1) If a training program meets the regulations for accreditation the program shall be reaccredited. A training program accreditation shall expire one year from date of reaccreditation and shall not be transferable.

(2) A training program seeking reaccreditation shall submit an application to the Authority no later than 60 days before its accreditation expires. If a training program does not submit its application for reaccreditation by that date, the Authority cannot guarantee that the program will be reaccredited before the end of the accreditation period.

(3) The application shall contain:

(a) The training program's name, address, and telephone number;

(b) List of courses for which it is applying for reaccreditation;

(c) Description of any changes or updates to the training facility or equipment; and

(d) The certified statement as described in OAR 333-069-0050(4) below.

(4) The training program's application for reaccreditation shall contain a statement signed by the training program manager certifying that:

(a) The course materials, for each course, meet the minimum training curricula requirements, as appropriate;

(b) The training manager, principal instructors, and guest instructors meet the qualifications in OAR 333-068-0030(1) through 333-068-0030(4);

(c) The training program manager complies at all times with all requirements in OAR 333-068-0030;

(d) The quality control program meets the requirements in OAR 333-068-0025(h); and

(e) The record keeping and reporting requirements of OAR 333-068-0060 shall be followed.

(5) An audit may be performed by the Authority to verify the certified statement and the contents of the application.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 19-1997, f. & cert. ef. 12-12-97; PH 4-2011, f. & cert. ef. 6-16-11

333-068-0055
Suspensions, Revocation and Modification of Accredited Training Course Curriculum

(1) After notice and a hearing, the Authority may suspend, revoke, or modify a training program's accreditation if a training program, training manager, or other person with supervisory authority over the program has:

(a) Misrepresented the contents of the training course to the Authority and/or student population;

(b) Failed to submit required notifications in a timely manner;

(c) Failed to maintain required records;

(d) Falsified accreditation records, instructor qualifications, or other accreditation information;

(e) Failed to comply with the training standards and requirements for accreditation of training programs or to deliver the course according to the content and format described in the training program's application for accreditation and granted provisional approval by the Authority.

(f) Failed to comply with federal, state or local lead-based paint statutes or regulations.

(2) In addition to an administrative or judicial finding of violation, execution of a consent agreement in settlement of an enforcement action constitutes evidence of a failure to comply with relevant statutes or regulations.

(3) Training programs shall permit representatives of the Authority to attend any training course for the purpose of evaluation or monitoring of the course without charge.

(4) Prior to suspending, revoking, or modifying an accreditation of a training program the program shall be notified in writing of procedures in accordance with ORS 183.310 to 183.540.

(5) A training program, for whom the Authority has suspended or revoked a training course, must initiate a new application process with the Authority for re-instatement of the training program and may do so after 45 days following the date of the suspension or revocation.

(6) The Authority shall maintain a list, available to the public, of parties whose accreditation has been suspended, revoked, or modified.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 19-1997, f. & cert. ef. 12-12-97; PH 4-2011, f. & cert. ef. 6-16-11

333-068-0060
Training Course Record-Keeping

(1) Accredited training programs shall maintain, and make available to the Authority if requested, the following records:

(a) All documents specified in OAR 333-068-0030 that demonstrate the qualifications listed in OAR 333-068-0030(2), (3), and (4) for training manager, principal instructors, and work practice instructors;

(b) Current curriculum, course materials and documents reflecting any changes made to these materials;

(c) Course test blueprint;

(d) Information on how hands-on assessment is conducted including, but not limited to, who conducts the assessment, how skills are graded, what facilities are used, and the pass/fail rate;

(e) The quality control plan;

(f) Results of student's hands-on skills assessments and course tests and a copy of each student's course completion certificate; and

(g) Any other material submitted as part of the program's application for accreditation.

(2) All training course records shall be retained a minimum of seven years at the location specified on the training course accreditation application.

(3) The Authority shall be notified 30 days prior to any change in the training program's current application.

(4) Accredited or provisionally accredited training programs shall provide the Authority with a course roster of persons who have successfully completed the training course within 30 days of course completion.

(5) Accredited or provisionally accredited training programs shall notify the Authority with the location and dates of each course a minimum of 30 days prior to course starting date.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 19-1997, f. & cert. ef. 12-12-97; PH 4-2011, f. & cert. ef. 6-16-11

333-068-0065
Fees

The following fees are established:

(1) A non-refundable application fee of $750 for accreditation of a standard lead-based paint inspector or supervisor training

course and $500 for accreditation of a standard lead-based paint risk assessor or worker training course; a non-refundable application fee of $600 for a refresher lead-based paint activities training course covering more than two disciplines; and a non-refundable application fee of $500 for an inspector or supervisor refresher training course; and $350 for a risk assessor or a worker refresher training course.

(2) A non-refundable annual reaccreditation application fee of $300 for any initial standard lead-based paint activities training course for each discipline; a non-refundable annual reaccreditation application fee of $200 for a refresher training course covering more than two disciplines; and a non-refundable annual renewal application fee of $100 for a refresher training course covering up to two disciplines.

(3) For initial accreditation application, the following non-refundable fees shall apply for each standard training or refresher training course: Training manager: $175; Each additional instructor or guest instructor: $90.

(4) For annual reaccreditation application, the following non-refundable fees shall apply for each standard training or refresher training course: Training manager: $100; Each additional instructor or guest instructor: $50.

(5) Applicants for accreditation shall pay no more than the maximum single training manager fee for each training manager. An additional instructor or guest instructor fee shall be paid for every training course that is taught by the training manager.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 19-1997, f. & cert. ef. 12-12-97; OHD 1-1999, f. & cert. ef. 1-19-99; PH 4-2011, f. & cert. ef. 6-16-11

DIVISION 69

CERTIFICATION OF INDIVIDUALS AND FIRMS ENGAGED IN LEAD-BASED PAINT ACTIVITIES

333-069-0005
Authority, Purpose, Scope

(1) Authority. These rules are promulgated in accordance with and under the authority of ORS 431.920.

(2) Purpose:

(a) The purpose of these rules is to address Oregon's need for a qualified and properly trained workforce to perform inspection, risk assessment and removal of hazards associated with lead-based paint, to safeguard the environment and protect human health, and the health of building occupants, especially for high-risk groups (children under six years of age), from lead-based paint hazards.

(b) These rules prescribe the requirements for certification of individuals and firms engaged in lead-based paint activities in target housing and child-occupied facilities.

(c) These rules will establish work practice standards for the performance of lead-based paint inspection, risk assessment, and abatement activities for individuals and firms and will require that all lead-based paint activities be performed only by certified individuals and firms.

(3) Scope:

(a) These rules apply to all individuals and firms who are engaged in lead-based paint activities for compensation or where a child residing in the building has been identified as having an elevated blood lead level.

(b) These rules establish the requirement that lead-based paint activities be performed only by certified individuals and firms.

(c) These rules prescribe the requirements for, and the manner of, certifying competency of applicants for certification of lead-based paint inspector, risk assessor, supervisor, project designer, and worker, and of firms employing such individuals.

(d) These rules prescribe work practice standards for the removal or mitigation of lead-based paint hazards and for the performance of lead-based paint inspection and risk assessment, and those actions or circumstances that constitute failure to achieve or maintain competency, or that otherwise are contrary to the public interest, for which the Authority may assess civil penalties, deny, suspend, or revoke certification.

(e) These rules establish fees to the extent necessary to defray costs of those activities prescribed herein.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 5-1996(Temp), f. & cert. ef. 9-30-96; HD 6-1997, f. 4-25-97, cert. ef. 5-1-97; OHD 12-1998, f. & cert. ef. 10-27-98; PH 8-2003, f. & cert. ef. 6-20-03; PH 22-2010(Temp), f. & cert. ef. 9-24-10 thru 3-22-11; Administrative correction 4-25-11; PH 4-2011, f. & cert. ef. 6-16-11

333-069-0010
Adoption by Reference

All standards, listings and publications referred to in these rules are by those references made a part of these rules as though fully set forth.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 5-1996(Temp), f. & cert. ef. 9-30-96; HD 6-1997, f. 4-25-97, cert. ef. 5-1-97; OHD 12-1998, f. & cert. ef. 10-27-98

333-069-0015
Definitions

As used in these rules unless otherwise required by context:

(1) "Abatement" means any measure or set of measures designed to permanently eliminate lead-based paint hazards including, but not limited to:

(a) The removal of paint and dust, the permanent enclosure or encapsulation of lead-based paint, the replacement of painted surfaces or fixtures, or the removal or covering of soil, when lead-based paint hazards are present in such paint, dust or soil; and

(b) All preparation, cleanup, disposal, and post-abatement clearance examination activities associated with such measures,

(c) Specifically, abatement includes, but is not limited to:

(A) Projects for which there is a written contract or other documentation, which provides that an individual or firm will be conducting activities in or to a residential dwelling or child-occupied facility that results in permanent elimination of lead-based paint hazards or designed to permanently eliminate lead-based paint hazards and described in subsections (1)(a) and (1)(b) above.

(B) Projects resulting in the permanent elimination of lead-based paint hazards, conducted by certified and licensed firms or individuals, unless such projects are covered under subsection (1)(d) of this definition.

(C) Projects resulting in the permanent elimination of lead-based paint hazards, conducted by certified firms or individuals who, through their company name or promotional literature, represent, advertise, or hold themselves out to be in the business of performing lead-based paint activities, unless such projects are covered under subsection (1)(d) of this section.

(D) Projects resulting in the permanent elimination of lead-based paint hazards that are conducted in response to state or local abatement orders.

(d) Abatement does not include renovation, remodeling, landscaping or other activities, when such activities are not designed to permanently eliminate lead-based paint hazards, but, instead, are designed to repair, restore, or remodel a given structure or dwelling, even though these activities may incidentally result in a reduction or elimination of lead-based paint hazards. Furthermore, abatement does not include interim controls, operations and maintenance activities, or other measures and activities designed to temporarily, but not permanently, reduce lead-based paint hazards.

(2) "Accredited training program" means a training program accredited or provisionally accredited by the Authority, the Environmental Protection Agency (EPA), or an EPA-authorized state or tribal program, to provide training for individuals engaged in lead-based paint activities.

(3) "Arithmetic mean" means the algebraic sum of data values divided by the number of data values (e.g., the sum of the concentration of lead in several soil samples divided by the number of samples).

(4) "Authority" means the Oregon Health Authority.

(5) "Certified" means successful completion of a training program accredited by the Authority, passage of a certification examination administered by the Authority and satisfaction of any other requirements for the appropriate discipline, and submittal and approval of the appropriate application by the Authority for inspection, risk assessment or abatement activities in target housing and child-occupied facilities.

(6) "Certified firm" means a company, partnership, corporation, sole proprietorship, association, or other entity that performs lead-based paint activities to which the Authority has issued a certificate under these rules.

(7) "Chewable surface" means an interior or exterior surface painted with lead-based paint that a young child can mouth or chew. A chewable surface is the same as an accessible surface. Hard metal substrates and other materials that cannot be dented by the bite of a young child are not considered chewable.

(8) "Child-occupied facility" means a building, or a portion of a building, constructed prior to 1978, visited regularly by the same child, under six years of age, on at least two different days within any week (Sunday through Saturday period), provided that each day's visit lasts at least three hours and the combined weekly visit lasts at least six hours, and the combined annual visits last at least 60 hours. Child-occupied facilities may include, but are not limited to, day-care centers, preschools and kindergarten classrooms.

(9) "Clearance examination" means visual examination and clearance testing performed following abatement of lead-based paint or lead-based paint hazards using documented methodologies as defined in this rule. Such examination shall be performed by a person certified to perform risk assessments or lead-based paint inspections.

(10) "Clearance examination standards" means values that indicate the maximum amount of lead permitted in dust on a surface or in soil following completion of an abatement activity. Standards for lead in dust are 40 micrograms per square foot ($\mu g/ft^2$) on floors, 250 $\mu g/ft^2$ on interior window sills, and 400 $\mu g/ft^2$ on window troughs. The values for lead in soil are 400 parts per million (ppm) in play areas and 1,200 ppm in the remainder of the yard.

(11) "Common area" means a portion of a building that is generally accessible to all occupants that may include, but that is not limited to, hallways, stairways, laundry and recreational rooms, playgrounds, community centers, garages, and boundary fences.

(12) "Common area group" means a group of common areas that are similar in design, construction, and function. Common area groups include, but are not limited to hallways, stairwells, and laundry rooms.

(13) "Component" means an architectural element of a dwelling unit or common area identified by type and location, such as a bedroom wall, an exterior window sill, a baseboard in a living room, a kitchen floor, an interior window sill in a bathroom, a porch floor, stair treads in a common stairwell, or an exterior wall.

(14) "Concentration" means the relative content of a specific substance contained within a larger mass, such as the amount of lead (in micrograms per gram or parts per million by weight) in a sample of dust or soil.

(15) "Contact hour" means 60 minutes of lead-based paint related training, which may include a break of not more than 10 minutes.

(16) "Containment" means a process or arrangement of materials to protect workers and the environment by controlling exposure to the lead-contaminated dust and debris created during an abatement.

(17) "Course completion date" means the final date of classroom instruction and/or student examination of an accredited lead-based paint training course.

(18) "Course completion certificate" means documentation issued by an accredited training program to an individual as proof of successful completion of an Authority-accredited lead-based paint training course.

(19) "Critical barrier" means a containment structure that allows for the passage of persons or materials.

(20) "Demonstration testing" means the observation and scoring of a student's job task and equipment use skills taught during a course or continuing education instruction.

(21) "Deteriorated paint" means any interior or exterior paint or other coating that is peeling, chipping, chalking or cracking, or any paint or coating located on an interior or exterior surface or fixture that is otherwise damaged or separated from the substrate.

(22) "Discipline" means a specific type or category of lead-based paint activity.

(23) "Distinct painting history" means the application history, as indicated by the visual appearance or a record of application, over time, of paint or other surface coatings to a component or room.

(24) "Documented methodologies" are written methods or protocols used to sample for the presence of lead in paint, dust, and soil as recommended in U.S. Department of Housing and Urban Development (HUD) "Guidelines for the Evaluation and Control of Lead-Based Paint Hazards in Housing", and "EPA's Residential Sampling for Lead: Protocols for Dust and Soil Sampling".

(25) "Dripline" means the area within three feet surrounding the perimeter of a building.

(26) "Dust-lead hazard" means surface dust in a residential dwelling or child-occupied facility that contains a mass-per-area concentration of lead equal to or exceeding 40 $\mu g/ft^2$ on floors, 250 $\mu g/ft^2$ on interior window sills, or 400 $\mu g/ft^2$ based on wipe samples.

(27) "Emergency" means a situation in which failure to act promptly would likely result in immediate harm to persons or property.

(28) "Emergency lead-based paint abatement activities" means activities required in response to an elevated blood lead level determination, or federal, state, tribal or local emergency abatement order, or operations necessitated by non-routine failures of equipment, that were not planned but result from a sudden, unexpected event that, if not immediately attended to, presents a safety or public health hazard, or threatens equipment and/or property with significant damage.

(29) "Firm" means a sole proprietorship, corporation, association, partnership, or joint stock company.

(30) "Friction surface" means an interior or exterior surface that is subject to abrasion or friction, including, but not limited to, certain window, floor, and stair surfaces.

(31) "Hands-on training" means training during which students practice skills that they will be expected to perform at the worksite.

(32) "Impact surface" means an interior or exterior surface that is subject to damage by repeated sudden force such as certain parts of door frames.

(33) "Inspection" means a surface-by-surface investigation to determine the presence of lead-based paint and the provision of a report, in writing, explaining the results of the investigation.

(34) "Inspector" means an individual who is certified by the Authority and licensed by the Construction Contractors Board (CCB), except where exempt by these rules, to conduct in target housing and child-occupied facilities a surface-by-surface investigation to determine the presence of lead-based paint and the provision of a report, in writing; and conduct clearance procedures in accordance with OAR 333-069-0070. An inspector may also collect dust and soil samples and perform clearance examinations. An inspector may cite the applicable standard for the medium being sampled, but may not evaluate the results or assess risk.

(35) "Interior window sill" means the portion of the horizontal window ledge that protrudes into the interior of the room.

(36) "Job tasks" mean the specific activities performed in the context of work.

(37) "Lead-based paint" means paint or other surface coatings that contain lead equal to or in excess of 1.0 milligram per square centimeter or 0.5 percent by weight.

(38) "Lead-based paint activities" means, in the case of target housing and child-occupied facilities, inspection, risk-assessment, and abatement.

(39) "Lead-based paint hazard" means any condition that causes exposure to lead from lead-contaminated dust, lead-contaminated soil, lead-contaminated paint that is deteriorated or present in accessible surfaces, friction surfaces or impact surfaces that would result in adverse human health effects.

(40) "Lead hazard standard" means the amount of lead the Authority considers to be a hazard in target housing or child-occupied facilities. The standards for lead in dust are 40 micrograms per square foot ($\mu g/ft^2$) on floors, 250 $\mu g/ft^2$ on interior window sills, and 400 $\mu g/ft^2$ on window troughs. The standards for lead in soil are 400 parts per million (ppm) in play areas and 1,200 ppm in the remainder of the yard.

(41) "Licensed" means a person or firm who has been certified by the Authority in one or more disciplines and is licensed by the CCB.

(42) "Loading" means the quantity of specific substance present per unit of surface area, such as the amount of lead in micrograms contained in the dust collected from a certain surface area divided by the surface area in square feet or square meters.

(43) "Multi-family housing" means a housing property consisting of more than four dwelling units.

(44) "Notice of noncompliance" is a description, in writing, of activities conducted in violation of these rules observed or documented by the Authority, and of requirements for corrective action.

(45) "Paint in poor condition" means more than 10 square feet of deteriorated paint on exterior components with large surface areas; or more than two square feet of deteriorated paint on interior components with large surface areas (e.g., walls, ceilings, floors, doors); or more than 10 percent of the total surface area of the component is deteriorated on interior or exterior components with small surface areas (window sills, baseboards, soffits, trim).

(46) "Paint-lead hazard" means any of the following:

(a) Any lead-based paint on a friction surface that is subject to abrasion and where the lead dust levels on the nearest horizontal surface underneath the friction surface (e.g., the window sill, or floor) are equal to or greater than the dust-lead hazard levels identified in these rules.

(b) Any damaged or otherwise deteriorated lead-based paint on an impact surface that is caused by impact from a related building component (such as a door knob that knocks into a wall or a door that knocks against its door frame).

(c) Any chewable lead-based painted surface on which there is evidence of teeth marks.

(d) Any other deteriorated lead-based paint in any residential building or child-occupied facility or on the exterior of any residential building or child-occupied facility.

(47) "Permit" means a written authorization obtained from the Authority without which a painter may not remove or stabilize paint on target housing or pre-1978 child-occupied facilities.

(48) "Permanent" means having an expected design life of 20 years.

(49) "Permanently covered soil" means soil which has been separated from human contact by the placement of a barrier consisting of solid, relatively impermeable materials, such as pavement or concrete. Grass, mulch, and other landscaping materials are not considered permanent covering.

(50) "Person" means an individual.

(51) "Play area" means an area of frequent soil contact by children under six years of age as indicated by, but not limited to, such factors including the following: the presence of play equipment (e.g., sandboxes, swing sets, and sliding boards), toys, or other children's possessions, observations of play patterns, or information provided by parents, residents, care givers, or property owners.

(52) "Preliminary clearance" means clearance of interior living areas according to which an inspector or risk assessor determines that residual lead levels (as determined by laboratory analysis) do not exceed clearance examination standards.

(53) "Project designer" means an individual who is certified by the Authority and licensed by the CCB to interpret lead inspection or risk assessment reports and to develop plans, specifications, and project procedures for lead abatement projects in target housing and child-occupied facilities, including occupant notification and protection, clean-up and clearance, and abatement reports.

(54) "Public agency" means an entity that functions as part of a governmental body or organization at the local, state, or federal level.

(55) "Refresher training course" means a minimum seven hour training program accredited by the Authority to update an individual's knowledge and skills so that he/she can effectively and safely continue to practice in the field.

(56) "Residential building" means a building containing one or more residential dwellings.

(57) "Residential dwelling" means:

(a) A detached single family dwelling unit, including attached structures such as porches and stoops; or

(b) A single family dwelling unit in a structure that contains more than one separate residential dwelling unit, which is used or occupied, or intended to be occupied, in whole or in part, as the home or residence of one or more persons.

(58) "Risk assessment" means an on-site investigation to determine the existence, nature, severity, and location of lead-based paint hazards, and the provision of a report by the individual or the firm conducting the risk assessment, explaining the results of the investigation and options for reducing lead-based paint hazards.

(59) "Risk assessor" means an individual who is certified by the Authority and licensed by the CCB, unless where exempt by the rules, to conduct in target housing and child-occupied facilities on-site investigation to determine the existence, nature, severity, and location of lead-based paint hazards, and to provide a report explaining the results of the investigation and options for reducing lead-based paint hazards; and who may conduct a lead-hazard screen, in accordance with OAR 333-069-0070.

(60) "Room" means a separate part of the inside of a building, such as a bedroom, living room, dining room, kitchen, bathroom, laundry room, or utility room. To be considered a separate room, the room must be separated from adjoining rooms by built-in walls or archways that extend at least six inches from an intersecting wall. Half walls or bookcases count as room separators if built-in. Movable or collapsible partitions or partitions consisting solely of shelves or cabinets are not considered built-in walls. A screened in porch that is used as a living area is a room.

(61) "Sample quality control" means a plan or design which ensures the authenticity, integrity, and accuracy of samples, including dust, soil, and paint chip or film samples. Sample quality control also includes provisions for representative sampling and control samples.

(62) "Scope of work" means a written description of all of the abatement activities to be conducted at a specific abatement project site.

(63) "Soil-lead hazard" means bare soil on residential real property or on the property of a child-occupied facility that contains total lead equal to or exceeding 400 ppm in a play area or average of 1,200 ppm of bare soil in the remainder of the yard based on soil samples.

(64) "Soil sample" means a sample collected in a representative location using American Society for Testing Materials (ASTM) E1727, ''Standard Practice for Field Collection of Soil Samples for Lead Determination by Atomic Spectrometry Techniques,'' or equivalent method.

(65) "Supervisor" means an individual who is certified by the Authority and licensed by the CCB to either conduct or oversee and direct the work-site conduct of lead-based paint abatement and clearance activities in target housing and child-occupied facilities, and to prepare occupant protection plans and abatement reports in accordance with OAR 333-069-0070.

(66) "Target housing" means any housing constructed prior to 1978, except housing for the elderly or persons with disabilities (unless any one or more children under six years of age resides or is expected to reside in such housing for the elderly or persons with disabilities) or any zero-bedroom dwelling.

(67) "These rules" means OAR 333-069-0005 through 333-069-0090.

(68) "Weighted arithmetic mean" means the arithmetic mean of sample results weighted by the number of subsamples in each sample. Its purpose is to give influence to a sample relative to the surface area it represents. A single surface sample is comprised of a single subsample. A composite sample may contain from two to four subsamples of the same area as each other and of each single surface sample in the composite. The weighted arithmetic mean is obtained by summing, for all samples, the product of the sample's result multiplied by the number of subsamples in the sample, and dividing the sum by the total number of subsamples contained in all samples. For example the weighted arithmetic mean of a single surface sample containing 60 $\mu g/ft^2$, a composite sample (three subsamples) containing 100 $\mu g/ft^2$, and a composite sample (4 subsamples) containing 110 mg/ft^2 is 100 $\mu g/ft^2$. This result is based on the equation [60+(3*100) + (4*110)]/(1+3+4).

(69) "Window trough" means for a typical double-hung window, the portion of the exterior window sill between the interior window sill (or stool) and the frame of the storm window. If there is no storm window, the window trough is the area that receives both the upper and lower window sashes when they are both lowered. The window trough is sometimes referred to as the window ''well''.

(70) "Wipe sample" means a sample collected by wiping a representative surface of known area, as determined by ASTM E 1728, ''Standard Practice for Field Collection of Settled Dust Samples Using Wipe Sampling Methods for Lead Determination by Atomic Spectrometry Techniques, or equivalent method, with an acceptable wipe material as defined in ASTM E 1792, ''Standard Specification for Wipe Sampling Materials for Lead in Surface Dust.''

(71) "Worker" means an individual who is certified by the Authority and licensed by the CCB to conduct lead-based paint abatement activities in target housing and child-occupied facilities in accordance with OAR 333-069-0070.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 5-1996(Temp), f. & cert. ef. 9-30-96; HD 6-1997, f. 4-25-97, cert. ef. 5-1-97; OHD 12-1998, f. & cert. ef. 10-27-98; OHD 11-2000, f. & cert. ef. 12-8-00; OHD 4-2001(Temp) f. & cert. ef. 4-10-01 thru 10-5-01; OHD 25-2001, f. & cert. ef. 11-15-01; PH 8-2003, f. & cert. ef. 6-20-03; PH 22-2010(Temp), f. & cert. ef. 9-24-10 thru 3-22-11; Administrative correction 4-25-11; PH 4-2011, f. & cert. ef. 6-16-11

333-069-0020
Certification Required

(1) No person, firm, or public agency shall offer to perform or perform lead-based paint inspection, risk assessment, or abatement activities in target housing or child-occupied facilities without first receiving certification from the Authority and a license from the CCB, except if such a person, firm, or public agency is exempt from CCB licensing requirements.

(2) All certificates to perform lead-based paint activities shall expire on June 30, and are renewable upon meeting all of the requirements as determined by the Authority.

(3) Certified persons or firms conducting lead-based paint activities shall comply with the work practice standards for performing lead-based paint activities as prescribed in these rules. Painters shall follow the work practices described on the Permit application.

(4) It shall be considered a violation of these rules and the CCB regulations for any person to conduct any of the lead-based paint activities described in these rules unless the individual has received certification from the Authority and licensure from the CCB, except if such a person, is exempt from CCB licensing requirements.

(5) Applicants for inspector, risk assessor, project designer and supervisor shall pass with a score of 70 or more on a certification examination administered by the Authority for each discipline for which certification is desired.

(6) Individuals may take the certification examination no more than three times within six months of the course completion date of the accredited lead-based paint training course.

(7) If an individual applicant does not complete all certification requirements (including passing the certification examination for required disciplines) within six months of the course completion date of the accredited lead-based paint training course, the individual shall successfully complete the appropriate accredited standard or refresher training course before reapplying for certification.

(8) A certificate for an individual will be issued by the Authority in the form of an identification card and a numbered certificate. This card will identify each discipline for which a person is certified and must be available on demand for inspection at all times while conducting inspection, risk assessment, or abatement activities.

(9) A numbered certificate for a certified firm will be issued by the Authority.

(10) A public agency whose employees perform 'in house' lead-based paint services need not be a certified firm, but shall furnish the Authority with a letter of compliance certifying the following:

(a) The agency will use only certified individuals of the appropriate discipline to conduct lead-based paint activities as described in these rules;

(b) The agency will follow the standards for conducting lead-based paint activities as prescribed in these rules; and

(c) The agency will maintain records of all such activities per these rules.

(d) The letter of compliance will be signed by an individual authorized to sign on the agency's behalf.

(e) Any public agency determined by the Authority to be in violation of this exemption shall be subject to the certification requirements of a non-exempt firm.

(11) A firm or public agency that contracts with a certified firm or public agency to provide lead-based paint activities on its behalf need not be certified.

(a) The contracting firm or public agency shall submit to the Authority a letter of compliance stating the following:

(A) The firm or agency will use only certified firms and certified individuals of the appropriate discipline to conduct lead-based paint activities as described in these rules;

(B) The firm or agency will ensure that the standards for conducting lead-based paint activities as prescribed in these rules will be followed; and

(C) The firm or agency will maintain records of all such activities per these rules.

(D) The letter of compliance will be signed by an individual authorized to sign on the firm or the agency's behalf.

(b) The contracting firm shall submit to the Authority, upon request, a copy of the contract agreement between the contracting firm and the certified firm or firms.

(12) Employees or agents of regulatory agencies are exempt from these rules if:

(a) Those employees or agents are acting in a regulatory capacity;

(b) They are carrying out activities within the scope of the agency's regulatory authority; and

(c) They have been trained in a manner consistent with the public and environmental health objectives of these rules.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 5-1996(Temp), f. & cert. ef. 9-30-96; HD 6-1997, f. 4-25-97, cert. ef. 5-1-97; OHD 12-1998, f. & cert. ef. 10-27-98; PH 8-2003, f. & cert. ef. 6-20-03; PH 22-2010(Temp), f. & cert. ef. 9-24-10 thru 3-22-11; Administrative correction 4-25-11; PH 4-2011, f. & cert. ef. 6-16-11

333-069-0030
Eligibility

(1) Inspector. To qualify, an individual shall complete all elements on the application form and meet the following eligibility requirements:

(a) Successfully complete and receive a course completion certificate from an Authority accredited training program as an inspector;

(b) Pass the certification examination administered by the Authority for an inspector.

(2) Risk assessor. To qualify, an individual shall complete all elements on the application form and meet the following minimum eligibility requirements:

(a) Successfully complete and receive a course completion certificate from an Authority accredited training program as a risk assessor and inspector;

(b) Pass the certification exam administered by the Authority for a risk assessor;

(c) Have completed one of the following education and applicable experience criteria:

(A) Certification as an industrial hygienist, an engineer, a registered architect, certified safety professional, registered sanitarian, or registered environmental health specialist; or

(B) A bachelor's degree and one year of experience in a related field (e.g. lead, asbestos, environmental remediation work, or construction); or an associates degree and two years experience in a related field (e.g., lead, asbestos, environmental remediation work, or construction); or

(C) A high school diploma (or equivalent), plus at least three years of experience in a related field (e.g. lead, asbestos, environmental remediation work, or construction).

(3) Supervisor. To qualify, an individual shall complete all elements on the application form and meet the following minimum eligibility requirements:

(a) Successfully complete and receive a course completion certificate from an Authority accredited training program as a lead abatement supervisor;

(b) Pass the certification exam administered by the Authority for a supervisor;

(c) Have completed one of the following experience requirements:

(A) One year of experience as a certified lead-based paint abatement worker; or

(B) At least two years of experience in a related field (e.g. lead, asbestos, or environmental remediation work) or in the building trades.

(4) Abatement worker. To qualify, an individual shall complete all elements on the application form and successfully complete and receive a course completion certificate from an Authority accredited training program as a lead abatement worker.

(5) Project designer. To qualify, an individual shall comply with all application requirements and meet the following minimum eligibility requirements:

(a) Successfully complete and receive a course completion certificate from an Authority accredited training program as a lead abatement supervisor and project designer;

(b) Have completed one of the following education and applicable experience criteria:

(A) Bachelor's degree in engineering, architecture, or a related profession, and one year of experience in building construction and design or a related field; or

(B) Four years of experience in building construction and design or a related field; and

(C) Pass the certification examination administered by the Authority for a project designer.

(6) Applicants for certification may complete a refresher course in the same discipline in satisfaction of the training requirement if no more than one year has passed since the original course was completed and the original course was accredited by the Authority, EPA, or an EPA-authorized state or tribal program.

(7) The Authority may certify an individual who has been certified as an inspector, risk assessor, supervisor, project designer, or abatement worker by the EPA or an EPA-authorized state or tribal program upon receiving evidence that the individual has:

(a) Completed and received a course completion certificate from an accredited training course specific to the position for which the individual has applied and the course is accredited by the EPA or by a state or tribal program authorized by the EPA under 40 CFR 745.234;

(b) Met or exceeded all other eligibility requirements specified in OAR 333-069-0030 specific to the position applied for;

(c) Met all application requirements in OAR 333-069-0040; and

(d) Completed any additional requirements established by the Authority.

(8) Applicants for certification based on certification from another state or tribal program must document to the Authority that they have read and understand the certification and work practice standards as described in these rules.

(9) Certification based on a valid lead-based paint certification issued by the EPA or an EPA-authorized state or tribal program shall be issued with an expiration date not to exceed the date of expiration listed on the certification.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 5-1996(Temp), f. & cert. ef. 9-30-96; HD 6-1997, f. 4-25-97, cert. ef. 5-1-97; OHD 12-1998, f. & cert. ef. 10-27-98; PH 8-2003, f. & cert. ef. 6-20-03; PH 4-2011, f. & cert. ef. 6-16-11

333-069-0040
Application Requirements

(1) No person, firm or public agency shall conduct lead-based paint activities in or on target housing or child-occupied facilities without first applying to the Authority for and receiving certification to conduct such activities.

(2) Applications for certification or permit shall be accompanied with a check or money order made out to the 'Oregon Health Authority' in the amount as described in OAR 333-069-0090.

(3) Applications for a person shall be submitted on forms prescribed by the Authority and shall be accompanied, as appropriate, by:

(a) Documentation of applicant's training, experience, and education including:

(A) Lead-based paint training course completion certificate issued by an Authority-accredited training program.

(B) Documentation of experience must include name and address of employer, name and telephone number of supervisor; or indicate if self-employed. Documentation must also include employment dates, description of specific duties performed, estimated percentage of time associated with conducting inspections and assessing health, safety or environmental hazards. This documentation must be signed by supervisor or employer verifying, under penalty of perjury, that the information is true and correct. A self-employed individual must submit a notarized affidavit attesting to the work experience claimed for the purposes of application.

(C) Evidence of completion of educational requirements under OAR 333-069-0030, such as a transcript or diploma, if applicable.

(b) Two current, passport size photos.

(c) Applicant's name, printed or typed, date, and signature, verifying, under penalty of perjury, that all information submitted is true and correct.

(4) Applications for a certification or permit shall be submitted on forms prescribed by the Authority. Application materials can be obtained from the Authority's website.

(5) Applications for certification of a firm shall be accompanied by a letter of compliance certifying the following:

(a) The firm will employ only certified employees of the appropriate discipline to conduct lead-based paint activities as prescribed in these rules.

(b) The firm will follow the standards for conducting lead-based paint activities as prescribed in these rules.

(c) The firm shall maintain all records pursuant to these rules.

(d) The letter of compliance shall be signed by an officer of the firm, or an individual authorized to sign on the firm's behalf.

(6) Certified individuals, firms and permit holders shall notify the Authority within 30 calendar days of any change to the current application.

(7) For the purposes of application, photocopies of original documents are acceptable.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 5-1996(Temp), f. & cert. ef. 9-30-96; HD 6-1997, f. 4-25-97, cert. ef. 5-1-97; Administrative correction 8-25-97; OHD 12-1998, f. & cert. ef. 10-27-98; PH 8-2003, f. & cert. ef. 6-20-03; PH 22-2010(Temp), f. & cert. ef. 9-24-10 thru 3-22-11; Administrative correction 4-25-11; PH 4-2011, f. & cert. ef. 6-16-11

333-069-0050
Renewal and Recertification

(1) To maintain a permit or certification in a particular discipline, application for recertification shall be made annually to the Authority. Applicants shall submit completed application forms available from the Authority, postmarked 60 days or more before the date the current certification expires, and shall pay the appropriate fee per OAR 333-069-0090.

(2) Recertification is required for individuals by June 30, no more than three years after the issue date of an original certification or recertification, whichever is most recent. To obtain recertification, an individual shall fulfill the following:

(a) Submit to the Authority an application for recertification that shall include two current passport-size photos and the appropriate fee per OAR 333-069-0090; and

(b) Submit to the Authority a copy of the course completion certificate from an accredited lead-based paint standard or refresher training course in the appropriate discipline.

(3) An individual whose Authority certification has been expired for more than six months must complete a standard or refresher course in that discipline and pass a qualifying examination administered by the Authority. An individual whose Authority certification has been expired for more than one year shall successfully complete a standard course in that discipline and pass a qualifying examination administered by the Authority.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 5-1996(Temp), f. & cert. ef. 9-30-96; HD 6-1997, f. 4-25-97, cert. ef. 5-1-97; OHD 12-1998, f. & cert. ef. 10-27-98; PH 8-2003, f. & cert. ef. 6-20-03; PH 22-2010(Temp), f. & cert. ef. 9-24-10 thru 3-22-11; Administrative correction 4-25-11; PH 4-2011, f. & cert. ef. 6-16-11

333-069-0060
Certification Procedures

(1) The Authority shall inform the applicant, in writing, when his/her application is granted, denied or incomplete and of the additional information and/or documentation that is required to complete the application.

(a) If granted, a certificate shall be mailed to the applicant and the effective date shall be the issuance date of certification or recertification.

(b) A unique certification number will be assigned to each certificate holder.

(c) If an application is denied, the Authority shall state, in writing, the reasons for denial.

(d) An application may be withdrawn at any time by written request to the Authority.

(2) The Authority may take into consideration various factors in determining whether to grant or deny a permit or certification including, but not limited to:

(a) Failure to satisfy eligibility requirements for certification;

(b) Failure to satisfy training requirements;

(c) Failure to provide required documentation or information requested by the Authority;

(d) History of citations or violations of existing regulations or standards;

(e) History of revocation of a certificate;

(f) Making false or misleading statements in the application.

(3) Certification and permits shall be non-transferable.

(4) All certifications and permits shall expire on June 30.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 6-1997, f. 4-25-97, cert. ef. 5-1-97; OHD 12-1998, f. & cert. ef. 10-27-98; PH 8-2003, f. & cert. ef. 6-20-03; PH 22-2010(Temp), f. & cert. ef. 9-24-10 thru 3-22-11; Administrative correction 4-25-11; PH 4-2011, f. & cert. ef. 6-16-11

333-069-0070
Work Practice Standards

(1) When performing any lead-based paint activity described by a certified and licensed individual as an inspection, lead hazard screen, risk assessment or abatement, a certified and licensed person must perform that activity in compliance with these rules, documented methodologies, procedures and work practice standards.

(2) Inspection. An inspection shall be conducted only by a person certified by the Authority and licensed by the CCB as an inspector or risk assessor. Persons exempt from CCB licensing requirements shall be certified by the Authority. Employees of public agencies who conduct 'in-house' lead-based paint activities are exempt from licensing by the CCB.

(a) Locations shall be selected according to documented methodologies and tested for the presence of lead as follows:

(A) In target housing and child-occupied facilities, each component with a distinct painting history shall be tested, except those components determined to have been replaced after 1978 or to not contain lead-based paint; and

(B) In a multi-family dwelling or child-occupied facility, each component with a distinct painting history in every common area shall be tested, except those components determined to have been replaced after 1978 or to not contain lead-based paint.

(b) Paint shall be tested for the presence of lead using documented methodologies which incorporate sampling quality control procedures and all paint chip, dust, and soil samples shall be analyzed for detectable levels of lead by a laboratory accredited under the National Lead Laboratory Accreditation Program.

(c) Inspection reports shall be prepared and include at least:

(A) Inspection date;

(B) Building address;

(C) Date of construction;

(D) Apartment identification (numbers, letters, names if applicable);

(E) Name, address and telephone number of owner or owners of each unit;

(F) Name, signature, and certification number of each inspector and/or risk assessor conducting testing;

(G) Name, address and telephone number of the certified firm employing each inspector and/or risk assessor;

(H) Each testing method and device and/or sampling procedure employed for paint analysis, including sample quality control data, and if used, the serial number of any X-ray fluorescence (XRF) device; and

(I) Specific locations of each painted component tested and the results of the inspection expressed in appropriate units for the sampling method used.

(3) Lead hazard screen. A lead hazard screen shall be conducted only by a person certified by the Authority and licensed by the CCB as a risk assessor, except if such a person, is exempt from CCB licensing requirements, and shall be conducted as follows:

(a) Background information shall be collected about the physical characteristics of the target housing or child-occupied facility and occupant use patterns that may cause lead-based paint exposure to one or more children under six years of age.

(b) A visual inspection shall be conducted to determine the presence of any deteriorated paint and locate at least two dust sampling locations.

(c) If deteriorated paint is present, each deteriorated paint surface determined, using documented methodologies, to be in poor condition and to have a distinct painting history shall be tested for the presence of lead.

(d) In residential dwellings, two composite dust samples shall be collected, one from the floors and the other from the windows, in rooms, hallways or stairwells where one or more children under six years of age are likely to come in contact with dust.

(e) In multi-family dwellings and child-occupied facilities, floor and window composite dust sampling shall be conducted as specified in OAR 333-069-0070(3)(d). In addition, composite dust samples shall be collected in common areas where one or more children under six years of age are likely to come in contact with dust.

(f) All dust samples shall be collected using documented methodologies that incorporate sample quality control procedures and analyzed by a laboratory accredited under the National Lead Laboratory Accreditation Program to determine detectable lead.

(g) A lead hazard screen report shall be prepared by the risk assessor and include:

(A) Information in a risk assessment report as specified in section (4) of this rule, including paragraphs (4)(i)(A) through (4)(i)(N) and excluding paragraphs (4)(i)(O) through (4)(i)(R) of this rule. Additionally, any background information collected pursuant to the lead hazard screen shall be included.

(B) Any recommendations for follow-up risk assessment and other further actions.

(4) Risk assessment. A risk assessment of target housing or child-occupied facility shall be conducted only by a person certified by the Authority and licensed by the CCB as a risk assessor. Persons exempt from CCB licensing requirements shall be certified by the Authority. Employees of public agencies who conduct 'in-house' lead-based paint activities are exempt from licensing by the CCB. A risk assessment shall be conducted as follows:

(a) A visual inspection shall be conducted to locate the existence of deteriorated paint, assess the extent and cause of deterioration, and other potential lead-based hazards.

(b) Background information shall be collected regarding the physical characteristics and occupant use patterns that may cause lead-based paint exposure to one or more children under six years of age.

(c) The following surfaces which are determined, using documented methodologies, to have a distinct painting history, shall be tested for the presence of lead:

(A) Each friction surface or impact surface with visibly deteriorated paint.

(B) All other surfaces with visibly deteriorated paint.

(d) In residential dwellings, dust samples (either composite or single-surface samples) from the interior window sill(s) and floor shall be collected and analyzed for lead concentration in all living areas where one or more children under six years of age are most likely to come in contact with dust.

(e) For multi-family dwellings and child-occupied facilities, the samples required in subsection (4)(d) of this rule shall be taken. In addition, interior window sill and floor dust samples (either composite or single-surface samples) shall be collected and analyzed for lead concentration in the following locations:

(A) Common areas adjacent to sampled target house or child-occupied facility; and

(B) Other common areas in the building where the risk assessor determines that one or more children under six years of age are likely to come in contact with dust.

(f) For child-occupied facilities, interior window sill and floor dust samples (either composite or single-surface samples) shall be collected and analyzed in each room, hallway or stairwell utilized by one or more children under six years of age, and in other common areas in the child-occupied facility where the risk assessor determines one or more children under six years of age are likely to come in contact with dust.

(g) Soil samples shall be collected and analyzed for lead concentrations from the following locations:

(A) Exterior play areas where bare soil is present; and

(B) The remainder of the yard (i.e., non-play areas) where bare soil is present.

(h) Any paint, dust or soil sampling or testing shall be conducted using documented methodologies that incorporate sample quality control procedures and analyzed by a laboratory accredited under the National Lead Laboratory Accreditation Program to determine detectable lead.

(i) The certified risk assessor shall prepare a risk assessment report which shall include at a minimum the following information:

(A) Assessment date;

(B) Address of each building;

(C) Date of construction of buildings;

(D) Apartment identification (numbers, letters, names if applicable);

(E) Name, address and telephone number of each owner of each building;

(F) Name, signature, and certification number of each risk assessor conducting the assessment;

(G) Name, address and telephone number of the certified firm employing each risk assessor;

(H) Name, address and telephone number of each laboratory conducting analysis of collected samples;

(I) Results of the visual inspection;

(J) Testing method and sampling procedure employed for paint analysis;

(K) Specific locations of each painted component tested for the presence of lead;

(L) All data collected from on-site testing, including quality control data, and if used, the serial number of any X-ray fluorescence (XRF) device;

(M) All results of laboratory analysis on collected paint, soil, and dust samples;

(N) Any other sampling results;

(O) Any background information collected pursuant to subsection (4)(b) of this rule;

(P) To the extent used as part of the lead-based paint hazard determination, the results of any previous inspections or analyses for the presence of lead-based paint, or other assessments of lead-based paint related hazards;

(Q) A description of the location, type, and severity of identified lead-based paint hazards and any other potential lead hazards; and

(R) A description of interim controls and/or abatement options for each identified lead-based paint hazard and a recommended prioritization for addressing each hazard. If the use of an encapsulant or enclosure is recommended, the report shall recommend a maintenance and monitoring schedule for the encapsulant or enclosure.

(5) Abatement. An abatement shall be conducted only by a person certified by the Authority and licensed by the CCB. Persons exempt from CCB licensing requirements shall be certified by the Authority. Employees of public agencies who conduct 'in-house' lead-based paint activities are exempt from licensing by the CCB. Abatement shall be conducted as follows:

(a) A certified and licensed supervisor or project designer is required for each abatement project and shall be onsite during all work site preparation and during post-abatement cleanup of work areas. At all other times, the certified supervisor or project designer shall be onsite or available by telephone, pager, or answering service, and be able to be present at the work site in no more than two hours.

(b) A certified and licensed project designer is required for each abatement project that:

(A) Consists of 10 or more target housing units built prior to 1960;

(B) Consists of 20 or more target housing units built during or after 1960; or

(C) Consists of 25,000 square feet or more of target housing.

(c) The certified and licensed supervisor or project designer, as well as, the certified and licensed firm employing that supervisor shall ensure that all abatement activities are conducted according to the requirements of these rules and all federal, state and local requirements.

(d) A certified and licensed project designer may replace and assume the responsibilities of a certified and licensed supervisor required for an abatement project. If a certified and licensed project

designer provides supervision on an abatement project, the project designer shall be responsible for preparing the occupant protection plan and the abatement report.

(e) Any firm or individual conducting lead-based paint abatement activities in target housing or child-occupied facilities must notify the Authority at least seven business days before the start date of the project by completing and submitting a notice of abatement form available from the Authority.

(A) The notice of abatement shall specify the time of day that abatement activities will start and the date on which abatement activities will be completed.

(B) Amendments to or cancellations of the original notice of abatement, including completion-date changes must be submitted 24 hours prior to the original start date.

(C) In the event of an emergency, an original or amended notice of abatement describing the emergency must be submitted. Notification for lead-based paint abatement activities required in response to an elevated blood lead level (EBLL) determination, or federal, state, tribal, or local emergency abatement order should be received by the Authority as early as possible before, but must be received no later than the start date of the lead-based paint abatement activities. Should the start date and/or location provided to the Authority change, an updated notification must be received by the Authority on or before the start date provided in the notice of abatement to the Authority. Documentation showing evidence of an EBLL determination or a copy of the federal, state, tribal, or local emergency abatement order must be included in the written notification to take advantage of this abbreviated notification period.

(D) A request for waiver of the seven-business day advance notice requirement must be submitted in writing and granted in writing by the Authority before work under the waiver can start.

(E) The Authority may reject a notice of abatement form that has not been completed in full and signed by the applicant.

(f) A written occupant protection plan shall be developed prior to all abatement projects, be prepared by a certified and licensed supervisor or project designer, be unique to each target housing or child-occupied facility, describe the measures and management procedures that will be taken during the abatement to protect the building occupants from exposure to any lead-based paint hazards. The written occupant protection plan shall be present at the project site and must be made available on demand for inspection.

(g) A scope of work for the abatement project shall be present at the project site and must be made available on demand for inspection.

(h) These work practices shall be restricted during abatement:

(A) Open-flame burning or torching of lead-based paint is prohibited;

(B) Uncontained hydro blasting or high-pressure washing of lead-based paint is prohibited;

(C) Machine sanding or grinding or abrasive blasting or sandblasting of lead-based paint is prohibited unless used with High Efficiency Particulate Air (HEPA) exhaust control which removes particles of 0.3 microns or larger from the air at 99.97 percent or greater efficiency;

(D) Dry scraping of lead-based paint is permitted only in conjunction with heat guns or around electrical outlets or when treating defective paint spots totaling no more than two square feet in any room, hallway or stairwell or totaling no more than 20 square feet on exterior surfaces; and

(E) Operating a heat gun on lead-based paint is permitted only at temperatures below 1100 degrees Fahrenheit.

(i) When soil abatement is conducted:

(A) If the soil is removed:

(i) The soil shall be replaced by soil with a lead concentration as close to local background as practicable, but no greater than 400 ppm.

(ii) The soil that is removed shall not be used as top soil at another residential property or child-occupied facility.

(B) If the soil is not removed, the soil shall be permanently covered as defined in these rules.

(j) The following clearance procedures shall be performed only by a certified and licensed inspector or risk assessor and according to the following procedures:

(A) A visual inspection shall be performed to determine if deteriorated painted surfaces and/or visible amounts of dust, debris or residue are still present. If deteriorated painted surfaces or visible amounts of dust, debris or residue are present, these conditions must be eliminated prior to the continuation of the clearance procedures.

(B) If exterior work on a project cannot be completed due to inclement weather or other factors, the project supervisor may apply in writing to the Authority for authorization of a preliminary clearance.

(i) The application must include the following:

(I) The project address;

(II) The name and certification number of the abatement project supervisor or project designer;

(III) A description of the conditions that justify issuance of a waiver;

(IV) A description of the abatement work that remains to be done on the project;

(V) A schedule for completion of the abatement work that remains to be done; and

(VI) A plan for monitoring and controlling potential lead-based paint contamination until work can be completed.

(ii) At the conclusion of all work on a project for which preliminary clearance examination has been authorized, the project supervisor shall present the Authority with documentation that clearance testing has been performed on exterior and interior areas according to these rules and that all results are below clearance examination standards.

(C) Following the visual inspection and any post-abatement clean up required by paragraph (5)(j)(A) of this rule, clearance testing for lead in dust and/or soil shall be conducted. Clearance testing may be conducted by employing single-surface sampling techniques.

(D) Clearance testing shall be performed using documented methodologies that incorporate sample quality control procedures and shall be taken a minimum of one hour after completion of final cleanup activities.

(E) Post-abatement clearance examination activities shall be conducted based upon the extent or manner of work activities conducted in or on the target housing or child-occupied facility as follows:

(i) After conducting an abatement with containment between containment and non-containment areas, one dust sample shall be taken from one interior window sill and from one window trough (if present) and one dust sample shall be taken from the floors of no less than four rooms, hallways or stairwells within the containment area. In addition, one dust sample shall be taken from the floor outside the containment area. If a room containment consists of more than one critical barrier, one dust sample shall be taken outside each critical barrier. If there are fewer than four rooms, hallways or stairwells within the containment area, then all rooms, hallways or stairwells shall be sampled.

(ii) After conducting an abatement with no containment, two dust samples shall be taken from no fewer than four rooms, hallways or stairwells in the residential dwelling or child-occupied facility. One dust sample shall be taken from one interior window sill and from one window trough (if present) and one dust sample shall be taken from the floor of each room, hallway or stairwell selected. If there are fewer than four rooms, hallways or stairwells within the target housing or child-occupied facility then all rooms, hallways or stairwells shall be sampled.

(iii) Following exterior paint abatement, a visual inspection shall be conducted. All horizontal surfaces in the outdoor living area closest to the abated surfaces shall be found to be cleaned of visible dust and debris. The surfaces shall be recleaned when visible dust and debris is present. The visual inspection shall be conducted to determine the presence of paint chips on the dripline or next to the foundation below any exterior abated surface. Paint

chips, if present, shall be removed from the site and disposed of according to federal, state and local requirements.

(F) The rooms, hallways or stairwells selected for sampling shall be selected according to documented methodologies.

(G) The certified and licensed inspector or risk assessor shall compare residual lead levels (as determined by laboratory analysis) from each single surface dust sample with clearance examination standards as defined in these rules for lead in dust on floors and interior window sills, and window troughs, divided by half the number of subsamples in the composite sample. If the residual lead level in a single surface dust sample equals or exceeds the applicable clearance examination standard or if the residual lead level in a composite dust sample equals or exceeds the applicable clearance examination standard divided by half the number of subsamples in the composite sample, the components represented by the failed sample shall be recleaned and retested until clearance examination standards are met.

(k) In a multi-family dwelling with similarly constructed and maintained residential dwellings, random sampling for the purposes of clearance examination may be conducted provided:

(A) The certified individuals who work on or clean the residential dwellings do not know which residential dwelling will be selected for the random sample.

(B) The randomly selected residential dwellings shall be sampled and evaluated according to subsection (5)(j) of this rule.

(C) A sufficient number of residential dwellings are selected for dust sampling to provide a 95 percent level of confidence that no more than five percent or 50 of the residential dwellings (whichever is smaller) in the randomly sampled population exceeds the appropriate clearance examination standards.

(l) An abatement report shall be prepared by a certified and licensed supervisor or project designer and shall include as a minimum the following information:

(A) Start and completion dates of abatement;

(B) The name, address and telephone number of each certified firm conducting the abatement and the name of each supervisor or project designer assigned to the abatement project;

(C) The occupant protection plan;

(D) The name, address and signature of each certified and licensed inspector or risk assessor conducting the clearance examination and the date(s) that the clearance examination was performed;

(E) The results of the clearance examination and all soil analyses and the name of each laboratory conducting analysis of collected samples; and

(F) A detailed written description of the abatement, including abatement methods, location of rooms and/or components where abatement occurred, reason for selecting particular abatement methods for each component, and any suggested monitoring of encapsulants or enclosures.

(m) A clearance examination report shall be prepared by a certified inspector or risk assessor. The clearance examination report shall include the following information:

(A) The property address where the clearance examination occurred;

(B) The abatement cleanup completion date and time;

(C) The date and time of the clearance examination;

(D) Name and certification number of each inspector or risk assessor conducting the clearance;

(E) The signature of the inspector or risk assessor conducting the clearance;

(F) Name, address, telephone number, and certification number of the certified firm employing the inspector or risk assessor;

(G) Results of the visual inspection;

(H) Identification of containment or non-containment applications;

(I) Identification of location(s) where the clearance examination sample(s) were collected;

(J) Name, address, and telephone number of the laboratory analyzing the collected samples;

(K) All results of laboratory analysis on collected samples, including quality control results; and

(L) Documented methodology used for sampling.

(6) Sampling. Any paint chip, dust, or soil samples collected pursuant to these work practice standards shall be collected by a certified and licensed inspector or risk assessor. Persons exempt from CCB licensing requirements shall be certified by the Authority. Employees of public agencies who conduct 'in-house' lead-based paint activities are exempt from licensing by the CCB. Such samples shall be analyzed by a laboratory accredited under the National Lead Laboratory Accreditation Program.

(7) Composite sample. Composite dust sampling may only be conducted when conducting a lead hazard screen, risk assessment, or post abatement activities. If conducted, the composite dust samples shall consist of at least two subsamples, every component that is being tested shall be included in the sampling, and shall not consist of subsamples from more than one type of component.

(8) Reports or plans. All lead-based paint activity reports or plans shall be maintained by the certified firm or individual who prepared the report for no fewer than three years and six months. Also, the certified firm or individual shall provide copies of these reports to the building owner or client who contracted for the services, unless otherwise specified by contract, within 30 days of the lead-based paint activity, or within 15 days if a child under six years of age with a confirmed EBLL $\geq$10 μg/dL is an occupant of the building.

(9) Certified individuals and firms shall, upon request, make available to the Authority records and documents regarding regulated lead-based paint activities so that the Authority may inspect said records and documents for the purposes of monitoring compliance with these rules. The Authority shall respect the proprietary nature of business records.

(10) Signage. Every work site where lead-based paint abatement is being conducted shall bear signage warning of lead-based paint hazards.

(a) The text on warning signage shall warn of "Lead-Based Paint Hazards" and be readable from 30 feet.

(b) If the Authority determines that a paint-lead hazard, dust-lead hazard, or soil-lead hazard exists at target housing or pre-1978 child-occupied facilities, the Authority shall post signage to that effect on the building exterior in one or more visible locations.

(c) Signage posted by the Authority warning of lead hazards must remain in place until the lead hazard or hazards determined by the Authority have been remediated per clearance examination standards.

(11) Determinations.

(a) Lead-based paint is present:

(A) On any surface that is tested and found to contain lead equal to or in excess of 1.0 milligrams per square centimeter or equal to or in excess of 0.5 percent by weight; and

(B) On any surface similar to a surface tested in the same room equivalent that has a similar painting history and is found to be lead-based paint.

(b) A paint-lead hazard is present:

(A) On any friction surface that is subject to abrasion and where the lead dust levels on the nearest horizontal surface (e.g., the window sill or floor) are equal to or greater than the dust hazard levels identified in OAR 333-069-0015(9);

(B) On any chewable lead-based paint surface on which there is evidence of teeth marks;

(C) Where there is any damaged or otherwise deteriorated lead-based paint on an impact surface that is caused by impact from a related building component (such as a door knob that knocks into a wall or a door that knocks against a door frame); and

(D) If there is any other deteriorated lead-based paint in any residential building or child-occupied facility or on the exterior of any residential building or child-occupied facility.

(c) A dust lead-hazard is present in a residential dwelling or child-occupied facility:

(A) In a residential dwelling on floors and interior window sills when the weighted arithmetic mean lead loading for all

surfaces on floors, interior window sills and window troughs is equal to or greater than 40 μg/ft^2 for floors, 250 μg/ft^2 for interior window sills, and 400 μg/ft^2 for window troughs;

(B) On floors or interior window sills in an unsampled residential dwelling in a multi-family dwelling, if a dust-lead hazard is present on floors or interior window wills, respectively, in at least one sampled residential unit on the property; and

(C) On floors or interior window sills in an unsampled common area in a multi-family dwelling, if a dust-lead hazard is present on floors or interior window sills, respectively in at least one sampled common area in the same common area group on the property.

(d) A soil-lead hazard is present in a residential dwelling or child-occupied facility:

(A) In a play area when the soil-lead concentration from a play area sample of bare soil is equal to or greater than 400 ppm; or

(B) When the arithmetic mean lead concentration from a composite sample (or arithmetic mean of composite samples) of bare soil from the remainder of the yard for each residential building on a property is equal to or greater than 1,200 ppm.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 6-1997, f. 4-25-97, cert. ef. 5-1-97; OHD 12-1998, f. & cert. ef. 10-27-98; OHD 11-2000, f. & cert. ef. 12-8-00; PH 8-2003, f. & cert. ef. 6-20-03; PH 4-2011, f. & cert. ef. 6-16-11

333-069-0080
Denial, Suspension or Revocation of Certification

(1) The Authority may deny issuance of, suspend, or revoke certification for an individual or a firm for circumstances including but not limited to the following:

(a) Performing work requiring certification at a job site without having a current valid certificate identification card available at the job site for inspection;

(b) Permitting the duplication or use of the individual's own certificate by another;

(c) Performing work for which appropriate certification has not been received from the Authority;

(d) Having been subject to a final administrative order imposing a civil penalty or a criminal conviction for engaging in a prohibited act under Authority or CCB rules;

(e) Failing to comply with relevant local, state, or federal statutes or regulations including execution of a consent agreement in settlement of an enforcement action;

(f) Failing to comply with work practices and standards set forth in these rules and other generally accepted work practices;

(g) Obtaining certification through fraudulent representation of documentation satisfying eligibility requirements;

(h) Failing to renew certification or to recertify in a timely manner;

(i) Gaining admission to and completing education through fraudulent representation of initial or previous education documentation;

(j) Obtaining certification through fraudulent representation of certification requirements such as education, training, professional registration, or experience;

(k) Performing work requiring certification at a job site with individuals who are not certified;

(l) Failing to maintain required records; and

(m) Failing to comply with these rules including execution of a consent agreement in settlement of an enforcement action.

(2) The Authority may deny issuance of, suspend, or revoke certification for an individual for circumstances including but not limited to the following:

(a) Obtaining training documentation through fraudulent means, and/or;

(b) Gaining admission to and completing education through fraudulent representation of initial or previous education documentation.

(3) The Authority may deny issuance of, suspend, or revoke certification for a firm for circumstances including but not limited to the following:

(a) Performing work requiring certification at a job site with individuals who are not certified;

(b) Failing to maintain required records.

(4) Hearings on the denial, suspension or revocation of a certificate shall be conducted as a contested case in accordance with ORS 183.310 through 183.540.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: HD 6-1997, f. 4-25-97, cert. ef. 5-1-97; OHD 12-1998, f. & cert. ef. 10-27-98; PH 8-2003, f. & cert. ef. 6-20-03; PH 4-2011, f. & cert. ef. 6-16-11

333-069-0085
Schedule of Penalties

The Authority may assess penalties, not to exceed the actions or amount shown in the following guidelines:

(1) A level one violation includes, but is not limited to, the following violations:

(a) Offering to perform or performing lead-based paint activities without Authority certification and CCB licensing, unless specifically exempted by these rules.

(b) Clearance examination inconsistencies including, but not limited to, the following:

(A) Failure to conduct clearance examination;

(B) Allowing rehabitation before clearance has been achieved;

(C) Allowing rehabitation when lead hazard levels exceed the standard;

(c) The collection of samples as described in these rules by a non-certified individual or firm;

(d) Obtaining certification via fraud or duplication of certification documents;

(e) Conducting lead-based paint activities with a revoked, suspended or expired certification;

(f) Employing uncertified individuals to conduct lead-based paint activities;

(g) Failure to comply with a consent agreement or an administrative order;

(h) Falsification of results of lead-hazard sampling;

(i) Removing paint from target housing or child-occupied facilities without a permit;

(j) Use of prohibited abatement methods.

(2) A level two violation includes, but is not limited to, the following violations:

(a) Failure to comply with prescribed work practice standards;

(b) Improper collection or handling of samples or sampling information collected for an inspection, risk assessment, clearance, or lead-hazard screen;

(c) Failure to use a National Lead Laboratory Accreditation Program laboratory for analysis of samples referred to in subsection (2)(b) of this rule;

(d) Incomplete, missing or late reports;

(e) Failure to provide notice of abatement, or notice given in a manner that obstructs proper oversight;

(f) Failure to provide client with report of lead-based paint activity in a timely manner, as specified for in these rules;

(g) Failure to maintain or to provide for Authority inspection lead-based paint activities reports and documents;

(h) Performance by a certified individual of lead-based paint activity outside of the scope of that individual's certification;

(3) A level three violation includes, but is not limited to, the following violations:

(a) Conducting lead-based paint activities without a valid certification badge;

(b) Conducting in-house lead-based paint activities by a public agency without having submitted a letter of compliance to the Authority;

(c) Conducting lead-based paint activities that have been contracted for by a non-certified firm or agency, without the firm or agency having submitted a letter of compliance to the Authority;

(d) Conducting lead-based paint abatement without an occupant protection plan;

(4) The penalties for levels one, two and three as described in this rule will be assessed according to the following schedule:

(a) Level one:

(A) First offense: notice of noncompliance and up to $1,000.

(B) Second offense: notice of noncompliance, a fine of up to $3,000 and suspension of certification for up to 90 days.

(C) Third offense: notice of noncompliance, a fine of up to $5000 and either suspension of certification for up to 180 days or revocation of certification.

(b) Level two:

(A) First offense: notice of noncompliance and a fine of up to $500.

(B) Second offense: notice of noncompliance and a fine of up to $2,000.

(C) Third offense: notice of noncompliance, a fine of up to $5,000 and suspension of certification for up to 30 days.

(c) Level three:

(A) First offense: notice of noncompliance.

(B) Second offense: notice of noncompliance and/or a letter of warning.

(C) Third offense: notice of noncompliance and/or a letter of warning and a fine of up to $100.

(5) Violations that are not specifically addressed in sections (1) through (4) of this rule, such as in the case of serial violations of different levels, shall be assessed appropriate penalties by the Authority in accordance with the hazard to public health produced by the activity and the compliance history of the violator.

(6) Removal of signage. It shall be a violation to remove a sign posted by the Authority to warn the public of lead hazards, and such action shall be punishable by a fine of $100 per day.

(7) The Authority may revoke, suspend, or refuse to issue or reissue the certification or permit of any individual or firm who fails to pay on demand a civil penalty that has become due and payable.

(8) Procedures, including a hearing, pursuant to the assessment of a civil penalty shall be conducted according to ORS 183.745.

Stat. Auth.: ORS 431.920, 701.992

Stats. Implemented: ORS 431.920, 701.992

Hist.: PH 8-2003, f. & cert. ef. 6-20-03; PH 22-2010(Temp), f. & cert. ef. 9-24-10 thru 3-22-11; Administrative correction 4-25-11; PH 4-2011, f. & cert. ef. 6-16-11

333-069-0090
Fees

The following fees are established:

(1) Firms shall pay a non-refundable certification or recertification application fee of $85 for a one-year certification.

(2) Inspectors, risk assessors, supervisors, and project designers shall pay a non-refundable certification or recertification fee of $85 for a one year certification.

(3) Workers shall pay a non-refundable certification or recertification fee of $50 for a one-year certification.

(4) The fee for applications for certification received by the Authority between April 1 and June 30 shall be as follows: Worker, $25; all other disciplines, $45.

(5) The application fee for a permit for painting shall be $5.

Stat. Auth.: ORS 431.920

Stats. Implemented: ORS 431.920

Hist.: HD 6-1997, f. 4-25-97, cert. ef. 5-1-97; OHD 12-1998, f. & cert. ef. 10-27-98; PH 8-2003, f. & cert. ef. 6-20-03; PH 22-2010(Temp), f. & cert. ef. 9-24-10 thru 3-22-11; Administrative correction 4-25-11; PH 4-2011, f. & cert. ef. 6-16-11

DIVISION 70

PRE-RENOVATION EDUCATION AND RENOVATION, REPAIR AND PAINTING ACTIVITIES INVOLVING LEAD-BASED PAINT

333-070-0075
Authority, Purpose, Applicability

(1) Authority. These rules are promulgated in accordance with and under the authority of ORS 431.920.

(2) Purpose:

(a) The purpose of these rules is to address Oregon's need for a qualified and properly trained workforce to perform renovation, repair and painting of target housing and child-occupied facilities, and to safeguard the environment and protect the health of building occupants from lead-based paint hazards.

(b) These rules prescribe the requirements for certification of individuals and firms who perform for compensation renovation, repair and painting in target housing and child occupied facilities.

(c) These rules will establish work practice standards for the performance of renovation, repair and painting activities for certified individuals and certified renovation firms and will require that activities be performed only by certified individuals and certified renovation firms.

(d) These rules prescribe the requirements to ensure that owners and occupants of target housing and child-occupied facilities receive information on lead-based paint hazards before these renovations begin.

(3) Applicability:

(a) These rules apply to all certified individuals and certified renovation firms who perform for compensation renovation, repair and painting activities in target housing and child-occupied facilities as defined in OAR 333-070-0085, except for the following:

(A) Renovations in target housing or child-occupied facilities in which a written determination from a State of Oregon certified lead inspector or risk assessor that the components affected by the renovation are free of paint or other surface coatings that contain lead equal to or in excess of 1.0 milligrams/per square centimeter (mg/cm2) or 0.5 percent by weight.

(B) Renovations in target housing or child-occupied facilities in which a certified renovator tests each component affected by the renovation using an Environmental Protection Agency (EPA) recognized test kit as defined in OAR 333-070-0085. The renovator must follow the kit manufacturer's instructions. This determines that the components are free of paint or other surface coatings that contain lead equal to or in excess of 1.0 mg/cm2 or 0.5 percent by weight. If the components make up an integrated whole, such as the individual stair treads and risers of a single staircase, the renovator is required to test only one of the individual components, unless the individual components appear to have been repainted or refinished separately.

(b) The information distribution requirements in OAR 333-070-0095 do not apply to emergency renovation operations. Emergency renovations other than interim controls are also exempt from the warning sign, containment, waste handling, training, and certification requirements in OAR 333-070-0105 to the extent necessary to respond to the emergency. Emergency renovations are not exempt from the cleaning requirements of OAR 333-070-0090, which must be performed by certified renovators or individuals trained in accordance with OAR 333-070-0100, the cleaning verification requirements of OAR 333-070-0090, which must be performed by certified renovators, and the recordkeeping requirements of OAR 333-070-0110. Once the immediate emergency is over, lead safe work practices and all the requirements of these rules shall be in effect.

(c) These rules:

(A) Require that renovation, repair and painting activities must be performed by certified renovators and individuals who have on the job training by a certified renovator working for a certified renovation firm.

(B) Prescribe the requirements for, and the manner of, certifying competency of applicants for certification as a certified individual and of the certified renovation firms employing such individuals.

(C) Determine the work practice standards for renovation, repair and painting activities, and those actions or circumstances that constitute failure to achieve or maintain competency, or that otherwise are contrary to the public interest, for which the Authority may deny, suspend, or revoke certification.

(D) Establish the fees to the extent necessary to defray costs of those activities prescribed herein.

(d) A certified renovation firm who is licensed by the Construction Contractors Board (CCB) is not required to be certified by the Authority under these rules, but is subject to the work practice standards in these rules.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920 & 431.922
Hist.: PH 8-2010, f. & cert. ef. 4-26-10; PH 23-2010(Temp), f. & cert. ef. 9-24-10 thru 3-22-11; Administrative correction 4-25-11; PH 4-2011, f. & cert. ef. 6-16-11

333-070-0080
Adoption by Reference

All standards, listings and publications referred to in these rules are, by those references, made a part of these rules as though fully set forth.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: PH 8-2010, f. & cert. ef. 4-26-10

333-070-0085
Definitions

As used in these rules unless otherwise required by context:

(1) "Accredited training program" means a training program accredited or provisionally accredited by the Authority, EPA, or an EPA-authorized state or tribal program to provide training for individuals engaged in renovation, repair and painting activities.

(2) "Accreditation" means the process whereby the Authority has reviewed and approved a training program's written application with associated materials for accreditation, and has conducted an onsite audit finding the training program in compliance as specified in these rules.

(3) "Approved" means approved in writing by the Authority.

(4) "Audit' means a classroom evaluation of ongoing training. An audit involves verifying the course content, specific time requirements for each subject, hands-on training, classroom conditions, attendance size and other measures of the adequacy of the training provided.

(5) "Authority" means the Oregon Health Authority.

(6) "Certificate of mailing" means a United States Postal Service document that indicates when a piece of mail was presented to the Postal Service for mailing.

(7) "Certified dust sampling technician" means a technician who has successfully completed a dust sampling course accredited by the Authority, EPA, or an EPA-authorized state or tribal program.

(8) "Certified individual" means an individual certified by the Authority as a renovator or dust sampling technician.

(9) "Certified renovation firm" means a company, partnership, corporation, sole proprietorship, association, or other entity that has been certified by the Authority to conduct renovation under ORS 431.920 or licensed by the CCB under ORS 701.515.

(10) "Certified renovator" means a renovator who has successfully completed a renovator course accredited by the Authority, EPA, or an EPA-authorized state or tribal program.

(11) "Child-occupied facility" means a building, or a portion of a building, constructed prior to 1978, visited regularly by the same child, under age six, on at least two different days within any week (Sunday through Saturday), provided that each day's visit lasts at least three hours and the combined weekly visit lasts at least six hours, and the combined annual visits last at least sixty hours. Child-occupied facilities may include, but are not limited to, day-care centers, preschools and kindergarten classrooms. Child-occupied facilities may be located in target housing or in public or commercial buildings. With respect to common areas in public or commercial buildings that contain child-occupied facilities, the child-occupied facility encompasses only those common areas that are routinely used by children under age six, such as restrooms and cafeterias. In addition, with respect to exteriors of public or commercial buildings that contain child-occupied facilities, the child-occupied facility encompasses only the exterior sides of the building that are immediately adjacent to the child-occupied facility or the common areas routinely used by children under age six.

(12) "Cleaning verification card" means a card developed and distributed, or otherwise approved, by EPA for the purpose of determining, through comparison of wet and dry disposable cleaning cloths with the card, whether post-renovation cleaning has been properly completed.

(13) "Clearance examination standards" means values that indicate the maximum amount of lead permitted in dust on a surface or in soil following completion of a renovation activity. Standards for lead in dust are 40 micrograms per square foot ($\mu g/ft^2$) on floors, 250 $\mu g/ft^2$ on interior window sills, and 400 $\mu g/ft^2$ on window troughs. The values for lead in soil are 400 parts per million (ppm) in play areas and 1,200 ppm in the remainder of the yard.

(14) "Common areas" means portion(s) of a building that are generally accessible to all occupants. This may include, but is not limited to, hallways, stairways, laundry and recreational rooms, playgrounds, community centers, garages, and boundary fences. With respect to common areas in public or commercial buildings that contain child-occupied facilities, the child-occupied facility encompasses only those common areas that are routinely used by children under age six, such as restrooms and cafeterias. Common areas that children under age six only pass through, such as hallways, stairways, and garages are not common areas.

(15) "Component or building component" means specific design or structural elements or fixtures of a building or residential dwelling that are distinguished from each other by form, function, and location. These include, but are not limited to: interior components such as ceilings, crown molding, walls, chair rails, doors, door trim, floors, fireplaces, radiators and other heating units, shelves, shelf supports, stair treads, stair risers, stair stringers, newel posts, railing caps, balustrades, windows and trim (including sashes, window heads, jambs, sills or stools and troughs), built-in cabinets, columns, beams, bathroom vanities, counter tops, and air conditioners; and exterior components such as painted roofing, chimneys, flashing, gutters and downspouts, ceilings, soffits, fascias, rake boards, corner boards, bulkheads, doors and door trim, fences, floors, joists, lattice work, railings and railing caps, siding, handrails, stair risers and treads, stair stringers, columns, balustrades, windowsills or stools and troughs, casings, sashes and wells, and air conditioners.

(16) "Concentration" means the relative content of a specific substance contained within a larger mass, such as the amount of lead (in micrograms per gram or parts per million by weight) in a sample of dust or soil.

(17) "Containment" means a process or arrangement of materials to protect workers, occupants, the public, and the environment by controlling exposure to the lead-contaminated dust and debris created during renovation activities.

(18) "Course completion certificate" means documentation issued by an accredited training program to an individual as proof of successful completion of a Authority-accredited renovator or dust sampling technician training course or refresher training course.

(19) "Course completion date" means the final date of classroom instruction and/or student examination of an accredited renovator or dust sampling technician training course.

(20) "Critical barrier" means a containment structure that allows for the passage of persons or materials while maintaining containment.

(21) "Demonstration testing" means the observation and scoring of a student's job task and equipment use skills taught during a course or refresher training course.

(22) "Desk audit" means an audit of the training program to document proper records keeping, filing procedures and notifications required by the Authority.

(23) "Deteriorated paint" means any interior or exterior paint or other coating that is peeling, chipping, chalking, cracking, flaking, or any paint or coating located on an interior or exterior surface or fixture that is otherwise damaged or separated from the substrate.

(24) "Distinct painting history" means the application history, as indicated by the visual appearance or a record of application, over time, of paint or other surface coatings to a component or room.

(25) "Documented methodologies" are written methods or protocols used to sample for the presence of lead in paint, dust, and soil as recommended in U.S. Department of Housing and Urban Development "Guidelines for the Evaluation and Control of Lead-Based Paint Hazards in Housing" and "EPA's Residential Sampling for Lead: Protocols for Dust and Soil Sampling".

(26) "Dripline" means the area within three feet surrounding the perimeter of a building.

(27) "Dry disposable cleaning cloth" means a commercially available dry, electro-statically charged, white disposable cloth designed to be used for cleaning hard surfaces such as uncarpeted floors or counter tops.

(28) "Dust-lead hazard" means surface dust in a residential dwelling or child-occupied facility that contains a mass-per-area concentration of lead equal to or exceeding 40 $\mu g/ft^2$ on floors, 250 $\mu g/ft^2$ on interior window sills, and 400 $\mu g/ft^2$ in window troughs based on wipe samples.

(29) "Emergency" means a situation in which failure to act promptly would likely result in immediate harm to persons or property.

(30) "Emergency renovation operations" means renovation activities, such as operations necessitated by non-routine failures of equipment, that were not planned but result from a sudden, unexpected event that, if not immediately attended to, presents a safety or public health hazard, or threatens equipment or property with significant damage. Interim controls performed in response to an elevated blood lead level in a resident child are also emergency renovations.

(31) "EPA" means the United States Environmental Protection Agency.

(32) "EPA-authorized program" means a state or tribal program authorized by EPA to administer and enforce the provisions of 40 CFR § 745.324 and 40 CFR § 745.326.

(33) "Friction surface" means an interior or exterior surface that is subject to abrasion or friction, including, but not limited to, certain window, floor, and stair surfaces.

(34) "Guest instructor" means an individual who is responsible for providing less than 30 percent of training in any course.

(35) "Hands-on training" means training during which students practice skills that they will be expected to perform at the worksite.

(36) "HEPA vacuum" means a vacuum cleaner which has been designed with a high-efficiency particulate air (HEPA) filter as the last filtration stage. A HEPA filter is a filter that is capable of capturing particles of 0.3 microns with 99.97 percent efficiency. The vacuum cleaner must be designed so that all the air drawn into the machine is expelled through the HEPA filter with none of the air leaking past it.

(37) "Impact surface" means an interior or exterior surface that is subject to damage by repeated sudden force such as certain parts of door frames.

(38) "Inspection" means a surface-by-surface investigation to determine the presence of lead-based paint and the provision of a report, in writing, explaining the results of the investigation.

(39) "Interim controls" means a set of measures designed to temporarily reduce human exposure or likely exposure to lead-based paint hazards, including specialized cleaning, repairs, maintenance, painting, temporary containment, ongoing monitoring of lead-based paint hazards or potential hazards, and the establishment and operation of management and resident education programs.

(40) "Interactive/participatory teaching methods" mean instruction which consists of active participation of the students, such as brainstorming, hands-on training, demonstration and practice, small group problem-solving, learning games, discussions, risk mapping, field visits, walk-throughs, problem-posing, group work assignments, homework review sessions, question-and-answer periods, skits, or role-playing sessions. Lecture is not considered an interactive/participatory teaching method.

(41) "Job tasks" mean the specific activities performed in the context of work.

(42) "Lead-based paint" means paint or other surface coatings that contain lead equal to or in excess of 1.0 milligram per square centimeter or 0.5 percent by weight.

(43) "Lead-based paint hazard" means deteriorated lead-based paint, dust-lead hazard or soil-lead hazard as identified in these rules.

(44) "Lead-contaminated dust" means surface dust in residential dwellings or child-occupied facilities that contains an area or mass concentration of lead in excess of levels determined by the appropriate federal agency to pose a threat of adverse health effects in pregnant women or young children.

(45) "Minor repair and maintenance activities" means activities, including minor heating, ventilation or air conditioning work, electrical work, and plumbing, that disrupts six square feet or less of painted surface per room for interior activities, or 20 square feet or less of painted surface for exterior activities where none of the work practices prohibited or restricted by OAR 333-070-0090 are used and where the work does not involve window replacement or demolition of painted surface areas. When removing painted components, or portions of painted components, the entire surface area removed is the amount of painted surface disturbed. Jobs, other than emergency renovations, performed in the same room within the same 30 days are the same job for the purpose of determining whether the job is a minor repair and maintenance activity.

(46) "Multi-family housing" means a housing property consisting of more than four dwelling units.

(47) "Paint in poor condition" means more than 10 square feet of deteriorated paint on exterior components with large surface areas; or more than two square feet of deteriorated paint on interior components with large surface areas (e.g., walls, ceilings, floors, doors); or more than 10 percent of the total surface area of the component is deteriorated on interior or exterior components with small surface areas (e.g., window sills, baseboards, soffits, trim).

(48) "Paint-lead hazard" means any of the following:

(a) Any lead-based paint on a friction surface that is subject to abrasion and where the lead dust levels on the nearest horizontal surface underneath the friction surface (e.g., the window sill, or floor) are equal to or greater than the dust-lead hazard levels identified in these rules.

(b) Any damaged or otherwise deteriorated lead-based paint on an impact surface that is caused by impact from a related building component (such as a door knob that knocks into a wall or a door that knocks against its door frame).

(c) Any chewable lead-based painted surface on which there is evidence of teeth marks.

(d) Any other deteriorated lead-based paint in any residential building or child-occupied facility or on the exterior of any residential building or child-occupied facility.

(49) "Paint stabilization" means repairing any physical defect in the substrate of a painted surface that is causing paint deterioration, removing loose paint and other material from the surface to be treated, and applying a new protective coating or paint.

(50) "Pamphlet" means the EPA pamphlet titled Renovate Right: Important Lead Hazard Information for Families, Child Care Providers and Schools or any state pamphlet approved by EPA pursuant to 40 CFR 745.326 that is developed for the same purpose. This includes reproductions of the pamphlet when copied in full and without revision or deletion of material from the pamphlet (except for the addition or revision of state or local sources of information.

(51) "Permanent" means having an expected design life of 20 years.

(52) "Principal instructor" means the individual who has the primary responsibility for organizing and teaching a particular course.

(53) "Proficiency test" means any alternative to a conventional written examination that is used to measure a trainee's mastery of

course content. An oral examination offered to a trainee with a disability is an example of a proficiency test.

(54) "Provisional accreditation" means the Authority has reviewed and finds acceptable a training program's written application for accreditation, but has not conducted an on-site audit as specified in these rules.

(55) "Public agency" means an entity that functions as part of a governmental body or organization at the local, state, or federal level.

(56) "Recognized test kit" means a commercially available kit recognized by EPA under 40 CFR 745.88 as being capable of allowing a user to determine the presence of lead at levels equal to or in excess of 1.0 milligrams per square centimeter, or more than 0.5 percent lead by weight, in a paint chip, paint powder, or painted surface.

(57) "Refresher renovator of dust sampling technician training course" means a minimum training program accredited by the Authority to update an individual's knowledge and skills so that they can effectively and safely continue to practice in the field.

(58) "Renovation" means the modification of any existing structure, or portion thereof, that results in the disturbance of painted surfaces, unless that activity is performed as part of an abatement as defined by these rules. The term renovation includes, but is not limited to, the removal or modification of painted surfaces or painted components (e.g., modification of painted doors, surface preparation activity such as sanding, scraping, or other such activities that may generate paint dust); the removal of large structures (e.g., walls, ceiling, large surface re-plastering, major re-plumbing); and window replacement, weatherization projects (e.g., cutting holes in painted surfaces to install blown-in insulation or to gain access to attics, planning thresholds to install weather-stripping), and interim controls that disturb painted surfaces. A renovation performed for the purpose of converting a building, or part of a building, into target housing or a child-occupied facility is a renovation under this subpart. The term renovation does not include minor repair and maintenance activities.

(59) "Residential building" means a building containing one or more residential dwellings.

(60) "Residential dwelling" means:

(a) A detached single family dwelling unit, including attached structures such as porches and stoops; or

(b) A single family dwelling unit in a structure that contains more than one separate residential dwelling unit, which is used or occupied, or intended to be occupied, in whole or in part, as the home or residence of one or more persons.

(61) "Room" means a separate part of the inside of a building, such as a bedroom, living room, dining room, kitchen, bathroom, laundry room, or utility room. To be considered a separate room, the room must be separated from adjoining rooms by built-in walls or archways that extend at least six inches from an intersecting wall. Half walls or bookcases count as room separators if built-in. Movable or collapsible partitions or partitions consisting solely of shelves or cabinets are not considered built-in walls. A screened in porch that is used as a living area is a room.

(62) "RRP" means the U.S. EPA Renovation Repair and Painting Rule under 40 CFR § 745 Subpart E-Residential Property Renovation.

(63) "Site Visit' means a visit by the Authority to audit a training program and includes but is not limited to a review of: records, including course completion forms and attendance records; facilities; instructional curriculum; examination design, administration and security procedures and results, including those of demonstration testing; classroom instruction; audio-visual materials; course content; and coverage.

(64) "Soil lead hazard" means bare soil on residential property or on the property of a child-occupied facility that contains total lead equal to or exceeding 400 ppm in a play area or 1,200 ppm in the remainder of the yard based on soil samples.

(65) "Target housing" means any housing constructed prior to 1978, except housing for the elderly or persons with disabilities (unless one or more children under age six resides or is expected to reside in such housing for the elderly or persons with disabilities) or any zero-bedroom dwelling.

(66) "These rules" mean OAR 333-070-0075 through 333-070-0160.

(67) "Training hour" means 60 minutes of lead-based paint related training which may include a break of not more than 10 minutes.

(68) "Training instructor" means the individual responsible for organization of the course and oversight of the teaching of all course material, and who teaches at least 70 percent of the course.

(69) "Training manager" means the individual responsible for administering a training program and monitoring the performance of principal instructors and guest instructors.

(70) "Visual inspection" means:

(a) For interiors, that a certified renovator determines whether dust, debris, or residue is still present.

(b) For exteriors, that a certified renovator determines whether dust or debris is still present in and below the work area, including windowsills and the ground.

(71) "Wet disposable cleaning cloth" means a commercially available, pre-moistened white disposable cloth designed to be used for cleaning hard surfaces such as uncarpeted floors or counter tops.

(72) "Wet mopping system" means a device with the following characteristics: A long handle, a mop head designed to be used with disposable absorbent cleaning pads, a reservoir for cleaning solution, and a built-in mechanism for distributing or spraying the cleaning solution onto a floor, or a method of equivalent efficacy.

(73) "Work area" means the area that the certified renovator establishes to contain the dust and debris generated by a renovation.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.918
Hist.: PH 8-2010, f. & cert. ef. 4-26-10; PH 4-2011, f. & cert. ef. 6-16-11

333-070-0090
Work Practice Standards

All renovations must be performed in accordance with the work practice standards in this rule unless the renovation qualifies for one of the exceptions identified in OAR 333-070-0075(3)(a).

(1) Standards for renovation activities.

(a) Renovations must be performed by certified renovation firms using certified renovators as directed in OAR 333-070-0100.

(b) The responsibilities of certified renovation firms are set forth in OAR 333-070-0105.

(c) The responsibilities of certified renovators are set forth in OAR 333-070-0100.

(2) Occupant protection.

(a) A certified renovation firm shall:

(A) Post signs clearly defining the work area and warning occupants and other persons not involved in renovation activities to remain outside of the work area. To the extent practicable, these signs must be in the primary language of the occupants.

(B) Post signs before beginning the renovation and keep them in place and readable until the renovation and the post-renovation cleaning verification has been completed.

(C) Post signs at each entry to the renovation project work area, at a minimum.

(b) If warning signs have been posted in accordance with paragraph (2)(a)(A) of this rule, additional signs are not required.

(3) Containing the work area. A certified renovation firm shall:

(a) Isolate the work area so that no dust or debris leaves the work area while the renovation is being performed, before beginning the renovation;

(b) Maintain the integrity of the containment by ensuring that any plastic or other impermeable materials are not torn or displaced, and taking any other steps necessary to ensure that no dust or debris leaves the work area while the renovation is being performed; and

(c) Ensure that containment is installed in such a manner that it does not interfere with occupant and worker egress in an emergency.

(4) Interior renovations. A certified renovation firm shall:

(a) Remove all objects from the work area, including furniture, rugs, and window coverings, or cover them with plastic sheeting or other impermeable material with all seams and edges taped or otherwise sealed;

(b) Close and cover all ducts opening in the work area with taped-down plastic sheeting or other impermeable material;

(c) Close windows and doors in the work area;

(d) Cover doors with plastic sheeting or other impermeable material. Doors used as an entrance to the work area must be covered with plastic sheeting or other impermeable material in a manner that allows workers to pass through while confining dust and debris to the work area;

(e) Cover the floor surface, including installed carpet, with taped-down plastic sheeting or other impermeable material in the work area six feet beyond the perimeter of surfaces undergoing renovation or a sufficient distance to contain the dust, whichever is greater; and

(f) Use precautions to ensure that all personnel, tools, and other items, including the exteriors of containers of waste, are free of dust and debris before leaving the work area.

(5) Exterior renovations. A certified renovation firm shall:

(a) Close all doors and windows within 20 feet of the renovation. On multi-story buildings, close all doors and windows within 20 feet of the renovation on the same floor as the renovation, and close all doors and windows on all floors below that are the same horizontal distance from the renovation;

(b) Ensure that doors within the work area that will be used while the job is being performed are covered with plastic sheeting or other impermeable material in a manner that allows workers to pass through while confining dust and debris to the work area;

(c) Cover the ground with plastic sheeting or other disposable impermeable material extending 10 feet beyond the perimeter of surfaces undergoing renovation or a sufficient distance to collect falling paint debris, whichever is greater, unless the property line prevents 10 feet of such ground covering; and

(d) In adverse weather conditions (e.g. windy conditions), the certified renovation firm must take extra precautions in containing the work area to ensure that dust and debris from the renovation does not contaminate other buildings or other areas of the property or migrate to adjacent properties.

(6) Prohibited and restricted practices. The work practices listed below are prohibited during a renovation:

(a) Open-flame burning or torching of lead-based paint;

(b) The use of machines that remove lead-based paint through high speed operation such as sanding, grinding, power planing, needle gun, abrasive blasting, or sandblasting, unless such machines are used with HEPA exhaust control; and

(c) Operating a heat gun on lead-based paint is prohibited unless the temperature is below 1100 degrees Fahrenheit.

(7) Waste from renovations. A certified renovation firm shall:

(a) Contain waste from a renovation to prevent releases of dust and debris before the waste is removed from the work area for storage or disposal. If a chute is used to remove waste from the work area, it must be covered;

(b) Store and contain waste that has been collected from renovation activities in an enclosure, or behind a barrier that prevents release of dust and debris out of the work area and prevents access to dust and debris, at the conclusion of each work day and at the conclusion of the renovation; and

(c) Contain the waste to prevent release of dust and debris when transporting waste from renovation activities.

(8) Cleaning the work area. After a renovation has been completed, the certified renovation firm shall clean the work area until no dust, debris or residue remains.

(9) Interior and exterior renovations. A certified renovation firm shall:

(a) Collect all paint chips and debris and, without dispersing any of it, seal this material in a heavy-duty bag;

(b) Remove the protective sheeting;

(c) Mist the sheeting before folding it, fold the dirty side inward, and either tape shut to seal or seal in heavy-duty bags. Sheeting used to isolate contaminated rooms from non-contaminated rooms must remain in place until after the cleaning and removal of other sheeting; and

(d) Dispose of sheeting as waste.

(10) Additional cleaning for interior renovations. A certified renovation firm shall clean all objects and surfaces in the work area and within two feet of the work area in the following manner, cleaning from higher to lower:

(a) Walls. Clean walls starting at the ceiling and working down to the floor by either vacuuming with a HEPA vacuum or wiping with a damp cloth. Dust bags from HEPA machines must be properly contained and disposed. Changing of vacuum bag must occur in containment and wrapped and taped in plastic for disposal.

(b) Remaining surfaces. Thoroughly vacuum all remaining surfaces and objects in the work area, including furniture and fixtures, with a HEPA vacuum. The HEPA vacuum must be equipped with a beater bar when vacuuming carpets and rugs.

(c) Wipe all remaining surfaces and objects in the work area, except for carpeted or upholstered surfaces, with a damp cloth. Mop uncarpeted floors thoroughly, using a mopping method that keeps the wash water separate from the rinse water, such as the two-bucket mopping method, or using a wet mopping system.

(11) Standards for post-renovation cleaning verification of interiors. A certified renovation firm shall have a certified renovator:

(a) Perform a visual inspection to determine whether dust, debris or residue is still present. If dust, debris or residue is present, these conditions must be removed by re-cleaning and another visual inspection must be performed.

(b) After a successful visual inspection:

(A) Verify that each windowsill in the work area has been adequately cleaned, using the following procedure:

(i) Wipe the windowsill with a wet disposable cleaning cloth that is damp to the touch. If the cloth matches or is lighter than the cleaning verification card, the windowsill has been adequately cleaned.

(ii) If the cloth does not match and is darker than the cleaning verification card, re-clean the windowsill as directed in subparagraph (A)(i) of this subsection, then either use a new cloth or fold the used cloth in such a way that an unused surface is exposed, and wipe the surface again. If the cloth matches or is lighter than the cleaning verification card, that windowsill has been adequately cleaned.

(iii) If the cloth does not match and is darker than the cleaning verification card, wait for one hour or until the surface has dried completely, whichever is longer, and wipe the windowsill with a dry disposable cleaning cloth. After this wipe, the windowsill has been adequately cleaned.

(B) Wipe uncarpeted floors and countertops within the work area with a wet disposable cleaning cloth. Floors must be wiped using an application device with a long handle and a head to which the cloth is attached. The cloth must remain damp at all times while it is being used to wipe the surface for post-renovation cleaning verification. If the surface within the work area is greater than 40 square feet, the surface within the work area must be divided into roughly equal sections that are each less than 40 square feet. Wipe each such section separately with a new wet disposable cleaning cloth. If the cloth used to wipe each section of the surface within the work area matches the cleaning verification card, the surface has been adequately cleaned.

(i) If the cloth used to wipe a particular surface section does not match the cleaning verification card, re-clean that section of the surface as directed in paragraph (b)(B) of this section, then use a new wet disposable cleaning cloth to wipe that section again. If the cloth matches the cleaning verification card, that section of the surface has been adequately cleaned.

(ii) If the cloth used to wipe a particular surface section does not match the cleaning verification card after the surface has been re-cleaned, wait for one hour or until the entire surface within the work area has dried completely, whichever is longer.

(iii) After waiting for the entire surface within the work area to dry, wipe each section of the surface that has not yet achieved post-renovation cleaning verification with a dry disposable cleaning cloth. After this wipe, that section of the surface has been adequately cleaned.

(c) Remove the warning signs when the work area passes the post-renovation cleaning verification.

(12) Standards for post-renovation cleaning verification of exteriors. A certified renovation firm shall have a certified renovator:

(a) Perform a visual inspection to determine whether dust, debris or residue is still present on surfaces in and below the work area, including windowsills and the ground. If dust, debris or residue is present, these conditions must be eliminated and another visual inspection must be performed.

(b) Remove the warning signs when the area passes the visual inspection.

(13) Optional dust clearance testing. Cleaning verification need not be performed if the contract between the certified renovation firm and the person contracting for the renovation or another federal, state or local law or regulation requires:

(a) The certified renovation firm to perform dust clearance sampling at the conclusion of a renovation covered by this rule.

(b) The dust clearance samples are required to be collected by a certified inspector, risk assessor or dust sampling technician.

(c) The certified renovation firm is required to re-clean the work area until the dust clearance sample results are below the dust clearance standards in OAR 333-070-0085.

(14) Activities conducted after post-renovation cleaning verification. Activities that do not disturb paint, such as applying paint to walls that have already been prepared, are not regulated by this rule if they are conducted after post-renovation cleaning verification has been performed.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920 & 431.922
Hist.: PH 8-2010, f. & cert. ef. 4-26-10; PH 4-2011, f. & cert. ef. 6-16-11

333-070-0095
Information Distribution Requirements for the Pre-Renovation Notification Rule (406).

(1) Renovations in dwelling units. No more than 60 days before beginning renovation activities in any residential dwelling unit of target housing, a certified renovation firm performing the renovation shall:

(a) Provide the owner of the unit with the pamphlet; and:

(A) Obtain, from the owner, a written acknowledgment that the owner has received the pamphlet; or

(B) Obtain a certificate of mailing at least seven days prior to the renovation.

(b) If the owner does not occupy the dwelling unit, in addition to the requirements in subsection (a) of this section, a certified renovation firm shall provide an adult occupant of the unit with the pamphlet; and:

(A) Obtain, from the adult occupant, a written acknowledgment that the occupant has received the pamphlet; or

(B) Certify in writing that a pamphlet has been delivered to the dwelling and that the certified renovation firm performing the renovation has been unsuccessful in obtaining a written acknowledgment from an adult occupant. A certification must include:

(i) The address of the unit undergoing renovation;

(ii) The date and method of delivery of the pamphlet;

(iii) The name of the individual delivering the pamphlet;

(iv) The reason for lack of acknowledgment (e.g., occupant refuses to sign, no adult occupant available);

(v) The signature of a representative of the certified renovation firm performing the renovation; and

(vi) The date of signature.

(C) If receipt can not be obtained from the adult occupant, obtain a certificate of mailing at least seven days prior to the renovation.

(2) Renovations in common areas. No more than 60 days before beginning renovation activities in common areas of multi-unit target housing, the certified renovation firm performing the renovation shall:

(a) Provide the owner with the pamphlet, and:

(A) Obtain, from the owner, a written acknowledgment that the owner has received the pamphlet; or

(B) Obtain a certificate of mailing at least seven days prior to the renovation.

(b) Comply with one of the following:

(A) Notify the affected units in writing of the proposed renovation and make the pamphlet available upon request prior to the start of renovation. Such notification shall be accomplished by distributing written notification to each affected unit. The notice shall:

(i) Describe the general nature and locations of the planned renovation activities;

(ii) Include the expected starting and ending dates; and

(iii) Contain a statement of how the occupant can obtain the pamphlet and a copy of the records required by OAR 333-070-0110, at no cost to the occupants; or

(B) While the renovation is ongoing, post informational signs describing the general nature and locations of the renovation and the anticipated completion date. These signs must be posted in areas where they are likely to be seen by the occupants of all of the affected units. The signs must be accompanied by a posted copy of the pamphlet or information on how interested occupants can review a copy of the pamphlet or obtain a copy from the certified renovation firm at no cost to occupants. The signs must also include information on how interested occupants can review a copy of the records required by OAR 333-070-0110 or obtain a copy from the renovation firm at no cost to the occupants.

(c) Prepare, sign, and date a statement describing the steps performed to notify all occupants of the intended renovation activities and to provide the pamphlet.

(d) If the scope, locations, or expected starting and ending dates of the planned renovation activities change after the initial notification, and the certified renovation firm provided written initial notification to each affected unit, the certified renovation firm performing the renovation must provide further written notification to the owners and occupants providing revised information on the ongoing or planned activities. This subsequent notification must be provided before the certified renovation firm performing the renovation initiates work beyond that which was described in the original notice.

(3) Renovations in child-occupied facilities. No more than 60 days before beginning renovation activities in any child-occupied facility, the certified renovation firm performing the renovation shall:

(a) Provide the owner of the building with the pamphlet, and:

(A) Obtain, from the owner, a written acknowledgment that the owner has received the pamphlet; or

(B) Obtain a certificate of mailing at least seven days prior to the renovation.

(b) In addition to the requirements in subsection (a) of this section, if the operator of the child-occupied facility is not the owner of the building, provide the operator of the child-occupied facility with the pamphlet, and:

(A) Obtain, from the operator, a written acknowledgment the operator has received the pamphlet;

(B) Certify in writing that a pamphlet has been delivered to the operator and that the certified renovation firm performing the renovation has been unsuccessful in obtaining a written acknowledgment from the operator. Such certification shall comply with the requirements in paragraph (1)(b)(B) of this rule; or

(C) Obtain a certificate of mailing at least seven days prior to the renovation.

(c) Provide the parents and guardians of children using the child-occupied facility with the pamphlet and information describing

the general nature and locations of the renovation and the anticipated completion date by:

(A) Mailing or hand-delivering the pamphlet and the renovation information to each parent or guardian of a child using the child-occupied facility; or

(B) While the renovation is ongoing, post informational signs describing the general nature and locations of the renovation and the anticipated completion date. These signs must be posted in areas where they can be seen by the parents or guardians of the children frequenting the child-occupied facility. The signs must be accompanied by a posted copy of the pamphlet or information on how interested parents or guardians of children frequenting the child-occupied facility can review a copy of the pamphlet or obtain a copy from the renovation firm at no cost to the parents or guardians. The signs must also include information on how interested parents or guardians of children frequenting the child-occupied facility can review a copy of the records required by OAR 333-070-0110 or obtain a copy from the renovation firm at no cost to the parents or guardians; and

(C) Prepare, sign, and date a statement describing the steps performed to notify all parents and guardians of the intended renovation activities and to provide the pamphlet.

(4) Written acknowledgment. A written acknowledgment required by paragraphs (1)(a)(A), (1)(b)(A), (2)(a)(A), (4)(a)(A) and (4)(b)(A) of this rule must:

(a) Include the owner or occupant's name and a statement from the owner or occupant acknowledging receipt of the pamphlet prior to the start of renovation, the address of the unit undergoing renovation, the signature of the owner or occupant as applicable, and the date of signature;

(b) Be on a separate sheet of paper or part of any written contract or service agreement for the renovation; and

(c) Be written in the same language as the text of the contract or agreement for the renovation or, in the case of non-owner occupied target housing, in the same language as the lease or rental agreement or the pamphlet.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: PH 8-2010, f. & cert. ef. 4-26-10; PH 4-2011, f. & cert. ef. 6-16-11

333-070-0100
Renovator Certification and Dust Sampling Technician Certification and Responsibilities

(1) Renovator certification allows a certified individual to perform renovations covered by these rules.

(2) Dust sampling technician certification allows the individual to perform dust clearance sampling under OAR 333-070-0090. Optional dust sampling, procedures and determinations are contained in 333-069-0070(5)(j)(D); and sections (6) and (11).

(3) Renovator certification and dust sampling technician certification.

(a) To become a certified renovator or certified dust sampling technician, an individual must successfully complete the appropriate course accredited by the Authority, EPA, or an EPA-authorized state or tribal program. The course completion certificate serves as proof of certification.

(b) Individuals who have successfully completed an accredited abatement worker or supervisor course, or individuals who have successfully completed an EPA, HUD, or EPA/HUD model renovation training course may take an accredited refresher renovator training course in lieu of the initial renovator training course to become a certified renovator.

(c) To become a certified dust sampling technician, a certified inspector or risk assessor need only to take the dust sampling technician refresher course.

(d) To maintain renovator certification or dust sampling technician certification, an individual must complete a renovator or dust sampling technician refresher course accredited by the Authority, EPA or an EPA-authorized program within five years of the date the individual completed the initial course described in OAR 333-0070-0100. If the individual does not complete a refresher course within this time, the individual must re-take the initial course to become certified again.

(4) Renovator responsibilities. Certified renovators are responsible for ensuring compliance with OAR 333-070-0090 at all renovations to which they are assigned. A certified renovator shall:

(a) Perform all of the tasks described in OAR 333-070-0090 and either perform or direct workers to perform, all of the tasks described in 333-070-0090.

(b) Provide training to workers on the work practices they will be using in performing their assigned tasks.

(c) Be physically present at the work site:

(A) At the time the signs required by OAR 333-070-0090(2) are posted;

(B) While the work area containment required by OAR 333-070-0090(3) is being established; and

(C) While the work area cleaning required by OAR 333-070-0090(8) is performed.

(d) Regularly direct work being performed by other individuals to ensure that the work practices are being followed, including maintaining the integrity of the containment barriers and ensuring that dust or debris does not spread beyond the work area.

(e) Be available, either on-site or by telephone, at all times that renovations are being conducted.

(f) Use an EPA recognized test kit when requested by the party contracting for renovation services to determine whether components to be affected by the renovation contain lead-based paint. If the components make up an integrated whole, such as the individual stair treads and risers of a single staircase, the renovator is required to test only one of the individual components, unless the individual components appear to have been repainted or refinished separately.

(g) Have, at the work site, copies of their initial course completion certificate and their most recent refresher course completion certificate.

(h) Prepare the records required by OAR 333-070-0110.

(5) Dust sampling technician responsibilities. When performing optional dust clearance sampling as referenced in OAR 333-069-0070, paragraph (5)(j)(D); and sections (6) and (11) a certified dust sampling technician shall:

(a) Collect dust samples in accordance with 40 CFR § 745.227(e)(8), send the collected samples to a laboratory recognized by the EPA under § 405(b) of the Toxic Substances Control Act, National Lead Laboratory Accreditation Program, and compare the results to the clearance levels in accordance with 40 CFR § 745.227(e)(8)(C)(vii); and

(b) Have, at the work site, copies of their initial course completion certificate and their most recent refresher course completion certificate.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: PH 8-2010, f. & cert. ef. 4-26-10; PH 4-2011, f. & cert. ef. 6-16-11

333-070-0105
Certified Renovation Firm Certification and Responsibilities

(1) Initial certification.

(a) Firms that perform renovations for compensation shall:

(A) Apply to the Authority for certification to perform renovations or dust sampling by submitting a completed "Application for Certified Renovation Firms," signed by an authorized agent of the firm; and

(B) Pay the correct amount of fees.

(b) An application will be considered complete if it contains all of the information requested on the form and includes the correct amount of fees.

(c) If the Authority receives an incomplete application, it will request that the applicant submit the missing information or fee within 30 days. If an applicant fails to submit the requested information or the fee, the application will be returned to the applicant. An applicant who has had its application returned may reapply at any time.

(d) Within 30 days of declaring an application complete, the Authority shall:

(A) Approve the application if the Authority determines that the environmental compliance history of the applicant, its principals, or its key employees shows a willingness and ability to maintain compliance with environmental statutes or regulations; or

(B) Deny the application if the Authority determines that the environmental compliance history of the applicant, its principals, or its key employees demonstrates an unwillingness or inability to maintain compliance with environmental statutes or regulations.

(e) If the Authority approves the application, the Authority shall issue the applicant a certificate with an expiration date not more than five years from the date the application is approved.

(f) If the Authority denies the application it shall send the applicant a letter giving the reason for denying the application.

(2) Recertification.

(a) To maintain its certification, a certified renovation firm shall apply for recertification every five years, by submitting a timely and complete "Application for Certified Renovation Firms" with the required fee to the Authority.

(A) An application for recertification is timely if it is postmarked 60 days or more before the date the certified renovation firm's current certification expires. If the certified renovation firm's application is complete and timely, the certified renovation firm's current certification will remain in effect until its expiration date or until the Authority has made a final decision to approve or deny the recertification application, whichever is later.

(B) If the certified renovation firm submits a complete recertification application less than 60 days before its current certification expires, and the Authority does not approve the application before the expiration date, the certified renovation firm's current certification will expire and the certified renovation firm will not be able to conduct renovations until the Authority approves its recertification application.

(C) If the certified renovation firm fails to obtain recertification before the certified renovation firm's current certification expires, the certified renovation firm may not perform renovations or dust sampling and must apply for initial certification under section (1) of this rule.

(b) A recertification application will be considered complete if it contains all of the information requested on the form and includes the correct amount of fees.

(c) If the Authority receives an incomplete application, it will request a certified renovation firm to submit the missing information or fee within 30 days. If an applicant fails to submit the requested information or the fee, the application will be returned to the applicant.

(d) Within 60 days of declaring an application for recertification complete, the Authority shall:

(A) Approve a certified renovation firm's recertification application if the Authority determines that the environmental compliance history of the certified renovation firm, its principals, or its key employees shows a willingness and ability to maintain compliance with environmental statutes or regulations; or

(B) Deny a certified renovation firm's recertification application if the Authority determines that the environmental compliance history of the certified renovation firm, its principals, or its key employees demonstrates an unwillingness or inability to maintain compliance with environmental statutes or regulations.

(e) If the Authority approves a certified renovation firm's recertification application, the Authority shall issue the certified renovation firm a certificate with an expiration date not more than five years from the date the application is approved.

(f) If the Authority denies the recertification application it shall send the certified renovation firm a letter giving the reason for denying the application.

(3) Amendment of certification.

(a) A certified renovation firm shall amend its application for certification within 30 days of the date a change occurs to information included in the certified renovation firm's most recent application.

(b) If the certified renovation firm fails to amend its certification within 30 days of the date the change occurs, the certified renovation firm may not perform renovations or dust sampling until its certification is amended.

(c) To amend a certification, a certified renovation firm must submit a completed "Application for Certified Renovation Firms," signed by an authorized agent of the certified renovation firm, noting on the form that it is submitted as an amendment and indicating the information that has changed.

(d) If additional information is needed to process the amendment, the Authority will request the certified renovation firm to submit the necessary information. The certified renovation firm's certification is not amended until the certified renovation firm submits all the required information and the Authority has approved the amendment.

(e) Amending a certification does not affect the certification expiration date.

(4) The Authority will not refund the application fees if a certified renovation firm's application for initial or recertification is denied.

(5) A certified renovation firm that is denied initial certification or recertification shall have the right to a contested case hearing under ORS Chapter 183.

(6) A certified renovation firm that is denied initial or recertification may reapply for certification at any time by filing a new, complete application that includes the correct amount of fees.

(7) Certified renovation firm responsibilities. Certified renovation firms performing renovations shall ensure that:

(a) All individuals performing renovation activities on behalf of the certified renovation firm are either certified renovators or have been trained by a certified renovator as described in OAR 333-070-0100;

(b) A certified renovator is assigned to each renovation performed by the certified renovation firm and discharges all of the certified renovator responsibilities identified in OAR 333-070-0100;

(c) All renovations performed by the certified renovation firm are performed in accordance with the work practice standards as described in OAR 333-070-0090;

(d) The pre-renovation education requirements of OAR 333-070-0095 have been performed;

(e) The recordkeeping requirements of OAR 333-070-0110 are met; and

(f) The certified renovator is in compliance with the responsibilities as identified in OAR 333-070-0100 and 333-070-0090.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: PH 8-2010, f. & cert. ef. 4-26-10; PH 4-2011, f. & cert. ef. 6-16-11

333-070-0110
Certified Renovation Firm Recordkeeping and Reporting Requirements

(1) A certified renovation firm performing renovations must retain and, if requested, make available to the Authority all records required by these rules necessary to demonstrate compliance with these rules for a period of three years following completion of the renovation. The three-year retention requirement does not supersede longer obligations required by other provisions for retaining the same documentation.

(2) Records that must be retained pursuant to this rule shall include (where applicable):

(a) Records or reports certifying that a determination had been made by an inspector or risk assessor that lead-based paint is not present on the components affected by the renovation. These records or reports include:

(A) Reports prepared by a certified inspector or certified risk assessor (certified by the Authority, EPA, or an EPA-authorized state or tribal program);

(B) Records prepared by a certified renovator after using EPA-recognized test kits, including an identification of the manufacturer and model of any test kits used, a description of the components that were tested including their locations, and the result of each test kit used.

(b) Signed and dated acknowledgments of receipts;

(c) Certifications of attempted delivery as described;

(d) Certificates of mailing;

(e) Records of notification activities performed regarding common area renovations and renovations in child-occupied facilities;

(f) Documentation of compliance with OAR chapter 333, division 70, including documentation that a certified renovator was assigned to the project, that the certified renovator provided on-the-job training for workers used on the project, that the certified renovator performed or directed workers who performed all of the tasks as described in this rule and that the certified renovator performed the post-renovation cleaning verification. If the certified renovation firm was unable to comply with all of the requirements of this rule due to an emergency, the certified renovation firm must document the nature of the emergency and the provisions of the rule that were not followed. This documentation must include a copy of the certified renovator's training certificate, and a certification by the certified renovator assigned to the project that:

(A) Training was provided to workers (topics must be identified for each worker);

(B) Warning signs were posted at the entrances to the work area;

(C) If test kits were used, that the specified brand of kits was used at the specified locations and that the results were as specified;

(D) The work area was contained by:

(i) Removing or covering all objects in the work area (interiors);

(ii) Closing and covering all HVAC ducts in the work area (interiors);

(iii) Closing all windows in the work area (interiors) or closing all windows in and within 20 feet of the work area (exteriors);

(iv) Closing and sealing all doors in the work area (interiors) or closing and sealing all doors in and within 20 feet of the work area (exteriors);

(v) Covering doors in the work area that were being used to allow passage but prevent spread of dust;

(vi) Covering the floor surface, including installed carpet, with taped-down plastic sheeting or other impermeable material in the work area six feet beyond the perimeter of surfaces undergoing renovation or a sufficient distance to contain the dust, whichever is greater (interiors) or covering the ground with plastic sheeting or other disposable impermeable material anchored to the building extending 10 feet beyond the perimeter of surfaces undergoing renovation or a sufficient distance to collect falling paint debris, whichever is greater, unless the property line prevents 10 feet of such ground covering, weighted down by heavy objects (exteriors);

(vii) Installing (if necessary) vertical containment to prevent migration of dust and debris to adjacent property (exteriors);

(viii) Waste was contained on-site and while being transported off-site.

(E) The work area was properly cleaned after the renovation by:

(i) Picking up all chips and debris, misting protective sheeting, folding it dirty side inward, and taping it for removal;

(ii) Cleaning the work area surfaces and objects using a HEPA vacuum and/or wet cloths or mops (interiors);

(iii) The certified renovator performed the post-renovation cleaning verification (the results of which must be briefly described, including the number of wet and dry cloths used).

(3) When the final invoice for the renovation is delivered or within 30 days of the completion of the renovation, whichever is earlier, the renovation firm must provide information pertaining to compliance with this subpart to the following persons:

(a) The owner of the building; and

(b) An adult occupant of the residential dwelling, if the renovation took place within a residential dwelling, or an adult representative of the child-occupied facility, if the renovation took place within a child-occupied facility.

(4) When performing renovations in common areas of multi-unit target housing, renovation firms must post the information required by this subpart or instructions on how interested occupants can obtain a copy of this information. This information must be posted in areas where it is likely to be seen by the occupants of all of the affected units.

(5) The information required to be provided by OAR 333-070-0110(2) may be provided by completing the sample form titled "Sample Renovation Recordkeeping Checklist" or a similar form containing the test kit information required by OAR 333-070-0075(3)(a)(B) and the training and work practice compliance information required by 333-070-0090 and 333-070-0100.

(6) If dust clearance sampling is performed in lieu of cleaning verification as permitted by OAR 333-070-0090(13), the renovation firm must provide, when the final invoice for the renovation is delivered or within 30 days of completion of the renovation, whichever is earlier, a copy of the dust sampling report to:

(a) The owner of the building; and

(b) An adult occupant of the residential dwelling, if the renovation took place within a residential dwelling, or an adult representative of the child-occupied facility, if the renovation took place within a child-occupied facility.

(7) When performing renovations in common areas of multi-unit target housing, renovation firms must post these dust sampling reports or information on how interested occupants of the housing being renovated can obtain a copy of the report. This information must be posted in areas where they are likely to be seen by the occupants of all of the affected units.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: PH 8-2010, f. & cert. ef. 4-26-10; PH 4-2011, f. & cert. ef. 6-16-11

333-070-0115
Inspections and Enforcement

(1) The Authority may:

(a) Enter private or public property at any reasonable time with consent of the owner or custodian of the property to inspect, investigate, evaluate or conduct tests or take specimens or samples for testing, as necessary to determine compliance with ORS 431.920;

(b) Issue subpoenas to determine compliance with ORS 431.920;

(c) Suspend, revoke or modify a certification to perform lead-based paint activities or renovation if the holder of the certification fails to comply with state or federal statutes or regulations related to lead-based paint;

(d) Suspend, revoke or modify a certified renovator's certification if the renovator fails to comply with state or federal statutes or regulations related to lead-based paint; and

(e) Issue civil penalties not to exceed $5,000 per violation for a violation of ORS 431.920, or any of these rules, including failure or refusal to permit entry or inspection in accordance with this rule.

(A) In issuing civil penalties the Authority shall consider whether:

(i) The Authority made repeated attempts to obtain compliance;

(ii) The certified firm or individual has a history of noncompliance with environmental statutes or regulations;

(iii) The violation poses a serious risk to the public's health;

(iv) The certified firm or individual gained financially from the noncompliance; and

(v) There are mitigating factors, such as a certified firm's or individual's cooperation with an investigation or actions to come into compliance.

(B) The Authority shall document its consideration of the factors in paragraph (1)(e)(A) of this rule.

(C) Each day a violation continues is an additional violation.

(D) A civil penalty imposed under this rule shall comply with ORS 183.745.

(2) An individual who is issued a notice of suspension, revocation or modification shall have the right to a contested case hearing under ORS Chapter 183.

(3) The Authority shall maintain a publicly available list of individuals whose certification has been suspended, revoked, modified, or reinstated.

(4) Unless a final order specifies otherwise:

(a) An individual whose certification has been suspended must take a refresher training course (renovator or dust sampling technician) prior to certification being reinstated.

(b) An individual whose certification has been revoked shall take an initial renovator or dust sampling technician course in order to become certified again.

(c) A certified renovation firm whose certification has been revoked may reapply for certification after one year from the date of revocation.

(d) If the certified renovation firm's certification has been suspended and the suspension ends less than five years after the certified renovation firm was initially certified or re-certified, the certified renovation firm does not need to do anything to re-activate its certification once the period of suspension has expired.

Stat. Auth.: ORS 183.310-183.540, 183.745, 431.920, 431.922, 431.994
Stats. Implemented: ORS 183.310-183.540, 183.745, 431.920, 431.922, 431.994
Hist.: PH 8-2010, f. & cert. ef. 4-26-10; PH 4-2011, f. & cert. ef. 6-16-11

333-070-0120
Certification Fees and Refunds

(1) Fees for the certification of certified renovation firms.

(a) Certification: $250

(b) Recertification: $250

(2) Fee Waivers. A renovation firm that has applied to EPA for certification or is certified by the EPA may request a waiver of the certification fee if the firm:

(a) Is required to be certified by the Authority; and

(b) Provides documentation that the date of application to EPA for certification or the date of certification is prior to May 3, 2010.

(3) Refund policy.

(a) An incomplete application shall be returned with the application fee minus a $50 administration fee.

(b) If an applicant requests that a complete application be withdrawn within 30 days of its receipt by the Authority, the Authority shall refund the applicant $200 minus a $50 administration fee.

(c) No fees will be refunded if the Authority has begun to process an application.

(4) Lost certificate. A $15 fee will be charged for the replacement of a certified renovation firm certificate.

(5) Certificate replacement. Certified renovation firms seeking certificate replacement must submit the replacement application form and a payment of $15 in accordance with the instructions provided with the application package.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: PH 8-2010, f. & cert. ef. 4-26-10; PH 4-2011, f. & cert. ef. 6-16-11

333-070-0125
Training Program Accreditation Required

(1) A training program may seek accreditation to offer courses in either of the following disciplines: renovator or dust sampling technician. A training program may also seek accreditation to offer refresher courses for each of the above listed disciplines.

(2) Application process. The following are procedures a training program must follow to receive Authority accreditation to offer renovator courses or dust sampling technician courses:

(a) A training program seeking accreditation shall submit a written application with the appropriate fee to the Authority containing the following information:

(A) The training program's name, address, and telephone number;

(B) A list of courses for which it is applying for accreditation. For the purposes of this section, courses taught in different languages are considered different courses, and each must independently meet the accreditation requirements; and

(C) A statement signed by the training program manager certifying that the training program meets the requirements established in OAR 333-070-0130 and 333-070-0135. If a training program uses EPA model training materials, or training materials approved by an EPA-authorized program, the training program manager shall include a statement certifying that as well.

(b) If a training program does not use EPA model training materials or training materials approved by an EPA-authorized program, its application for accreditation shall also include:

(A) A copy of the student and instructor manuals, or other materials to be used for each course;

(B) A copy of the course agenda for each course; and

(C) When applying for accreditation of a course in a language other than English, a signed statement from a qualified, independent translator that they have compared the course to the English language version and found the translation to be accurate.

(c) All training programs shall include in their application for accreditation the following:

(A) A description of the facilities and equipment to be used for lecture and hands-on training;

(B) A copy of the course test blueprint for each course;

(C) A description of the activities and procedures that will be used for conducting the assessment of hands-on skills for each course; and

(D) A copy of the quality control plan as described in section (4) of OAR 333-070-0135.

(d) If the Authority receives an incomplete application, it will request that the applicant submit the missing information or fee within 30 days. If an applicant fails to submit the requested information or the fee, the application will be returned to the applicant. An applicant who has had its application returned may reapply at any time.

(e) If a training program meets the requirements in OAR 333-070-0130 and 333-070-0135, then the Authority will approve the application for accreditation no more than 60 days after receiving a complete application from the training program. In the case of approval, a certificate of accreditation shall be sent to the applicant.

(f) If the Authority denies the application it shall send the applicant a letter giving the reason for denying the application. An individual whose application is denied shall have the right to a contested case hearing under ORS Chapter 183.

(g) If the applicant's application is denied, the program may reapply for accreditation at any time.

(3) A training program may apply for accreditation to offer courses or refresher courses in as many disciplines as it chooses. A training program may seek accreditation for additional courses at any time as long as the program can demonstrate that it meets the requirements of OAR 333-070-0130 and 333-070-0135.

(4) A training program must not provide, offer, or claim to provide renovator or dust sampling technician courses without applying for and receiving accreditation from the Authority.

(5) Refresher courses only.

(a) A training program seeking accreditation to offer refresher training courses only shall submit a written application to the Authority containing the following information:

(A) The refresher training program's name, address, and telephone number;

(B) A list of courses for which it is applying for accreditation;

(C) A statement signed by the training program manager certifying that:

(i) The refresher training program meets the minimum requirements established by section (18) of OAR 333-070-0135; and

(ii) The training program uses EPA-developed model training materials, or training materials approved by a state or Indian tribe that has been authorized by the EPA under 40 CFR §745.324 to develop its refresher training course materials, if applicable.

(D) If the refresher training course materials are not based on EPA-developed model training materials or training materials approved by an authorized state or Indian tribe:

(i) A copy of the student and instructor manuals to be used for each course; and

(ii) A copy of the course agenda for each course.

(E) A description of the facilities and equipment to be used for lecture and hands-on training;

(F) A copy of the course test blueprint for each course;

(G) A description of the activities and procedures that will be used for conducting the assessment of hands-on skills for each course (if applicable); and

(H) A copy of the quality control plan as described in section (4) of OAR 333-070-0135.

(b) If the Authority receives an incomplete application, it will request that the applicant submit the missing information or fee within 30 days. If an applicant fails to submit the requested information or the fee, the application will be returned to the applicant. An applicant who has had its application returned may reapply at any time.

(c) If a refresher training program meets the requirements in section (5) of this rule, then the Authority will approve the application for accreditation no more than 60 days after receiving a complete application from the training program. In the case of approval, a certificate of accreditation shall be sent to the applicant.

(d) If the Authority denies the application it shall send the applicant a letter giving the reason for denying the application. An applicant who receives a denial shall have the right to a contested case hearing under ORS Chapter 183.

(6) Accreditation shall be valid for four years and shall not be transferrable.

(7) The Authority may accredit a training program that has been accredited by the EPA or an EPA-authorized state or tribal program upon receiving evidence of that accreditation and that the training program has:

(a) Completed any additional requirements established by the Authority; and

(b) The training manager has read and understands the accreditation standards as described in these rules.

(8) Accreditation based on a valid accreditation issued by EPA or an EPA-authorized state or tribal program shall be issued with an expiration date not to exceed the date of expiration listed on the EPA or EPA-authorized state or tribal accreditation.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: PH 8-2010, f. & cert. ef. 4-26-10

333-070-0130
Minimum Personnel Requirements for Training Program Accreditation

For a training program to obtain accreditation from the Authority to offer renovator courses or dust sampling technician courses, the program shall:

(1) Employ a training manager who has:

(a) At least two years of experience, education, or training in teaching workers or adults; or

(b) A bachelor's or graduate degree in building construction technology, engineering, industrial hygiene, safety, public health, education, business administration or program management or a related field; or

(c) Two years of experience in managing a training program specializing in environmental hazards; and

(d) Demonstrated experience, education, or training in the construction industry including: lead or asbestos abatement, painting, carpentry, renovation, remodeling, occupational safety and health, or industrial hygiene.

(2) Designate a qualified principal instructor for each course who has:

(a) Demonstrated experience, education, or training in teaching workers or adults;

(b) Successfully completed at least 16 hours of any EPA-accredited or EPA-authorized Lead-Based Paint Activities or Lead Renovation, Repair and Painting training program; and

(c) Demonstrated experience, education, or training in lead or asbestos abatement, painting, carpentry, renovation, remodeling, occupational safety and health, or industrial hygiene.

(3) Have a principal instructor responsible for the organization of the course and oversight of the teaching of all course material. The training manager may designate guest instructors as needed to provide instruction specific to the lecture, hands-on activities, or work practice components of a course.

(4) Have documents that serve as evidence that training managers and principal instructors have the education, work experience, training requirements or demonstrated experience, specifically listed in sections (1) and (2) of this rule. This documentation need not be submitted with the accreditation application, but, if not submitted, shall be retained by the training program as required by the recordkeeping requirements contained in OAR 333-070-0150. Those documents include the following:

(a) Official academic transcripts or diploma as evidence of meeting the education requirements.

(b) Resumes, letters of reference, or documentation of work experience, as evidence of meeting the work experience requirements.

(c) Certificates from lead-specific training courses, as evidence of meeting the training requirements.

(5) Ensure the availability of, and provide adequate facilities for, the delivery of the lecture, course test, hands-on training, and assessment activities. This includes providing training equipment that reflects current work practices and maintaining or updating the equipment and facilities as needed.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: PH 8-2010, f. & cert. ef. 4-26-10; PH 4-2011, f. & cert. ef. 6-16-11

333-070-0135
Minimum Curriculum Requirements for Training Program Accreditation

(1) In order to become accredited in the following disciplines a training program shall provide training courses that meet the following training hour requirements:

(a) The renovator course must provide a minimum of eight training hours, with a minimum of two hours devoted to hands-on training activities. Hands-on training activities must cover renovation methods that minimize the creation of dust and lead-based paint hazards, interior and exterior containment and cleanup methods, and post-renovation cleaning verification.

(b) The dust sampling technician course shall provide a minimum of eight training hours, with a minimum of two hours devoted to hands-on training activities. Hands-on training activities must cover dust sampling methodologies.

(2) A student shall be required to pass a course test or a proficiency test and a hands-on-skill assessment for each course offered.

(a) The training manager is responsible for maintaining the validity and integrity of the hands-on skills assessment or proficiency test to ensure that it accurately evaluates the trainees' performance of the work practices and procedures associated with the course topics contained in sections (16), (17) and (18) of this rule.

(b) The training manager is responsible for maintaining the validity and integrity of the course test to ensure that it accurately evaluates the trainees' knowledge and retention of the course topics.

(c) The course test shall be developed in accordance with the test blueprint submitted with the training accreditation application.

(3) The training program shall issue unique course completion certificates to each individual who passes the training course. The course completion certificate shall include:

(a) The name, a unique identification number, and address of the individual;

(b) The name of the particular course that the individual completed;

(c) Dates of course completion/test passage; and

(d) For renovator and dust sampling technician course completion certificates, a photograph of the individual.

(4) The training manager shall develop and implement a quality control plan. The plan shall be used to maintain and improve the quality of the training program over time. This plan shall contain at least the following elements:

(a) Procedures for periodic revision of training materials and the course test to reflect innovations in the field.

(b) Procedures for the training manager's annual review of principal instructor competency.

(5) Courses offered by the training program must teach the work practice standards contained in OAR 333-070-0090, in such a manner that trainees are provided with the knowledge needed to perform the renovations they will be responsible for conducting.

(6) The training manager shall be responsible for ensuring that the training program complies at all times with all of the requirements in this rule.

(7) The Authority may audit the training program to verify the contents of the application for accreditation as described in OAR 333-070-0130 and 333-070-0135.

(8) The training manager shall provide the Authority with notification of all renovator or dust sampling technician courses offered. The original notification must be received by the Authority at least seven business days prior to the start date of any renovator or dust sampling technician course.

(9) The training manager shall provide the Authority updated notification when renovator or dust sampling technician courses will begin on a date other than the start date specified in the notification, as follows:

(a) For renovator or dust sampling technician courses beginning prior to the start date provided to the Authority, an updated notification must be received by the Authority at least seven business days before the new start date.

(b) For renovator or dust sampling technician courses beginning after the start date provided to the Authority, an updated notification must be received by the Authority at least two business days before the start date.

(10) The training manager shall update the Authority of any change in location of renovator or dust sampling technician courses at least seven business days prior to the start date.

(11) The training manager shall update the Authority regarding any course cancellations, or any other change to the original notification. Updated notifications must be received by the Authority at least two business days prior to the start date.

(12) Each notification required by sections (8) through (11) of this rule, including updates shall include the following:

(a) Notification type (original, update, cancellation);

(b) Training program name, the Authority accreditation number, address, and telephone number;

(c) Course discipline, type (initial/ refresher), and the language in which instruction will be given;

(d) Date(s) and time(s) of training;

(e) Training location(s), telephone number, and address;

(f) Principal instructor's name; and

(g) Training manager's name and signature.

(13) Renovator or dust sampling training courses may not begin on a date, or at a location other than that specified in the original notification unless an updated notification identifying a new start date or location is submitted, in which case the course must begin on the new start date and/or location specified in the updated notification.

(14) The training manager shall provide the Authority notification after the completion of any renovator or dust sampling technician course. This notice must be received by the Authority no later than 10 business days following course completion. The notification shall include the following:

(a) Training program name, accreditation number, address, and telephone number;

(b) Course discipline and type (initial/refresher);

(c) Date(s) of training;

(d) The following information for each student who took the course:

(A) Name;

(B) Address;

(C) Date of birth;

(D) Course completion certificate number;

(E) Course test score; and

(F) A digital photograph of the student;

(e) Training manager's name and signature.

(15) Notifications required by this rule can be accomplished by using an Authority approved form or can be provided in writing with the information.

(a) All notifications shall be in writing and submitted to the Authority:

(A) By mail through the U.S. Postal Service or other commercial delivery service;

(B) By facsimile;

(C) In person; or

(D) Electronically via electronic mail or through the Authority's web-based system if one is established.

(b) A training program providing notifications through the U.S. Postal Service should allow three additional business days for delivery in order to ensure that the Authority receives the notification by the required date.

(c) Instructions for notifications and sample forms can be obtained from the Authority's website at www.healthoregon.org/lead.

(16) Renovator Training Course. A renovator training course shall include the following subjects:

(a) Role and responsibility of a renovator;

(b) Background information on lead and its adverse health effects;

(c) Background information on, HUD, OSHA, and other federal, state, and local regulations and guidance that pertains to lead-based paint and renovation activities;

(d) Procedures for using EPA recognized test kits to determine whether paint is lead-based paint;

(e) Renovation methods to minimize the creation of dust and lead-based paint hazards;

(f) Interior and exterior containment and cleanup methods;

(g) Methods to ensure that the renovation has been properly completed, including cleaning verification, and clearance testing;

(h) Waste handling and disposal;

(i) Providing on-the-job training to other workers; and

(j) Record preparation.

(17) Dust sampling technician. A dust sampling technician course shall include the following subjects:

(a) Role and responsibility of a dust sampling technician;

(b) Background information on lead and its adverse health effects;

(c) Background information on federal, state, and local regulations and guidance that pertains to lead-based paint and renovation activities;

(d) Dust sampling methodologies;

(e) Clearance standards and testing; and

(f) Report preparation.

(18) Requirements for the accreditation of refresher training programs. A training program may seek accreditation to offer refresher training courses in either of the following disciplines: renovator and dust sampling technician. To obtain the Authority accreditation to offer refresher training, a training program shall meet the following minimum requirements:

(a) Each refresher course shall review the curriculum topics of the full-length courses listed under sections (16) and (17) of this rule, as appropriate. In addition, to become accredited to offer refresher training courses, training programs shall ensure that their courses of study include, at a minimum, the following:

(A) An overview of current safety practices relating to lead-based paint in general, as well as specific information pertaining to the appropriate discipline.

(B) Current laws and regulations relating to lead-based paint in general, as well as specific information pertaining to the appropriate discipline.

(C) Current technologies relating to lead-based paint in general, as well as specific information pertaining to the appropriate discipline.

(D) Refresher courses for renovator and dust sampling technician must last a minimum of four training hours.

(E) For each course offered, the training program shall conduct a hands-on assessment (if applicable), and at the completion of the course, a course test.

(19) A training program may apply for accreditation of a refresher course concurrently with its application for accreditation of a corresponding training course as described in OAR 333-070-0135(1).

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: PH 8-2010, f. & cert. ef. 4-26-10; PH 4-2011, f. & cert. ef. 6-16-11

333-070-0140
Re-Accreditation of Training Programs

(1) Unless reaccredited, a training program's accreditation (including refresher training accreditation) shall expire four years after the date of issuance. If a training program meets the requirements of this rule, the training program shall be reaccredited.

(2) A training program seeking reaccreditation shall submit an application to the Authority no later than 60 days before its accreditation expires. If a training program does not submit its application for reaccreditation by that date, the Authority cannot guarantee that the program will be reaccredited before the end of the accreditation period.

(3) The training program's application for reaccreditation shall contain:

(a) The training program's name, address, and telephone number.

(b) A list of courses for which it is applying for reaccreditation.

(c) A description of any changes to the training facility, equipment or course materials since its last application was approved that adversely affects the student's ability to learn.

(d) A statement signed by the program manager stating:

(A) That the training program complies at all times with all requirements in OAR 333-070-0130 and 333-070-0135 as applicable; and

(B) The recordkeeping and reporting requirements of OAR 333-070-0150 shall be followed.

(e) A payment of appropriate fees in accordance with these rules.

(4) The Authority may audit the training program to verify the contents of the application for reaccreditation as described in OAR 333-070-0140.

(5) If the Authority receives an incomplete application, it will request that the applicant submit the missing information or fee within 30 days. If an applicant fails to submit the requested information or the fee, the application will be returned to the applicant. An applicant who has had its application returned may reapply at any time.

(6) If a training program meets the requirements in section (2) of this rule, then the Authority will approve the application for reaccreditation no more than 60 days after receiving a complete application from the training program. In the case of approval, a certificate of accreditation shall be sent to the applicant.

(7) If the Authority denies the application it shall send the applicant a letter giving the reason for denying the application. An applicant whose application is denied shall have the right to a contested case hearing under ORS Chapter 183.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: PH 8-2010, f. & cert. ef. 4-26-10; PH 4-2011, f. & cert. ef. 6-16-11

333-070-0145
Suspending, Revoking, or Denying a Training Program's Accreditation; Civil Penalties

(1) The Authority may:

(a) Enter private or public property at any reasonable time with consent of the owner or custodian of the property to inspect or investigate as necessary to determine compliance with ORS 431.920;

(b) Issue subpoenas to determine compliance with ORS 431.920;

(c) Suspend, revoke, or deny an accreditation if the holder of the accreditation fails to comply with state or federal statutes or regulations related to lead-based paint; and

(d) Issue civil penalties not to exceed $5,000 per violation for a violation of ORS 431.920, or any of these rules, including failure or refusal to permit entry or inspection in accordance with this rule.

(A) In issuing civil penalties the Authority shall consider whether:

(i) The Authority made repeated attempts to obtain compliance;

(ii) The training program has a history of noncompliance with environmental statutes or regulations;

(iii) The violation poses a serious risk to the public's health;

(iv) The training program gained financially from the noncompliance; and

(v) There are mitigating factors, such as the training program's cooperation with an investigation or actions to come into compliance.

(B) The Authority shall document its consideration of the factors in paragraph (1)(d)(A) of this rule.

(C) Each day a violation continues is an additional violation.

(D) A civil penalty imposed under this rule shall comply with ORS 183.745.

(2) An accredited training program that is issued a notice of suspension, revocation or denial shall have the right to a contested case hearing under ORS Chapter 183.

(3) The Authority shall maintain a publicly available list of training programs whose accreditation has been suspended, revoked, denied, or reinstated.

(4) Unless a final order specifies otherwise:

(a) An accredited training program whose accreditation has been revoked may reapply for reaccreditation after one year from the date of revocation.

(b) If the training program's accreditation has been suspended and the suspension ends less than four years after the training program was initially accredited or reaccredited, the training program does not need to do anything to reactivate its accreditation once the period of suspension has expired.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: PH 8-2010, f. & cert. ef. 4-26-10; PH 4-2011, f. & cert. ef. 6-16-11

333-070-0150
Training Program Record Keeping Requirements

An accredited training program shall:

(1) Maintain, and make available to the Authority upon request, the following records:

(a) All documents that demonstrate the qualifications of the training manager and principal instructors.

(b) Current curriculum/course materials and documents reflecting any changes made to these materials.

(c) The course test blueprint.

(d) Information regarding how the hands-on assessment is conducted including, but not limited to:

(A) Who conducts the assessment;

(B) How the skills are graded;

(C) What facilities are used;

(D) The pass/fail rate;

(E) The quality control plan as described in section (4) of OAR 333-070-0135; and

(F) Results of the students' hands-on skills assessments and course tests, and a record of each student's course completion certificate.

(e) Any other material not listed above in this section that was submitted to the Authority as part of the program's application for accreditation.

(2) Retain the records required at the address specified on the training program accreditation application or as amended for a minimum of three years and six months.

(3) If a training program modifies its application by changing its address, it shall also notify the Authority in writing within 30 days of its intent to transfer records to the new address.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: PH 8-2010, f. & cert. ef. 4-26-10

333-070-0160
Accreditation Fees

The following fees are established:

(1) Course Fee Schedule:

(a) Course — Accreditation Fee — Reaccreditation fee:

(b) Renovator Initial — $560 — $340:

(c) Dust Sampling Technician Initial — $560 — $340:

(d) Renovator Refresher — $400 — $310:

(e) Dust Sampling Technician Refresher — $400 — $310

(2) Student Fee Schedule:

(a) Course — Fee:

(b) Renovator Initial — $17:

(c) Renovator Refresher — $17:

(d) Dust Sampling Technician Initial — $17:

(e) Dust Sampling Refresher — $17.

(f) The student fee is to be paid by the training program at the completion of each training course. The $17 fee is per student that successfully completes the course. The fee shall be paid by the training program to the Authority within 10 days after completion of the training course.

(3) Fee Waivers. A training program, that has applied for accreditation by the EPA to provide Renovator or Dust Sampling Technician training may request a waiver of the accreditation fees if the training program provides documentation that the date of application for accreditation by EPA or date of accreditation is prior to May 3, 2010.

(4) Firms with current accreditation by EPA or an EPA-authorized state or tribal program shall pay a prorated fee of the appropriate fee listed above, divided by 48, times the number of months remaining in the current accreditation, beginning with the month following application to the Authority.

Stat. Auth.: ORS 431.920
Stats. Implemented: ORS 431.920
Hist.: PH 8-2010, f. & cert. ef. 4-26-10; PH 4-2011, f. & cert. ef. 6-16-11

DIVISION 71

SPECIAL INPATIENT CARE FACILITIES

333-071-0000
Licensing Procedures and Definitions

As used in OAR chapter 333, division 71, unless the context requires otherwise, the following definitions apply:

(1) "Health Care Facility" (HCF) has the meaning given the term in ORS 442.015, and includes but is not limited to the following classifications:

(a) "Hospital" means an establishment with an organized medical staff with permanent facilities that include inpatient beds, and with medical services, including physician services and continuous nursing services under the supervision of registered nurses, to provide diagnosis and medical or surgical treatment primarily for, but not limited to, acutely ill patients and accident victims, or to provide treatment for the mentally ill or to provide treatment in special inpatient care facilities. "Special inpatient care facilities" are facilities with inpatient beds and other facilities designed and utilized for special health care purposes, to include but not be limited to: Rehabilitation center, college infirmary, chiropractic facility, facility for the treatment of alcoholism or drug abuse, freestanding hospice facility, infirmary for the homeless, critical access hospital, or inpatient care facility meeting the requirements of ORS 441.065, and any other establishment falling within a classification established by the Division, after determination of the need for such classification and the level and kind of health care appropriate for such classification.

(b) An "ambulatory surgical center" or ambulatory surgical facility means a health care facility without patient beds, not sponsored by a hospital which performs outpatient surgery not routinely or customarily performed in a physician's or dentist's office, and is able to meet health facility licensure requirements. In the case of outpatient surgery involving termination of pregnancy, procedures routinely and customarily done in physicians' offices are the following:

(A) Dilation and curettage;

(B) Suction curettage;

(C) Sharp curettage;

(D) Dilation and evacuation.

(c) A "hospital associated ambulatory surgery center" means an ambulatory surgical service that is separately identifiable; physically, administratively and financially independent, distinct from other operations of the hospital, and is not located proximate to or adjoining the hospital's campus. The hospital associated ambulatory surgery center performs surgery not routinely or customarily performed in the physician's or dentist's office, and is able to meet health facility licensure requirements. In the case of outpatient surgery involving termination of pregnancy, procedures routinely and customarily done in physicians' offices are the following:

(A) Dilation and curettage;

(B) Suction curettage;

(C) Sharp curettage;

(D) Dilation and evacuation.

(d) "Freestanding birth center" means a health care facility licensed for the primary purpose of performing low risk deliveries.

(2) "Authentication" means verification that an entry in the patient medical record is genuine.

(3) "Certified Nursing Assistant" (CNA) means a person who holds a current, valid Oregon CNA certificate by meeting the requirements specified by the Oregon State Board of Nursing; and who assists licensed nursing personnel in the provision of nursing care.

(4) "Certified Registered Nurse Anesthetist" (CRNA) means a registered nurse licensed by the Oregon State Board of Nursing as a certified registered nurse anesthetist.

(5) "Certified Nurse Midwife" (CNMW) means a registered nurse certified by the Oregon State Board of Nursing (OSBN) as a nurse practitioner midwife.

(6) "Chiropractor" means a person licensed under ORS Chapter 684 to practice chiropractic.

(7) "Critical Access Hospital" means an acute care inpatient facility located in an eligible rural area and which meets those requirements as delineated by the Office of Rural Health and approved by the Health Care Financing Administration (HCFA).

(8) "Division" means the Oregon Health Authority, Public Health Division.

(9) "Freestanding Hospice Facility" (FSHF) means a health care facility which:

(a) Only admits patients who have been certified by the attending physician to be terminally ill, to have a life expectancy not to exceed 12 months, and have given up active treatment aimed at cure; and

(b) Complies with ORS Sections 443.850 and 443.860.

(10) "Governing Body" means the body or person legally responsible for the direction and control of the operation of the facility.

(11) "Governmental Unit" means the state, or any county, municipality, or other political subdivision, or any related department, division, board or other agency.

(12) "Health Care Facility Licensing Law" means ORS 441.005 to 441.990 and rules thereunder.

(13) " Infirmary for the Homeless" means a facility designed to provide inpatient medical care to indigent, homeless members of the community.

(14) "Inpatient Beds" means a bed in a facility available for occupancy by a patient who will or may be cared for and treated on an overnight basis.

(15) "Licensed" means that the person or facility to whom the term applies is currently licensed, certified or registered by the proper authority to follow his or her profession or vocation within the State of Oregon, and when applied to a health care facility means that the facility is currently and has been duly and regularly licensed by the state Public Health Division.

(16) "Licensed Nurse" means a Registered Nurse (RN) or a Licensed Practical Nurse (LPN).

(17) "Licensed Practical Nurse" (LPN) means a person licensed under ORS Chapter 678 to practice practical nursing.

(18) "Major Alteration" means changes other than repair or replacement of building materials and equipment with materials and equipment of a similar type.

(19) "Naturopath" means a person licensed under ORS Chapter 685 to practice naturopathy.

(20) "New Construction" means a new building or an addition to an existing building.

(21) "NFPA" means National Fire Protection Association.

(22) "Nurse Practitioner" (NP) means a registered nurse who has been certified by the Oregon State Board of Nursing (OSBN) as qualified to practice in an expanded specialty role within the practice of nursing.

(23) "Nursing Assistant" means a person who assists licensed nursing personnel in the provision of nursing care.

(24) "Oregon Sanitary Code" means the Food Sanitation Rules, OAR 333-150-0000 through 333-168-0020 except 333-157-0000 through 333-158-0030.

(25) "Patient audit" means review of the medical record and/or physical inspection of a patient.

(26) "Person" means an individual, a trust or estate, a partnership, corporation, (including associations, joint stock, companies and insurance companies, a state or a political subdivision or instrumentality including a municipal corporation) of a state.

(27) "Physician" means a person licensed under ORS Chapter 677 to practice medicine.

(28) "Physician's Assistant" means a person who is registered as a physician's assistant in accordance with ORS Chapter 677.

(29) "Podiatrist" means a person licensed under ORS Chapter 677 to practice podiatry.

(30) "Podiatry" means the diagnosis or the medical, physical or surgical treatment of ailments of the human foot, except treatment involving the use of a general or spinal anesthetic unless the treatment is performed in a hospital certified in the manner described in subsection (2) of ORS 441.055 and is under the supervision of or in collaboration with a physician licensed to practice medicine by the Board of Medical Examiners for the State of Oregon. "Podiatry" does not include the administration of general or spinal anesthetics or the amputation of the foot.

(31) "Registered Nurse" (RN) means a person licensed under ORS Chapter 678.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.015 - 441.087
Hist.: HD 13-1987, f. 9-1-87, ef. 9-15-87; HD 11-1988, f. & cert. ef. 5-27-88; HD 5-1989, f. 7-14-89, cert. ef. 8-1-89; OHD 6-1999, f. & cert. ef. 10-22-99

333-071-0005
Issuance of License

(1) Application for a license to operate a health care facility shall be in writing on a form provided by the Division including demographic, ownership and administrative information. The form shall specify such information required by the Division.

(2) No person or health care facility licensed pursuant to the provisions of ORS Chapter 441, shall in any manner or by any means assert, represent, offer, provide or imply that such person or facility is or may render care or services other than that which is permitted by or which is within the scope of the license issued to such person or facility by the Division nor shall any service be offered or provided which is not authorized within the scope of the licensed issued to such person or facility.

(3) Each application for license renewal shall accurately reflect only the number of beds the facility is then presently capable of operating considering existing equipment, and ancillary service capability of the facility and the physical requirements as specified within these rules and regulations. The number of beds to be licensed shall not exceed the number of beds reflected in the license to be renewed unless approved by the Division.

(4) Separate licenses are not required for separate buildings operated as an integrated unit by the same management. Special inpatient care beds and other services approved by the Division may be included within the scope of the license of the hospital and do not require a separate license.

(5) The license shall be conspicuously posted in the area where patients are admitted.

(6) No license shall be issued or renewed for any Health Care Facility that offers or proposes to develop a new health service subject to ORS 442.320, unless a certificate of need has first been issued therefore pursuant to 442.340.

(7) A facility license that has been suspended or revoked may be reissued after the Division determines that compliance with HCF laws has been achieved satisfactorily.

(8) Submission of Plans, OAR 333-071-0140, shall also apply.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.020 - 441.025
Hist.: HD 17-1987(Temp), f. 10-13-87, ef. 10-15-87 thru 4-15-88; HD 11-1988, f. & cert. ef. 5-27-88; HD 5-1989, f. 7-14-89, cert. ef. 8-1-89; OHD 6-1999, f. & cert. ef. 10-22-99

333-071-0010
Annual License Fee

The following license fee applies to special inpatient facilities, (alcohol and drug abuse treatment facilities, college infirmaries, christian science facility, chiropractic facilities, freestanding hospice facilities, infirmaries for the homeless, critical access hospitals):

(1) Less than twenty-six beds, the annual license fee will be $750.

(2) Twenty-six beds or more beds and fewer than 50 beds, the annual license fee will be $1,000.

(3) Fifty or more beds and fewer than 100 beds, the annual license fee will be $1,900.

(4) One hundred or more beds and fewer than 200 beds, the annual license fee will be $2,900.

(5) More than two hundred beds, the annual license fees will be $3,400.

Stat. Auth.: ORS 441.011
Stats. Implemented: ORS 441.020
Hist.: HD 11-1988, f. & cert. ef. 5-27-88; HD 5-1989, f. 7-14-89, cert. ef. 8-1-89; OHD 6-1999, f. & cert. ef. 10-22-99

333-071-0015
Expiration and Renewal of License

Each license to operate a health care facility shall expire on December 31 following the date of issue, and if a renewal is desired, the licensee shall make application at least 30 days prior to the expiration date upon a form prescribed by the Division.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.025
Hist.: HD 11-1988, f. & cert. ef. 5-27-88; HD 5-1989, f. 7-14-89, cert. ef. 8-1-89

333-071-0020
Denial or Revocation of License

(1) A license for any health care facility may be denied, suspended or revoked by the Division when the Division finds that there has been a substantial failure to comply with the provisions of Health Care Facility licensing law.

(2) A person or persons in charge of a health care facility shall not permit, aid or abet any illegal act affecting the welfare of the patient.

(3) A license shall be denied, suspended or revoked in any case where the State Fire Marshal or representative of the State Fire Marshal, certified that there is a failure to comply with all applicable laws, lawful ordinances, and rules relating to safety from fire.

(4) A license may be suspended or revoked for failure to comply with a Division order arising from a health care facility's substantial lack of compliance with the rules or statutes.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.030
Hist.: HD 11-1988, f. & cert. ef. 5-27-88; HD 5-1989, f. 7-14-89, cert. ef. 8-1-89

333-071-0025
Return of Facility License

Each license certificate in the licensee's possession shall be returned to the Division immediately on the suspension or revocation of the license, failure to renew the license by December 31, or if operation is discontinued by the voluntary action of the licensee.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: HD 11-1988, f. & cert. ef. 5-27-88

333-071-0030
Classification

(1) The various types of health care facilities within the provisions of ORS Chapter 441 are classified as follows:

(a) Hospital Classifications:

(A) General Hospital;

(B) Mental Hospital or Psychiatric Hospital;

(C) Orthopedic Hospital;

(D) Special Inpatient Care Facility:

(i) Chiropractic Facility;

(ii) Alcohol and/or Drug Abuse Treatment Facility;

(iii) Infirmary: College Infirmary or Student Health Center;

(iv) Rehabilitation Center;

(v) Christian Science Facility;

(vi) Infirmary for the Homeless;

(vii) Freestanding Hospice Facility;

(viii) Critical Access Hospital.

(b) Ambulatory Surgical Center;

(c) Hospital Associated Ambulatory Surgical Center;

(d) Freestanding Birthing Center.

(2) The classification of each health care facility shall be so designated on the license.

(3) Health care facilities licensed by the Division shall neither assume a descriptive title or be held out under any descriptive title other than the classification title established by the Division and under which the facility is licensed. This not only applies to the name on the facility but where stationery, advertising and other representations are involved: General Hospitals may be described as hospitals without modifications by the term "general."

(4) No change in the licensed classification of any health care facility, as set out in this rule, shall be allowed by the Division unless such facility shall file a new application, accompanied by the required license fee, with the Division, if the Division finds that the applicant and facility comply with HCF laws and the regulations of the Division relating to the new classification for which application for licensure is made, the Division shall issue a license for such classification.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.085
Hist.: HD 13-1987, f. 9-1-87, ef. 9-15-87; HD 11-1988, f. & cert. ef. 5-27-88; HD 5-1989, f. 7-14-89, cert. ef. 8-1-89; OHD 6-1999, f. & cert. ef. 10-22-99

333-071-0035
Hearings

Upon written notification by the division of revocation, suspension or denial to issue or renew a license, a written request by the facility for a hearing in accordance with ORS 183.310 to 183.500 shall be granted by the Division.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.037
Hist.: HD 11-1988, f. & cert. ef. 5-27-88

333-071-0040
Adoption by Reference

All rules, standards and publications referred to in OAR 333-071 are made a part thereof. Copies are available for inspection in the Division during office hours. Where publications are in conflict with the rules, the rules shall govern.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: HD 11-1988, f. & cert. ef. 5-27-88; HD 5-1989, f. 7-14-89, cert. ef. 8-1-89

333-071-0045
Division Procedures

Inspections and investigations:

(1) Complaints:

(a) Any person may make a complaint to the Public Health Division regarding violations of health care facility, laws or regulations. A complaint investigation will be carried out as soon as practicable and may include but not be limited to, as applicable to facts alleged: Interview of the complainant, patient(s), witnesses, and HCF management and staff; observations of the patient(s), staff performance, patient environment and physical environment; and review of documents and records.

(b) Copies of all complaint investigations, which are not exempt from disclosure, will be available from the Division provided that the identity of any patient referred to in an investigation will not be disclosed without legal authorization.

(2) Inspections:

(a) The Division may, in addition to any inspections conducted pursuant to complaint investigations, conduct at least one general inspection of each HCF to determine compliance with HCF laws during each calendar year and at such other times as the Division deems necessary.

(b) Inspections may include but not be limited to those procedures stated in subsection (1)(a) of this rule.

(c) The inspection may include a patient audit, the results of which shall be summarized on the licensing survey form.

(d) When documents and records are requested under section (1) or (2) of this rule, the HCF shall make the requested materials available to the investigator for review and copying.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.057 & 441.060
Hist.: HD 29-1988, f. & cert. ef. 5-27-88; HD 5-1989, f. 7-14-89, cert. ef. 8-1-89

333-071-0050
Governing Body Responsibility

The governing body of each health care facility shall be responsible for the operation of the facility, the selection of the medical staff and the quality of care rendered in the facility. The governing body shall:

(1) Ensure that all health care personnel for whom state licenses or registration are required are currently licensed or registered;

(2) Ensure that physicians, nurse practitioners, and physicians' assistants admitted to practice in the facility are granted privileges consistent with their individual training, experience and other qualifications;

(3) Ensure that procedures for granting, restricting and terminating privileges exist and that such procedures are regularly reviewed to assure their conformity to applicable law; and

(4) Ensure that physicians, nurse practitioners, and physicians' assistants admitted to practice in the facility are organized into a medical staff insofar as applicable in such a manner as to effectively review the professional practices of the facility for the purposes of reducing morbidity and mortality and for the improvement of patient care.

(5) In a Critical Access Hospital, the governing body shall be responsible for the development of a plan by which a person, presenting for services when no patients and staff members are in the facility, is able to contact a health care practitioner who is either a doctor of medicine or osteopathy, a physician assistant, or a nurse practitioner. The governing body shall ensure that a practitioner with training or experience in emergency care is on call and immediately available by telephone or radio contact, and available on site within 30 minutes, on a 24-hours a day basis.

(6) This section is not applicable to facilities meeting the requirements of ORS 441.065.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: HD 17-1987(Temp), f. 10-13-87, ef. 10-15-87 thru 4-15-88; HD 11-1988, f. & cert. ef. 5-27-88; HD 5-1989, f. 7-14-89, cert. ef. 8-1-89; OHD 6-1999, f. & cert. ef. 10-22-99

333-071-0055
Medical Staff

(1) The physicians, nurse practitioners and physician assistants organized into a medical staff pursuant to OAR 333-071-0050 shall propose medical staff by-laws to govern the medical staff. The bylaws shall include, but not be limited to the following:

(a) Procedures for physicians, nurse practitioners and physician assistants admitted to practice in the facility to organize into a medical staff;

(b) Procedures for insuring that physicians, nurse practitioners and physician assistants admitted to practice in the facility are granted privileges consistent with their individual training, experience and other qualifications;

(c) Provisions establishing a frame work for the medical staff to nominate, elect, appoint or remove officers and other persons to carry out medical staff activities with accountability to the governing body;

(d) Procedures for insuring that physicians, nurse practitioners and physician assistants admitted to practice in the facility are currently licensed by the Oregon Medical Board for the State of Oregon or the Oregon State Board of Nursing;

(e) Procedures for insuring that the facility's procedures for granting, restricting and terminating privileges are followed and that such procedures are regularly reviewed to assure their conformity to applicable law; and

(f) Procedures for insuring that physicians, nurse practitioners and physician assistants provide services within the scope of the privileges granted by the governing body.

(2) Amendments to medical staff bylaws shall be accomplished through a cooperative process involving both the medical staff and the governing body. Medical staff bylaws shall be adopted, repealed or amended when approved by the medical staff and the governing body. Approval shall not be unreasonably withheld by either. Neither the medical staff nor the governing body shall withhold approval if such repeal, amendment, or adoption is mandated by law, statute or regulation or is necessary to obtain or maintain accreditation or to comply with fiduciary responsibilities or if the failure to approve would subvert the state moral or ethical purposes of this institution.

(3) Physicians and all other health care practitioners with individual admitting privileges are subject to applicable provisions of the medical staff bylaws and rules governing admission and staff privileges.

(4) This section is not applicable to facilities meeting the requirements of ORS 441.065.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: HD 17-1987(Temp), f. 10-13-87, ef. 10-15-87 thru 4-15-88; HD 11-1988, f. & cert. ef. 5-27-88; HD 5-1989, f. 7-14-89, cert. ef. 8-1-89; OHD 6-1999, f. & cert. ef. 10-22-99

333-071-0057
Personnel

(1) Health care facility shall maintain a sufficient number of qualified personnel to provide effective patient care and all other related services.

(2) There shall be written personnel policies and procedures which shall be made available to personnel.

(3) Provisions shall be made for orientation.

(4) Provisions shall be made for an annual continuing education plan.

(5) There shall be a job description for each position which delineates the qualifications, duties, authority and responsibilities inherent in each position.

(6) There shall be an annual work performance evaluation for each employee with appropriate records maintained.

(7) There shall be an employee health program for the protection of patients.

(a) Pursuant to OAR 333-019-0205:

(A) A person who is diagnosed to have a health care facility restrictable disease shall not engage, as long as she/he is communicable, in any occupation in which he/she provides personal care to or has direct contact with patients in a health care facility. This restriction is removed by the written certification of the local health officer (or designee or) a licensed medical doctor (in concurrence with the local health officer) that the person is no longer communicable.

(B) Examples of health care facility restrictable diseases include but are not restricted to:

(i) Amebiasis;
(ii) Chickenpox;
(iii) Cholera;
(iv) Diphtheria;
(v) Hepatitis A;
(vi) Measles;
(vii) Meningococcal Disease;
(viii) Mumps;
(ix) Pediculosis;
(x) Pertussis;
(xi) Plague;
(xii) Rubella;
(xiii) Salmonellosis;
(xiv) Scabies;
(xv) Shigellosis;
(xvi) Staphylococcal Infections;
(xvii) Streptococcal Infections;
(xviii) Tuberculosis, active pulmonary.

(C) The infection control committee of the health care facility shall adopt policies to restrict the working of employees with health care facility restrictable diseases. When measures have been taken to prevent the transmission of disease and these measures are in accordance with written procedures approved by the infection control committee of the facility after consultation with the local health officer, infectious employees may work in a health care facility. Nothing in these rules prohibits health care facilities and local health departments from adopting additional or more stringent rules for exclusion from these facilities.

(b) Pursuant to OAR 333-019-0405:

(A) Any employee working in a health care facility who does not have a documented history of a positive tuberculin test shall have a Mantoux method tuberculin test applied and interpreted within two weeks of first employment.

(B) If the tuberculin test is negative, the employee does not need to have further routine tuberculin skin tests, except as outlined in paragraph (7)(b)(F) of this rule.

(C) If the tuberculin test is positive or if the employee has a previously documented positive tuberculin skin test, and if the employee has not had adequate chemotherapy, the employee shall have a chest X-ray and medical evaluation to identify communicable tuberculosis within two weeks of first employment.

(D) Tuberculin positive employees who do not have communicable tuberculosis and who complete one year of isoniazid preventive therapy tuberculosis and who complete one year of isoniazid preventive therapy (or adequate anti-tuberculosis chemotherapy) shall be released from further routine tuberculosis screening activities.

(E) Tuberculin positive employees who do not have communicable tuberculosis shall have a medical evaluation for the presence of any of the following risk factors: evidence of inadequately treated past tuberculosis disease, history of close exposure to a case of communicable pulmonary tuberculosis within the previous two years, acquired immunodeficiency syndrome, history of a negative tuberculin test within the previous two years, diabetes mellitus (severe or poorly controlled), diseases associated with severe immunologic deficiencies, immuno-suppressive therapy, silicosis, gastrectomy, or excessive alcohol intake. Tuberculin positive employees with any of these risk factors who have not completed one year of isoniazid preventive therapy shall have annual chest X-rays for the duration of their employment. Tuberculin positive employees who have not completed one year of isoniazid preventive therapy and who do not have any of the risk factors shall be released from further tuberculosis surveillance. The facility shall

have a policy to assure that a change in risk status of such an individual will be identified.

(F) Tuberculin negative employees of health care facilities whose work has the potential for frequent or periodic close exposure to persons with communicable tuberculosis or laboratory specimens of M. tuberculosis shall have periodic tuberculin tests at intervals to be specified by the facility's infection control committee, or by the facility's administrative policy when there is no infection control committee.

(G) An employee whose employment never requires him/her to be in a room where patients or residents might enter, and who does not handle clinical specimens or other material from patients or their rooms, may be exempted from the requirements of paragraph (b)(A)–(F) of this section. An example of such an employee would be an administrative person or research worker whose place of work is remote from patient or residential care areas and who does not come in contact with clinical specimens.

(H) In the event that a case of communicable tuberculosis is diagnosed in an employee or patient of a health care facility, the facility shall conduct an investigation to identify contacts. The local health department shall assist in the investigation and shall assure that the investigation follows the guidelines of the American Thoracic Society referred to in OAR 333-017-0005(3).

(I) The actions taken under paragraphs (b)(A) through (H) of this section and all results thereof shall be fully documented for each employee. Such documentation is subject to review by authorized representatives of the Division.

(8)(a) Any person admitted to a facility for treatment of alcoholism, or rehabilitation center, who does not have a documented history of a positive tuberculin test shall have a Mantoux method tuberculin test within two weeks of first admission. If the admission tuberculin test is negative, the patient is not required to have periodic tuberculin tests.

(b) If an admission tuberculin skin test is positive, or if the patient has had a previously documented positive tuberculin test, and the patient has not had adequate chemotherapy, the patient shall have a chest X-ray and medical evaluation to identify communicable tuberculosis unless such an X-ray and evaluation has been performed within the preceding three months. If communicable tuberculosis is suspected or diagnosed, the patient shall be cared for in general accordance with AFB isolation as follows: In health care facilities, cases of current pulmonary tuberculosis shall be placed in AFB isolation or the appropriate disease-specific precautions until they have been determined to be non-infectious by the infection control committee of the facility or the local health officer (or designee). In health care facilities, suspected cases of pulmonary tuberculosis shall be placed in AFB isolation until the diagnosis of infectious pulmonary tuberculosis has been excluded by the attending licensed medical doctor.

(c) The admission skin test and chest X-ray requirements in subsections (8)(a) and (b) do not apply to persons readmitted to the same facility after having been directly discharged to a hospital and readmitted directly from the hospital.

(d) The tuberculin positive patient who does not have tuberculosis disease shall be offered isoniazid preventive therapy according to the American Thoracic Society guidelines. Tuberculin positive patients who have not completed one year of isoniazid preventive therapy shall have annual chest X-rays while at the facility. Such patients who are under age 65, and do not have any of the risk factors described in subsection (7)(a)(C) of this rule shall be released from further routine tuberculosis surveillance following three negative yearly chest X-rays.

(e) The actions taken under subsections (8)(a) through (d) of this rule and all results thereof shall be fully documented for each patient. Such documentation is subject to review by authorized representatives of the Division.

(9) Only subsections (1)–(6) of this rule apply to facilities meeting the requirements of ORS 441.065.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: HD 5-1989, f. 7-14-89, cert. ef. 8-1-89 ; OHD 6-1999, f. & cert. ef. 10-22-99

333-071-0060
Medical Records

(1) A medical record shall be maintained for every patient admitted for care in all Health Care Facilities.

(2) A legible reproducible medical record in ink or typescript shall include at least the following (if applicable):

(a) Admitting identification data including date of admission.

(b) Chief compliant.

(c) Pertinent family and personal history.

(d) Medical history, physical examination report and provisional diagnosis:

(A) If a patient is readmitted within a month's time for the same condition, the previous medical history and physical examination report, with an interval note, will suffice.

(B) If a medical history and physical examination report which complies with the above requirements has been completed within 7 days prior to admission, it may be used as the admission history and physical as provided in the medical staff rules and regulations.

(e) Clinical laboratory reports as well as reports on any special examinations. (The original report shall be authenticated and recorded in the patient's medical record.)

(f) X-ray reports shall be recorded in the medical record and shall bear the identification (authentication) of the originator of the interpretation.

(g) Signed or authenticated report of consultant when such services have been obtained.

(h)(A) All entries in a patient's medical record must be dated, timed and authenticated. Verification of an entry requires use of a unique identifier, i.e., signature, code, thumb print, voice print, or other means, which allows identification of the individual responsible for the entry.

(B) Verbal orders may be accepted by those individuals authorized by law and/or scope of practice and by medical staff rules and regulations and shall be countersigned or authenticated by the prescriber within 24 hours, except in the case of Freestanding Hospice Facilities, in which verbal orders must be countersigned by the house physician in 72 hours and by the attending physician within seven days.

(C) A single signature or authentication of the physician, dentist, podiatrist or other individual authorized within the scope of his or her professional license on the medical record does not suffice to cover the entire content of the record.

(i) Records of assessment and intervention, including graphic charts and medication records and appropriate personnel notes.

(j) Summary including final diagnosis.

(k) Date of discharge and discharge note.

(l) Autopsy report if applicable.

(m) Such signed documents as may be required by law.

(3) The completion of the medical record shall be the responsibility of the attending practitioner. The dentist, podiatrist or other individual authorized within the scope of his or her professional license shall complete those portions of the record which pertain to his/her portion of the patient's care. The appropriate individual shall separately sign or authenticate the history and physical examination, operative report, progress notes, orders and the summary. In a facility using unlicensed house officers, the attending physician shall countersign, without 24 hours, all entries written by such house officers. Externs working in a program may be considered house officers. The physician, dentist, podiatrist or other individual authorized within the scope of his or her professional license shall also authenticate any clinical entries which he/she makes himself/herself. A single signature or authentication of the physician, dentist, podiatrist or other individual authorized within the scope of his or her professional license on the face sheet of the medical record does not suffice to cover the entire content of the record:

(a) Medical records shall be completed by the physician, dentist, podiatrist or other individual authorized within the scope of his or her professional license within four weeks following the patient's discharge.

(b) If a patient is transferred to another health care facility, transfer information shall accompany the patient. Transfer information shall include but not be limited to facility from which transferred, name of physician to assume care, date and time of discharge, current medical findings, current nursing assessment, current history and physical, diagnosis, orders from a physician for immediate care of the patient, operative report, if applicable; TB test, if applicable; other information germane to patient's condition. If discharge summary is not available at time of transfer, it shall be transmitted as soon as available.

(4) Diagnoses and operations shall be expressed in standard terminology.

(5) The medical records shall be filed in a manner which renders them easily retrievable. Medical records shall be protected against unauthorized access, fire, water and theft.

(6) Medical records are the property of the health care facility. The medical record, either in original, electronic or microfilm form, shall not be removed from the institution except where necessary for a judicial or administrative proceeding. Authorized personnel of the Division shall be permitted to review medical records. When a health care facility uses off-site storage for medical records, arrangements must be made for delivery of these records to the health care facility when needed for patient care or other health care facility activities. Precautions must be taken to protect patient confidentiality.

(7) All medical records shall be kept for a period of at least ten years after the date of last discharge. Original medical records may be retained on paper, microfilm, electronic or other media.

(8) If a health care facility changes ownership all medical records in original, electronic or microfilm form shall remain in the facility or related institution, and it shall be the responsibility of the new owner to protect and maintain these records.

(9) If any facility shall be finally closed, its medical records may be delivered and turned over to any other facility or facilities in the vicinity willing to accept and retain the same as provided in section (7) of this rule.

(10) All original clinical records or photographic or electronic facsimile thereof, not otherwise incorporated in the medical record, such as X-rays, electrocardiograms, electroencephalograms, and radiological isotope scans shall be retained for seven years after patient's last discharge if professional interpretations of such graphics are included in the medical records.

(11) If a qualified medical record practitioner, RRA (Registered Record Administrator) or ART (Accredited Record Technician) is not the Director of the Medical Records Department, periodic and at least annual consultation must be provided by a qualified medical records consultant, RRA/ART. The visits of the medical records consultant shall be of sufficient duration and frequency to review medical record systems and assure quality records of the patients. Contract for such services shall be available to the Division.

(12) A current written policy on the release of medical record information including patient access to his/her medical record shall be maintained in the medical records department.

(13) This section is not applicable to facilities meeting the requirements of ORS 441.065.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: HD 17-1987(Temp), f. 10-13-87, ef. 10-15-87 thru 4-15-88; HD 11-1988, f. & cert. ef. 5-27-88; HD 5-1989, f. 7-14-89, cert. ef. 8-1-89; OHD 6-1999, f. & cert. ef. 10-22-99

333-071-0065
Quality Assurance

The governing body must ensure that there is an effective, written, facility-wide quality assurance program to evaluate and monitor the quality and appropriateness of patient care, including contracted services. Written documentation of quality assurance activities shall be recorded at least quarterly. This section does not apply to those facilities meeting the requirements of ORS 441.065.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: HD 17-1987(Temp), f. 10-13-87, ef. 10-15-87 thru 4-15-88; HD 11-1988, f. & cert. ef. 5-27-88; HD 5-1989, f. 7-14-89, cert. ef. 8-1-89

333-071-0070
Medically Related Patient Care Services

(1) Medically-related patient care services: The facility must have an ongoing plan consistent with available community and facility resources, to provide or make available social work, psychological, and educational services to meet the medically-related needs of its patients. The facility also must have an effective, ongoing discharge planning program that facilitates the provision of follow-up care.

(a) Discharge planning must be initiated in a timely manner.

(b) Patients, along with necessary medical information, must be transferred or referred to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care.

(2) This section does not apply to facilities meeting the requirements of ORS 441.065.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: HD 11-1988, f. & cert. ef. 5-27-88; OHD 6-1999, f. & cert. ef. 10-22-99

333-071-0073
Physician Services

(1) No patient shall be admitted to the facility except on the order of a physician or a nurse practitioner. The admitting medical staff member for the facility shall provide sufficient information at the time of admission to establish that care can be provided to meet the needs of the patient. Admission medical information shall include a statement concerning the admitting diagnosis and general condition of the patient. Other pertinent medical information, orders for medication, diet and treatments shall also be provided, and a medical history and a physical.

(2) Orders pertinent to the care of the patient shall be initiated, dated, timed and signed by the practitioner ordering the care. The disposition of these orders shall be documented in the patient's medical record.

(3) Visits from practitioners shall be according to patient's needs. Initial and ongoing assessments shall be performed for each patient and the results and observations recorded in the medical record.

(4) A M.D. or D.O. physician or nurse practitioner to whom admitting privileges have been granted shall be responsible, as permitted by the individual's scope of practice, for the care of any medical problem that may be present on admission or that may arise during an inpatient stay for dental, podiatric or other purpose. Patients in a Critical Access Hospital will have care provided by a member of the medical staff under the individual's scope of practice.

(5) No medication or treatment shall be given except on the order of one duly authorized to give such orders within the State of Oregon.

(6) Each facility shall provide for one or more appropriate practitioners on the medical staff to be called in the event of an emergency.

(7) This section does not apply to facilities meeting the requirements of ORS 441.065.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: HD 5-1989, f. 7-14-89, cert. ef. 8-1-89; OHD 6-1999, f. & cert. ef. 10-22-99

333-071-0075
Nursing Care Management

(1) The nursing care of each patient in a health care facility shall be the responsibility of a registered nurse (R.N.).

(2) The nurse will only provide services to the clients for which she/he is educationally and/or experientially prepared and for which competency has been maintained.

(3) The R.N. shall be responsible and accountable for managing the nursing care of her/his assigned patients. She/he shall coordinate the nursing functions and tasks for those patients with the functions and tasks of physicians and other health care

providers. The responsible R.N. shall ensure that the following activities are completed:

(a) Summarize the admission status of the patient within 4 hours;

(b) Develop and document, within 8 hours, a plan of care for nursing services for the patient, based on the patient assessment and realistic, understandable, achievable patient goals consistent with ORS 851-045-0010, Standards of R.N. Scope of Practice.

(c)(A) Observe and report to the nurse manager and the patient's practitioner when appropriate, any significant changes in the patient's condition that warrant interventions that have not been previously prescribed or planned for;

(B) When the R.N. questions the efficacy, need or safety of continuation of medications being administered by that R.N. to a patient therein, the R.N. shall report that question to the practitioner authorizing the medication and shall seek further instructions concerning the continuation of the medication.

(4)(a) The Health Care Facility shall maintain documentation of certification of CNA's, which shall be available on request to Division personnel.

(b) CNAs must be certified by the Oregon State Board of Nursing prior to assuming nursing assistant duties.

(c) The Health Care Facility shall maintain documentation that Certified Medication Aides (CMAs) hold current certification with the Oregon State Board of Nursing. This documentation shall be available on request to Division personnel.

(5) This section does not apply to facilities meeting the requirements of ORS 441.065.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: HD 11-1988, f. & cert. ef. 5-27-88; HD 5-1989, f. 7-14-89, cert. ef. 8-1-89; OHD 6-1999, f. & cert. ef. 10-22-99

333-071-0077
Nurse Executive

(1) In a freestanding Hospice Facility, the nurse executive position shall be full-time (40 hours per week). Time spent in professional association workshops, seminars and continuing education may be counted as his/her duties in considering whether or not he/she is full-time.

(2) In all Special Inpatient Care Facilities, the nurse executive shall have had progressive responsibility in managing in a health care setting. The nurse executive shall be a registered nurse licensed in Oregon with a baccalaureate degree or other advanced degree or appropriate equivalent experience, with emphasis in management preferred.

(3) In all Special Inpatient Care Facilities, the nurse executive shall have written administrative authority, responsibility and accountability for assuring functions and activities of the nursing services department and shall participate in the development of any policies that affect the nursing services department. This includes budget formation, implementation and evaluation. The nurse executive shall ensure the:

(a) Development and maintenance of a nursing service philosophy, objective, standards of practice, policy and procedure manuals and job descriptions for each level of nursing service personnel;

(b) Development and maintenance of personnel policies of recruitment, orientation, in-service education, supervision, evaluation and termination of nursing service staff or ensure it is done by another department;

(c) Development and maintenance of policies and procedures for determination of nursing staff's capacity for providing nursing care for any patient seeking admission to the facility;

(d) Development and maintenance of a quality assurance program for nursing service;

(e) Coordination of nursing service departmental function and activities with the function and activities of other departments;

(f) Ensure participation with the administrator and other department directors in development and maintenance of practices and procedures that promote infection control, fire safety and hazard reduction.

(4) In all Special Inpatient Care Facilities, whenever the nurse executive is not available in person or by phone, she/he shall designate in writing a specific registered nurse or nurses, licensed to practice in Oregon, to be available in person or by phone to direct the functions and activities of the nursing services department.

(5) This section does not apply to facilities meeting the requirements of ORS 441.065.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: HD 5-1989, f. 7-14-89, cert. ef. 8-1-89; OHD 6-1999, f. & cert. ef. 10-22-99

333-071-0080
Nursing Services

(1) The facility shall provide a nursing service department which provides 24-hours, 7 days per week, nursing care, except in the case of College Infirmary which must provide 24 hour nursing only during periods of operation and except in the case of a Critical Access Hospital which must provide 24-hour nursing only when inpatients are present in the facility.

(2) The nursing services department shall be under the direction of a Nurse Executive who is a registered nurse, licensed to practice in Oregon.

(3) The facility shall be responsible for developing, and implementing under the direction of the Nurse Executive, a written staffing plan consistent with the scope of practice for R.N.'s and L.P.N.'s:

(a) Each staffing plan shall make allowances for sickness, vacations, vacancies and other absences and shall list the service(s) or persons to be called for replacement of nursing personnel. Nursing care required by different types of patients shall be the major consideration in determining number, quality and categories of nursing personnel needed.

(b) Each staffing plan shall establish minimum numbers of nursing staff personnel (licensed nurses and nursing assistants) on specified shifts. In no case shall fewer than one registered nurse and one other nursing care staff member be on duty when a patient is present.

(4) This section does not apply to facilities meeting the requirements of ORS 441.065.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: HD 17-1987(Temp), f. 10-13-87, ef. 10-15-87 thru 4-15-88; HD 11-1988, f. & cert. ef. 5-27-88; HD 5-1989, f. 7-14-89, cert. ef. 8-1-89; OHD 6-1999, f. & cert. ef. 10-22-99

333-071-0082
Surgical Services in Critical Access Hospitals (CAH)

Surgical services, if provided, must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the Critical Access Hospital in accordance with the designation requirements under paragraph (1) of this section.

(1) Designation of qualified practitioners. The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by:

(a) A doctor of medicine or osteopathy, including an osteopathic practitioner;

(b) A doctor of dental surgery or dental medicine; or

(c) A doctor of podiatric medicine.

(2) Anesthetic risk and evaluation. A qualified practitioner must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner.

(3) Administration of anesthesia. The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope of practice laws. Anesthetics must be administered by:

(a) A qualified anesthesiologist;

(b) A doctor of medicine or osteopathy other than an anesthesiologist;

(c) A doctor of dental surgery or dental medicine;

(d) A doctor of podiatric medicine;

(e) A certified registered nurse anesthetist;

(f) A supervised trainee in an approved anesthesia educational program.

(4) Discharge. All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: OHD 6-1999, f. & cert. ef. 10-22-99

333-071-0084
Blood and Blood Products in Critical Access Hospitals

The facility provides, either directly or under arrangements, the following:

(1) Services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis.

(2) If blood banking services are provided under an arrangement, the arrangement is approved by the facility's medical staff and by the persons directly responsible for the operation of the facility.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: OHD 6-1999, f. & cert. ef. 10-22-99

333-071-0085
Dietary

An organized dietary department shall be directed by qualified personnel and shall conform to the requirements in the Oregon Food Sanitation Rules, OAR 333-150-0000, and 333-160-0000 and shall meet the following criteria:

(1) The facility shall employ supportive personnel competent to carry out the functions of the dietary service;

(2) The quality and appropriateness of nutritional care provided by the dietetic service shall be regularly reviewed and evaluated;

(3) Services of a consulting dietician shall be obtained;

(4) Arrangements may be made for outside services. All food services shall meet the requirements of the Oregon Food Sanitation Rules.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: HD 17-1987(Temp), f. 10-13-87, ef. 10-15-87 thru 4-15-88; HD 11-1988, f. & cert. ef. 5-27-88

333-071-0090
Laboratory

The facility shall provide, or shall have a written contract with a licensed clinical laboratory under ORS Chapter 438 and OAR chapter 333, division 24, or its equivalent. A list of available tests and procedures shall be maintained. This section does not apply to facilities meeting the requirements of ORS 441.065.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: HD 17-1987(Temp), f. 10-13-87, ef. 10-15-87 thru 4-15-88; HD 11-1988, f. & cert. ef. 5-27-88

333-071-0095
Transfer

(1) The facility shall have a procedure which provides for transfer of patients to an acute care setting as appropriate.

(2) Transfer information shall include but not be limited to facility from which transferred, name of physician to assume care, current medical findings, current nursing assessment, diagnosis and other information germane to patient's condition.

(3) This section does not apply to facilities meeting the requirements of ORS 441.065.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: HD 17-1987(Temp), f. 10-13-87, ef. 10-15-87 thru 4-15-88; HD 11-1988, f. & cert. ef. 5-27-88

333-071-0100
Accommodations for Patients

(1) There shall be provided for each patient a good bed: mattress and pillow with a protective cover and necessary bed coverings; and other appropriate furniture.

(2) Freestanding Hospice Facilities shall also provide the following:

(a) Bedside table and chair;

(b) A reading light;

(c) An electrically operated call system which registers at the nurses' station. The call system cord shall be secured in a manner which will prevent the patient from injuring him/herself with it.

(3) According to his/her needs, each patient shall be provided with individual equipment, such as bedpans, bedpan covers, urinals, washbasins, emesis basins, mouthwash cups, soap, washcloths, towels and drinking glasses. Single patient use items must be identified with patient name and/or room number and disposed of upon patient discharge.

(4) Equipment such as wheelchairs, walkers, geri chairs, and crutches shall be readily available for patients needing this equipment.

(5) Separate storage space for clothing, toilet articles, and other personal belongings of patients shall be provided.

(6) In multiple-bed rooms, opportunity for patient privacy shall be provided by flame retardant curtains or screen. Cubicle curtains or screens are not required for beds assigned to pediatric patients.

(7) The use of torn or unclean bed linen is prohibited.

(8) After the discharge of any patient, the bed, bed furnishing, bedside furniture and equipment shall be thoroughly cleansed and disinfected prior to re-use. Mattresses shall be professionally renovated when necessary.

(9) Hot water bags and electric heating pads or blankets may be used only on the written order of the physician.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: HD 17-1987(Temp), f. 10-13-87, ef. 10-15-87 thru 4-15-88; HD 11-1988, f. & cert. ef. 5-27-88; HD 5-1989, f. 7-14-89, cert. ef. 8-1-89

333-071-0105
Building Requirements

(1) Patient Care Units:

(a) In the care of rehabilitation centers, a minimum of 80 square feet of floor space per bed is required in semi-private rooms and wards.

(b) In all other Special Inpatient Care Facilities, a minimum of 70 square feet of floor space per bed is required in semi-private rooms and wards.

(c) 100 square feet of floor space shall be provided in private rooms.

(d) No more than four beds shall be placed in each patient room.

(e) All rooms shall be entered from an exit corridor.

(f) All patient rooms shall have one or more windows, the overall size shall be not less than one-tenth the room floor area. The windows shall be fitted so as to provide natural ventilation, or a mechanical ventilation system shall be provided including a system for exhausting smoke directly to the exterior in accordance with the provisions of NFPA 90A, 1985 edition.

(g) Storage space for clothing, toilet articles, and other personal belongings of the patient shall be provided.

(2) If social space and space for patient dining is necessary to support the program needs, a minimum of 30 square feet per patient is required.

(3) A room or space for group therapy activities is required, if applicable.

(4) A room shall be available for examination and treatment of patients. (May be omitted if the unit is connected to or a part of a general hospital).

(5) Separate consultation room(s) as necessary to support the program needs of the facility shall be provided. (Consultation may

be performed in the examination/treatment room when the number of alcohol treatment beds is less than 16).

(6) If Physical Therapy Services are provided by the facility, the following elements shall be present:

(a) Treatment Area(s). It shall have space and equipment for thermotherapy, diathermy, ultrasonics and hydrotherapy. Provisions shall be made for a cubicle curtain around each individual treatment area. Provisions shall include handwashing facilities, (one lavatory or sink may serve more than one cubicle);

(b) Exercise area;

(c) Storage for clean linen, supplies, and equipment;

(d) Storage for soiled linen and equipment;

(e) Service sink;

(f) Wheelchair and stretcher storage.

(7) If Occupational Therapy Services are provided by the facility, the following elements shall be present:

(a) Therapy area shall include sink;

(b) Storage for supplies and equipment;

(c) Treatment area.

(8) In facilities for the treatment of alcoholism and drug abuse, a minimum of one patient room for detoxification, located to allow direct observation by nursing staff, shall be provided. Windows in detoxification rooms shall be of a security type that can only be opened by keys or tools that are under the control of the staff. An adjoining or closely available toilet room and handwashing lavatory is also required serving detoxification patients only. The detoxication area must comply with the Group I, Division 3 of the State Structural Specialty Code.

(9) Degree of security required shall be as determined by the program, but operation of such shall be restricted to inhibit possible tendency for escape, suicide, and to limit potential for self-inflicted injury.

(10) Where glass fragments may create a hazard, safety glazing and/or other appropriate security measures are recommended.

(11) Additional Requirements:

(a) An Administrative center or nurses station;

(b) Storage for administrative supplies;

(c) Charting facilities for nurses and doctors;

(d) Toilet room for staff;

(e) Janitor closet;

(f) Clean storage room or enclosed cabinet spaces for clean supplies and linen storage;

(g) Separate enclosed soiled utility or holding room for soiled linens and refuse;

(h) Equipment storage room; (May be combined with clean supply room if space allows for both functions.);

(i) Linen Services:

(A) On-Site Processing. If linen is to be processed on the site, the following shall be provided:

(i) Laundry processing room with commercial-type equipment which can process seven days' needs within a regularly scheduled work week. Handwashing facilities shall be provided. Soiled linen receiving, holding and sorting area;

(ii) Storage for laundry supplies;

(iii) Clean linen inspection and mending room or area;

(iv) Clean linen storage, issuing, and holding room or area;

(v) Cart sanitizing facilities and cart storage area. The sanitizing facilities may be combined with those required for dietary facilities.

(B) If linen is processed off-site, following shall be provided:

(i) Soiled linen holding room;

(ii) Clean linen receiving, holding, inspection, and storage room(s);

(iii) Cart sanitizing facilities and cart storage area. The sanitizing facilities may be combined with those required for dietary facilities.

(12) The building shall be kept clean and in good repair.

(13) Rehabilitation centers must provide handicap accessibility for the patient's activities of daily living.

Stat. Auth.: ORS 441.055

Stats. Implemented: ORS 441.055

Hist.: HD 17-1987(Temp), f. 10-13-87, ef. 10-15-87 thru 4-15-88; HD 11-1988, f. & cert. ef. 5-27-88; HD 5-1989, f. 7-14-89, cert. ef. 8-1-89

333-071-0110
Pharmacy

(1) Special Inpatient Care Facilities are subject to ORS Chapter 689 and all the rules thereunder as applicable.

(2) Pharmacy services shall be in accordance with ORS Chapter 689 and OAR 855-041-0105 through 855-041-0140.

(3) Provision shall be made for convenient and prompt 24-hour distribution of drugs to patients. This may be from a medicine preparation room or unit, a self-contained medicine dispensing unit, or by another approved system meeting the rules of the Board of Pharmacy. If used, a medicine preparation room or unit shall be under the nursing staff's visual control and contain a work counter, refrigerator and locked storage for biologicals and drugs. A medicine dispensing unit may be located at the nurses' station, in the clean workroom, or in an alcove or other space under direct control of nursing or pharmacy staff.

(4) Storage and disposal of drugs: Old medications, including special prescriptions for patients who have left the facility, shall be disposed of by incineration or other equally effective method, except narcotics and other drugs under the drug abuse law, which shall be handled in the manner prescribed by the Drug Enforcement Administration of the United State Department of Justice.

(5) Dispensing of drugs: Drugs shall not be supplied or given to either inpatients or outpatients, unless ordered by a physician or individual authorized within the scope of his or her professional license to prescribe drugs; and such order shall be in writing over the physician's or other authorized individual's signature or authentication.

(6) In a Special Inpatient Care Facility having a drug room and no pharmacy, the drug room must be supervised by a licensed pharmacist who provides his or her services with sufficient professionalism, quality and availability to adequately protect the safety of the patients and to properly serve the needs of the facility, pursuant to OAR 855-041-0135.

(7) This section does not apply to facilities meeting the requirements of ORS 441.065.

Stat. Auth.: ORS 441.055

Stats. Implemented: ORS 441.055

Hist.: HD 17-1987(Temp), f. 10-13-87, ef. 10-15-87 thru 4-15-88; HD 11-1988, f. & cert. ef. 5-27-88

333-071-0115
Infection Control

(1) Each Health Care Facility shall establish an active facility-wide infection control program. In the hospital the program shall be under the direction of a multi-disciplinary committee which shall be responsible for investigating, controlling and preventing infections in the facilities. This committee shall include representation from major departments and services and shall provide for consultation from other departments and services. Each Health Care Facility shall be responsible for developing written policies and for annual review of such policies, relating to at least the following:

(a) Identification of existing or potential infections in patients and employes.

(b) Control of factors affecting the transmission of infections.

(c) Provisions for orienting and educating all employes and volunteers on the cause, transmission, and prevention of infections.

(d) Collection, analysis, and use of data relating to infections in the hospital.

(2) Each Health Care Facility shall be responsible for the implementation of policies under section (1) of this rule.

(3) All Health Care Facilities shall maintain compliance with the current publication of the rules of the Division for the control of communicable diseases.

(4) Written isolation procedures in accordance with Center for Communicable Disease Control Guidelines universal precautions shall be established and followed by all Health Care Facility personnel for control and prevention of cross-infection between patients, departments and services. Guidelines can be obtained

from U.S. Department of Health and Human Services, Public Health Center for Disease Control, Atlanta, GA 30333. Any guidelines published and distributed by the Division shall also be taken into consideration.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: HD 17-1987(Temp), f. 10-13-87, ef. 10-15-87 thru 4-15-88; HD 11-1988, f. & cert. ef. 5-27-88; HD 5-1989, f. 7-14-89, cert. ef. 8-1-89

333-071-0120
Sanitary Precautions

(1) Provisions shall be made for the proper cleaning of linen and other washable goods and proper disposal of all refuse.

(2) All garbage and refuse shall be stored and disposed of in a manner that will not create a nuisance or a public health hazard and by a method approved by the Local Health Officer.

(3) Measures shall be taken to prevent the entry of rodents, flies, mosquitoes, and other insects. Adequate measures shall include but are not limited to preventing their entry through doors, windows, or other outside opening.

(4) The walls and floors shall be of a durable and cleanable composition necessary to maintain a sanitary environment appropriate to the use of the area. The building shall be kept clean and in good repair.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: HD 17-1987(Temp), f. 10-13-87, ef. 10-15-87 thru 4-15-88; HD 11-1988, f. & cert. ef. 5-27-88

333-071-0125
Safety and Emergency Precautions

(1) Telephone communication to summon help in case of fire or other emergency shall be available.

(2) In accordance with ORS Chapter 479 and the rules thereunder all requirements of the State Fire Marshal shall be met.

(3) When required, emergency power facilities shall be tested monthly and shall be in readiness at all times for use in all areas required in NFPA 99 and the National Electrical Code.

(4) Emergency preparedness:

(a) The health care facility shall develop, maintain, update, train, and exercise an emergency plan for the protection of all individuals in the event of an emergency, in accordance with the regulations as specified in **Oregon Fire Code** (OAR chapter 837, division 40).

(A) The health care facility shall conduct at least two drills every year that document and demonstrate that employees have practiced their specific duties and assignments, as outlined in the emergency preparedness plan.

(b) The emergency plan shall include the contact information for local emergency management.

(c) The summary of the emergency plan shall be sent to the Authority within one year of the filing of this rule. New facilities that have submitted licensing documents to the state before this provision goes into effect will have one year from the date of license application to submit their plan. All other new facilities shall have a plan prior to licensing. The Authority shall request updated plans as needed.

(d) The emergency plan shall address all applicable hazards that may include, but is not limited to, the following:

(A) Chemical emergencies;
(B) Dam failure;
(C) Earthquake;
(D) Fire;
(E) Flood;
(F) Hazardous material;
(G) Heat;
(H) Hurricane;
(I) Landslide;
(J) Nuclear power plant emergency;
(K) Pandemic;
(L) Terrorism; or
(M) Thunderstorms.

(e) The emergency plan shall address the provision of sufficient supplies for patients and staff to shelter in place for a minimum of four days under the following conditions:

(A) Extended power outage;
(B) No running water;
(C) Replacement of food or supplies is unavailable; and
(D) Staff members do not report to work as scheduled.

(f) The emergency plan shall address evacuation, including:

(A) Identification of individual positions' duties while vacating the building, transporting, and housing residents;
(B) Method and source of transportation;
(C) Planned relocation sites;
(D) Method by which each patient will be identified by name and facility of origin by people unknown to them;
(E) Method for tracking and reporting the physical location of specific patients until a different entity resumes responsibility for the resident; and
(F) Notification to the Authority about the status of the evacuation.

(g) The emergency plan shall address the clinical and medical needs of the patients, including provisions to provide:

(A) Storage of and continued access to medical records necessary to obtain care and treatment of patients, and the use of paper forms to be used for the transfer of care or to maintain care on-site when electronic systems are not available;
(B) Continued access to pharmaceuticals, medical supplies and equipment, even during and after an evacuation; and
(C) Alternative staffing plans to meet the needs of the patients when scheduled staff members are unavailable. Alternative staffing plans may include, but is not limited to, on-call staff, the use of travelers, the use of management staff, or the use of other emergency personnel.

(h) The emergency plan shall be made available as requested by the Authority and during licensing and certification surveys. Each plan will be re-evaluated and revised as necessary or when there is a significant change in the facility or population of the health care facility.

(i) A checklist for inpatient health care facilities has been developed in conjunction with the Office of the State Fire Marshal to assist facilities in developing emergency plans and ensuring compliance with the State Fire Marshal's administrative rules.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 441.020, 442.015
Stats. Implemented: ORS 441.020, 442.015
Hist.: HD 17-1987(Temp), f. 10-13-87, ef. 10-15-87 thru 4-15-88; HD 11-1988, f. & cert. ef. 5-27-88; HD 5-1989, f. 7-14-89, cert. ef. 8-1-89; PH 13-2008, f. & cert. ef. 8-15-08

333-071-0130
Plumbing and Sanitation Requirements

(1)(a) Separate men's and women's toilet facilities shall be provided at a rate of one per eight patient beds conveniently located to serve patients and provide for individual privacy, except in the case of Freestanding Hospice Facilities, which shall provide the following:

(b) Each patient shall have access to a toilet room without entering the general corridor area. One toilet room shall serve no more than four beds and no more than two patient rooms. The toilet room shall contain a toilet and a lavatory. The lavatory may be omitted from a toilet room which serves a single-bed room if the patient room contains a lavatory.

(2) Adequate handwashing facilities, including hot and cold running water, soap and single use sanitary towels shall be provided for the total facility population. A handwashing facility shall be available in or in a reasonable proximity to each toilet room and in close proximity to the administrative center or nurses' station.

(3) Bathing facilities for patients shall be provided to include at least one shower or tub for each 12 beds, serving patient rooms not containing bathing facilities directly adjoining the room. Rehabilitation Centers shall make available special bathing facilities for the physically disabled.

(4) Partitions between fixtures shall be provided when there are multiple toilet and/or bathing facilities. These partitions shall be at least six feet in height and provide for privacy closure.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: HD 17-1987(Temp), f. 10-13-87, ef. 10-15-87 thru 4-15-88; HD 11-1988, f. & cert. ef. 5-27-88; HD 5-1989, f. 7-14-89, cert. ef. 8-1-89

333-071-0135
Construction Requirements

Special Inpatient Care Facilities shall comply with all requirements of the State Structural, Plumbing, Mechanical and Electrical Specialty Codes in effect at the time of initial licensure and current code for construction or additions to existing facilities as enforced by the Oregon Building Codes Division and local jurisdictions having authority.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: HD 17-1987(Temp), f. 10-13-87, ef. 10-15-87 thru 4-15-88; HD 11-1988, f. & cert. ef. 5-27-88

333-071-0140
Submission of Plans

Any party proposing to make certain alterations or additions to an existing health care facility or to construct new facilities shall, before commencing such alteration, addition or new construction, submit plans and specifications to the Licensing Plan Review Program, Oregon Health Authority, Public Health Division for preliminary inspection and approval or recommendations with respect to compliance with Public Health Division rules for compliance to National Fire Protection Association standards when the facility is also to be Medicare or Medicaid certified. Submissions shall be in accord with rules of the Licensing Plan Review Program, OAR 333, division 675. Plans should also be submitted to the local building division having authority for review and approval in accordance with state building codes.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: HD 11-1988, f. & cert. ef. 5-27-88; OHD 6-1999, f. & cert. ef. 10-22-99

333-071-0145
Exceptions to Rules (All HCFs)

(1) While all Health Care Facilities are required to maintain continuous compliance with the Division's rules, these requirements do not prohibit the use of alternative concepts, methods, procedures, techniques, equipment, facilities, personnel qualifications or the conducting of pilot projects or research. Requests for exceptions to the rules must be:

(a) Submitted to the Division in writing; and

(b) Identify the specific rule for which an exception is requested; and

(c) The special circumstances relied upon to justify the exception; and

(d) What alternatives were considered, if any, and why alternatives (including compliance) were not selected; and

(e) Demonstrate that the proposed exception is desirable to maintain or improve the health safety of the patients, and will not jeopardize patient health and safety; and

(f) The proposed duration of the exception.

(2) Upon finding that the facility has satisfied the conditions of this rule, the Division may grant an exception.

(3) The facility may implement an exception only after written approval from the Public Health Division.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055
Hist.: HD 11-1988, f. & cert. ef. 5-27-88

DIVISION 72

HEALTH CARE PRACTITIONER REFERRALS

333-072-0200
Purpose

The purpose of these rules is to establish notice requirements for patient choice and financial interest as required in ORS 441.098 when health practitioners refer patients for diagnostic testing or health care treatment or services.

Stat. Auth.: ORS 441.098
Stats. Implemented: ORS 441.098
Hist.: PH 15-2014, f. & cert. ef. 6-2-14

333-072-0205
Applicability

These rules do not apply to a referral for a diagnostic test or health care treatment or service:

(1) When a patient is receiving inpatient hospital services or emergency department services if the referral is for a diagnostic test or health care treatment or service to be provided while the patient is in the hospital or emergency department.

(2) When a referral is made to a particular facility after the initial referral of the patient to that facility, when notice was provided at the initial referral in accordance with these rules.

(3) When a patient has been directed or transferred to a facility for emergency department services.

(4) When a patient is being directed back to the referring practitioner by the practitioner or facility who received the referral.

Stat. Auth.: ORS 441.098
Stats. Implemented: ORS 441.098
Hist.: PH 15-2014, f. & cert. ef. 6-2-14

333-072-0210
Definitions

As used in OAR 333-072-0200 through 333-072-0225 the following definitions apply:

(1) "Emergency department services" means services provided in the part of a licensed hospital facility open 24 hours a day to provide acute care treatment and services for a wide range of illnesses and injuries.

(2) "Facility" means a hospital, outpatient clinic owned by a hospital, ambulatory surgical center, freestanding birthing center as defined in ORS 442.015, or a facility that receives Medicare reimbursement as an independent diagnostic testing facility.

(3) "Financial interest" means the direct or indirect ownership interest of five percent or more held by a health practitioner or the practitioner's immediate family member.

(4)(a) "Health practitioner" means a physician, podiatric physician and surgeon, dentist, direct entry midwife, certified nurse practitioner, licensed registered nurse who is certified by the Oregon State Board of Nursing as a nurse midwife nurse practitioner, licensed physician assistant or medical imaging licensee under ORS 688.405 to 688.605.

(b) "Health practitioner" does not include a provider in health maintenance organizations as that term is defined in ORS 750.005.

(5) "Immediate family member" means a health practitioner's spouse, domestic partner, child, stepchild, mother, father or sibling.

(6) "Inpatient hospital services" means all medical and nursing services provided to persons who require 24-hour supervision because of acute or chronic medical or psychiatric illness.

(7) "Outpatient clinic owned by a hospital" means a satellite or mobile satellite indorsed under a hospital's license under OAR 333-500-0025.

(8) "Physician" has the meaning given that term in ORS 677.010.

(9) "Referral" means the direction of a patient to a facility for a diagnostic test or health care treatment or service.

(10) "These rules" means OAR 333-072-0200 through 333-072-0225.

Stat. Auth.: ORS 441.098
Stats. Implemented: ORS 441.098
Hist.: PH 15-2014, f. & cert. ef. 6-2-14

333-072-0215
Requirements for Notification of Patient Choice

(1) A referral for a diagnostic test or health care treatment or service shall be based on the patient's clinical needs and personal health choices.

(2) A health practitioner may not deny, limit or withdraw a referral solely because the patient chooses to have the diagnostic test or health care treatment or service at a facility other than the one recommended by the health practitioner.

(3) A health practitioner or the practitioner's designee shall provide written or oral notice of patient choice at the time the patient establishes care with the practitioner. The notice shall include the following:

(a) The patient has a choice and when referred to a facility for a diagnostic test or health care treatment or service the patient may receive the diagnostic test or health care treatment or service at a facility other than the one recommended by the health practitioner.

(b) If the patient chooses to have the diagnostic test, health care treatment or service at a facility different from the one recommended by a practitioner, the patient is responsible for determining the extent or limitation of coverage for the diagnostic test, health care treatment or service at the facility chosen by the patient.

(c) A health practitioner may not deny, limit or withdraw a referral solely because the patient chooses to have the diagnostic test or health care treatment or service at a facility other than the one recommended by the health practitioner.

(4) Health practitioners shall also post notice of patient choice in a conspicuous place. The posted notice shall include the information set forth in subsections (3)(a) and (b) of this rule.

(5) At the time of referral health practitioners may provide written or oral notice of patient choice. The notice shall include the information set forth in subsection (3)(a) of this rule.

(6) Practitioners must document all oral notifications.

Stat. Auth.: ORS 441.098
Stats. Implemented: ORS 441.098
Hist.: PH 15-2014, f. & cert. ef. 6-2-14; PH 21-2014(Temp), f. & cert. ef. 7-28-14 thru 1-24-15; PH 22-2014(Temp), f. & cert. ef. 8-7-14 thru 1-24-15; PH 2-2015, f. & cert. ef. 1-16-15

333-072-0220
Requirement for Notice of Financial Interest

If a health practitioner refers a patient for a diagnostic test or health care treatment or service to a facility in which the health practitioner or an immediate family member has a financial interest of five percent or more, the practitioner or the practitioner's designee shall provide notice of that financial interest orally and in writing at the time of the referral.

Stat. Auth.: ORS 441.098
Stats. Implemented: ORS 441.098
Hist.: PH 15-2014, f. & cert. ef. 6-2-14

333-072-0225
Violations and Enforcement

(1) A health practitioner who fails to comply with these rules shall be subject to investigation and disciplinary action in accordance with ORS 441.098.

(2) When investigating an allegation that notice was not provided in accordance with ORS 441.098 and these rules, the Oregon Health Licensing Agency and a health professional regulatory board may:

(a) Review documentation of a health practitioner's policies and procedures for provision of notice and accept the policies and procedures as proof that notice was given in accordance with the policies.

(b) Rely on the practitioner's documentation of notice as proof that notice was given, if no policies or procedures exist.

Stat. Auth.: ORS 441.098
Stats. Implemented: ORS 441.098
Hist.: PH 15-2014, f. & cert. ef. 6-2-14

DIVISION 76

SPECIAL HEALTH CARE FACILITIES

Ambulatory Surgical Centers ASC

333-076-0001
Referenced Codes and Standards

The codes and standards referenced in these rules shall be considered part of the requirements of these rules to the prescribed extent of each such reference. Where differences occur between provisions of these rules and referenced codes and standards, the provisions of the most restrictive code shall apply.

(1) 2010 Oregon Structural Specialty Code (OSSC);

(2) 2010 Oregon Mechanical Specialty Code;

(3) 2010 Oregon Energy Efficiency Specialty Code;

(4) 2010 Oregon Electrical Specialty Code (OESC);

(5) 2011 Oregon Plumbing Specialty Code;

(6) 2010 Oregon Fire Code (OFC);

(7) National Fire Protection Association, NFPA 101 Life Safety Code, 2000 Edition;

(8) National Fire Protection Association, NFPA 99 Standard for Healthcare Facilities, 1999 Edition;

(9) National Fire Protection Association, NFPA 110 Standard for Emergency and Standby Power Systems, 2002 Edition;

(10) National Fire Protection Association, NFPA 90A Standard for Installation of Air-Conditioning and Ventilating Systems, 1996 Edition;

(11) National Fire Protection Association, NFPA 255 Standard Method of Test of Surface Burning Characteristics of Building Materials, 2000 Edition;

(12) National Fire Protection Association, NFPA 801 Standard for Fire Protection for Facilities Handling Radioactive Materials, 1998 Edition OSHA and radiology;

(13) Illuminating Engineering Society, IES RP 28, 2007 Edition;

(14) Illuminating Engineering Society, IES RP 29, 2006 Edition with Errata;

(15) American National Standards Institute/American Society of Sanitary Engineering, ANSI/ASSE 6000, 2004 edition;

(16) ASHRAE Standard 170-2008 *Ventilation of Health Care Facilities*;

(17) Underwriters Laboratories, Inc.; UL 1069 Hospital Signaling and Nurse Call Equipment, 7th edition, revised January 22, 2009;

(18) National Fire Protection Association, NFPA 13, Standard for Installation of Sprinkler Systems, 1999 Edition;

(19) National Fire Protection Association, NFPA 72, Standard for Installation of Sprinkler Systems, 1999 Edition.

Stat. Auth.: ORS 441.025 & 441.060
Stats. Implemented: ORS 441.025 & 441.060
Hist.: PH 5-2012, f. 3-30-12, cert. ef. 4-1-12

333-076-0101
Definitions

As used in OAR chapter 333, division 76 unless the context requires otherwise, the following definitions apply:

(1) "Ambulatory Surgical Center" (ASC) means:

(a) A facility or portion of a facility that operates exclusively for the purpose of providing surgical services to patients who do not require hospitalization and for whom the expected duration of services does not exceed 24 hours following admission.

(b) Ambulatory surgical center does not mean:

(A) Individual or group practice offices of private physicians or dentists that do not contain a distinct area used for outpatient surgical treatment on a regular and organized basis, or that only provide surgery routinely provided in a physician's or dentist's office using local anesthesia or conscious sedation; or

(B) A portion of a licensed hospital designated for outpatient surgical treatment.

(2) "Authentication" means verification that an entry in the patient medical record is genuine.

(3) "CMS" means Centers for Medicare and Medicaid Services.

(4) "Certified ambulatory surgical center" means a facility that is licensed by the Division and is certified by the CMS as meeting the conditions for coverage for ambulatory surgical services, 42 CFR 416, Subpart C.

(5) "Certified Nurse Anesthetist" (CRNA) means a registered nurse certified by the Council on Certification of Nurse Anesthetists and licensed by the Oregon State Board of Nursing (OSBN).

(6) "Certified Nursing Assistant" (CNA) means a person who is certified by the Oregon State Board of Nursing (OSBN) to assist licensed nursing staff in the provision of nursing care.

(7) "Conditions for Coverage" mean the applicable federal regulations that ASCs are required to comply with in order to participate in the federal Medicare and Medicaid programs.

(8) "Conscious sedation" has the same meaning as "moderate sedation."

(9) "Deemed" means a health care facility that has been inspected by an approved accrediting organization and has been approved by the CMS as meeting CMS Conditions of Participation.

(10) "Deep sedation" means an induced controlled state of depressed consciousness in which the patient experiences a partial loss of protective reflexes, as evidenced by the inability to respond purposefully either to physical stimulation or to verbal command and the patient's ability to independently and continuously maintain an airway may be impaired.

(11) "Direct ownership" has the meaning given the term 'ownership interest' in 42 CFR 420.201.

(12) "Division" means the Public Health Division of the Oregon Health Authority.

(13) "Financial interest" means a five percent or greater direct or indirect ownership interest.

(14) "General anesthesia" means an induced controlled state of unconsciousness in which the patient experiences complete loss of protective reflexes, as evidenced by the inability to independently maintain an airway, the inability to respond purposefully to physical stimulation, or the inability to respond purposefully to verbal command.

(15) "Governing body" means the body or person legally responsible for the direction and control of the operation of the facility.

(16) "Health Care Facility" (HCF) has the meaning given the term in ORS 442.015.

(17) "Health Care Facility Licensing Law" means ORS 441.015-441.990 and rules thereunder.

(18) "High complexity non-certified""‘ means a facility that is licensed by the Division, is not CMS certified, and performs surgical procedures involving deep sedation or general anesthesia.

(19) "Hospital" has the meaning given that term in ORS 442.015.

(20) "Indirect ownership" has the meaning given the term 'indirect ownership interest' in 42 CFR 420.201.

(21) "Licensed" means that the person or facility to whom the term is applied is currently licensed, certified or registered by the proper authority to follow his or her profession or vocation within the State of Oregon, and when applied to a health care facility means that the facility is currently and has been duly and regularly licensed by the Division.

(22) "Licensed Nurse" means a Registered Nurse (RN) or a Licensed Practical Nurse (LPN).

(23) "Licensed Practical Nurse" (LPN) means a person licensed under ORS chapter 678 to practice practical nursing.

(24) "Local anesthesia" means the administration of an agent that produces a transient and reversible loss of sensation in a circumscribed portion of the body.

(25) "Moderate complexity non-certified" means a facility licensed by the Division, is not CMS certified, and performs procedures requiring not more than conscious sedation.

(26) "Moderate sedation" means an induced controlled state of minimally depressed consciousness in which the patient retains the ability to independently and continuously maintain an airway and to respond purposefully to physical stimulation and to verbal command. Formerly referred to as conscious sedation.

(27) "New construction" means a new building or an addition to an existing building.

(28) "NFPA" means National Fire Protection Association.

(29) "Nursing staff" means a person licensed by the OSBN as a registered nurse (RN), licensed practical nurse (LPN) or certified as a nursing assistant (CNA).

(30) "Patient audit" means review of the medical record or physical inspection of a patient.

(31) "Person" means an individual, a trust or estate, or a partnership or corporation (including associations, joint stock companies and insurance companies, a state or a political subdivision or instrumentality including a municipal corporation).

(32) "Physician" means a person licensed under ORS chapter 677 to practice medicine by the Oregon Medical Board.

(33) "Podiatrist" means a person licensed under ORS chapter 677 to practice podiatry.

(34) "Podiatry" means the diagnosis or the medical, physical or surgical treatment of ailments of the human foot, except treatment involving the use of a general or spinal anesthetic unless the treatment is performed in a hospital certified in the manner described in subsection (2) of ORS 441.055 and is under the supervision of or in collaboration with a physician licensed to practice medicine by the Oregon Medical Board. "Podiatry" does not include the administration of general or spinal anesthetics or the amputation of the foot.

(35) "Registered Nurse" (RN) means a person licensed as a Registered Nurse under ORS chapter 678.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.015-ORS 441.065, 441.098, & 442.015
Hist.: HD 3-1990, f. 1-8-90, cert. ef. 1-15-90; PH 4-2006(Temp), f. & cert. ef. 3-2-06 thru 8-1-06; Administrative correction 8-22-06;PH 25-2006, f. 10-31-06, cert. ef. 11-1-06; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10; PH 7-2016, f. & cert. ef. 2-24-16; PH 28-2016, f. & cert. ef. 10-6-13

333-076-0106
Issuance of License and Fees

(1) As used in this rule, the term "deemed status" means an ASC that has been inspected by a CMS-approved national accrediting organization, has been found to meet or exceed all applicable Medicare conditions, and CMS finds the ASC to be in compliance.

(2) Application for a license to operate an ASC shall be in writing on a form provided by the Division, including demographic, ownership and administrative information. The form shall specify such information required by the Division.

(3) For purposes of determining the correct license fee required under ORS 441.020 and this rule:

(a) "Procedure room" means a room where surgery or invasive procedures are performed; and

(b) "Invasive procedure" means a procedure requiring insertion of an instrument or device into the body through the skin or a body orifice for diagnosis or treatment, and operative procedures in which skin or mucous membranes and connective tissue are incised, or an instrument is introduced through a natural body orifice.

(4) Upon receipt of an application and the license fee as described in ORS 441.020, the Division shall review the application and conduct an on-site inspection of the ASC.

(5) In lieu of an onsite inspection required under section (3) of this rule, the Division may accept:

(a) CMS certification by a federal agency or accrediting organization; or

(b) A survey conducted within the previous three years by an accrediting organization approved by the Division, if:

(A) The certification or accreditation is recognized by the Division as addressing the standards and conditions for coverage requirements of the CMS and other standards set by the Division and an ASC provides the Division with a letter from CMS indicating its deemed status;

(B) The ASC notifies the Division of any exit interview conducted by the federal agency or accrediting body and permits the Division to participate; and

(C) The ASC provides copies of all documentation concerning the certification or accreditation requested by the Division.

(6) If the deemed status of an ASC changes, the ASC administrator must notify the Division.

(7) No person or ASC licensed pursuant to the provisions of ORS chapter 441, shall in any manner or by any means assert, represent, offer, provide or imply that such person or facility is or may render care or services other than that which is permitted by or which is within the scope of the license issued to such person or facility by the Division nor shall any service be offered or provided which is not authorized within the scope of the license issued to such person or facility.

(8) The Division shall issue a license to an ASC that:

(a) Submits a completed application as described in section (1) of this rule;

(b) Submits the license fee as described in ORS 441.020;

(c) Successfully completes the survey requirements established in this rule or provides documentation acceptable to the Division under section (4) of this rule; and

(d) Is found by the Division to be in compliance with applicable statutes and these rules.

(9) In determining whether to license an ASC pursuant to ORS 441.025, the Division shall consider only factors relating to the health and safety of individuals to be cared for therein and the ability of the operator of the ASC to safely operate the facility, and shall not consider whether the ASC is or will be a governmental, charitable, or other nonprofit institution or whether it is or will be an institution for profit.

(10) The license shall be conspicuously posted in the area where patients are admitted.

(11) A facility license that has been suspended or revoked may be reissued after the Division determines that compliance with HCF laws has been achieved satisfactorily.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.022 & 441.025
Hist.: HD 3-1990, f. 1-8-90, cert. ef. 1-15-90; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10; PH 28-2016, f. & cert. ef. 10-6-13

333-076-0108
Expiration and Renewal of License

Each license to operate an ASC shall expire on December 31 following the date of issue, and if a renewal is desired, the licensee shall make application at least 30 days prior to the expiration date upon a form prescribed by the Division as described in OAR 333-076-0106.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: HD 3-1990, f. 1-8-90, cert. ef. 1-15-90; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-076-0109
Denial or Revocation of a License

(1) A license for any ASC may be denied, suspended or revoked by the Division when the Division finds that there has been a substantial failure to comply with the provisions of Health Care Facility licensing law.

(2) A person or persons in charge of an ASC shall not permit, aid or abet any illegal act affecting the welfare of the license.

(3) A license shall be denied, suspended or revoked in any case where the State Fire Marshal certifies that there was failure to comply with all applicable laws, lawful ordinances and rules relating to safety from fire.

(4) A license may be suspended or revoked for failure to comply with a Division order arising from an ASC's substantial lack of compliance with the rules or statutes.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025 & 441.030
Hist.: HD 3-1990, f. 1-8-90, cert. ef. 1-15-90; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-076-0110
Return of Facility License

Each license certificate in the licensee's possession shall be returned to the Division immediately on the suspension or revocation of the license, failure to renew the license by December 31, or if operation is discontinued by the voluntary action of the licensee.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: HD 3-1990, f. 1-8-90, cert. ef. 1-15-90

333-076-0111
Classification

(1) Ambulatory surgical centers shall be classified as follows:

(a) Certified;

(b) High complexity non-certified; and

(c) Moderate complexity non-certified.

(2) The classification of each ASC shall be so designated on the license.

(3) ASCs licensed by the Division shall neither assume a descriptive title nor be held out under any descriptive title other than the classification title established by the Division and under which the facility is licensed. This not only applies to the name on the facility but where stationery, advertising and other representations are involved.

(4) No change in the licensed classification of any ASC, as set out in this rule, shall be allowed by the Division unless such facility shall file a new application, accompanied by the required license fee, with the Division. If the Division finds that the applicant and facility comply with HCF laws and the regulations of the Division relating to the new classification for which application for licensure is made, the Division shall issue a license for such classification.

Stat. Auth.: ORS 441.025 & 441.086
Stats. Implemented: ORS 441.025 & 441.086
Hist.: HD 3-1990, f. 1-8-90, cert. ef. 1-15-90; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-076-0112
Hearings

Upon written notification by the Division of revocation, suspension or denial to issue or renew a license, a written request by the facility for a hearing in accordance with ORS 183.413 to 183.500 shall be granted by the Division.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 183.413 - 183.500 & 441.037
Hist.: HD 3-1990, f. 1-8-90, cert. ef. 1-15-90

333-076-0113
Adoption by Reference

All rules, standards and publications referred to in OAR 333-076 are made a part thereof. Copies are available for inspection in the Division during office hours. Where publications are in conflict with the rules, the rules shall govern.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: HD 3-1990, f. 1-8-90, cert. ef. 1-15-90

333-076-0114
Inspections and Complaint Investigations

(1) Complaints:

(a) Any person may make a complaint to the Division regarding violation of health care facility laws or regulations. A complaint investigation will be carried out as soon as practicable and may include but not be limited to, as applicable to facts alleged: interviews of the complainant, patient(s), witnesses, and ASC management and staff; observations of the patient(s), staff performance, patient environment and physical environment; and review of documents and records;

(b) An ASC shall post a notice in the facility, in a prominent place and size that must include, but is not limited to the following: "If you have concerns about this ambulatory surgical center and the services provided here, contact the Public Health Division, Health Care Regulation and Quality Improvement Program: 800 NE Oregon Street, Suite 305, Portland OR 97232; 971-673-0540."

(c) Information obtained by the Division during an investigation of a complaint or reported violation is confidential and not subject to public disclosure under ORS 192.410 to 192.505. Upon the conclusion of the investigation, the Division may publicly release a report of its findings but may not include information in the report that could be used to identify the complainant or any patient at the ASC.

(d) The Division may use any information obtained during an investigation in an administrative or judicial proceeding concerning the licensing of an ASC, and may report information obtained during an investigation to a health professional regulatory board as defined in ORS 675.160 as that information pertains to a licensee of the board.

(2) Inspections:

(a) The Division will, in addition to any inspections conducted pursuant to complaint investigations, conduct at least one general inspection of each ASC to determine compliance with HCF laws at least once every three years and at such other times as the Division deems necessary. The Division may accept certificates from accrediting organizations approved by the Division as evidence of compliance with acceptable standards in lieu of ASC inspections;

(b) Facilities providing approved accrediting organization certificates as evidence of compliance shall also be required to provide to the Division (or to have previously provided) with each license application (and license renewal application):

(A) All approved accrediting organizations survey and inspection reports; and

(B) Written evidence of all corrective actions underway, or completed, in response to approved accrediting organizations recommendations; including all progress reports.

(c) Inspections will include but not be limited to those procedures stated in subsection (1)(a) of this rule;

(d) The inspection may include a patient audit, the results of which shall be summarized on the licensing survey form;

(e) When documents and records are requested under section (1) or (2) of this rule, the ASC shall make the requested materials available to the investigator for review and copying.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025, 441.060 & 441.086
Hist.: HD 3-1990, f. 1-8-90, cert. ef. 1-15-90; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-076-0115
Governing Body Responsibility

The governing body of each ASC shall be responsible for the operation of the facility, the selection of the medical staff and the quality of care rendered in the facility. The governing body shall:

(1) Insure that all health care personnel for whom state licenses or registration are required are currently licensed or registered;

(2) Insure that physicians admitted to practice in the facility are granted privileges consistent with their individual training, experience and other qualifications;

(3) Insure that procedures for granting, restricting and terminating privileges exist and that such procedures are regularly reviewed to assure their conformity to applicable law;

(4) Insure that physicians admitted to practice in the facility are organized into a medical staff insofar as applicable in such a manner as to effectively review the professional practices of the facility for the purposes of reducing morbidity and mortality and for the improvement of patient care; and

(5) Insure that a physician is not denied medical staff membership or privileges at the facility solely on the basis that the physician holds medical staff membership or privileges at another ASC.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025 & 441.055
Hist.: HD 11-1980, f. & ef. 9-10-80; HD 25-1983(Temp), f. & ef. 12-21-83; HD 23-1985, f. & ef. 10-11-85; Renumbered from 333-023-0163(1); HD 3-1990, f. 1-8-90, cert. ef. 1-15-90, Renumbered from 333-076-0100(1)(a) & (b); PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-076-0120
Medical Staff

(1) The physicians organized into a medical staff pursuant to OAR 333-076-0115 shall propose medical staff bylaws to govern the medical staff. The bylaws shall include, but not be limited to the following:

(a) Procedures for physicians admitted to practice in the facility to organize into a medical staff;

(b) Procedures for insuring that physicians admitted to practice in the facility are granted privileges consistent with their individual training, experience and other qualifications;

(c) Provisions establishing a framework for the medical staff to nominate, elect, appoint or remove officers and other persons to carry out medical staff activities with accountability to the governing body;

(d) Procedures for insuring that physicians admitted to practice in the facility are currently licensed by the Oregon Medical Board;

(e) Procedures for insuring that the facility's procedures for granting, restricting and terminating privileges are followed and that such procedures are regularly reviewed to assure their conformity to applicable law; and

(f) Procedures for insuring that physicians provide services within the scope of the privileges granted by the governing body.

(2) Amendments to medical staff bylaws shall be accomplished through a cooperative process involving both the medical staff and the governing body. Medical staff bylaws shall be adopted, repealed or amended when approved by the medical staff and the governing body. Approval shall not be unreasonably withheld by either. Neither the medical staff nor the governing body shall withhold approval if such repeal, amendment or adoption is mandated by law, statute or regulation or is necessary to obtain or maintain accreditation or to comply with fiduciary responsibilities or if the failure to approve would subvert the stated moral or ethical purposes of this institution.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.086
Hist.: HD 3-1990, f. 1-8-90, cert. ef. 1-15-90

333-076-0125
Personnel

(1) As used in this rule, "person" means any:

(a) ASC employee;

(b) ASC contractor;

(c) Health care practitioner granted privileges by the ASC; or

(d) ASC volunteer or student.

(2) The facility shall maintain a sufficient number of qualified personnel to provide effective patient care and all other related services.

(3) There shall be written personnel policies and procedures which shall be made available to personnel.

(4) Provisions shall be made for orientation.

(5) Provisions shall be made for an annual continuing education plan.

(6) There shall be a job description for each position which delineates the qualifications, duties, authority and responsibilities inherent in each position.

(7) There shall be an annual work performance evaluation for each employee with appropriate records maintained.

(8) There shall be an employee health screening program for the purpose of protecting patients and employees from communicable diseases, including but not limited to requiring tuberculosis testing for employees in accordance with section (10) of this rule.

(9) An ASC shall restrict the work of employees with restrictable diseases in accordance with OAR 333-019-0010.

(10) Each ASC shall formally assess the risk of tuberculosis transmission among ASC employees, contractors, health care practitioners granted privileges by the ASC, volunteers or students, and shall comply with the "*Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings*," published by the Centers for Disease Control and Prevention (Morbidity and Mortality Weekly Report, vol. 54, number RR-17, December 30,

2005 or by following recommendations otherwise approved by the Division.

(11) An ASC shall obtain documentation that tuberculosis (TB) testing has been conducted in a manner consistent with the CDC guidelines for any person who enters an ASC and who has contact with patients, enters rooms that patients may enter, or who handles clinical specimens or other material from patients or their rooms.

(a) An ASC shall require documentation of baseline TB screening conducted in accordance with the CDC Guidelines, within six weeks of the date of hire, date of executed contract or date of being granted ASC credentials.

(b) For persons hired, contracted with or granted ASC privileges prior to December 15, 2010, an ASC shall obtain documentation of compliance with CDC Guidelines by February 1, 2011.

(12) An ASC that is classified as "potential ongoing transmission" under CDC Guidelines shall consult with the Oregon TB control program within the Division, for guidance on the extent of TB testing required.

(13) If an ASC learns that a person or a patient at the hospital is diagnosed with communicable TB, the ASC shall notify the local public health authority and conduct an investigation to identify contacts. If the Division or local public health authority conducts its own investigation, an ASC shall cooperate with that investigation and provide the Division or local public health authority with any information necessary for it to conduct its investigation.

(14) An ASC shall notify the local public health administrator of its intent to discharge a patient known to have active TB disease.

(15) The actions taken under this rule and all results thereof shall be fully documented for each employee. Such documentation is subject to review by authorized representatives of the Division.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 441.025

Stats. Implemented: ORS 433.411, 441.025, 441.057, 441.162, 678.362

Hist.: HD 3-1990, f. 1-8-90, cert. ef. 1-15-90; PH 4-2006(Temp), f. & cert. ef. 3-2-06 thru 8-1-06; Administrative correction 8-22-06; PH 25-2006, f. 10-31-06, cert. ef. 11-1-06; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-076-0130
Policies and Procedures

The governing body shall have a formal organizational plan with written policies, procedures and by-laws that are enforced and that clearly set forth the organizational plan with written responsibilities, accountability and relationships of professional and other personnel including volunteers.

(1) The clinical services of each ASC shall be under the supervision of a manager who shall be an RN or a physician.

(2) The following are written policies and procedures that the ASC shall develop and implement:

(a) Types of procedures that may be performed in the facility;

(b) Types of anesthesia that may be used including storage procedures. Where inhalation anesthetics and medical gases are used there shall be procedures to assure safety in storage and use;

(c) Criteria for evaluating patient before admission and before discharge or transfer;

(d) Nursing service activities;

(e) Infection control;

(f) Visitor's conduct and control;

(g) Criteria and procedures for admission of physicians, dentists, or other individuals within the scope of his or her license, to the staff;

(h) Content and form of medical records;

(i) Procedures for storage and dispensing of clean and sterile supplies and equipment and the processing and sterilizing of all supplies, instruments and equipment used in procedures unless disposable sterile packs are used;

(j) Procedures for the disposal of pathological and other potentially infectious waste and contaminated supplies. Guidelines established by the Division shall be used in developing these procedures;

(k) Procedures for the procurement, storage and dispensing of drugs;

(l) If the program calls for the serving of snacks or other foods procedures shall be written covering space, equipment and supplies. Arrangements may be made for outside services. All food services shall meet the requirements of the Food Sanitation Rules, OAR 333-150-0000;

(m) Procedures for the cleaning, storage and handling of soiled linen and the storage and handling of clean linen;

(n) Policies and procedures relating to routine laboratory testing;

(o) A policy and procedure which assures at least annual training in emergency procedures, including, but not limited to:

(A) Procedures for fire and other disaster;

(B) Infection control measures; and

(C) For staff involved in direct patient care, procedures for life threatening situations including, but not limited to, cardiopulmonary resuscitation and the life saving techniques for choking;

(p) Policies and procedures for essential life saving measures and stabilization of a patient and arrangements for transfer to an appropriate facility;

(q) Procedures for notifying patients orally and in writing of any financial interest as required by ORS 441.098;

(r) Requirements for informed consent signed by the patient or legal representative of the patient for diagnostic and treatment procedures; such policies and procedures shall address informed consent of minors in accordance with provisions in ORS 109.610, 109.640, 109.670, and 109.675; and

(s) Requirements for identifying persons responsible for obtaining informed consent and other appropriate disclosures and ensuring that the information provided is accurate.

Stat. Auth.: ORS 441.025 & 441.057

Stats. Implemented: ORS 441.025, 441.057, 441.162, & 678.362

Hist.: HD 11-1980, f. & ef. 9-10-80; HD 25-1983(Temp), f. & ef. 12-21-83; HD 23-1985, f. & ef. 10-11-85; Renumbered from 333-023-0163(1); HD 3-1990, f. 1-8-90, cert. ef. 1-15-90, Renumbered from 333-076-0100(2)(a) & (b)(A) - (Q); PH 4-2006(Temp), f. & cert. ef. 3-2-06 thru 8-1-06; Administrative correction 8-22-06; PH 25-2006, f. 10-31-06, cert. ef. 11-1-06; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-076-0135
Nursing Services

(1) An RN shall be responsible for the nursing care provided to the patients.

(2) The number and types of nursing staff and surgical technologists shall be based on the needs of the patients and the types of services performed.

(3) At least one RN and one other nursing staff or medical assistant shall be on duty at all times patients are present.

(4) Nurses who supervise the recovery area shall have current training in resuscitation techniques and other emergency procedures.

Stat. Auth.: ORS 441.025

Stats. Implemented: ORS 441.025

Hist.: HD 11-1980, f. & ef. 9-10-80; HD 25-1983(Temp), f. & ef. 12-21-83; HD 23-1985, f. & ef. 10-11-85; Renumbered from 333-023-0163(1); HD 3-1990, f. 1-8-90, cert. ef. 1-15-90, Renumbered from 333-076-0100(4)(a) - (c); PH 4-2006(Temp), f. & cert. ef. 3-2-06 thru 8-1-06; Administrative correction 8-22-06; PH 25-2006, f. 10-31-06, cert. ef. 11-1-06; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10; PH 7-2016, f. & cert. ef. 2-24-16

333-076-0137
Surgery Services

(1) For purposes of this rule:

(a) "Circulating nurse" means a registered nurse who is responsible for coordinating the nursing care and safety needs of the patient in the operating room and who also meets the needs of the operating room team members during surgery.

(b) "Rural or medically underserved community" means a geographic area of Oregon that is 10 or more miles from the geographic center of a population center of 40,000 or more individuals.

(c) "Surgical technology" means intraoperative surgical patient care that involves:

(A) Preparing an operating room for surgical procedures by ensuring that surgical equipment is functioning properly and safely;

(B) Preparing an operating room and the sterile field for surgical procedures by preparing sterile supplies, instruments and equipment using sterile techniques;

(C) Anticipating the needs of a surgical team based on knowledge of human anatomy and pathophysiology and how those fields relate to the surgical patient and the patient's surgical procedure; and

(D) Performing tasks as directed in an operating room, including:

(i) Passing instruments, equipment or supplies;

(ii) Sponging or suctioning of an operative site;

(iii) Preparing and cutting suture material;

(iv) Transferring fluids or drugs;

(v) Handling specimens;

(vi) Holding retractors and other equipment;

(vii) Applying electrocautery to clamps on bleeders;

(viii) Connecting drains to suction apparatus;

(ix) Applying dressings to closed wounds; and

(x) Assisting in counting supplies and instruments, including sponges and needles.

(2) An ASC, regardless of classification, shall comply with this rule.

(3) An ASC shall have operating rooms that conform to the applicable requirements in OAR 333-076-0185.

(4) An ASC's operating rooms must be supervised by an experienced registered nurse or doctor of medicine or osteopathy.

(5) The duties of a circulating nurse performed in an operating room of an ASC shall be performed by a registered nurse licensed under ORS 678.010 through 678.410. In all cases requiring general anesthesia, a circulating nurse shall be assigned to, and present in, an operating room for the duration of the surgical procedure unless it becomes necessary for the circulating nurse to leave the operating room as part of the surgical procedure. While assigned to a surgical procedure, a circulating nurse may not be assigned to any other patient or procedure.

(6) Nothing in section (5) precludes a circulating nurse from being relieved during a surgical procedure by another circulating nurse assigned to continue the surgical procedure.

(7) In order for a person to practice surgical technology at an ASC, the ASC governing body shall ensure that the following provisions are met by the individual:

(a) Documentation showing that the person has completed a training program for surgical technologists in a branch of the armed forces of the United States or in the United States Public Health Service Commissioned Corp and completes 16 hours of continuing education as described in section (11) of this rule every two years; or

(b) Completion of a surgical technology education program accredited by the Commission on Accreditation of Allied Health Education Program (CAAHEP) or the Accrediting Bureau of Health Education Schools (ABHES) and certification as a surgical technologist issued by the National Board of Surgical Technology and Surgical Assisting (NBSTSA); or

(c) Documentation that a person has practiced surgical technology at least two years between January 1, 2014 and January 1, 2017 in a hospital, ambulatory surgical center or as an employee of a federal government agency or institution and completes 16 hours of continuing education as described in section (11) of this rule every two years.

(8) Notwithstanding subsection (7)(b), an ASC may allow a person who is not certified by the NBSTSA to practice surgical technology at the hospital for 12 months after the person completes an educational program accredited by the CAAHEP or ABHES.

(9) An ASC located in a rural or medically underserved community may allow a person to practice surgical technology at the ASC who does not meet the requirements specified in section (7) of this rule until July 1, 2017. After July 1, 2017, a person not meeting the requirements specified in section (7) of this rule, may work at an ASC in a rural or medically underserved community while the person is attending an educational program accredited by the CAAHEP or ABHES. Such persons are exempt from the educational requirements for three years from the date on which the person began practicing at the ASC.

(10) These rules do not prohibit a licensed practitioner from performing surgical technology if the practitioner is acting within the scope of the practitioner's license and an ASC allows the practitioner to perform such duties.

(11)(a) The continuing education requirements described in subsections (7)(a) and (7)(c) shall:

(A) Consist of 16 hours every two years;

(B) Be tracked by the surgical technologist and is subject to audit by the ASC in which the person is practicing; and

(C) Be relevant to the medical-surgical practice of surgical technology.

(b) Continuing education may include but is not limited to:

(A) Continuing education credits approved by the Association for Surgical Technologist;

(B) Healthcare sponsored conferences, forums, seminars, symposiums or workshops;

(C) Online distance learning courses;

(D) Live lectures at national conferences; or

(E) College courses.

(12) An ASC shall conduct a random audit of a representative sample of the surgical technologists employed by the ASC every two years to verify compliance with educational requirements.

(13) The requirements identified in sections (7), (8), and (10) through (12) of this rule become effective on July 1, 2016.

Stat. Auth.: ORS 441.025 & ORS 676.890
Stats. Implemented: ORS 441.025, 676.870 – 676.890 & 678.362
Hist.: PH 7-2016, f. & cert. ef. 2-24-16; PH 28-2016, f. & cert. ef. 10-6-13

333-076-0140
Anesthesia Services (If Provided)

(1) General or spinal anesthesia shall be administered only by a physician or a certified nurse anesthetist. Either the physician or the CRNA shall be present for the administration of general or spinal anesthetics, during anesthesia, and the recovery of the patients when any general or spinal anesthesia is used.

(2) In all areas where flammable anesthetics are used, such rooms shall be equipped and maintained in compliance with provisions of the current issue of NFPA 99, Standard for Health Care Facilities, unless the governing body's written policy forbids the use or storage of flammable anesthetics in the facility.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: HD 11-1980, f. & ef. 9-10-80; HD 25-1983(Temp), f. & ef. 12-21-83; HD 23-1985, f. & ef. 10-11-85; Renumbered from 333-023-0163(1); HD 3-1990, f. 1-8-90, cert. ef. 1-15-90, Renumbered from 333-076-0100(5)(a) & (b); PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-076-0145
Storage, Disposal and Dispensing of Drugs

(1) In an ASC that does not have a pharmacy on the premises, stock quantities of prescription drugs, including local anesthetics shall be stored on the premises only when such drugs have been obtained for dispensation or administration to his/her respective patients by a physician, dentist, podiatrist or other person authorized within the scope of his/her license to so dispense or administer such drugs. Prescribed drugs already prepared for patients in the ASC may also be stored on the premises.

(2) Old medications, including special prescriptions for patients who have left the facility, shall be disposed of by incineration or other equally effective method, except narcotics and other drugs under the drug abuse law, which shall be handled in the manner prescribed by the Drug Enforcement Administration of the United States Department of Justice.

(3) Drugs shall not be administered to patients unless ordered by a physician, dentist, podiatrist or individual authorized within the scope of his or her professional license to prescribe drugs; and

such order shall be in writing over the physician's or other authorized individual's signature or authentication.

(4) Prescription drugs dispensed by a physician shall be personally dispensed by the physician. Nonjudgmental dispensing functions may be delegated to staff assistants when the accuracy and completeness of the prescription is verified by the physician.

(5) The dispensing physician shall label prescription drugs with the following information:

(a) Name of patient;

(b) The name and address of the dispensing physician;

(c) Date of dispensing;

(d) The name of the drug. If the dispensed drug does not have a brand name, the prescription label shall indicate the generic name of the drug dispensed along with the name of the drug distributor or manufacturer, its quantity per unit and the directions for its use stated in the prescription. However, if the drug is a compound, the quantity per unit need not be stated;

(e) Cautionary statements, if any, as required by law; and

(f) When applicable, and as determined by the Oregon Board of Pharmacy, an expiration date after which the patient should not use the drug.

(6) Prescription drugs shall be dispensed in containers complying with the federal Poison Prevention Packaging Act unless the patient requests a noncomplying container.

(7) Pharmacist and pharmacy personnel providing services to the ASC are subject to ORS Chapter 689 and the rules thereunder.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: HD 11-1980, f. & ef. 9-10-80; HD 25-1983(Temp), f. & ef. 12-21-83; HD 23-1985, f. & ef. 10-11-85; Renumbered from 333-023-0163(1); HD 3-1990, f. 1-8-90, cert. ef. 1-15-90, Renumbered from 333-076-0100(6); PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-076-0150
Emergency Services

The facility shall provide services, equipment and staff necessary to implement emergency medical care protocols.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: HD 11-1980, f. & ef. 9-10-80; HD 25-1983(Temp), f. & ef. 12-21-83; HD 23-1985, f. & ef. 10-11-85; Renumbered from 333-023-0163(1); HD 3-1990, f. 1-8-90, cert. ef. 1-15-90, Renumbered from 333-076-0100(7)(a) - (c)

333-076-0155
Laboratory Services

(1) Laboratory services shall be available for every patient either through the use of a licensed clinical laboratory in the facility or a written contract with a licensed clinical laboratory.

(2) Any tissue removed during surgery except those exempted under OAR 333-076-0165, shall be submitted for histological examination by a pathologist. A written report of findings shall be filed in the patient's record in accordance with 333-076-0165.

(3) OAR 333-024-0005 through 333-024-0350 shall also apply.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: HD 11-1980, f. & ef. 9-10-80; HD 25-1983(Temp), f. & ef. 12-21-83; HD 23-1985, f. & ef. 10-11-85; Renumbered from 333-023-0163(1); HD 3-1990, f. 1-8-90, cert. ef. 1-15-90, Renumbered from 333-076-0100(8)(a) & (b); PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-076-0160
Care of Patients

(1) Each patient shall be evaluated for all risk factors before a surgical procedure may be performed in accordance with 42 CFR 416.42 and 416.52.

(2) Each patient shall be observed for post-operative complications under the direct supervision of a licensed registered nurse. Patients shall be observed for post-procedure complications until their conditions are stable.

(3) No medications or treatments shall be given without the order of a physician or other individual authorized within the scope of his/her license.

(4) At the time of discharge from the ASC, each patient must be evaluated by a physician, or by an anesthetist as defined by 45 CFR 410.69(b) for proper anesthesia recovery.

(5) Written instruction shall be given to patients on discharge covering signs and symptoms of complications as well as any necessary follow-up instructions for routine and/or emergency care.

(6) Each facility shall adopt and observe written patient care policies.

(7) Patient care policies shall be evaluated annually and rewritten as needed. Documentation of the evaluation is required.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025 & 441.086
Hist.: HD 11-1980, f. & ef. 9-10-80; HD 25-1983(Temp), f. & ef. 12-21-83; HD 23-1985, f. & ef. 10-11-85; Renumbered from 333-023-0163(1); HD 3-1990, f. 1-8-90, cert. ef. 1-15-90, Renumbered from 333-076-0100(9)(a) - (e); PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-076-0165
Medical Records

(1) A medical record shall be maintained for every patient admitted for care.

(2) A legible reproducible medical record shall include at least the following (if applicable):

(a) Admitting identification data including date of admission;

(b) Chief complaint;

(c) Pertinent family and personal history;

(d) History and physical. This history and physical shall be completed no more than 30 days prior to the initiation of any procedure. Sufficient time shall be allowed between examination and the initiation of any procedure, to permit review of tests;

(e) Clinical laboratory reports as well as reports on any special examinations. (The original report shall be authenticated and recorded in the patient's medical record.);

(f) X-ray reports shall be recorded in the medical record and shall bear the identification (authentication) of the originator of the interpretation;

(g) Signed or authenticated report of consultant when such services have been obtained;

(h) All entries in patient's medical record must be dated, timed, and authenticated:

(A)Verification of an entry requires use of a unique identifier, i.e., signature, code, thumbprint, voice print or other means, which allows identification of the individual responsible for the entry;

(B) Verbal orders may be accepted by those individuals authorized by law and by medical staff rules and regulations and shall be countersigned or authenticated within two business days by the ordering health care practitioner or another health care practitioner who is responsible for the care of the patient;

(C) A single signature or authentication of the physician, dentist, podiatrist or other individual authorized within the scope of his or her professional license on the medical record does not suffice to cover the entire content of the record.

(i) Records of assessment and intervention, including but not limited to preprocedure vital sign records, graphic charts, medication records and appropriate personnel notes;

(j) Anesthesia record including records of anesthesia, analgesia and medications given in the course of the operation and postanesthetic condition, signed or authenticated by the person making the entry;

(k) A record of operation dictated or written immediately following surgery and including a complete description of the operation procedures and findings, postoperative diagnostic impression, and a description of the tissues and appliances, if any, removed;

(l) Postanesthesia Recovery (PAR) progress notes including but not limited to vital sign records and other appropriate clinical notes;

(m) Pathology report on tissues and appliances, if any, removed at the operation. The following tissues and appliances may be exempted from pathology exam:

(A) Specimens that, by their nature or condition, do not permit fruitful examination, including but not limited to a cataract, ortho-

pedic appliance, foreign body, or portion of rib removed only to enhance operative exposure;

(B) Therapeutic radioactive sources, the removal of which shall be guided by radiation safety monitoring requirements;

(C) Traumatically injured members that have been amputated and for which examination for either medical or legal reasons is not considered necessary;

(D) Specimens known to rarely, if ever, show pathological change, and the removal of which is highly visible postoperatively, including but not limited to the foreskin from circumcision of a newborn infant;

(E) Placentas that are grossly normal and have been removed in the course of operative and nonoperative obstetrics;

(F) Teeth, provided that the number, including fragments, is recorded in the medical record.

(n) Summary including final diagnosis;

(o) Date of discharge and discharge note;

(p) Autopsy report if applicable;

(q) Informed consent forms that document:

(A) The name of the ASC where the procedure or treatment was undertaken;

(B) The specific procedure or treatment for which consent was given;

(C) The name of the health care practitioner performing the procedure or administering the treatment;

(D) That the procedure or treatment, including the anticipated benefits, material risks, and alternatives was explained to the patient or the patient's representative or why it would have been materially detrimental to the patient to do so, giving due consideration to the appropriate standards of practice of reasonable health care practitioners in the same or a similar community under the same or similar circumstances;

(E) The manner in which care will be provided in the event that complications occur that require health services beyond what the ASC has the capability to provide. If the ASC has entered into agreements with more than one hospital, the patient must be provided with the most likely possible option, but that the transfer hospital may be dependent on the type of problem encountered.

(F) The signature of the patient or the patient's legal representative; and

(G) The date and time the informed consent was signed by the patient or the patient's legal representative;

(r) Documentation of the disclosures required in ORS 441.098;

(s) Such signed documents as may be required by law.

(3) The completion of the medical record shall be the responsibility of the attending physician:

(a) Medical records shall be completed by the physician, dentist, podiatrist or other individual authorized within the scope of his or her professional license within four weeks following the patient's discharge;

(b) If a patient is transferred to another health care facility, transfer information shall accompany the patient. Transfer information shall include but not be limited to facility from which transferred, name of physician to assume care, date and time of discharge, current medical findings, current nursing assessment, current history and physical, diagnosis, orders from a physician for immediate care of the patient, operative report, if applicable; TB test, if applicable; other information germane to patient's condition. If discharge summary is not available at time of transfer, it shall be transmitted as soon as available.

(4) Diagnoses and operations shall be expressed in standard terminology.

(5) The medical records shall be filed in a manner which renders them easily retrievable. Medical records shall be protected against unauthorized access, fire, water and theft.

(6) Medical records are the property of the ASC. The medical record, either in original, electronic or microfilm form, shall not be removed from the institution except where necessary for a judicial or administrative proceeding. Authorized personnel of the Division shall be permitted to review medical records. When an ASC uses off-site storage for medical records, arrangements must be made for delivery of these records to the health care facility when needed for patient care or other health care facility activities. Precautions must be taken to protect patient confidentiality.

(7) All medical records shall be kept for a period of at least 10 years after the date of last discharge. Original medical records may be retained on paper, microfilm, electronic or other media.

(8) If an ASC changes ownership all medical records in original, electronic or microfilm form shall remain in the ASC or related institution, and it shall be the responsibility of the new owner to protect and maintain these records.

(9) If any ASC shall be finally closed, its medical records may be delivered and turned over to any other health care facility in the vicinity willing to accept and retain the same as provided in section (7) of this rule.

(10) All original clinical records or photographic or electronic facsimile thereof, not otherwise incorporated in the medical record, such as x-rays, electrocardiograms, electroencephalograms, and radiological isotope scans shall be retained for seven years after patient's last discharge if professional interpretations of such graphics are included in the medical records.

(11) A current written policy on the release of medical record information including patient access to his/her medical record shall be maintained in the facility.

(12) The Division may require the facility to obtain periodic and at least annual consultation from a qualified medical records consultant, RHIA/RHIT. The visits of the medical records consultant shall be of sufficient duration and frequency to review medical record systems and assure quality records of the patients. Contract for such services shall be available to the Division upon request.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: HD 3-1990, f. 1-8-90, cert. ef. 1-15-90; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10; PH 28-2016, f. & cert. ef. 10-6-16

333-076-0170
Quality Assessment and Performance Improvement

(1) The governing body of an ASC must ensure that there is an effective, facility-wide quality assessment and performance improvement program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors.

(2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC. Written documentation of quality assessment and performance improvement activities shall be recorded at least quarterly.

(3) After an analysis of the causes for adverse events, the ASC must develop and implement facility-wide preventive strategies and ensure that staff are trained in and familiar with these strategies.

(4) The ASC must set priorities for its performance improvement activities that:

(a) Focus on high risk, high volume and problem prone areas;

(b) Consider incidence, prevalence and severity of problems in those areas; and

(c) Affect health outcomes, patient safety and quality of care.

(5) An ASC already in operation and not certified by CMS on December 15, 2010 must be in compliance with this section by June 15, 2011.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: HD 3-1990, f. 1-8-90, cert. ef. 1-15-90; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-076-0175
Infection Control

(1) Each ASC shall establish and maintain an active facility-wide infection control program for the control and prevention of infection. The program shall be managed by a qualified individual and overseen by a multi-disciplinary committee which shall be

responsible for investigating, controlling and preventing infections in the facility.

(2) Each ASC shall be responsible for developing written policies and for annual review of such policies, relating to at least the following:

(a) Identification of existing or potential infections in patients, employees, medical staff, and health care practitioners with ASC privileges;

(b) Control of factors affecting the transmission of infections and communicable diseases;

(c) Provisions for orienting and educating all employees, medical staff, health care practitioners with ASC privileges and volunteers on the cause, transmission, and prevention of infections;

(d) Collection, analysis, and use of data relating to infections in the ASC.

(3) Each ASC shall be responsible for the development, implementation and annual review of policies under section (2) of this rule.

(4) An ASC shall comply with all rules of the Division for the control of communicable diseases.

(5) Written isolation procedures in accordance with current Universal Precautions for Prevention of Transmission of HIV and Other Bloodborne Infections shall be established and followed by all ASC personnel for control and prevention of cross-infection. Guidelines can be obtained from U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Atlanta, GA 30333. Any guidelines published and distributed by the Division shall also be taken into consideration.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: HD 3-1990, f. 1-8-90, cert. ef. 1-15-90; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-076-0180
Inservice Training for Nurses

(1) Each year the inservice training agenda for nurses shall include at least the following:

(a) Infection control measures;

(b) Emergency procedures including, but not limited to, procedures for fire and other disaster;

(c) Procedures for life-threatening situations including, but not limited to, cardiopulmonary resuscitation and the life-saving techniques for choking victims; and

(d) Other special needs of the patient population.

(2) The facility shall assure that each licensed/certified employee is knowledgeable of the laws/rules governing his/her performance and that employees function within those performance standards.

(3) Documentation of such training shall include the date, content, duration and names of attendees.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: HD 3-1990, f. 1-8-90, cert. ef. 1-15-90; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-076-0185
Physical Environment

(1) Applicability. OAR 333-076-0185 shall apply to:

(a) An ambulatory surgical center not licensed on April 1, 2012; or

(b) A major alteration to an ambulatory surgical center for which plans were not submitted to the Division on or before April 1, 2012; provided, however, that OAR 333-076-0185 shall apply only to the major alteration and shall not apply to any other area of the ambulatory surgical center.

(2) For the purpose of this rule the following definitions apply:

(a) "Major alteration" means any structural change to the foundation, floor, roof, or exterior or load bearing wall of a building, or the extension of an existing building to increase its floor area, where such structural change or extension affects patient care or safety. "Major alteration" also means the modification of an existing building that results in a change in use, even if the modification does not include any structural change to the building, where such modification affects patient care or safety. "Major alteration" does not include cosmetic upgrades to the interior or exterior of an existing building, including but not limited to changes to wall finishes, floor coverings and casework.

(b) "Change in use" means altering the purpose of an existing room. "Change in use" does not include the sale of an ASC if the new owner provides services in the same class of operating rooms pursuant to section (15) of this rule.

(3) Notification of Alteration: If an ASC proposes any of the following alterations the ASC must notify the Division. The Division shall determine, on a case-by-case basis, whether such alterations constitute a "change in use". If an alteration affects patient care, patient safety, is a change of use, or includes any of the following, the alteration is subject to this rule:

(a) Addition of surgical services, to the extent the additional surgical services can not be performed in the class of operating rooms existing in the ASC pursuant to section (15) of this rule;

(b) Replacement of equipment in the ASC that is permanently connected to major building components, such as: power, heating, ventilation, air conditioning, plumbing or medical gas; and

(c) Addition of doors to pre-operative holding areas or post-anesthesia care units.

(4) Functional Program.

(a) An ASC shall provide a description of its functional program when plans are submitted for review, along with additional requirements found in OAR 333-675-0000.

(b) The functional program describes in detail the purpose of the project, department relationships and flow of patients, staff, visitors and supplies as applicable, size and function of each space, description of those services necessary for the complete operation of the ASC, type of anesthesia used, average recovery time, special design feature(s), occupant load, numbers of staff and patients, visitors and vendors, issue of privacy/confidentiality for patients, level of medical gas system per NFPA 99, and type of central electrical system.

(5) Location. Building entrances used to reach outpatient services shall be at grade level, clearly marked, and located so patients need not go through other activity areas. Travel patterns shall preclude unrelated traffic within the unit.

(6) Mixed Uses. An ASC is a distinct entity and must be separate and distinguishable from any other health care facility or office-based physician practice, but the ASC may share a reception area, waiting room and public toilet rooms with the other health care facility or office-based physician practice. Medicare-certified ASCs are subject to specific requirements related to sharing spaces with another health care facility or office-based physician practice. An ASC that is Medicare-certified must be distinct from any other health care facility or office-based physician practice as required in 42 CFR 416.2 and 42 CFR 416.44(a)(2) and (b).

(7) Conformance to Building and Fire and Life Safety Codes. ASCs shall conform to the editions of the **Oregon State Building Code**, as defined in ORS 455.010(8), under which they were constructed. ASCs to be certified for Medicare reimbursement shall meet standards of the **National Fire Protection Association (NFPA) #101 and #99 Codes**.

(8) Administrative and Public Areas. An ASC shall have:

(a) An entrance sheltered from inclement weather and accessible to the disabled. If a separate door is provided for the discharge of patients, it must be sheltered from inclement weather and shall be accessible to the disabled;

(b) A reception counter or desk;

(c) Toilet(s) for public use conveniently accessible from the waiting area without passing through patient care or staff work areas or suites;

(d) Telephone access for local phone calls for patients;

(e) Conveniently accessible drinking water;

(f) Conveniently accessible wheelchair storage;

(g) Space(s) for private interviews relating to financing and credit discussions;

(h) Space for business transactions, records storage and administrative and professional staff to work, including but not limited to space designated for computers, printers, fax machines, and copiers if required by the functional program;

(i) Secure and safe storage for medical records of all media type, located to maintain the confidentiality of records and either restricted to staff movement or remote from treatment and public areas. Space required shall be defined by the functional program;

(j) Special storage for staff personal effects with locking drawers or cabinets; and

(k) General storage for supplies and equipment as identified in the functional program.

(9) Environmental Services Room (Housekeeping Closet). An ASC shall have an environmental services room that contains a floor receptor or service sink and storage space for housekeeping supplies and equipment, and that is at least 16 square feet.

(10) Layout. An ASC shall provide three areas — unrestricted, semi-restricted, and restricted — that are defined by the physical activities performed in each area.

(a) Unrestricted area. For the purpose of this rule, unrestricted areas shall include a central control point established to monitor the entrance of patients, personnel, and materials into the restricted areas. (Street clothes are permitted in this area, and traffic is not limited.)

(b) Semi-restricted area. For the purpose of this rule, semi-restricted areas shall include the peripheral support areas of the surgical suite, where traffic is limited to authorized personnel and patients, and where personnel are required to wear surgical attire and hair coverings. A semi-restricted area includes but is not limited to:

(A) Storage areas for clean and sterile supplies;

(B) Work areas for storage and processing of instruments;

(C) Corridors leading to the restricted areas of the surgical suite; and

(D) Scrub sink areas.

(c) Restricted area. For the purpose of this rule, restricted areas are areas where surgical attire and hair coverings are required, and where masks are required due to the presence of open sterile supplies or scrubbed people. A restricted area includes but is not limited to:

(A) Operating and other procedure rooms; and

(B) The clean core (if required by the functional program).

(d) Signs shall be provided at all entrances to restricted areas indicating surgical attire required.

(11) Special Patient Care Rooms. In ASCs with a functional program that includes treatment of patients with known infectious disease or populations with known compromised or suppressed immune systems, the need for and number of airborne infection isolation rooms and protective environment rooms shall be determined by an infection control risk assessment (ICRA).

(a) Airborne Infection Isolation (AII) Room. For the purpose of this rule, Airborne Infection Isolation refers to the isolation of patients infected with organisms spread by airborne droplet nuclei and shall have:

(A) Only one bed and a hand-washing station (placement of an additional hand-washing station outside the room entrance shall be permitted);

(B) An area for gowning and storage of clean and soiled materials located either directly outside or inside the entry door to the patient room;

(C) A separate room with a toilet and hand-washing station;

(D) Perimeter walls, a ceiling, and floor, including penetrations, that are sealed tightly so that air does not infiltrate the environment from the outside or from other spaces;

(E) Self-closing devices on all room exit doors;

(F) Doors with edge seals;

(G) Window treatments and privacy curtains:

(i) Window treatments and privacy curtains shall be smooth-surfaced, easy-to-clean, wipeable, and non-pleated;

(ii) Fabric drapes and curtains shall not be used for window treatments;

(iii) Use of fabric privacy curtains shall be permitted if they are washable. A wipeable fabric with a smooth surface is preferable.

(b) Anteroom. An anteroom to a patient isolation room is not required; however, if an anteroom is part of the design concept, it shall meet the following requirements:

(A) Space for persons to don personal protective equipment before entering the patient room; and

(B) Doors with self-closing devices.

(c) Protective Environment (PE) Rooms. For the purpose of this rule, Protective Environment Room refers to a patient room that is designed to protect a high risk, immunocompromised patient from human and environmental airborne pathogens.

(A) When determined by an Infection Control Risk Assessment (ICRA) and the functional program, special design considerations and ventilation shall be required to ensure the protection of patients who are highly susceptible to infection; and

(B) The room(s) shall meet the requirements of subsection (11)(a) except for paragraph (C).

(12) Non-invasive Procedure & Consultation Room. A non-invasive procedure and consultation room is not a "procedure room" for purposes of ORS 441.020. A non-invasive procedure and consultation room shall have:

(a) A minimum clear floor area of 120 square feet with a minimum room dimension of 10 feet;

(b) A room arrangement that permits a minimum clear dimension of 3 feet at each side and at the foot of the bed;

(c) A hand-washing station;

(d) A counter or shelf space for writing or electronic documentation; and

(e) Visual and acoustical privacy for private medical consultations and confidential communication with patients and their families/legal guardians.

(13) Sterilization Facilities: An ASC shall have space and a system for sterilizing equipment and supplies either on-site or off-site. If located on site, sterilization facilities shall be located in a semi-restricted area and shall include a separate area for cleaning and decontamination of instruments prior to sterilization. Sterilization facilities shall include, but are not limited to, a high-speed sterilizer or other sterilizing equipment for immediate or emergency use, as required by the functional program.

(a) When sterilization is provided off-site, a room for the adequate handling (receiving and distribution) and on-site storage of sterile supplies, that meet paragraph (13)(c)(C) of this rule shall be provided.

(b) Provisions shall be made for sanitizing clean and soiled carts or vehicles consistent with the needs of the particular transportation system.

(c) An on-site processing facility shall include:

(A) A decontamination room for the exclusive use of the surgical suite. If the room has a door or pass through opening for decontaminated instruments between the decontamination room and a clean workroom it shall have a self closing door, but it may not have a direct connection with an operating room. A decontamination room shall include:

(i) A flushing-rim clinical sink or equivalent flush-rim fixture unless the decontamination room is used only for temporary holding of soiled material;

(ii) A hand-washing station; and

(iii) A work counter unless the decontamination room is used only for temporary holding of soiled material.

(B) A clean assembly/workroom that is physically separated from soiled work areas that has adequate space for the designated number of work areas as defined in the functional program as well as space for storage of clean supplies, sterilizer carriages (if used), and instrumentation. Access to this area shall be restricted. A clean/assembly workroom shall contain:

(i) A hand-washing station;

(ii) Workspace; and

(iii) Equipment for terminal sterilizing of medical and surgical equipment and supplies.

(C) Storage for sterile supplies and packs, including provisions for ventilation, humidity, and temperature control.

(i) The sterile supply storage area shall have a floor area as required per the functional program.

(ii) As described in paragraph (13)(c)(B) of this rule, location of the sterile supply storage in an area within the clean assembly/workroom shall be permitted if it is a permanently designated area.

(14) Linen Services. Designated space in the post-anesthesia recovery area(s) shall be provided for clean and soiled linen.

(a) On-site Processing Area. If the functional program requires linen to be processed on site, the area shall:

(A) Be large enough to accommodate a washer, a dryer, and any plumbing equipment needed to meet the temperature requirements of 160 degrees;

(B) Be divided into distinct soiled (sort and wash) and clean (dry and fold) areas;

(C) Have storage for laundry supplies and clean linen; and

(D) Have a hand-washing station within 10 feet without passing through a door.

(b) Off-site Laundry Service Areas. If the functional program requires linen to be processed off site, the area within the ASC shall have a:

(A) Soiled linen holding area or designated and dedicated area for a soiled laundry cart; and

(B) Clean linen storage area that protects linen from soil or damage.

(15) Operating Rooms. The size and location of the operating rooms shall depend on the level of care and equipment specified in the functional program.

(a) Class A Operating Room. For the purpose of this rule, a Class A operating room is for surgery and other procedures that require minimal sedation including but not limited to minor surgical procedures performed under topical and local infiltration blocks with or without oral or intramuscular preoperative sedation. A surgical procedure performed in a Class A operating room could also be performed in a Class B or C operating room.

(A) Space requirements. Class A operating rooms shall have a minimum clear floor area of 150 square feet within a minimum clear dimension of 12 feet.

(B) Clearances. There shall be a minimum clear distance of 3 feet 6 inches at each side, the head, and the foot of the operating table.

(C) Location. Class A operating rooms may be accessed from the semi-restricted corridors of the surgical suite or from an unrestricted corridor adjacent to the surgical suite.

(b) Class B Operating Room. For the purposes of this rule a Class B operating room is for surgery and other procedures that require conscious sedation. A procedure performed in a Class B operating room could also be performed in a Class C operating room.

(A) Space requirements. Class B operating rooms shall have a minimum clear floor area of 250 square feet with a minimum clear dimension of 15 feet.

(B) Clearances. Room arrangement shall permit a minimum clear dimension of 3 feet 6 inches at each side, the head, and the foot of the operating table.

(C) Location. Class B operating rooms shall be accessed from the semi-restricted corridors of the surgical suite.

(c) Class C Operating Room. For the purpose of this rule a Class C operating room is for surgery and procedures that require general anesthesia or deep sedation.

(A) Space requirements. Class C operating rooms shall have a minimum clear floor area of 400 square feet and a minimum clear dimension of 18 feet.

(B) Clearances. Room arrangement shall permit a minimum clear dimension of 4 feet at each side, the head, and the foot of the operating table.

(C) Location. Class C operating rooms shall be accessed from the semi-restricted corridors of the surgical suite.

(d) Each operating room shall have access to at least one medical image viewer located as required by the functional program.

(e) All operating rooms shall be equipped with an emergency communication system designed and installed to effectively summon additional qualified staff support with no more than push activation of an emergency call switch.

(f) An operating room is considered a procedure room for the purposes of determining the appropriate fee under ORS 441.020.

(16) Pre-operative Support Areas.

(a) Location. Pre-operative holding areas shall be under direct visual control of the nursing staff. Pre-operative holding can be shared with post-operative if the functional program defines patient management.

(A) For a Class A operating room the minimum number of patient stations within the pre-operative holding areas is as follows:

(i) At least one patient station if the operating room is accessed from the semi-restricted area.

(ii) None if the operating room is accessed from an unrestricted area and the functional program allows for pre-operative care to be carried out in the operating room.

(B) For a Class B operating room, at least one patient station within the pre-operative holding areas is required. A patient station may consist of a bed, chair or stretcher.

(C) For Class C operating room, at least one patient station per Class C operating room is required.

(D) In an ASC with Class B and Class C operating rooms, area shall be provided to accommodate stretcher and chair space.

(b) Area. Each pre-operative holding area shall provide a minimum clear floor area of 80 square feet for each patient station.

(c) Clearances. Each pre-operative holding area shall have a minimum clear dimension of 5 feet between patient and 4 feet between patient and adjacent walls (at the stretcher's or chair's side and foot).

(d) Patient privacy. Provisions such as cubicle curtains shall be made for patient privacy.

(e) Hand-washing station. Hands-free or wrist blade-operable controls shall be available, with at least one station for every six positions or fewer and for each major fraction thereof. Hand-washing stations shall be uniformly distributed to provide convenient access from each patient position. Travel distance to a hand-washing station shall not exceed 20 feet, and shall be located without passing through a door. Travel distances shall be calculated from the foot of the patient station to the hand-washing station.

(f) Documentation space. A counter, table, area for a desk, or storage for a movable table shall be provided.

(g) Change Area. A separate area(s) shall be provided for outpatients to change from street clothing to hospital gowns and prepare for surgery. If the ASC has four or fewer operating rooms, the change area can also be a holding area(s). The change area shall include the following:

(A) Lockers, or acceptable provisions made for securing patients' personal effects; and

(B) Toilet(s). The patient toilet room(s) shall be separate from public use toilet(s) and located to permit access from pre- and post-operative holding areas.

(17) Recovery Areas.

(a) When determining the number of recovery positions required, an ASC shall take into consideration the types of surgery and procedures performed in the ASC, the types of anesthesia used, average recovery periods, and anticipated staffing levels.

(b) Recovery areas shall be accessible directly from the semi-restricted area. If pre-operative holding areas, Phase 2 areas and recovery areas are required per the functional program, these spaces may be shared if the number of patient positions meet the most restrictive requirements of both pre and post operative areas.

(c) Nurse Control Station. The nurse control station shall have direct sightline to patients in acute recovery stations.

(d) If pediatric surgery is practiced, the functional program and physical environment design shall address the following:

(A) Locations of pediatric recovery stations;

(B) Space for parents;

(C) Sound attenuation; and

(D) Proximity of patient stations to a nursing station.

(e)(A) Post-anesthesia recovery positions. Room(s) for post-anesthesia recovery in an ASC shall be provided in accordance with the functional program;

(B) Number. A minimum of one recovery station per operating room shall be provided. A recovery area analysis shall determine the need for additional recovery stations. In the absence of a recovery area analysis approved by the Division, the minimum number of post-anesthesia recovery positions shall be as follows:

(i) Three recovery positions for each Class C operating room;

(ii) Two recovery positions for each Class B operating room;

(iii) One recovery position for each Class A operating room.

(f) Area. When a patient cubicle is used for each patient care station, a minimum clear floor area of 80 square feet shall be provided. Space shall also be provided for additional equipment described in the functional program.

(g) Clearances. Each post-anesthesia recovery area shall provide a minimum clear dimension of 5 feet between patient stretchers or beds, 4 feet between patient stretchers or beds and adjacent walls (at the stretcher's sides and foot), and at least 3 feet from the foot of the stretcher or bed to the closed cubicle curtain.

(h) Patient privacy. Provisions for patient privacy such as cubicle curtains shall be made.

(i) Hand-washing station. Hands-free or wrist blade-operable controls shall be available, with at least one station for every six positions or fewer and for each major fraction thereof. Hand-washing stations shall be uniformly distributed to provide convenient access from each patient position. Travel distance to a hand-washing station shall not exceed 20 feet, and shall be located without passing through a door. Travel distances shall be calculated from the foot of the patient station to the hand-washing station.

(j) Patient toilet room(s). In an ASC with three or more operating rooms, a dedicated patient toilet room shall be provided in the recovery area.

(k) Support areas for post-anesthesia recovery rooms. If the post-anesthesia recovery room(s) is located immediately adjacent to the surgical suite, sharing of these support areas shall be permitted;

(A) Supply storage. Storage space shall be determined by the functional program, however, at least 15 cubic feet needs to be provided.

(B) Receptacles for soiled linen and waste holding shall be provided and meet the requirements of NFPA 101, 20.7.5.5.

(C) Documentation space. A counter, table, area for a desk, or storage for a movable table shall be provided.

(D) Drug distribution station. Each recovery area shall have a drug distribution station that includes:

(i) An area for the storage and preparation of medications administered to patients;

(ii) A refrigerator for pharmaceuticals and double-locked storage for controlled substances if required by the functional program; and

(iii) Convenient access to a hand-washing station without passing through a door.

(E) Nourishment facilities within a recovery area shall have:

(i) A sink, work counter, refrigerator, storage cabinets, and equipment for serving nourishment as required by the functional program; and

(ii) A hand-washing station that is located in the nourishment area or adjacent to the nourishment area.

(18) Phase 2 Recovery.

(a) A Phase 2 recovery area shall be provided if required by the functional program.

(b) Location of the Phase 2 recovery area within the post-anesthesia recovery area shall be permitted, but the Phase 2 area shall be an identifiably separate and distinct part of the post-anesthesia recovery area. Phase 2 recovery stations can be shared with recovery stations if the functional program defines patient management.

(c) Area. When a patient cubicle is used for each patient care station, the design shall provide a minimum of 50 square feet for each patient in a lounge chair with space for additional equipment described in the functional program.

(d) Clearances.

(A) The design shall provide a minimum clear dimension of 4 feet between the sides of adjacent lounge chairs and between the foot of the lounge chairs and the nearest obstruction.

(B) When permanent partitions (full or partial height or width) are used to partially define the patient care station (rather than cubicle curtains), a minimum clear dimension of 3 feet shall be provided on the side of the lounge chair.

(e) Patient privacy. Provisions for patient visual privacy such as cubicle curtains shall be made.

(f) Hand-washing station. Hands-free or wrist blade-operable controls shall be available, with at least one station for every six positions or fewer and for each major fraction thereof. Hand-washing stations shall be uniformly distributed to provide convenient access from each patient position. Travel distance to a hand-washing station shall not exceed 20 feet, and shall be located without passing through a door. Travel distances shall be calculated from the foot of the patient station to the hand-washing station;

(g) Patient toilet room(s). In an ASC with two or fewer operating rooms, a patient toilet room shall be provided in or adjacent to the Phase 2 recovery area. In an ASC with three or more operating rooms, a patient toilet room shall be provided in the Phase 2 recovery area.

(h) Support areas for Phase 2 recovery (if provided) shall provide the following:

(A) Clear sightlines and easy access from the post-anesthesia recovery area to the nurse control station;

(B) Storage space for supplies and equipment;

(C) Documentation space. A counter, table, area for a desk, or storage for a movable table; and

(D) Space for family members.

(19) Support for the Surgical Service Areas: The following shall be provided in the surgical service areas:

(a) Visual surveillance by nursing staff of all traffic entering the semi-restricted corridor (the passage used to access operating rooms and ancillary semi-restricted areas) per the functional program;

(b) Medication storage. Drug storage shall be provided. A refrigerator for pharmaceuticals and double-locked storage for controlled substances shall be provided if required by the functional program;

(c) Scrub facilities. With the exception of ASCs providing exclusively gastrointestinal endoscopy services, an ASC shall have a scrub station(s) trimmed with foot, knee, or electronic controls. Single-lever wrist blades shall not be permitted. Scrub station(s) shall be provided at the entrance to each operating room. A scrub station may serve two operating rooms if it is located on the same wall, and between the two entrances. Scrub stations shall be arranged to minimize splatter on nearby personnel or supply carts. A dedicated hand wash station with hands-free controls shall be provided in each room used for gastrointestinal endoscopy services.

(d) Equipment and supply storage. Equipment storage room(s) shall be provided for equipment and supplies used in the surgical service areas. The combined area of equipment and clean clinical supply storage room(s) shall have a minimum floor area of 50 square feet for each operating room(s) up to two and an additional 25 square feet per additional operating room. Equipment storage room(s) shall be located within the semi-restricted area;

(e) Anesthesia supply storage. An area shall be provided for storing anesthesia equipment and supplies, as defined by the functional program. This space shall be located within the semi-restricted area;

(f) Medical gas storage. An area shall be provided for the storage of medical gas(es) used in the ASC, including adequate space for reserve cylinders. Such space shall meet **National Fire Protection Association 99** standards;

(g) Stretcher storage area. In an ASC that provides Class B and C operating rooms, a stretcher storage area for at least one stretcher shall be provided. This storage area shall be convenient for use and located outside the required width of the exit access corridor;

(h) Staff lounge and toilet facilities. Staff lounge toilet facilities shall be provided in an ASC with three or more operating rooms. The toilet room shall be near the recovery area;

(i) Staff lockers. Appropriate change area(s) shall be provided for male and female staff working within the surgical suite (a unisex locker area with one or more private changing rooms shall be permitted.) For an ASC that provides services in Class B and C operating rooms, this area(s) shall be designed to effect a one-way traffic pattern so that personnel entering from outside the surgical suite can change and move directly into the suite's semi-restricted corridor. As least one staff shower shall be provided that is conveniently accessible to the surgical suite and recovery areas;

(j) Environmental services room (housekeeping closet). An environmental services room shall be provided exclusively for the surgical suite. This room shall contain a floor receptor or service sink and storage space for housekeeping supplies and equipment and shall be at least 16 square feet;

(k) Emergency equipment/supply storage. Provisions shall be made for access to and use of emergency resuscitation equipment and supplies (crash cart(s) and anesthesia carts) within 60 feet and at least one per floor of patient care areas;

(l) Fluid waste disposal. Fluid waste disposal facilities shall be provided and shall be located so that they are convenient to the operating rooms and recovery areas. A clinical sink or equivalent equipment in a soiled workroom shall meet this requirement in the operating room area, and a toilet equipped with a bedpan-cleaning device or a separate clinical sink shall meet the requirement in the recovery area.

(20) Details and Finishes:

(a) Corridor width. Public corridors shall have a minimum width of 5 feet, except that corridors connecting the operating room section and the post anesthesia care unit and at least one ambulance transfer exit, where patients are transported on stretchers or beds, shall have a minimum width of 6 feet. The semi-restricted corridor shall have a minimum width of 8 feet in areas used to transport patients on gurneys between pre-operative, procedure, and post-anesthesia recovery areas. Passages and corridors used exclusively for staff access shall be a minimum of 3 feet 8 inches in clear width. Items such as provisions for drinking water, telephone booths, vending machines, etc., shall not restrict corridor traffic or reduce the corridor width below the required minimum. In-corridor storage or parking space for portable equipment shall not overlap required corridor widths. Width shall also meet OFC 1018.2.

(b) Doors and door hardware. The minimum door width for patient use shall be 3 feet. Door openings requiring gurney/stretcher access shall have a minimum clear width of 3 feet 8 inches;

(c) Hand-washing stations. Hand sanitation dispensers shall be provided in addition to hand-washing stations. The number and location of both hand-washing stations and hand sanitation dispensers shall be determined by ICRA;

(A) Hand-washing stations used by medical and nursing staff, patients, and food handlers shall be trimmed with valves that can be operated without hands. Single-lever or wrist blade devices shall be permitted. Sensor-regulated water fixtures shall meet user need for temperature and length of time the water flows. Electronic faucets shall be capable of functioning during loss of normal power. Knee control, foot pedal, electronic or other devices that allow operation without use of the hands are acceptable.

(B) Sinks in hand-washing stations shall be designed with deep basins to prevent splashing to areas where direct patient care is provided, particularly those surfaces where sterile procedures are performed and medications are prepared.

(C) The area of the basin shall not be less than 144 square inches with a minimum 9 inch width or length.

(d) Clinical sinks.

(A) Handles on clinical sinks shall be at least 6 inches long.

(B) Clinical sinks shall have an integral trap wherein the upper portion of the water trap provides a visible seal.

(e) Provisions for hand drying shall be required at all hand-washing stations except scrub sinks.

(A) Hand-washing stations shall include a hand-drying device that does not require hands to contact the dispenser.

(B) If provided, hand towels shall be directly accessible to sinks.

(f) Cleansing agents. Hand-washing stations shall include liquid or foam soap dispensers.

(g) Toilet rooms for patient use in surgery and recovery areas shall be equipped with doors and hardware that permit access from the outside in emergencies. When such rooms have only one opening, the doors shall open outward or be otherwise designed to open without pressing against a patient who may have collapsed within the room.

(h) Radiation protection requirements for X-ray and gamma ray installations shall conform with National Council on Radiation Protection and Measurements (NCRP) reports 102, 147, and 151 and all applicable state requirements. Testing is to be coordinated with the Division's Radiation Protection Services program to prevent duplication of test observations or construction inspections. Provision shall be made for testing completed installations before use. All defects shall be corrected before approval.

(i) The minimum ceiling height of an ASC shall be 7 feet 10 inches, with the following exceptions:

(A) Ceiling height in corridors, storage rooms, toilet rooms, and other minor rooms shall not be less than 7 feet 8 inches;

(B) Radiographic and other rooms containing ceiling-mounted equipment shall have ceilings of sufficient height to accommodate the equipment and fixtures; and

(C) Boiler rooms shall have ceiling clearances not less than 2 feet 6 inches above the main boiler header and connecting pipe.

(j) Ceilings. Ceiling finishes shall be appropriate for the areas in which they are located and shall be as follows:

(A) Semi-restricted areas.

(i) Ceiling finishes in semi-restricted areas such as clean corridors, central sterile supply spaces, specialized radiographic rooms, and Class A operating rooms shall be smooth, scrubbable, nonabsorptive, nonperforated, capable of withstanding cleaning with chemicals, and without crevices that can harbor mold and bacteria growth.

(ii) Perforated, tegular, serrated, or highly textured tiles shall not be used.

(B) Restricted areas.

(i) Ceilings in restricted areas such as operating rooms shall be monolithic, scrubbable, and capable of withstanding chemicals. Cracks or perforations in these ceilings are not allowed.

(ii) All access openings in ceilings in restricted areas shall be gasketed.

(C) Mechanical and electrical rooms. Suspended ceilings may be omitted in mechanical and electrical rooms/spaces unless required for fire safety purposes.

(k) Floor finishes shall be appropriate for the areas in which they are located and shall:

(A) Be easy to maintain, readily cleanable and appropriately wear-resistant;

(B) In all areas such as clean corridors, central sterile supply spaces, specialized radiographic rooms, and Class A operating rooms, be washable, smooth and able to withstand chemical cleaning;

(C) In areas such as operating rooms, environmental services rooms, and soiled holding or utility rooms, be scrubbable, able to withstand chemical cleaning, and monolithic, with an integral base of at least 6 inches;

(D) In clinical areas, be constructed of materials that allow the easy movement of all required wheeled equipment;

(E) Provide smooth transitions between different flooring materials;

(F) Allow for ease of ambulation and self-propulsion. Carpet and carpet with padding in patient areas shall be glued down or

stretched taut and free of loose edges or wrinkles that might create hazards or interfere with the operation of lifts, wheelchairs, walkers, wheeled carts, or patients utilizing orthotic devices;

(G) In all areas subject to wet cleaning methods, not be physically affected by germicidal or other types of cleaning solutions;

(H) Be slip-resistant for flooring surfaces in wet areas (e.g., kitchens, showers and baths), ramps, entries from exterior to interior space, and areas that include water for patient services; and

(I) Joints for flooring openings for pipes, ducts, and conduits shall be tightly sealed to minimize entry of pests. Joints of structural elements shall be similarly sealed.

(l) Wall finishes shall be cleanable and washable. In the vicinity of plumbing fixtures, wall finishes shall be smooth and moisture resistant.

(A) Wall finishes in areas such as clean corridors, central sterile supply spaces, specialized radiographic rooms, and minor surgical procedure rooms shall be washable, smooth, and able to withstand chemical cleaning.

(B) Wall finishes in areas such as operating rooms, delivery rooms, and trauma rooms shall be scrubbable, able to withstand chemical cleaning, and monolithic.

(C) Wall finish treatments shall not create ledges or crevices that can harbor dust and dirt.

(D) Wall surfaces in wet areas (e.g. environmental services rooms) shall be monolithic and all seams shall be covered or sealed.

(E) Wall bases in areas routinely subjected to wet cleaning shall be monolithic and coved with the floor, tightly sealed to the wall, and constructed without voids.

(F) Wall areas penetrated by pipes, ducts, and conduits shall be tightly sealed to minimize the entry of rodents and insects. Joints of structural elements shall be similarly sealed.

(G) Sharp, protruding corners shall be avoided.

(H) Wall protection devices and corner guards shall be durable and scrubbable.

(21) Elevators. Electric or hydraulic elevators are required if the ASC has patient spaces located on other than the grade-level entrance floor. The elevator shall be sized to accept a gurney or stretcher plus an attendant.

(a) Dimensions. Cars shall have a minimum inside floor dimension of not less than 5 feet.

(b) Leveling device. Elevators shall be equipped with a two-way automatic level-maintaining device with an accuracy of ±one-half inch.

(c) Elevator controls:

(A) Elevator call buttons and controls shall not be activated by heat or smoke. Light beams, if used for operating door reopening devices without touch, shall be used in combination with door-edge safety devices and shall be interconnected with a system of smoke detectors so the light control feature will be overridden or disengaged should it encounter smoke at any landing.

(B) Elevator controls, alarm buttons, and telephones shall be accessible to wheelchair occupants and usable by the blind.

(d) Emergency power must comply with NFPA 99 requirements.

(22) Mechanical system design.

(a) In new construction, the mechanical system shall be designed and constructed for overall efficiency in accord with the **Oregon Mechanical Specialty Code** and the **Oregon Energy Efficiency Specialty Code**, as enforced by the Oregon Building Codes Division or local jurisdictions having authority.

(b) Efficiency. The mechanical system shall be designed for overall efficiency and appropriate life-cycle cost.

(c) Use of recognized energy-saving mechanisms such as variable-air-volume (VAV) systems, load shedding, programmed controls for unoccupied periods (nights and weekends, etc.), and use of natural ventilation may be considered.

(d) Air-handling systems shall be designed with an economizer cycle where appropriate to use outside air.

(e) VAV systems. The energy-saving potential of VAV systems is recognized, and the standards herein are intended to maximize appropriate use of such systems. Any system used for occupied areas shall include provisions to avoid air stagnation in interior spaces where thermostat demands are met by temperatures of surrounding areas. Reference Table 1 contains minimum ventilation and airflow requirements.

(f) Recirculating rooms units (such as induction unit and unit ventilators) may be used in individual rooms for heating and cooling purposes except as noted in Table 1. Outdoor air requirements shall be met by separate air handling systems with proper filtration. Reference Table 2 contains the filtration requirements.

(g) Vibration isolators. Mechanical equipment, ductwork, and piping shall be mounted on vibration isolators.

(h) System valves. Supply and return mains and risers for cooling, heating, and steam systems shall be equipped with valves to isolate the various sections of each system. Each piece of equipment shall have valves at the supply and return ends.

(i) Testing and documentation.

(A) Prior to licensure of an ASC, all systems shall be tested and operated to demonstrate to the owner or its designated representative that the installation and performance of these systems conform to design intent. Test results shall be documented for maintenance files.

(B) Upon completion of the installation, the owner of an ASC shall ensure that a complete set of manufacturer's operating, maintenance, and preventive maintenance instructions; a parts list; and complete procurement information, including equipment numbers and descriptions, has been obtained.

(C) An ASC shall ensure that staff who operate the systems shall be provided with instructions for proper operation of systems and equipment. Required information shall include all safety or code ratings as needed.

(23) Ventilation and space-conditioning requirements. All rooms and areas used for patient care shall have ventilation per Table 1. Although natural ventilation shall be permitted, mechanical ventilation shall be provided in all patient care rooms and areas in an ASC.

(24) HVAC Requirements for Specific Locations.

(a) Airborne infection isolation (AII) rooms. These special ventilation areas have an inward air movement relationship to adjacent areas where a patient with airborne infectious diseases may be a risk to the surrounding area. If AII rooms are required per the functional program, the HVAC design must meet the requirements of OAR 333-535-0300.

(b) Protective environment (PE) rooms. These special ventilation areas have an outward air movement relationship to adjacent areas where the patient may be at risk from the surrounding areas. If PE rooms are provided per the functional program, the PE rooms must meet the requirements of OAR 333-535-0300.

(c) Operating rooms.

(A) Air distribution.

(i) Operating room air supply shall be from ceiling outlets near the center of the work area for effective air movement control. Laminar flow design diffusers shall be used in Class B and C operating rooms as required by the functional program.

(ii) Each operating room shall have a minimum of two air inlets located as remotely from each other as possible. The return air inlets shall be located near the floor level in Class B and C operating rooms.

(B) Ventilation rates.

(i) The ventilation systems for Class B and C operating rooms shall operate at all times, except during maintenance and conditions requiring shutdown by the building's fire alarm system.

(ii) During unoccupied hours, operating room air change rates may be reduced, provided that the positive room pressure is maintained as required and the required air changes are automatically re-established any time the space is being utilized.

(iii) Ventilation systems serving Class A Operating Rooms and Class B Operating Rooms used for Endoscopy may be shut off during unoccupied periods if these areas will not have an inward air pressure relationship to adjacent areas.

(C) Humidity and smoke venting requirements in anesthetizing locations shall be designed per NFPA 99.

(d) Anesthesia storage rooms. The ventilation systems for inhalation anesthesia storage rooms shall conform to the requirements for medical gas storage as described in NFPA 99.

(e) ETO sterilizer space. The space that houses ethylene oxide (ETO) sterilizers shall be designed per OAR 333-535-0300.

(25) Thermal Insulation and Acoustical Provisions. Insulation shall be provided within the building to conserve energy, protect personnel, prevent vapor condensation, and reduce noise.

(a) Renovation.

(A) Existing accessible insulation within areas of ASCs to be modernized shall be inspected, then repaired, or replaced, as determined by inspection.

(B) If existing lined ductwork is reworked in a renovation project, the liner seams and punctures shall be resealed.

(b) Duct linings exposed to air movement shall not be used in ducts serving operating rooms, recovery rooms, central sterile processing, and protective environment rooms. This requirement shall not apply to terminal units and sound attenuators that have coverings over such lining meeting ASTM C1071.

(26) HVAC Air Distribution.

(a) Return air systems. For all areas in Table 1, return air shall be via ducted systems. The bottoms of ventilation openings shall be at least 6 inches above the floor.

(b) Humidifiers, if provided, shall meet the requirements of OAR 333-535-0300.

(c) Construction requirements. Ducts that penetrate construction intended to protect against X-ray, magnetic, RFI, or other radiation shall not impair the effectiveness of the protection.

(d) Exhaust systems.

(A) To enhance the efficiency of recovery devices required for energy conservation, combined exhaust systems shall be permitted unless otherwise noted.

(B) Local exhaust systems shall be used whenever possible in place of dilution ventilation to reduce exposure to hazardous gases, vapors, fumes, or mists.

(C) Fans serving exhaust systems shall be located at the discharge end and shall be readily serviceable.

(D) Airborne infection isolation rooms and other rooms containing contaminated exhaust such as bronchoscopy, decontamination, and sterilizer equipment rooms shall not be served by exhaust systems incorporating air to air heat recovery such as heat wheels. Heat recovery systems are acceptable if there is complete isolation of air streams, such as run-around loops.

(e) Fresh air intakes shall be located at least 25 feet from exhaust outlets of ventilating systems, combustion equipment stacks, medical-surgical vacuum systems, plumbing vents, or areas that may collect vehicular exhaust or other noxious fumes. Plumbing vents that terminate above the level of the top of the air intake may be located as close as 10 feet.

(f) New and remodeled ventilation system installations shall be designed and balanced at project completion to provide directional flow as shown in Table 1. A log shall be prepared showing actual ventilation rates at each supply, return and exhaust grill, and be made available to Division on request.

(g) Ventilation Hoods. If lab exhaust hoods, safety cabinets or fume hoods are required per the functional program, these systems shall meet the requirements of OAR 333-535-0300.

(27) HVAC Filters.

(a) Filter requirements. Air handling system filtration shall meet the requirements of Table 2.

(b) Filter frames. Filter frames shall be durable and proportioned to provide an airtight fit with the enclosing ductwork. All joints between filter segments and enclosing ductwork shall have gaskets or seals to provide a positive seal against air leakage.

(28) Plumbing Systems.

(a) Standards. Unless otherwise specified herein, all plumbing systems shall be designed and installed in accordance with the Oregon Plumbing Specialty Code.

(b) Testing and documentation.

(A) All plumbing systems shall be tested to demonstrate that equipment installation and operation is appropriate and functional. Test results shall be documented for maintenance files.

(B) Upon completion of the installation, the owner shall be furnished with a complete set of manufacturer's operating, maintenance, and preventative maintenance instructions; a parts list; and complete procurement information, including equipment numbers and descriptions.

(C) Operating staff persons shall be provided with instructions for proper operation of systems and equipment. Required information shall include all safety or code ratings as needed.

(29) Plumbing and Other Piping Systems.

(a) General piping and valves.

(A) All piping, except control-line tubing, fire sprinkler, sanitary waste, vent, and condensate drain shall be identified.

(B) All valves shall be tagged, and a valve schedule shall be developed for permanent record and reference.

(b) Potable water supply systems. The following standards shall apply to potable water supply systems:

(A) Valves. Each water service main, branch main, riser, and branch to a group of fixtures shall have valves.

(i) Stop valves shall be provided for each fixture.

(ii) Appropriate panels for access shall be provided at all valves where required.

(B) Dead-end piping (risers with no flow, branches with no fixture) shall not be installed. In renovation projects, dead-end piping shall be removed. Empty risers, mains, and branches installed for future use shall be permitted and shall be valved at the connection to the main.

(c) Hot water systems. The following standards shall apply to hot water systems. These requirements do not apply to ASCs that do not perform invasive operations or procedures.

(A) Hot water distribution systems serving patient care areas shall be under constant recirculation to provide continuous hot water at each hot water outlet. Non-recirculated fixture branch piping shall not exceed 25 ft in length.

(B) Provisions shall be included in the domestic hot water system to limit *Legionella* bacteria and opportunistic waterborne pathogens.

(C) Domestic hot water system in an ASC with Class C operating rooms shall provide backup equipment for hot water and sterilizer needs.

(d) Plumbing Fixtures.

(A) Hand-washing stations used by medical and nursing staff, patients, and food handlers shall be trimmed with valves that can be operated without hands. Single-lever or wrist blade devices shall be permitted. Sensor-regulated water fixtures shall meet user need for temperature and length of time the water flows. Electronic faucets shall be capable of functioning during loss of normal power when the ASC is required to have an emergency generator.

(B) Clinical sinks shall have an integral trap wherein the upper portion of the water trap provides a visible seal. Handles on clinical sink faucets shall be at least 6 inches long.

(30) Hemodialysis piping. Where the functional program includes hemodialysis, the requirements of OAR 333-700-0130 shall be met.

(31) Drainage systems.

(a) Piping.

(A) Drain lines from sinks used for acid waste disposal shall be made of acid-resistant material. Drain lines from automatic blood-cell counters using sodium azide shall be made of copper and lead free materials.

(B) Drainage piping shall not be installed within the ceiling or exposed in Class B and C operating rooms. Where exposed overhead drain piping in these areas is unavoidable, special provisions such as FM 1680 fittings or drain pans shall be made to protect the space below from leakage, condensation, or dust particles.

(b) Floor drains.

(A) Floor drains shall not be installed in operating rooms, except as permitted in dedicated cystoscopy rooms.

(B) If a floor drain is installed in a dedicated cystoscopy room, it shall contain a non-splash, horizontal-flow flushing bowl beneath the drain plate.

(c) Plaster traps. Where plaster traps are used, provisions shall be made for appropriate access and cleaning.

(32) Medical Gas and Vacuum Systems. Station outlets shall be provided per Table 3. The use of portable medical gas systems shall be considered for ASCs with Class A operating rooms per the functional program.

(a) Medical gas and vacuum systems. When provided, piped in medical gas and vacuum systems shall be installed, tested, and verified prior to use in accordance with NFPA 99, Gas and Vacuum System Chapter and Other Health Care Facility Chapter. When additions or modifications are made to a system, the new and existing components in the immediate zone or area located upstream (for vacuum systems) and downstream (for medical gas systems) of the altered section shall be tested and verified.

(b) Anesthesia scavenging system. Each space routinely used for administering inhalation anesthesia shall be served by a scavenging system to vent waste gases. Gases from the scavenging system shall be exhausted directly to the outside. If the medical vacuum system is used, the gas collecting system shall be arranged so that it does not interfere with the patient's respiratory system. The anesthesia evacuation system may be a dedicated air exhaust system, provided the part used for anesthesia gas scavenging exhausts directly to the outside and is not part of the recirculation system.

(33) Communications Systems.

(a) Locations for terminating telecommunications and information system devices shall be provided.

(b) A space shall be provided for central equipment locations. Special air conditioning and voltage regulation shall be provided when recommended by the manufacturer.

(34) Electronic Safety and Security Systems and Fire Alarm System. Any fire alarm system shall be as required by NFPA 101 and installed per NFPA 72.

(35) Electrical Systems.

(a) Applicable standards.

(A) All electrical material, systems, and equipment, including conductors, controls, and signaling devices, shall be installed in compliance with applicable sections of OESC and NFPA 99. In addition, an ASC must meet the specific ambulatory health care requirements found at NFPA 99 (Other Health Care Facilities Chapter).

(B) All electrical material and equipment shall be listed as complying with available standards of listing agencies or other similar established standards where such standards are required.

(b) Testing and documentation.

(A) Electrical installations, including alarm and communication systems, shall be tested to demonstrate that equipment installation and operation is appropriate and functional. Test results shall be documented for maintenance files.

(B) Upon completion of the installation, a complete set of manufacturer's operating, maintenance, and preventative maintenance instructions; a parts list; and complete procurement information, including equipment numbers and descriptions shall be available on site.

(C) Operating staff persons shall be provided with instructions for proper operation of systems and equipment. Required information shall include all safety or code ratings as needed.

(D) Essential electrical system, grounding system, and receptacles shall be tested per NFPA 99.

(36) Electrical Distribution and Transmission.

(a) Switchboards.

(A) Main switchboards shall be located in an area separate from plumbing and mechanical equipment and shall be accessible to authorized persons only.

(B) Switchboards shall be convenient for use and readily accessible for maintenance.

(C) Switchboards shall be located in dry, ventilated spaces free from corrosive or explosive fumes or gases or any flammable material.

(b) Panelboards.

(A) Panelboards serving normal lighting and appliance circuits shall be located on the same floor as the circuits they serve.

(B) Panelboards serving critical branch emergency circuits shall be located on each floor.

(C) Panelboards serving life safety emergency circuits may also serve one floor above and/or below.

(c) Ground-fault circuit interrupters.

(A) Ground-fault circuit interrupters (GFCIs) shall comply with OESC.

(B) When GFCIs are used in critical care areas, provisions shall be made to ensure that other essential equipment is not affected by activation of one interrupter.

(37) Power Generating and Storing Equipment.

(a) Emergency electrical service. Emergency lighting and power shall be provided in accordance with **NFPA 99**, **NFPA 101**, and **NFPA 110**.

(b) Emergency generator systems are required in an ASC that administers inhalation anesthetics and where a patient requires electrical life support equipment as part of the surgical protocol. An ASC that is required to have an emergency generator system must also meet the specific ambulatory health care requirements found at NFPA 99 (Other Health Care Facilities Chapter).

(38) Lighting.

(a) Lighting shall conform to the recommended lighting standards for public buildings contained in the OSSC (Means of Egress Illumination), Illuminating Engineering Society (IES) RP-29 Hospitals and Health Care Facilities. Approaches to buildings and parking lots, and all occupiable spaces within the building shall have illuminated fixtures as necessary.

(b) Procedure rooms. A portable or fixed examination light shall be provided for procedure rooms.

(c) Operating rooms. Operating rooms shall have general lighting in addition to special lighting units provided at surgical tables. General lighting and special lighting shall be on separate circuits.

(39) Receptacles (Convenience Outlets).

(a) Duplex grounded-type receptacles (convenience outlets) shall be installed in all areas in sufficient quantities for tasks to be performed as needed. Duplex receptacles shall be provided per Table 4.

(b) Emergency system receptacles. Electrical receptacle cover plates or electrical receptacles supplied from the emergency systems shall be distinctively colored or marked for identification. If color is used for identification purposes, the same color shall be used throughout the ASC.

(40) Call Systems.

(a) General. Signaling and nurse call equipment shall be provided in an ASC with Class B and C operating rooms and shall include the following types of call stations: patient stations, staff assist, bath stations, and code call stations.

(A) Call station locations shall be as required in Table 5.

(B) Call stations shall report to an attended location with electronically supervised visual and audible annunciation.

(C) Call system master stations shall be located at the nurse control station and shall provide audible/visual prompting and display all pending calls.

(D) In addition to these rules, call systems shall meet the requirements of Underwriters Laboratory (UL) 1069: *Standards for Hospital Signaling and Nurse Call Equipment* and state and local requirements.

(E) Alternate technologies including radio frequency systems, shall be permitted for call systems in an ASC with Class A operating rooms.

(b) Patient stations. Patient stations shall be provided to allow each patient to summon assistance from the nursing staff. Use of a dual call station shall be permitted when beds are located adjacent to each other.

(A) The patient station shall be equipped with the following:

(i) A visible signal once it has been activated. An indicator light or call assurance lamp that remains lighted until a call is cancelled shall be provided. In rooms containing two or more patient stations, call assurance lamps shall be provided at each station; and

(ii) A reset switch for canceling a call.

(B) The patient station shall activate a visible signal in the corridor at the patient's door or at the nurse station within the room with the patients under constant visual surveillance and at the master station.

(c) Bath stations. Bath stations shall be located to the side of toilets within 12 inches of the front of the toilet bowl and 3 to 4 feet above the floor. A bath station with a pull string that can be activated by a patient lying on the floor shall be provided at each room containing a patient water closet, tub, or shower. An alarm in these areas shall be able to be turned off only at the bath station where it is initiated.

(d)(A) Code call stations. Commonly referred to as a "Code Blue," code call stations are meant for use during a life-threatening situation to summon assistance from others throughout the unit or department.

(B) The code call station shall be equipped with a continuous audible or visual confirmation to the person who initiated the code call.

(e) Staff assist call stations. Staff assist call stations are meant for use during a non-life threatening situation to summon assistance from others throughout the unit or department.

[ED. NOTE: Tables & publications referenced are available from the agency.]

Stat. Auth.: ORS 441.025 & 441.060

Stats. Implemented: ORS 441.025 & 441.060

Hist.: HD 11-1980, f. & ef. 9-10-80; HD 25-1983(Temp), f. & ef. 12-21-83; HD 23-1985, f. & ef. 10-11-85; Renumbered from 333-023-0163(1); HD 3-1990, f. 1-8-90, cert. ef. 1-15-90, Renumbered from 333-076-0100(11)(a)-(k); PH 5-2012, f. 3-30-12, cert. ef. 4-1-12

Ambulatory Surgical Centers ASC

333-076-0190
Emergency Preparedness

(1) The ASC shall develop, maintain, update, train and exercise an emergency plan for the protection of all individuals in the event of an emergency, in accordance with the regulations as specified in **Oregon Fire Code** (Oregon Administrative Rules chapter 837, division 40).

(a) The ASC shall conduct at least two drills every year that document and demonstrate that employees have practiced their specific duties and assignments, as outlined in the emergency preparedness plan.

(2) The emergency plan shall include the contact information for local emergency management. Each facility shall have documentation that the local emergency management office has been contacted and that the facility has a list of local hazards identified in the county hazard vulnerability analysis.

(3) The summary of the emergency plan shall be sent to the Division within one year of the filing of this rule. New facilities that have submitted licensing documents to the state before this provision goes into effect will have one year from the date of license application to submit their plan. All other new facilities shall have a plan prior to licensing. The Division shall request updated plans as needed.

(4) The emergency plan shall address all local hazards that have been identified by local emergency management that may include, but is not limited to, the following:

(a) Chemical emergencies;

(b) Dam failure;

(c) Earthquake;

(d) Fire;

(e) Flood;

(f) Hazardous material;

(g) Heat;

(h) Hurricane;

(i) Landslide;

(j) Nuclear power plant emergency;

(k) Pandemic;

(l) Terrorism; or

(m) Thunderstorms.

(5) The emergency plan shall address the availability of sufficient supplies for staff and patients to shelter in place or at an agreed upon alternative location for a minimum of two days, in coordination with local emergency management, under the following conditions:

(a) Extended power outage;

(b) No running water;

(c) Replacement of food or supplies is unavailable;

(d) Staff members do not report to work as scheduled; and

(e) The patient is unable to return to the pre-treatment shelter.

(6) The emergency plan shall address evacuation, including:

(a) Identification of individual positions' duties while vacating the building, transporting, and housing residents;

(b) Method and source of transportation;

(c) Planned relocation sites;

(d) Method by which each patient will be identified by name and facility of origin by people unknown to them;

(e) Method for tracking and reporting the physical location of specific patients until a different entity resumes responsibility for the patient; and

(f) Notification to the Division about the status of the evacuation.

(7) The emergency plan shall address the clinical and medical needs of the patients, including provisions to provide:

(a) Storage of and continued access to medical records necessary to obtain care and treatment of patients, and the use of paper forms to be used for the transfer of care or to maintain care on-site when electronic systems are not available.

(b) Continued access to pharmaceuticals, medical supplies and equipment, even during and after an evacuation; and

(c) Alternative staffing plans to meet the needs of the patients when scheduled staff members are unavailable. Alternative staffing plans may include, but is not limited to, on-call staff, the use of travelers, the use of management staff, or the use of other emergency personnel.

(8) The emergency plan shall be made available as requested by the Division and during licensing and certification surveys. Each plan will be re-evaluated and revised as necessary or when there is a significant change in the facility or population of the ASC.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 441.025

Stats. Implemented: ORS 441.025

Hist.: PH 13-2008, f. & cert. ef. 8-15-08; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-076-0250
Violations

In addition to non-compliance with any health care facility licensing law or conditions for coverage, it is a violation to:

(1) Refuse to cooperate with an investigation or survey, including but not limited to failure to permit Division staff access to the ASC, its documents or records;

(2) Fail to implement an approved plan of correction;

(3) Fail to comply with all applicable laws, lawful ordinances and rules relating to safety from fire;

(4) Refuse or fail to comply with an order issued by the Division;

(5) Refuse or fail to pay a civil penalty; or

(6) Fail to comply with rules governing the storage of medical records following the closure of an ASC.

Stat. Auth.: ORS 441.025

Stats. Implemented: ORS 441.015, 441.025 & 441.030

Hist.: PH 26-2010, f. 12-14-10, cert. ef. 12-15-10; PH 28-2016, f. & cert. ef. 10-6-13

333-076-0255
Informal Enforcement

(1) If, during an investigation or survey Division staff document violations of health care facility licensing laws or conditions for coverage, the Division may issue a statement of deficiencies that cites the law alleged to have been violated and the facts supporting the allegation.

(2) A signed plan of correction must be received by the Division within 10 business days from the date the statement of deficiencies was mailed to the ASC. A signed plan of correction will not be used by the Division as an admission of the violations alleged in the statement of deficiencies.

(3) An ASC shall correct all deficiencies within 60 days from the date of the exit conference, unless an extension of time is requested from the Division. A request for such an extension shall be submitted in writing and must accompany the plan of correction.

(4) The Division shall determine if a written plan of correction is acceptable. If the plan of correction is not acceptable to the Division, the Division shall notify the ASC administrator in writing and request that the plan of correction be modified and resubmitted no later than 10 working days from the date the letter of non-acceptance was mailed to the administrator.

(5) If the ASC does not come into compliance by the date of correction reflected on the plan of correction or 60 days from date of the exit conference, whichever is sooner, the Division may propose to deny, suspend, or revoke the ASC license, or impose civil penalties.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.015 & 441.025
Hist.: PH 26-2010, f. 12-14-10, cert. ef. 12-15-10; PH 28-2016, f. & cert. ef. 10-6-13

333-076-0260
Formal Enforcement

(1) If, during an investigation or survey Division staff document substantial failure to comply with health care facility licensing laws, conditions for coverage or if an ASC fails to pay a civil penalty imposed under ORS 441.170, the Division may issue a Notice of Proposed Suspension or Notice of Proposed Revocation in accordance with ORS 183.411 through 183.470.

(2) The Division may issue a Notice of Imposition of Civil Penalty for violations of health care facility licensing laws.

(3) At any time the Division may issue a Notice of Emergency License Suspension under ORS 183.430(2).

(4) If the Division revokes an ASC license, the order shall specify when, if ever, the ASC may reapply for a license.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.015, 441.025, 441.030 & 441.037
Hist.: PH 26-2010, f. 12-14-10, cert. ef. 12-15-10; PH 28-2016, f. & cert. ef. 10-6-13

333-076-0265
Civil Penalties, Generally

(1) A licensee that violates a health care facility licensing law, including OAR 333-076-0250 (violations), is subject to the imposition of a fine not to exceed $500 per day per violation.

(2) In addition to the penalties under section (1) of this rule, civil penalties may be imposed for violations of ORS 441.015 to 441.063, 441.086 or program rules.

(3) In determining the amount of a civil penalty the Division shall consider whether:

(a) The Division made repeated attempts to obtain compliance;

(b) The licensee has a history of noncompliance with health care facility licensing laws;

(c) The violation poses a serious risk to the public's health;

(d) The licensee gained financially from the noncompliance; and

(e) There are mitigating factors, such as a licensee's cooperation with an investigation or actions to come into compliance.

(4) The Division shall document its consideration of the factors in section (3) of this rule.

(5) Each day a violation continues is an additional violation.

(6) A civil penalty imposed under this rule shall comply with ORS 183.745.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.030 & 441.990
Hist.: PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-076-0270
Approval of Accrediting Organizations

(1) An accrediting organization must request approval by the Division to ensure that ASCs meet state licensing standards.

(2) An accrediting organization shall request approval in writing and shall provide, at a minimum:

(a) Evidence that it is a nationally recognized Medicare accreditation program approved by CMS; or

(b) If the accrediting organization is not approved by CMS, provide:

(A) Documentation of program policies and procedures that its accreditation process meets state licensing standards;

(B) Accreditation history; and

(C) References from a minimum of two health care facilities currently receiving services from the organization.

(3) If the Division finds that an accrediting organization has the necessary qualifications to certify that state licensing standards have been met, the Division will enter into an agreement with the accrediting organization permitting it to accredit ASCs in Oregon.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.062
Hist.: PH 26-2010, f. 12-14-10, cert. ef. 12-15-10; PH 28-2016, f. & cert. ef. 10-6-13

Birthing Centers

333-076-0450
Definitions

(1) "Free Standing Birth Center" ("Birthing Center" or "Center") means any health care facility (HCF), licensed for the primary purpose of performing low risk deliveries that is not a hospital, or in a hospital, and where births are planned to occur away from the mother's usual residence following normal, uncomplicated pregnancy.

(2) "Division" means the Oregon Health Authority, Public Health Division.

(3) "Low Risk Pregnancy" means a normal, uncomplicated prenatal course as determined by documentation of adequate prenatal care, and anticipation of a normal uncomplicated labor and birth, as defined by reasonable and generally accepted criteria of maternal and fetal health.

(4) "Absolute risk factors" are those conditions that, if present, prohibit care in a birthing center.

(5) "Patient audit" means review of the clinical record and/or physical inspection of a client.

(6) "Reasonable and generally accepted criteria" means criteria or standards of care adopted by professional groups for maternal, fetal and neonatal health care, and generally accepted and followed by the care providers to whom they apply, and accepted by the Division as reasonable.

Stat. Auth.: ORS 441.025 & 442.015
Stats. Implemented: ORS 441.086 & 442.015
Hist.: HD 26-1985, f. & ef. 10-28-85; HD 2-1990, f. 1-8-90, cert. ef. 1-15-90, Renumbered from 333-076-0400; PH 15-2006, f. & cert. ef. 6-27-06

333-076-0470
Licensing

(1) Application for a license to operate a Birthing Center must be in writing on a form provided by the Division, including demographic, ownership and administrative information. The form must specify such information required by the Division.

(2) No health care facility licensed pursuant to the provisions of ORS Chapter 441, may in any manner or by any means assert, represent, offer, provide or imply that such facility is or may render care or services other than that which is permitted by or that is within the scope of the license issued to such facility by the Division nor may any service be offered or provided that is not

authorized within the scope of the license issued to such facility or licensed practitioner providing services in the facility.

(3) The Birthing Center license must be conspicuously posted in the area where clients are admitted.

(4) A license that has been suspended or revoked may be reissued after the Division determines that compliance with Health Care Facility laws has been achieved satisfactorily.

Stat. Auth.: ORS 441.015 & 442.015
Stats. Implemented: ORS 441.015 & 442.015
Hist.: HD 2-1990, f. 1-8-90, cert. ef. 1-15-90; PH 15-2006, f. & cert. ef. 6-27-06

333-076-0490
Submission of Plans

(1) Any party proposing to make certain alterations or additions to an existing health care facility or to construct new facilities must, before commencing such alteration, addition or new construction, submit plans and specifications to the Division for preliminary inspection and approval of recommendations with respect to compliance with Division rules. Submissions shall be in accord with, OAR 333-675-0000. Plans should also be submitted to the local building division having authority for review and approval in accordance with state building codes.

(2) Centers must keep the Division informed of any changes in ownership, organizational structure, procedures performed and privileges permitted and any information requested on the application form, in writing within 30 days of the change. Failure to notify the Division may result in revocation of license.

Stat. Auth.: ORS 441.060 & 442.015
Stats. Implemented: ORS 441.060 & 442.015
Hist.: HD 2-1990, f. 1-8-90, cert. ef. 1-15-90; PH 15-2006, f. & cert. ef. 6-27-06

333-076-0510
Expiration and Renewal of License

Each license to operate a Birthing Center will expire on December 31 following the date of issue, and if a renewal is desired, the licensee must make application at least 30 days prior to the expiration date upon a form prescribed by the Division as described in OAR 333-076-0470.

Stat. Auth.: ORS 441.025 & 442.015
Stats. Implemented: ORS 441.025 & 442.015
Hist.: HD 2-1990, f. 1-8-90, cert. ef. 1-15-90; PH 15-2006, f. & cert. ef. 6-27-06

333-076-0530
Denial or Revocation of a License

(1) A license for any Birthing Center may be denied, suspended or revoked by the Division when the Division finds that there has been a substantial failure to comply with the provisions of Health Care Facility licensing law.

(2) A person or persons in charge of a Birthing Center must not permit, aid or abet any illegal act affecting the welfare of the license.

(3) A license will be denied, suspended or revoked in any case where the State Fire Marshal certifies that there was failure to comply with all applicable laws, lawful ordinances and rules relating to safety from fire.

(4) A license may be suspended or revoked for failure to comply with a Division order arising from a Center's substantial lack of compliance with the rules or statutes.

Stat. Auth.: ORS 441.030 & 442.015
Stats. Implemented: ORS 441.030 & 442.015
Hist.: HD 2-1990, f. 1-8-90, cert. ef. 1-15-90; PH 15-2006, f. & cert. ef. 6-27-06

333-076-0550
Return of Facility License

Each license certificate in the licensee's possession must be returned to the Division immediately on the suspension or revocation of the license, failure to renew the license by December 31, or if operation is discontinued by the voluntary action of the licensee.

Stat. Auth.: ORS 441.086 & 442.015
Stats. Implemented: ORS 441.086 & 442.015
Hist.: HD 2-1990, f. 1-8-90, cert. ef. 1-15-90; PH 15-2006, f. & cert. ef. 6-27-06

333-076-0560
Classification

(1) Health care facilities licensed by the Division may neither assume a descriptive title or be held out under any descriptive title other than the classification title established by the Division and under which the facility is licensed.

(2) No change in the licensed classification of any health care facility, as set out in this rule, may be allowed by the Division unless such facility files a new application, accompanied by the required license fee, with the Division. If the Division finds that the applicant and facility comply with Health Care Facility laws and the regulations of the Division relating to the new classification for which application for licensure is made, the Division may issue a license for such classification.

Stat. Auth.: ORS 441.025 & 442.015
Stats. Implemented: ORS 441.025 & 442.015
Hist.: HD 2-1990, f. 1-8-90, cert. ef. 1-15-90; PH 15-2006, f. & cert. ef. 6-27-06

333-076-0570
Hearings

Upon written notification by the Division of revocation, suspension or denial to issue or renew a license; a written request by the Center for a hearing in accordance with ORS 183.310 to 183.500 may be granted by the Division.

Stat. Auth.: ORS 441.037 & 442.015
Stats. Implemented: ORS 441.037 & 442.015
Hist.: HD 2-1990, f. 1-8-90, cert. ef. 1-15-90; PH 15-2006, f. & cert. ef. 6-27-06

333-076-0590
Adoption by Reference

All rules, standards and publications referred to in this division are made a part thereof. Copies are available for inspection at the Division during office hours. Where publications are in conflict with the rules, the rules govern.

Stat. Auth.: ORS 441.025 & 442.015
Stats. Implemented: ORS 441.086 & 442.015
Hist.: HD 2-1990, f. 1-8-90, cert. ef. 1-15-90; PH 15-2006, f. & cert. ef. 6-27-06

333-076-0610
Division Procedures

Inspections and investigations:

(1) Complaints:

(a) Any person may make a complaint to the Division regarding violation of health care facility laws or regulations. A complaint investigation will be carried out as soon as practicable and may include but not be limited to, as applicable to facts alleged:

(A) Interviews of the complainant, client(s), witnesses, and Center management and staff;

(B) Observations of the client(s), staff performance, client environment and physical environment; and

(C) Review of documents and records.

(b) Copies of all complaint investigations will be available from the Division provided that the identity of any complainant and any client referred to in an investigation will not be disclosed without legal authorization.

(2) Inspections:

(a) The Division may, in addition to any inspections conducted pursuant to complaint investigations, conduct at least one general inspection of each Center to determine compliance with Health Care Facility laws during each calendar year and at such other times as the Division deems necessary;

(b) Inspections may include but not be limited to those procedures stated in subsection (1)(a) of this rule;

(c) The inspection may include a client audit;

(d) When documents and records are requested under sections (1) or (2) of this rule, the Center must make the requested materials available to the investigator for review and copying.

Stat. Auth.: ORS 441.025 & 442.015
Stats. Implemented: ORS 441.086 & 442.015
Hist.: HD 2-1990, f. 1-8-90, cert. ef. 1-15-90; PH 15-2006, f. & cert. ef. 6-27-06

333-076-0630
Administration

Each Center must have a governing body or person clearly identified as being legally responsible for setting of policies and procedures, and assuring that they are implemented.

Stat. Auth.: ORS 441.025 & 442.015
Stats. Implemented: ORS 441.086 & 442.015
Hist.: HD 26-1985, f. & ef. 10-28-85; HD 2-1990, f. 1-8-90, cert. ef. 1-15-90, Renumbered from 333-076-0410; PH 15-2006, f. & cert. ef. 6-27-06

333-076-0650
Service Restrictions

(1) Procedures permitted, including surgical procedures, must be limited to those directly pertaining to pregnancy, labor and delivery care of women experiencing low risk pregnancy. Procedures performed will be consistent with the individual practitioner's licensure and/or scope of practice. Tubal ligation and abortion must not be performed. Table I outlines absolute risk factors that, if present on admission to the birthing center for labor and delivery, would prohibit admission to the birthing center. Table II outlines absolute risk factors that, if they develop during labor and delivery, require transfer of the client to a higher level of care. Table III outlines absolute risk factors that, if they develop during the postpartum period in the mother or infant, would require transfer to a higher level of care. [Tables not included. See ED. NOTE.]

(2) General, spinal, caudal, and/or epidural anesthesia must not be administered in the Center.

(3) Labor shall not be induced, stimulated, or augmented with chemical agents during the first or second stages of labor.

(4) Chemical agents may be administered within the individual practitioner's scope of practice to inhibit labor, as a temporary measure, until referral/transfer of the client is complete.

[ED. NOTE: Tables referenced are available from the agency.]
Stat. Auth.: ORS 441.025 & 442.015
Stats. Implemented: ORS 441.025 & 442.015
Hist.: HD 26-1985, f. & ef. 10-28-85; HD 2-1990, f. 1-8-90, cert. ef. 1-15-90, Renumbered from 333-076-0415; PH 15-2006, f. & cert. ef. 6-27-06

333-076-0670
Policies and Procedures

Each Center must have a detailed Policies and Procedures Manual in easily accessible form, that has been approved by the governing body or person. In order to be approved by the Division for licensing purposes, these policies and procedures must meet North American Registry of Midwives (NARM) standards. All the above noted policies must be made available to representatives of the Division on request, and subject to their approval. Failure of approval will be adequate reason for the finding of deficiencies that must be corrected for continuation of licensure. The policies must be implemented as applicable, and there must be documented evidence of implementation of the above noted policies. The policies and procedures that will be developed as applicable and implemented include:

(1) A detailed organizational chart that shows the governing body or person, and clearly delineates lines of authority, responsibility and accountability for each position included in the organization, including volunteers.

(2) Staffing — The governing body or person must ensure, through the policies and procedures, that there are adequate numbers of qualified and, where required, licensed or registered personnel on duty and immediately available to provide services intended for mothers and families, and to provide for safe maintenance of the Center.

(3) Detail of procedures to be permitted, and by whom, and method of determining the qualifications and privileges of all personnel. Staff will be required to provide documented evidence of such qualifications. Such evidence must be maintained by the Center.

(4) System for ensuring 24-hour coverage of the Center, including constant attendance by qualified attendants while a client is in the Center.

(5) System for training and for continuing education for all personnel according to their assigned duties and evaluation of skills consistent with the individual practitioners' scopes of practice. All personnel providing direct client care must be trained in cardiopulmonary resuscitation (CPR) and there must be a record of current CPR certification. In addition there must be present at each birth one practitioner trained in care and resuscitation of the newborn.

(6) System delineating how and when the Center will seek consultation with clinical specialists in obstetrics and pediatrics in order to ensure that all services, policies, and procedures meet North American Registry of Midwives (NARM) standards.

(7) Protocol for referral or transfer to appropriate health care facilities all clients whose risk status exceeds that for "low risk pregnancy."

(8) Procedures by which risk status will be assessed during the antepartal, intrapartal, and post partum period, and the identification of medical and social factors which exclude women, fetuses and newborns from the low-risk group; and for the annual review of these methods. Documentation of such assessments must be maintained in client's clinical records. Only those clients for whom prenatal and intrapartum history, physical examination, and laboratory screening procedures have demonstrated a low risk pregnancy and labor will be accepted into the Center for childbirth.

(9) System by which the Center will ensure the presence and continuing maintenance, as recommended by the manufacturer(s), of equipment needed to provide low risk maternity care, and to initiate emergency procedures in life-threatening events to the mother or baby.

(10) Plan and protocols for ensuring that emergency situations in either the mother or newborn are recognized in a timely fashion, and care is provided within the limits of the practitioner's scope of practice.

(11) System delineating how emergency transportation will be promptly available for transport of the mother and/or newborn to a health care facility with the capacity for emergency care of women, in all the stages of labor, and newborns. The written policy must include a listing of situations for the mother and/or newborn that would have the potential to necessitate emergency transfer. The policy must also include the requirement that a transfer plan for each patient be developed.

(12) Systems for ensuring the orientation and education of women and families registering for care at the Center so that they will be informed as to the benefits and risks of the services available to them at the Center and the qualifications and licensure status of practitioners at the Center. They must be fully informed of the risk criteria as defined in OAR 333-076-0650 and provide written consent. The client, as a part of the informed consent, must also agree in advance to transfer to another clinician or appropriate health care facility, should the need occur due to the development of unexpected risk factors after admission to the Center. The client must be informed of the benefits and risks of such a transfer.

(13) System for the sterilization of equipment and supplies, unless only pre-packaged and pre-sterilized items are used.

(14) System to ensure the performance of appropriate laboratory studies and to ensure that the results are available in a timely manner.

(15) System for the storage and administration of drugs. All medications must be prescribed and/or administered within the individual practitioner's licensure and/or scope of practice.

(16) System to ensure the timely administration of Rh immune globulin to the mother, where applicable.

(17) System to ensure the timely appropriate administration of Vitamin K to the newborn, according to rules of the Division.

(a) The purpose of ORS 433.303 to 433.314 is to protect newborn infants against hemorrhagic disease of the newborn.

(b) The Vitamin K forms suitable for use are forms of Vitamin K1 (Phytonadione), available in injectable or oral forms: as Mephyton for oral use, or as aquamephyton or konakion for injectable use. The Vitamin K dose is to be administered within the first 24 hours of delivery. Menadione (Vitamin K3) is not recommended for prophylaxis and treatment of hemorrhagic disease of the newborn.

(c) The dose of any of the Vitamin K1 forms to be administered is one dose of 0.5 to 1.0 mg., if given by injection, or one dose of 1.0 to 2.0 mg. if given orally.

(d) A parent may, after being provided a full and clear explanation, decline to permit the administration of Vitamin K based on religious tenets and practices. In this event, the parent must sign a form acknowledging his/her understanding of the reason for administration of Vitamin K and possible adverse consequences in the presence of a person who witnessed the instruction of the parent, and who must also sign the form. The form must become a part of the clinical record of the newborn infant.

(18) System to ensure the timely and appropriate collection of blood from the newborn for testing by the Oregon State Public Health Laboratory, Newborn Screening Program, for the Metabolic Diseases listed in 333-024-0210.

(19) System to ensure that pulse oximetry screening is performed on every newborn infant delivered at the Birthing Center before the infant is discharged in conformance with the following requirements:

(a) The pulse oximetry screening must be performed using evidence-based guidelines such as those recommended by Strategies for Implementing Screening for Critical Congenital Heart Disease, AR Kemper et al., Pediatrics 2011;128(5): e1259–1267.

(b) The Birthing Center must have policies and procedures based on the guidelines required by subsection (a) of this section for:

(A) Determining what is considered a positive screening result; and

(B) Determining what follow-up services, treatment or referrals must be provided if a newborn infant has a positive screening result.

(c) A Federal Drug Administration (FDA) approved motion tolerant pulse oximeter must be used.

(d) The pulse oximetry screening must be performed no sooner than 24 hours after birth or as close to discharge of the newborn infant as possible.

(e) Before performing pulse oximetry screening on newborn infants, individuals must have received training on how to correctly operate the pulse oximeter and the policies and procedures associated with the screening. The Birthing Center must document this training.

(f) If a newborn infant is admitted to a hospital as the result of a transfer from the Birthing Center before a pulse oximetry screening is performed, the hospital from which the newborn infant is discharged to home is responsible for performing the screening.

(g) The Birthing Center must provide the following notifications and document them in the newborn infant's medical record:

(A) Prior to the pulse oximetry screening, notify a parent or legal representative of the newborn about the reasons for the screening and the risks and consequences of not screening.

(B) Following the pulse oximetry screening, notify the health care provider responsible for the newborn infant and the infant's primary care provider of the results of the screening.

(C) Following the pulse oximetry screening and prior to discharge, notify a parent or legal representative of the newborn infant of the screening result, an explanation of its meaning and, if it is a positive screening result, provide information about the importance of timely diagnosis and intervention.

(h) A parent or legal representative of a newborn infant may decline pulse oximetry screening and, if screening is declined, the Birthing Center must document the declination in the newborn infant's medical record.

(i) Following the pulse oximetry screening, the Birthing Center, in accordance with the applicable standard of care, must provide any appropriate follow-up services or treatment for the newborn infant if necessary or provide a referral to a parent or legal representative of the newborn for follow-up services or treatment if necessary.

(j) The Birthing Center must document in the newborn infant's medical record that the screening was performed, the screening result, the names of the health care providers who were notified of the screening result, and any follow-up services or treatment or referral for services or treatment.

(k) No newborn infant may be refused screening because of the inability of a parent or legal representative to pay for the screening.

(20) Protocol delineating the steps to ensure the prompt and safe evacuation of the Center in the event of emergency situations, such as fire. The Center must ensure the evaluation of staff in managing such situations by periodic drills for fire, and/or other emergencies. Such drills must be documented.

(21) System of infection control to address the prevention and early recognition of the possibility of infection, and timely and acceptable methods of control. This includes written documentation of the problem, and measures taken for control, and must at least meet the requirements of the rules of the Division. Documentation must also include methods for the control and prevention of cross-infection between clients and services in accordance with 2003 Center for Disease Control and Prevention "Guidelines for Environmental Infection Control in Health-Care Facilities."

(22) System to be used for the prevention of Ophthalmia Neonatorum in the newborn OAR 333-019-0036(2). Prophylaxis for Gonococcal Ophthalmia Neonatorum:

(a) The practitioner attending the birth of an infant must, after evaluating the infant as being at risk and within two hours of delivery, instill appropriate prophylactic antibiotic ointment from single patient use applicators into each eye of the newborn infant;

(b) Parent(s) refusing to allow prophylaxis for their infant(s) must be informed, by the attending Health Care Provider, of the risks attendant to such action and must sign a witnessed affidavit to testify that they have been so informed and nonetheless refuse to allow prophylaxis.

(c) If Vitamin K and/or Gonococcal Ophthalmia Neonatorum Prophylaxis cannot be administered by the individual delivering the newborn, methods must be described to ensure that these services are arranged by referral.

(23) System to ensure that appropriate vital records are filed according to the rules of the Division.

(24) System for a semi-annual clinical record audit to evaluate the care process and outcome.

Stat. Auth.: ORS 441.025 & 442.015
Stats. Implemented: ORS 441.025 & 442.015
Hist.: HD 26-1985, f. & ef. 10-28-85; HD 2-1990, f. 1-8-90, cert. ef. 1-15-90, Renumbered from 333-076-0420; PH 15-2006, f. & cert. ef. 6-27-06; PH 18-2013(Temp), f. 12-31-13, cert. ef. 1-1-14 thru 6-29-14; PH 18-2014, f. & cert. ef. 6-17-14

333-076-0690
Health and Medical Records

Health and Clinical Records must be developed according to procedures outlined in the Policy and Procedures Manual as a legal record and an instrument for the continuity of care and must include:

(1) Contents — The records of each client must contain:

(a) Demographic data, initial prenatal physical examination, laboratory tests and evaluation of risk status;

(b) Continuous periodic prenatal examination and evaluation of risk status;

(c) A signed informed consent (refer also to OAR 333-076-0670(12));

(d) History, physical examination and risk assessment on admission to the Center in labor (including assessment of mother and fetus);

(e) Continuous assessment of the mother and fetus during labor and delivery;

(f) Labor summary;

(g) The emergency transport plan for the client;

(h) Physical assessment of newborn, including Apgar scores and vital signs;

(i) Post partum evaluation of the mother;

(j) Discharge summary for mother and newborn;

(k) Documentation of consultation, referral, and/or transfer;

(l) Signed documents as may be required by law; and

(m) Records of newborn and stillborn infants must include, in addition to the requirement for medical records, the following information:

(A) Date and hour of birth, birth weight and length of infant, period of gestation, sex, and condition of infant on delivery;

(B) Mother's name;

(C) Record of ophthalmic prophylaxis and Vitamin K administration or refusal of same; and

(D) Progress notes including:

(i) Temperature, weight and feeding data;

(ii) Number, consistency and color of stools;

(iii) Urinary output;

(iv) Condition of eyes and umbilical cord;

(v) Condition and color of skin; and

(vi) Motor behavior.

(2) All entries in a client's labor record must be dated, timed, and authenticated. Verification of an entry requires use of a unique identifier, i.e., signature, code, thumbprint, voice print or other means, that allows identification of the individual responsible for the entry.

(3) A single signature or authentication of the responsible practitioner on the clinical record does not suffice to cover the entire content of the record.

(4) The completion of the clinical record must be the responsibility of the attending practitioner.

(5) The Center will ensure that the prenatal and intrapartal records are available at the time of admission and in the event of transfer to the care of another clinician or health care facility.

(6) Storage — The records will be stored in such a way as to minimize the chance of their destruction by fire or other source of loss or damage and to ensure prevention of access by unauthorized persons.

(7) Records are the property of the Center, and will be kept confidential unless released by the permission of the client. An exception is that they may be reviewed by representatives of the Division, and will be provided in copy form to such representatives on request.

(8) All clinical records must be kept for a period of at least twenty-one years after the date of last discharge. Original clinical records may be retained on paper, microfilm, electronic or other media.

(9) If a Center changes ownership all clinical records in original, electronic, or microfilm form must remain in the Center, and it must be the responsibility of the new owner to protect and maintain these records.

(10) If a Birthing Center must be closed, its clinical records may be delivered and turned over to any other health care facility in the vicinity willing to accept and maintain the same as provided in section (8) of this rule.

(11) If a qualified clinical record practitioner, RHIA (Registered Health Information Administrator) or RHIT (Registered Health Information Technician) is not the Director of the Clinical Records Department, the Division may require the Center to obtain periodic and at least annual consultation from a qualified clinical records consultant, RHIA/RHIT. The visits of the clinical records consultant must be of sufficient duration and frequency to review clinical record systems and assure quality records of the clients. Contract for such services must be available to the Division.

Stat. Auth.: ORS 441.025 & 442.015

Stats. Implemented: ORS 441.025 & 442.015

Hist.: HD 26-1985, f. & ef. 10-28-85; HD 2-1990, f. 1-8-90, cert. ef. 1-15-90, Renumbered from 333-076-0425; PH 15-2006, f. & cert. ef. 6-27-06

333-076-0710
Physical Facility

(1) Design — The Center may be an adaptation of a house. It must include birthing rooms of adequate size to meet the needs to accomplish the procedures specified in the Policies and Procedures and must meet applicable codes for ordinary construction and for water supply and sewage disposal. The building and equipment must be kept clean and in good repair. The Center must include:

(a) Toilet facilities for staff, mothers and families;

(b) Bath facilities;

(c) Hand washing facilities and single use towel dispensers adjacent or closely available to all examining or birth rooms;

(d) Examination areas;

(e) Laundry facilities (unless laundry is done elsewhere);

(f) Kitchen facilities;

(g) Adequate storage areas for emergency equipment;

(h) Separate storage for clean/sterile supplies and equipment;

(i) Storage areas for laboratory equipment and sterilizing, if applicable;

(j) Space for resuscitation of the newborn; and

(k) Reception and family facilities.

(2) Client Environment:

(a) There must be provided for each client a good bed, mattress and pillow with protective coverage, and necessary bed coverings;

(b) No towels, wash cloths, bath blankets, or other linen which comes directly in contact with the client will be interchangeable from one client to another unless it is first laundered;

(c) The use of torn or unclean bed linen is prohibited; and

(d) After the discharge of any client, the bed, bed furnishings, bedside furniture and equipment must be thoroughly cleaned and disinfected prior to reuse. Mattresses must be professionally renovated when necessary.

(3) Provision must be made for the safe disposal of any bodily wastes that result from procedures performed in accordance with Centers for Disease Control and Prevention recommendations and state law.

(4) Fire and Safety — State and local fire and life-safety codes apply with specific attention to demonstration of adequate ingress and egress of occupants, placement of smoke alarms, emergency lighting, fire extinguishers or sprinkler systems, fire escape routes, and fire reporting plans. The Center must have an emergency plan in effect on premises available to all staff. There must be evidence of an annual fire inspection.

(5) Emergency Access — Hallways and doorways must be so sized and arranged as to ensure the reasonable access of equipment in the event of the need for emergency transport.

(6) Emergency preparedness:

(a) The health care facility shall develop, maintain, update, train, and exercise an emergency plan for the protection of all individuals in the event of an emergency, in accordance with the regulations as specified in Oregon Fire Code (OAR 837-040).

(A) The health care facility shall conduct at least two drills every year that document and demonstrate that employees have practiced their specific duties and assignments, as outlined in the emergency preparedness plan.

(b) The emergency plan shall include the contact information for local emergency management. Each facility shall have documentation that the local emergency management office has been contacted and that the facility has a list of local hazards identified in the county hazard vulnerability analysis.

(c) The summary of the emergency plan shall be sent to the Authority within one year of the filing of this rule. New facilities that have submitted licensing documents to the state before this provision goes into effect will have one year from the date of license application to submit their plan. All other new facilities shall have a plan prior to licensing. The Authority shall request updated plans as needed.

(d) The emergency plan shall address all local hazards that have been identified by local emergency management and may include, but is not limited to, the following:

(A) Chemical emergencies;

(B) Dam failure;

(C) Earthquake;

(D) Fire;

(E) Flood;

(F) Hazardous material;

(G) Heat;

(H) Hurricane;

(I) Landslide;

(J) Nuclear power plant emergency;
(K) Pandemic;
(L) Terrorism; or
(M) Thunderstorms.
(e) The emergency plan shall address the availability of sufficient supplies for staff and patients to shelter in place or at an agreed upon alternative location for a minimum of two days, in coordination with local emergency management, under the following conditions:
(A) Extended power outage;
(B) No running water;
(C) Replacement of food or supplies is unavailable;
(D) Staff members do not report to work as scheduled; and
(E) The patient is unable to return to the pre-treatment shelter.
(f) The emergency plan shall address evacuation, including:
(A) Identification of individual positions' duties while vacating the building, transporting, and housing residents;
(B) Method and source of transportation;
(C) Planned relocation sites;
(D) Method by which each patient will be identified by name and facility of origin by people unknown to them;
(E) Method for tracking and reporting the physical location of specific patients until a different entity resumes responsibility for the patient; and
(F) Notification to the Authority about the status of the evacuation.
(g) The emergency plan shall address the clinical and medical needs of the patients, including provisions to provide:
(A) Storage of and continued access to medical records necessary to obtain care and treatment of patients, and the use of paper forms to be used for the transfer of care or to maintain care on-site when electronic systems are not available.
(B) Continued access to pharmaceuticals, medical supplies, and equipment, even during and after an evacuation; and
(C) Alternative staffing plans to meet the needs of the patients when scheduled staff members are unavailable. Alternative staffing plans may include, but is not limited to, on-call staff, the use of travelers, the use of management, or the use of other emergency personnel.
(h) The emergency plan shall be made available as requested by the Authority and during licensing and certification surveys. Each plan will be re-evaluated and revised as necessary or when there is a significant change in the facility or population of the health care facility.

Stat. Auth.: ORS 441.020 & 442.015
Stats. Implemented: ORS 441.020 & 442.015
Hist.: HD 26-1985, f. & ef. 10-28-85; HD 2-1990, f. 1-8-90, cert. ef. 1-15-90, Renumbered from 333-076-0430; PH 15-2006, f. & cert. ef. 6-27-06; PH 13-2008, f. & cert. ef. 8-15-08

DIVISION 80

ORGAN PROCUREMENT ORGANIZATIONS TISSUE BANKS — EYE BANKS

333-080-0040
Definitions

(1) As used in this section of Oregon Administrative Rules:
(a) "Entity" means an individual, corporation, business trust, partnership, limited liability company, association, joint venture or an instrumentality of an entity.
(b) "Eye bank" means an entity that is licensed or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage or distribution of human eyes or parts of human eyes.
(c) "Health care facility" has the meaning given that term in ORS 442.015.
(d) "Organ procurement organization" means an entity designated by the United States Secretary of Health and Human Services as an organ procurement organization.
(e) "Tissue bank" means an entity that is licensed or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage or distribution of tissue for transplants.
(2) Tissue banks and eye banks must be registered with and regulated by the United States Food and Drug Administration.
(3) A health care facility that performs organ transplants must:
(a) Be a member of the Organ Procurement and Transplantation Network established by the National Organ Transplant Act of 1984;
(b) Be regulated by the United States Department of Health and Human Services; and
(c) Use an organ procurement organization to obtain organs for transplants.
(4) A health care facility that performs tissue or corneal transplants must obtain the tissue or corneas from a tissue bank or an eye bank that is registered with and regulated by the United States Food and Drug Administration.

Stat. Authority: ORS 441.015
Stats. Implemented: ORS 183.745, ORS 441.015, ORS 441.079, ORS 441.082
Hist.: PH 5-2008, f. 3-7-08, cert. ef. 7-1-08

333-080-0050
Registration and Civil Penalties

(1) An organ procurement organization, tissue bank or eye bank may not do business in Oregon unless it has registered with the Oregon Health Authority. Registration with the Authority must be completed within 30 days after the implementation of these rules on July 1, 2008.
(a) The Authority shall develop a registration form and the transplant organizations shall, at least 30 days prior to implementation, obtain and mail the required form to the Authority.
(2) Each organ procurement organization, tissue bank and eye bank shall provide to the Authority, at least every three years, current documentation of designation, certification and inspection as evidence of compliance with national standards and requirements under federal law.
(3) The Authority may impose a civil penalty not to exceed $1,000 against an organ procurement organization, tissue bank or eye bank doing business in this state for failure to:
(a) Register with the Authority;
(b) Report loss of designation, accreditation or certification within 60 days of the loss; or
(c) Supply the Authority with requested current documentation of designation, certification and inspection.
(d) For the first violation the civil penalty shall be $250;
(e) For the second violation the civil penalty shall be $500;
(f) For the third and any subsequent violations, the civil penalty shall be $1000.
(4) Civil penalties under this section shall be imposed in the manner provided under ORS 183.745.

Stat. Authority: ORS 441.015
Stats. Implemented: ORS 183.745, ORS 441.015, ORS 441.079, ORS 441.082
Hist.: PH 5-2008, f. 3-7-08, cert. ef. 7-1-08

DIVISION 81

NONTRANSPLANT ANATOMICAL RESEARCH RECOVERY ORGANIZATIONS

333-081-0000
Purpose

The purpose of these rules is to establish standards for licensure of Nontransplant Anatomical Research Recovery Organizations.

Stat. Auth.: ORS 438.705-438.720 & 438.994
Stats. Implemented: ORS 438.705-438.720 & 438.994
Hist.: PH 6-2014, f. 1-30-14, cert. ef. 2-1-14

333-081-0005
Definitions

As used in OAR 333-081-0000 through 333-081-0090 the following definitions apply:

(1) "Accrediting body" means an entity that is approved by the Public Health Division and meets the requirements of ORS 438.720(2).

(2) "Anatomical material" has the meaning given that term in ORS 438.705(1).

(3) "Division" means the Public Health Division of the Oregon Health Authority.

(4) "Donor" has the meaning given that term in ORS 97.953.

(5) "Human Remains" has the meaning given that term in ORS 97.010.

(6) "Nontransplant anatomical research recovery organization" or "NARRO" has the meaning given that term in ORS 438.705(3) and is defined as follows:

(a) A NARRO means a person that engages in the recovery or distribution of anatomical material from a donor for research or education purposes other than transplanting the anatomical material or therapy.

(b) A NARRO does not include:

(A) A hospital or other health care facility as those terms are defined in ORS 442.015;

(B) A public corporation as defined in ORS 353.010;

(C) A public or private institution of higher education; or

(D) A clinical laboratory, as defined in ORS 438.010, that is:

(i) Licensed under ORS 438.010 to 438.510; and

(ii) Owned or controlled by, or under common ownership with, a hospital described in paragraph (A) of this subsection.

(7) "Survey" means an inspection of the premises or records of either an applicant for licensure as a NARRO or of a licensed NARRO in order to determine the extent to which that entity is in compliance with ORS 438.710 and 438.715 and these rules.

Stat. Auth.: ORS 438.710 & 438.720
Stats. Implemented: ORS 438.705-438.720 & 438.994
Hist.: PH 6-2014, f. 1-30-14, cert. ef. 2-1-14

333-081-0010
Application for Licensure

(1) Persons meeting the definition of a NARRO as set out in ORS 438.705(3) and OAR 333-081-0005(5) may not act as a NARRO or hold themselves out as a NARRO unless licensed as such by the Division.

(2) An applicant wishing to apply for a license to operate a NARRO shall submit an application on the most current form prescribed by the Division and pay the application fee specified in OAR 333-081-0035.

(3) An applicant that has obtained accreditation from an accrediting body approved by the Division shall provide proof of accreditation to the Division with its license application and shall include:

(a) All of the approved accrediting body survey and inspection reports; and

(b) Written evidence of all corrective actions underway or completed in response to the approved accrediting body recommendations including progress reports.

(4) If any of the information delineated in a NARRO's most recent application changes at a time other than the annual renewal date, it must submit a revised application to the Division within 30 calendar days of the change.

(5) Notwithstanding section (4) of this rule, a NARRO must submit a revised application to the Division 30 calendar days prior to any of the following changes:

(a) Change in ownership or management, acquisition by or of, or merger with another NARRO;

(b) Change in facilities because of expansion, relocation, renovations or structural changes that affect NARRO operations; and

(c) Change in the scope of operations of the NARRO.

(6) In order to allow the Division to determine whether any of the changes reported in accordance with section (4) or (5) of this rule may affect NARRO compliance with NARRO licensing laws and rules, the Division may request NARRO documents, records or other materials for review or it may conduct an on-site inspection.

(7) If a NARRO loses accreditation, it shall immediately notify the Division and surrender its license in accordance with OAR 333-081-0045.

Stat. Auth.: ORS 438.710 & 438.720
Stats. Implemented: ORS 438.705-438.720 & 438.994
Hist.: PH 6-2014, f. 1-30-14, cert. ef. 2-1-14

333-081-0015
Review of License Application

(1) Following receipt of a completed application and the required fee, the Division must conduct a survey in accordance with OAR 333-081-0050 to determine whether the NARRO is in compliance with ORS 438.710 & 438.715 and these rules.

(2) In lieu of conducting a survey, the Division may accept proof of accreditation by an accrediting body approved by the Division.

Stat. Auth.: ORS 438.710 & 438.720
Stats. Implemented: ORS 438.705-438.720 & 438.994
Hist.: PH 6-2014, f. 1-30-14, cert. ef. 2-1-14

333-081-0020
Approval of License Application

(1) The Division must notify an applicant in writing if a license application is approved and must include a copy of the license.

(2) The Division will issue a license only for the premises and person(s) named in the application and it may not be transferred or assigned.

(3) A licensed NARRO must post the license in a conspicuous location where it is viewable by the public.

Stat. Auth.: ORS 438.710 & 438.720
Stats. Implemented: ORS 438.705-438.720 & 438.994
Hist.: PH 6-2014, f. 1-30-14, cert. ef. 2-1-14

333-081-0025
Denial of License Application

If the Division intends to deny a license application, it shall issue a Notice of Proposed Denial of License Application in accordance with ORS 183.411 through 183.470.

Stat. Auth.: ORS 438.710 & 438.720
Stats. Implemented: ORS 438.705-438.720 & 438.994
Hist.: PH 6-2014, f. 1-30-14, cert. ef. 2-1-14

333-081-0030
Expiration and Renewal of License

(1) An initial or renewed license expires two years after the date of issuance or renewal.

(2) If the ownership of a NARRO changes, a new license is required.

(3) If renewal or a new license is sought because of a change of ownership, the licensee shall make application at least 45 days prior to the change of ownership using a form prescribed by the Division.

Stat. Auth.: ORS 438.710 & 438.720
Stats. Implemented: ORS 438.705-438.720 & 438.994
Hist.: PH 6-2014, f. 1-30-14, cert. ef. 2-1-14

333-081-0035
Fees

(1) The fee for an initial or renewed NARRO license is $1,750.

(2) All application fees are non-refundable.

Stat. Auth.: ORS 438.710
Stats. Implemented: ORS 438.710
Hist.: PH 6-2014, f. 1-30-14, cert. ef. 2-1-14

333-081-0040
Denial, Suspension or Revocation of License

(1) A license for a NARRO may be denied, suspended or revoked by the Division if a licensed NARRO has failed to comply with Oregon Laws 2013, chapter 356, sections 2 and 3, OAR 333-081-0080 or for violations of laws, regulations or administrative rules that governs how it obtains, processes and distributes donor material.

(2) If the Division intends to suspend or revoke a NARRO license, it shall do so in accordance with ORS 183.411 through 183.470.

Stat. Auth.: ORS 438.710 & 438.720
Stats. Implemented: ORS 438.705-438.720 & 438.994
Hist.: PH 6-2014, f. 1-30-14, cert. ef. 2-1-14

333-081-0045
Return of License

Each license certificate in the licensee's possession shall be returned to the Division immediately upon the suspension or revocation of the license, failure to renew the license by the date of expiration, loss of accreditation or if operation is discontinued by the voluntary action of the licensee.

Stat. Auth.: ORS 438.705-438.720 & 438.994
Stats. Implemented: ORS 438.705-438.720 & 438.994
Hist.: PH 6-2014, f. 1-30-14, cert. ef. 2-1-14

333-081-0050
Surveys

(1) The Division must, in addition to any investigations conducted pursuant to OAR 333-081-0065, conduct at least one survey of each NARRO prior to licensure and once every two years thereafter as a requirement of licensing and at such other times as the Division deems necessary.

(2) In lieu of an on-site inspection required by section (1) of this rule, the Division may accept proof of accreditation by an accrediting body approved by the Division if the NARRO:

(a) Gives the Division sufficient advance notice to allow the Division to participate in any exit interviews conducted by the accrediting body; and

(b) Provides the Division with copies of all documentation concerning the accreditation that it requests.

(3) A NARRO must permit Division staff access to its premises during a survey.

(4) A survey may include, but is not limited to:

(a) Interviews of NARRO management and staff;

(b) On-site observations of the NARRO premises, staff performance and activities; and

(c) Review of documents, records and other materials required to be kept by OAR 333-081-0070.

(5) A NARRO shall make all requested documents and records available to the surveyor for review and copying.

(6) Following a survey, Division staff may conduct an exit conference with a NARRO agency owner, administrator, or designee. During an exit conference, Division staff must:

(a) Inform the NARRO owner, administrator or designee of the preliminary findings of the inspection; and

(b) Give the owner, administrator or designee a reasonable opportunity to submit additional facts or other information to the surveyor in response to those findings.

(7) Following a survey, Division staff must prepare and provide the NARRO owner or administrator specific and timely written notice of the findings.

(8) If no deficiencies are found during a survey, the Division must issue written findings to the NARRO owner or administrator indicating that fact.

(9) Upon conclusion of a survey the Division must, upon request, publicly release the written documents described in sections (7) and (8) of this rule in accordance with the Oregon Public Records Act.

(10) If deficiencies are found, the Division must take informal or formal enforcement action in accordance with OAR 333-081-0085 and 333-081-0090.

Stat. Auth.: ORS 438.710 & 438.720
Stats. Implemented: ORS 438.705-438.720 & 438.994
Hist.: PH 6-2014, f. 1-30-14, cert. ef. 2-1-14

333-081-0055
Approval of Accrediting Bodies

(1) If the Division finds that an accrediting body has the necessary qualifications to certify that state licensing standards have been met, the Division will accept accreditation from the accrediting body in accordance with the requirements of OAR 333-081-0050(2).

(2) In order to allow the Division to make the finding set forth in section (1) of this rule, the accrediting body must request approval in writing using the most recent approval form provided by the Division and shall provide, at a minimum:

(a) Documentation of program policies and procedures that show that its accreditation process at least meets the requirements set out in Oregon Laws 2013, chapter 356, section 4(2) and these rules;

(b) Documentation evidencing that the accrediting body has the resources and expertise to successfully carry out the accreditation process; and

(c) An attestation that it, or any of its owners or employees, does not have a direct or indirect financial interest in any of the NARROs that it seeks to accredit.

Stat. Auth.: ORS 438.720
Stats. Implemented: ORS 438.720
Hist.: PH 6-2014, f. 1-30-14, cert. ef. 2-1-14

333-081-0060
Complaints

(1) Any person may make a complaint to the Division regarding an allegation as to violations of Oregon Laws 2013, chapter 356, sections 2 and 3 or these rules.

(2) Upon conclusion of an investigation, the Division shall, upon request, publicly release a report of its findings in accordance with the Oregon Public Records Act. The Division may use any information obtained during an investigation in an administrative or judicial proceeding concerning the licensing of a NARRO.

(3) If a complaint involves an allegation of criminal conduct or an allegation that is within the jurisdiction of another local, state, or federal agency, the Division shall refer the matter to that agency.

Stat. Auth.: ORS 438.710 & 438.720
Stats. Implemented: ORS 438.705-438.720 & 438.994
Hist.: PH 6-2014, f. 1-30-14, cert. ef. 2-1-14

333-081-0065
Investigations

(1) As soon as practicable after receiving a complaint, taking into consideration the nature of the complaint, Division staff must begin an investigation.

(2) An investigation may include but is not limited to:

(a) Interviews of the complainant, persons identified by the complainant as having knowledge of the facts alleged in the complaint, NARRO management and staff, and other persons having knowledge of the practices of the NARRO; and

(b) On-site observations of staff performance and of the physical environment of the NARRO facility; and

(c) Review of documents, records and other materials.

(3) A NARRO must permit Division staff access to its premises during an investigation.

Stat. Auth.: ORS 438.710 & 438.720
Stats. Implemented: ORS 438.705-438.720 & 438.994
Hist.: PH 6-2014, f. 1-30-14, cert. ef. 2-1-14

333-081-0070
Records

(1) A NARRO must keep and maintain a legible, reproducible record of each donor from whom it obtains anatomical material. This record must include at least the following:

(a) Documentation showing that the donor donated the anatomical material for the purpose of research or education. However, if the decision to donate is made after the donor's death, documentation that the donation was made by a person authorized to make an anatomical gift under the process set out in ORS 97.965 and that this person donated the anatomical material for the purpose of research or education is required;

(b) The name, address and phone number of each person that had possession of the donor's anatomical material before the organization took possession of the anatomical material;

(c) Documentation of the disposition of the donor's anatomical material by the NARRO, including the name, address and phone

number of each person to whom it provides anatomical material from the donor; and

(d) A copy of the disclosure given to a relative or personal representative of the donor if any anatomical material is returned to them as required by OAR 333-081-0075(2).

(2) The NARRO must keep and maintain a legible, reproducible record of the notice required by ORS 438.715(4) and OAR 333-081-0075 and provided to each individual from whom the NARRO agrees to accept an offer of the donation of anatomical material. If an offer of anatomical material is not subsequently rescinded or rejected, this record must be included in the donor record for each individual.

(3) The records required by sections (1) and (2) of this rule must be kept and maintained by the NARRO for a minimum of 10 years from the date that the NARRO takes possession of the donor's anatomical material and shall be kept and maintained in the following manner:

(a) It must be kept in a manner that renders it easily and completely retrievable;

(b) Reasonable precautions must be taken to protect the record from unauthorized access and from destruction including, but not limited to, fire, water, and theft;

(c) Authorized employees of the Division must be permitted to review the records upon request;

(d) If a NARRO changes ownership, all records must remain with the successor NARRO and it shall be the responsibility of the new owner to protect and maintain these records; and

(e) Before a NARRO terminates its business, it must notify the Division where the records will be stored and, if the location changes, those responsible must notify the Division of each successive location.

Stat. Auth.: ORS 438.710 & 438.720
Stats. Implemented: ORS 438.705-438.720 & 438.994
Hist.: PH 6-2014, f. 1-30-14, cert. ef. 2-1-14

333-081-0075
Notice

(1) As required by ORS 438.715(4), when a NARRO accepts an offer from an individual to donate anatomical material it must provide that individual notice that clearly explains:

(a) How the NARRO intends to dispose of the anatomical material if donated, and whether and how any anatomical material may be returned;

(b) Whether or not the NARRO guarantees the coverage of costs related to transporting and disposing of the anatomical material and, if all costs will not be covered, what costs will be the responsibility of the individual making the donation; and

(c) What costs will be covered by the NARRO and what costs will be the responsibility of the individual making the donation if the individual or relative or personal representative subsequently rescinds, or the NARRO later rejects, the offer of anatomical material.

(2) If a NARRO returns any anatomical material to a relative or personal representative of a donor, the NARRO must provide that person with a notice that discloses whether all or part of the donor's body is being returned.

(3) The notice required by sections (1) and (2) of this rule must be in writing and be printed in at least 14-point type.

Stat. Auth.: ORS 438.710 & 438.720
Stats. Implemented: ORS 438.705-438.720 & 438.994
Hist.: PH 6-2014, f. 1-30-14, cert. ef. 2-1-14

333-081-0080
NARRO Duties

In addition to the requirements set out in these rules, a NARRO shall dispose of any anatomical material not returned to a relative or personal representative of the donor in accordance with all laws pertaining to the disposition of human remains. This requirement does not apply to anatomical material that the NARRO has recovered or distributed for research or educational purposes.

Stat. Auth.: ORS 438.710 & 438.720
Stats. Implemented: ORS 438.705-438.720 & 438.994
Hist.: PH 6-2014, f. 1-30-14, cert. ef. 2-1-14

333-081-0085
Informal Enforcement

(1) If during an investigation or survey Division staff document violations of NARRO licensing rules or laws, the Division may issue a statement of deficiencies that cites the law or rule alleged to have been violated and the facts supporting the allegation.

(2) Upon receipt of a statement of deficiencies, a NARRO shall be provided an opportunity to dispute the Division's survey findings but must still comply with sections (3) and (4) of this rule. The following conditions apply:

(a) If a NARRO desires an informal conference to dispute the Division's survey findings, the NARRO must submit a request in writing to the Division within 10 business days after receipt of the statement of deficiencies. The written request must include a detailed explanation of why the NARRO believes the statement of deficiencies is incorrect;

(b) A NARRO may not seek a delay of any enforcement action against it on the grounds the informal dispute resolution has not been completed; and

(c) If a NARRO is successful in demonstrating some or all of the deficiencies should not have been cited, the Division must withdraw or reissue the statement of deficiencies, removing such deficiencies and rescinding or modifying any remedies issued for such deficiencies. A reissued statement of deficiencies must include a statement that it supersedes the previous statement of deficiencies and shall clearly identify the date of the superseded statement of deficiencies.

(3) A signed plan of correction from a NARRO must be mailed to the Division within 10 business days from the date the statement of deficiencies was received by the NARRO. A signed plan of correction will not be used by the Division as an admission of the violations alleged in the statement of deficiencies.

(4) A NARRO must correct all deficiencies within 60 days from the date of the receipt of the statement of deficiencies, unless an extension of time is granted by the Division. A request for such an extension must be submitted in writing and must accompany the plan of correction.

(5) The Division must determine if a written plan of correction is acceptable. If the plan of correction is not acceptable to the Division, the Division must notify the NARRO owner or administrator in writing:

(a) Identifying which provisions in the plan the Division finds unacceptable;

(b) Citing the reasons the Division finds the provisions unacceptable; and

(c) Requesting that the plan of correction be modified, resubmitted and received by the Division no later than 10 business days from the date notification of non-compliance was received by the NARRO owner or administrator.

(6) If the NARRO does not come into compliance by either the date of correction reflected in the plan of correction or a Division approved extension as provided for in section (4) of this rule, or 60 days from the date of receipt of the statement of deficiencies, whichever is sooner, the Division may propose to deny, suspend or revoke the agency license or impose civil penalties.

Stat. Auth.: ORS 438.710 & 438.720
Stats. Implemented: ORS 438.705-438.720 & 438.994
Hist.: PH 6-2014, f. 1-30-14, cert. ef. 2-1-14

333-081-0090
Formal Enforcement

(1) If during an investigation or survey Division staff document ongoing or substantial failure to comply with NARRO laws or rules, or if a NARRO fails to pay a civil penalty imposed under ORS 438.994(1) and these rules, the Division may issue a Notice of Proposed Suspension or Notice of Proposed Revocation in accordance with ORS 183.411 through 183.470.

(2) The Division may impose civil penalties for violations of ORS 438.710 or 438.715 or these rules, in accordance with ORS 183.745. Civil penalties imposed under this rule shall not exceed $1000 per violation.

(3) At any time the Division may issue a Notice of Emergency License Suspension under ORS 183.430.

(4) If the Division revokes a NARRO license, the order shall specify when, if ever, the NARRO may reapply for a license.

Stat. Auth.: ORS 438.710 & 438.720
Stats. Implemented: ORS 438.705-438.720 & 438.994
Hist.: PH 6-2014, f. 1-30-14, cert. ef. 2-1-14

DIVISION 95

LEAD HAZARDS

Environmental Inspection, Testing and Assessment in Private Residential Buildings

333-095-0000
Definitions

As used in OAR 333-095-0000 through 333-095-0030, unless the context requires otherwise:

(1) "Administrator" means the Administrator of the Oregon Public Health Division or any authorized representative. Authorized representatives include employees of the Public Health Division and employees of the affected county health agency having jurisdiction.

(2) "Division" means the Public Health Division of the Oregon Health Authority.

(3) "Dwelling" means any enclosed space that is wholly or partially used or intended to be used for living, sleeping, cooking, or eating purposes by humans, and includes all grounds and other buildings on the affected property.

(4) "Imminent Hazard" means a condition or combination of conditions such that a person or persons are potentially exposed to lead containing materials that are likely to cause acute illness or serious impairment.

(5) "Inspection" means an on-site investigation that may include visual observations, interviews with persons, technical tests and measurements, documentation of conditions, taking of photographs, and collection of samples for testing elsewhere.

(6) "Lead Hazard" means any condition or combination of conditions in which metallic lead, combined lead or ionic lead is present in or around a dwelling and could potentially be inhaled or ingested by persons.

(7) "Owner" and "Operator" mean any person or persons who jointly or severally hold legal title to or are purchasing any dwelling or premise on contract; or who are responsible for the care or control of any dwelling or premise as owner, agent of the owner, executor, administrator, trustee, or guardian. For purposes of public ownership, "owner" is defined as the chief executive officer of the government entity which owns, leases or otherwise controls the property.

(8) "Person" means any individual, partnership, association, firm, corporation, or joint venture; and includes agencies of municipal, county, state and federal government.

(9) "Premise" or "Premises" means any dwelling or other place of habitation; school; care facility; public or governmental institution; or place of volunteer employment. Premises include the grounds and any other buildings associated with and used by the occupants. These rules do not include employee exposures or workplace conditions that effect only employees who are subject to Federal OSHA or Oregon OSHA jurisdiction.

(10) "Screening" means medical and administrative procedures by which the concentration of lead in the blood of persons is measured.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 431.110 - 431.180
Hist.: HD 1-1993, f. & cert. ef. 2-12-93

333-095-0010
Purpose

It is the purpose of these rules to:

(1) Ensure that inspection of dwellings and other nonoccupational premises thought to pose elevated risk of lead exposure to occupants can be performed;

(2) Ensure that investigations and assessments can be done thoroughly and promptly when screening or other evidence indicates a need for such inspections; and

(3) Ensure that persons who are likely to be exposed to hazardous levels of environmental lead are advised of the hazard.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 431.110 - 431.180
Hist.: HD 1-1993, f. & cert. ef. 2-12-93

333-095-0020
Investigations

When results from screening tests, or other medical or diagnostic evidence, or environmental evidence indicates that occupants of any dwelling or other premises are or may be suffering from elevated lead levels, the Division may inspect the dwelling or premises to identify sources of lead exposure. Inspections may also be initiated to follow-up on any other evidence that any dwelling or premise presents a serious risk of lead exposure to any occupant. The owner(s) and occupant(s) of any such dwelling or premise shall allow access to authorized lead investigators of the Division or of the local health department having jurisdiction, so long as the access is requested during regular working hours and appropriate identification and credentials are shown by the inspector(s). Access shall be allowed to all parts of the dwelling and premises. Inspectors may test or collect samples for testing any part of the dwelling or premises and may photograph or otherwise document the conditions found.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 431.110 - 431.180
Hist.: HD 1-1993, f. & cert. ef. 2-12-93

333-095-0030
Notification of Occupants

If investigation and testing of any premise reveals the presence of hazardous levels of lead in forms that present exposure hazards to occupants, the Administrator may notify such occupants of the hazards.

Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 431.110 - 431.180
Hist.: HD 1-1993, f. & cert. ef. 2-12-93

DIVISION 100

CONTROL OF RADIATION IN OREGON

General Requirements

333-100-0001
Scope

Except as otherwise specifically provided, these rules apply to all persons who acquire receive, possess, use, transfer, own, or dispose of any source of radiation; provided, however, that nothing in these rules shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission.

NOTE: Attention is directed to the fact that state regulation of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the state and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 of the Commission's regulations.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

333-100-0005
Definitions

The following definitions apply to OAR chapter 333 divisions 100, 102, 103, 106, 111, 116, 118, 119, 120, 121, 122, 123, and 124. Additional definitions used only in a certain division can be found in that division.

(1) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

(2) "Accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV. For purposes of this definition, "particle accelerator" is an equivalent term.

(3) "Accelerator-produced material" means any material made radioactive by a particle accelerator.

(4) "Act" means Oregon Revised Statutes 453.605 through 453.807.

(5) "Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq), defined as one disintegration per second, and the curie (Ci), defined as 3.7 x 1010 disintegrations per second.

(6) "Adult" means an individual 18 or more years of age.

(7) "Agreement State" means any state with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689). States not entering an agreement under the Act are considered a non-agreement state.

(8) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

(9) "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive material, composed wholly or partly of licensed material, exist in concentrations:

(a) In excess of the derived air concentrations (DACs) specified in Appendix B, Table I, column 3, to 10 CFR Part 20.1001 to 20.2401; or

(b) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

(10) "ALARA" (acronym for "As Low As Reasonably Achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.

(11) "Alert" means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.

(12) "Annual" means occurring every year or within a consecutive twelve month cycle.

(13) "Annual Limit on Intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the Reference Man that could result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Appendix B, Table I, Columns 1 and 2, to 10 CFR Part 20.1001 to 20.2401.

(14) "As Low As Reasonably Achievable" see "ALARA."

(15) "Authority" means the Oregon Health Authority.

(16) "Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include sources of radiation from radioactive or special nuclear materials regulated by the Authority.

(17) "Becquerel" (Bq) means one disintegration per second.

(18) "Bioassay" means the determination of kinds, quantities or concentrations, and, in some cases, the locations, of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these rules, "radiobioassay" is an equivalent term.

(19) "Brachytherapy" means a method of radiation therapy in which sealed sources are utilized to deliver dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

(20) "Byproduct material" means:

(a) Any radioactive material, except special nuclear material, yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or utilizing special nuclear material;

(b) The tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction process. Underground ore bodies depleted by such solution extraction operations do not constitute "byproduct material" within this definition;

(c) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(d) Any material that:

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(C) Any discrete source of naturally occurring radioactive material, other than source material, that:

(i) The Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate state and federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

(21) "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year must begin in January and subsequent calendar quarters must be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant may change the method observed for determining calendar quarters except at the beginning of a calendar year.

(22) "Calibration" means the determination of:

(a) The response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or

(b) The strength of a source of radiation relative to a standard.

(23) "CFR" means Code of Federal Regulations.

(24) "Chelating agent" means amine polycarboxylic acids, hydroxy-carboxylic acids, gluconic acid, and polycarboxylic acids.

(25) "Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. For purposes of these rules, "lung class" or "inhalation class" are equivalent terms. Materials are classified as D, W, or Y, which applies to a range of clearance half-times:

(a) For Class D, Days, of less than 10 days;

(b) For Class W, Weeks, from 10 to 100 days; and

(c) For Class Y, Years, of greater than 100 days.

(26) "Clinical laboratory" means a laboratory licensed pursuant to ORS 438.110 through 438.140.

(27) "Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

(28) "Committed dose equivalent" (HT, 50) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

(29) "Committed effective dose equivalent" (HE, 50) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues (HE, 50 = ∑WT,HT,50).

(30) "Contamination" (Radioactive) means deposition or presence of radioactive material in any place where it is not desired, and particularly in any place where its presence can be harmful. The harm may be in compromising the validity of an experiment or a procedure, or in being a source of danger to persons. Contamination may be divided into two types: Fixed and removable. Removable contamination may be transferred easily from one object to another by light rubbing or by the use of weak solvents such as water or alcohol. Removable contamination is evaluated and recorded in units of microcuries or dpm. Fixed contamination is not easily transferred from one object to another and requires mechanical or strong chemicals to remove it from its current location. Fixed contamination is evaluated and recorded in units of mR/hr.

(31) "Curie" means that amount of radioactive materials which disintegrates at the rate of 37 billion atoms per second.

(32) "Declared pregnant woman" means a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

(33) "Decommission" means to remove (as a facility) safely from service and reduce residual radioactivity to a level that permits:

(a) Release of the property for unrestricted use and termination of license; or

(b) Release of the property under restricted conditions and termination of the license.

(34) "Deep dose equivalent" (Hd) which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm2).

(35) "Depleted uranium" means source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

(36) "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by Reference Man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these rules, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of Appendix B to 10 CFR Part 20.1001 to 20.2401.

(37) "Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

(38) "Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of these rules, "radiation dose" is an equivalent term.

(39) "Dose equivalent" (HT) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem (see "Rem"). (See OAR 333-100-0070(2) for SI equivalent sievert.)

(40) "Dose limits" means the permissible upper bounds of radiation doses established in accordance with these rules. For purposes of these rules, "limits" is an equivalent term.

(41) "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring equipment in order to determine the radiation dose delivered to the equipment.

(42) "Effective dose equivalent" (HE) means the sum of the products of the dose equivalent to the organ or tissue (HT) and the weighting factor (WT) applicable to each of the body organs or tissues that are irradiated (HE = WT HT).

(43) "Electronic product" means any manufactured product or device or component part of such a product or device that is capable of generating or emitting electromagnetic or sonic radiation such as, but not limited to, X-rays, ultrasonic waves, microwaves, laser light or ultraviolet light.

(44) "Embryo/fetus" means the developing human organism from conception until the time of birth.

(45) "Entrance or access point" means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

(46) "Exclusive use" (also referred to in other regulations as "sole use" or "full load") means the sole use of a conveyance by a single consignor and for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee.

(47) "Explosive material" means any chemical compound, mixture, or device that produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

(48) "Exposure" means:

(a) The quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The SI unit of exposure is the coulomb per kilogram.

(b) Being exposed to ionizing radiation or to radioactive material.

(49) "Exposure rate" means the exposure per unit of time, such as roentgen per minute (R/min) and milliroentgen per hour (mR/hr).

(50) "External dose" means that portion of the dose equivalent received from any source of radiation outside the body.

(51) "Extremity" means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

(52) "Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (300 mg/cm2).

(53) "Fixed gauge" means a measuring or controlling device that is intended to be mounted at a specific location, stationary, not to be moved, and is not portable.

(54) "Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

(55) "General license" means a license granted by rule, in contrast to an issued license, to acquire, own, possess, use, or transfer radioactive material or a device that contains radioactive material.

(56) "Generally applicable environmental radiation standards" means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

(57) "Gray" (Gy) means the International System of Units (SI), unit of absorbed dose. One gray is equal to an absorbed dose of one joule per kilogram (100 rad). (See OAR 333-100-0070(2))

(58) "Hazardous waste" means those wastes designated as hazardous by U.S. Environmental Protection Agency regulations in 40 CFR Part 261.

(59) "Healing arts" means:

(a) The professional disciplines authorized by the laws of this state to use X-rays or radioactive material in the diagnosis or treatment of human or animal disease. For the purposes of this division they are Medical Doctors, Osteopaths, Dentists, Veterinarians, Chiropractors, and Podiatrists; or

(b) Any system, treatment, operation, diagnosis, prescription, or practice for the ascertainment, cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, injury or unhealthy or abnormal physical or mental condition.

(60) "Human use" means the internal or external administration of radiation or radioactive material to human beings.

(61) "Individual" means any human being.

(62) "Individual monitoring" means:

(a) The assessment of dose equivalent by the use of devices designed to be worn by an individual;

(b) The assessment of committed effective dose equivalent by bioassay (see Bioassay) or by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours; or

(c) The assessment of dose equivalent by the use of survey data.

(63) "Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.

(64) "Inhalation class" (see "Class").

(65) "Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the Authority.

(66) "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

(67) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

(68) "Ionizing radiation" means any electromagnetic or particulate radiation capable of producing ions, directly or indirectly, in its passage through matter. It includes any or all of the following: Alpha particles, beta particles, electrons, positrons, gamma rays, X-rays, neutrons, high-speed electrons, high-speed protons, fission fragments and other atomic and subatomic particles; but not sound or radio waves, or visible, infrared, or ultraviolet light.

(69) "Laser" means any device which, when coupled with an appropriate laser energy source, can produce or amplify electromagnetic radiation by the process of controlled stimulated emission.

(70) "License" means a license issued by the Authority in accordance with rules adopted by the Authority.

(71) "Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license granted or issued by the Authority. For the purpose of meeting the definition of a Licensing State by the Conference of Radiation Control Program Directors, Inc. (CRCPD), Naturally Occurring and Accelerator Produced Radioactive Material (NARM) refers only to discrete sources of NARM. Diffuse sources of NARM are excluded from consideration by the CRCPD for Licensing State designation purposes.

(72) "Licensee" means any person who is licensed by the Authority in accordance with these rules and the Act.

(73) "Licensing state" means any state with rules or regulations equivalent to the Suggested State Regulations for Control of Radiation relating to, and having an effective program for, the regulatory control of NARM.

(74) "Limits" (dose limits) means the permissible upper bounds of radiation doses.

(75) "Lost or missing licensed or registered source of radiation" means licensed or registered source(s) of radiation whose location is unknown. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

(76) "Lung class" (see "Class").

(77) "Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in division 118 of this chapter.

(78) "Member of the public" means an individual, except when that individual is receiving an occupational dose.

(79) "Minor" means an individual less than 18 years of age.

(80) "Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these rules, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

(81) "NARM" means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.

(82) "Natural radioactivity" means radioactivity of naturally occurring nuclides.

(83) "Naturally-occurring radioactive material" (NORM) means any nuclide that is found in nature as a radioactive material (and not technologically produced).

(84) "Natural thorium" means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

(85) "Natural uranium" means a mixture of the uranium isotopes 234, 235 and 238 (approximately 0.7 weight percent uranium- 235 and the remainder by weight essentially uranium-238), found in nature, that is neither enriched nor depleted in the isotope uranium 235.

(86) "Nonstochastic effect" means a health effect that varies with the dose and a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these rules, "deterministic effect" is an equivalent term.

(87) "Normal form radioactive material" means radioactive material that has not been demonstrated to qualify as "special form radioactive material". See "Special form."

(88) "NRC" is the acronym for Nuclear Regulatory Commission.

(89) "Nuclear Regulatory Commission" ("NRC" or "Commission") means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

(90) "Package" means the packaging together with its radioactive contents as presented for transport.

(91) "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one MeV.

(92) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing.

(93) "Personnel monitoring equipment" means devices such as film badges, pocket dosimeters, and thermoluminescent dosimeters designed to be worn or carried by an individual for the purpose of estimating the dose received by the individual. See "Individual monitoring devices."

(94) "Pharmacist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

(95) "Physician" means an individual licensed by the Oregon Medical Board to dispense drugs in the practice of medicine.

(96) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

(97) "Portable gauge" means a measuring or controlling device that is intended to be portable and is not fixed to a specific location. All portable gauges require a specific license (there is no general license granted for portable generally licensed devices in the State of Oregon).

(98) "Program" means the Radiation Protection Services section of the Public Health Division of the Oregon Health Authority.

(99) "Pyrophoric liquid" means any liquid that ignites spontaneously in dry or moist air at or below 130OF (54.4OC).

(100) "Pyrophoric solid" means any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

(101) "Qualified expert" means an individual, approved by the Authority, who has demonstrated, pursuant to these rules, that he/she possesses the knowledge, skills, and training to measure ionizing radiation, to evaluate radiation parameters, to evaluate safety techniques, and to advise regarding radiation protection needs. The individual must:

(a) Be certified in the appropriate field by the American Board of Radiology, the American Board of Health Physics, the American Board of Medical Physics or the American Board of Nuclear Medicine Science; or

(b) Hold a master's or doctor's degree in physics, biophysics, radiological physics, health physics, or medical physics and have completed one year of documented, full time training in the appropriate field and also one year of documented, full time work experience under the supervision of a qualified expert in the appropriate field. To meet this requirement, the individual must have performed the tasks required of a qualified expert during the year of work experience; or

(c) Receive approval from the Authority for specific activities.

(102) "Quality factor" (Q) means the modifying factor (listed in Tables 1004(b).1 and 1004(b).2 of 10 CFR Part 20.1004 provided at the end of this division) that is used to derive dose equivalent from absorbed dose.

(103) "Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

(104) "Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray). See OAR 333-100-0070(2) for SI equivalent gray.

(105) "Radiation" means:

(a) Ionizing radiation including gamma rays, X-rays, alpha and beta particles, protons, neutrons, and other atomic or nuclear particles or rays;

(b) Any electromagnetic radiation which can be generated during the operations of electronic products and which the Authority has determined to present a biological hazard to the occupational or public health and safety but does not include electromagnetic radiation which can be generated during the operation of an electronic product licensed by the Federal Communications Commission;

(c) Any sonic, ultrasonic or infrasonic waves which are emitted from an electronic product as a result of the operation of an electronic circuit in such product and which the Authority has determined to present a biological hazard to the occupational or public health and safety.

(106) "Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

(107) "Radiation machine" means any device capable of producing radiation except those which produce radiation only from radioactive material.

(108) "Radiation safety officer" means:

(a) An individual who has the knowledge, responsibility, and authority to apply appropriate radiation protection rules; or

(b) The representative of licensee management, authorized by the Authority, and listed on the specific license as the radiation safety officer, who is responsible for the licensee's radiation safety program.

(109) "Radioactive material" means any solid, liquid, or gas that emits radiation spontaneously.

(a) Radioactive material, as used in these rules, includes: byproduct material, naturally occurring radioactive material, accelerator produced material, and source material, as defined in this rule.

(b) Radioactive material, as used in these rules, does not include special nuclear material.

(110) "Radioactive waste" means radioactive material that is unwanted or is unusable, as defined in division 50 of chapter 345. No radioactive material may be disposed of in Oregon except as provided in division 50 of chapter 345.

(111) "Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

(112) "Reference Man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of the Reference Man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."

(113) "Registrant" means any person who is registered with the Authority and is legally obligated to register with the Authority pursuant to these rules and the Act.

(114) "Registration" means the identification of any material or device emitting radiation, and the owner of such material or device must furnish information to the Authority in accordance with the rules adopted by the Authority.

(115) "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189 and Parts 390-397.

(116) "Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).

(117) "Research and development" means:

(a) Theoretical analysis, exploration, or experimentation; or

(b) The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

(118) "Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

(119) "Restricted area" means an area to which access is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. A restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

(120) "Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58 x 10-4 Coulombs/kilogram of air (see "Exposure" and division 120).

(121) "Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.

(122) "Screening" means the use of a systematic approach to obtain cursory examinations of a person or group of persons without regard to specific clinical indications.

(123) "Sealed source" means radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

(124) "Sealed Source and Device Registry" means the national registry that contains all the registration certificates, generated by both the U.S. Nuclear Regulatory Commission and Agreement States, that summarize the radiation safety information for sealed sources and devices and describe the licensing and use conditions approved for the product.

(125) "Shallow dose equivalent" (Hs), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm2) averaged over an area of one square centimeter.

(126) "SI" means the abbreviation for the International System of Units.

(127) "Sievert" means the International System of Units (SI), unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem). (See OAR 333-100-0070(2)).

(128) "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

(129) "Source material" means:

(a) Uranium or thorium or any combination of uranium and thorium in any physical or chemical form; or

(b) Ores that contain by weight one-twentieth of one percent (0.05 percent) or more of uranium, thorium, or any combination thereof. Source material does not include special nuclear material.

(130) "Source material milling" means any activity that result in the production of byproduct material, as defined by this rule.

(131) "Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation. Source of radiation, pursuant to this rule, includes, but is not limited to, radiation facilities, radiation producing machines, radiation producing devices, radioactive material sealed and unsealed form (normal form and special form), and radioactive material uses.

(132) "Special form radioactive material" means radioactive material that satisfies the following conditions:

(a) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(b) The piece or capsule has at least one dimension not less than five millimeters (0.2 inch); and

(c) It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, and a special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in effect on March 31. 1996, and constructed prior to April 1, 1998, may continue to be used. Any other special form encapsulation either designed or constructed after April 1, 1998, must meet requirements of this definition applicable at the time of its design or construction.

(133) "Special nuclear material" means:

(a) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the U.S. Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

(b) Any material artificially enriched by any of the foregoing but does not include source material.

(134) "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination must not exceed one.

For example, the following quantities in combination does not exceed the limitation and are within the formula: * * 175 (grams U-235)/350 + 50 (grams U-233)/200 + 50 (grams Pu)/200 = 1.

(135) "Specific activity of a radionuclide" means the radioactivity of the radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

(136) "Stochastic effect" means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

(137) "Supervision" as used in these rules, means the responsibility for, and control of, the application, quality, radiation safety and technical aspects of all sources of radiation possessed, used and stored through authorization granted by the Authority.

(138) "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

(139) "Termination" means:

(a) The end of employment with the licensee or registrant or, in the case of individuals not employed by the licensee or registrant, the end of work assignment in the licensee's or registrant's restricted area in a given calendar quarter, without expectation or specific scheduling of re-entry into the licensee's or registrant's restricted area during the remainder of that calendar quarter; or

(b) The closure of a registered or licensed facility and conclusion of licensed or registered activities, pursuant to a registration or specific license.

(140) "Test" means the process of verifying compliance with an applicable rule.

(141) "These rules," mean all parts of the Oregon Administrative Rules promulgated under ORS 453.605 through 453.807.

(142) "Total effective dose equivalent" (TEDE) means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

(143) "Total organ dose equivalent" (TODE) means the sum of the deep dose equivalent (DDE) and the committed dose equivalent (CDE) to the organ receiving the highest dose as described in OAR 333-120-0650(1)(d).

(144) "Transport index" means the dimensionless number (rounded up to the first decimal place) placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number expressing the maximum radiation level in millirem per hour at one meter from the external surface of the package.

(145) "U.S. Department of Energy" means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Admin-

istration and to the Administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237 42 U.S.C. 5814, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977).

(146) "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

NOTE: "Ore" refers to fuel cycle materials pursuant to 10 CFR Part 150.

(147) "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant. For purposes of these rules, "uncontrolled area" is an equivalent term.

(148) "Uranium — depleted, enriched" means:

(a) "Depleted uranium" means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

(b) "Enriched uranium" means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

(149) "Validation certificate" means the official document issued upon payment to the Authority of the appropriate fee listed in division 103 of this chapter. The license or registration is subject and void without the annual validation certificate.

(150) "Waste" means radioactive waste.

(151) "Week" means seven consecutive days starting on Sunday.

(152) "Weighting factor" (WT) for an organ or tissue (T) means:

(a) The proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of WT are:

(A) Gonads 0.25;

(B) Breast 0.15;

(C) Red Bone Marrow 0.12;

(D) Lung 0.12;

(E) Thyroid 0.03;

(F) Bone Surfaces 0.03;

(G) Remainder 0.30 (see note below);

(H) Whole Body 1.00.

NOTE: Assignment of 0.30 for the remaining organs results from a weighting factor of 0.06 for each of five "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

(b) For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, WT = 1.0, has been specified. The use of other weighting factors for external exposure may be approved on a case-by-case basis until such time as specific guidance is issued.

(153) "Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

(154) "Worker" means an individual engaged in work under a license or registration issued by the Authority and controlled by a licensee or registrant, but does not include the licensee or registrant.

(155) "Working level" (WL) means any combination of short-lived radon progeny in one liter of air that will result in the ultimate emission of 1.3 x 105 MeV of potential alpha particle energy. The short-lived radon-222 progeny are: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220 the progeny are: polonium-216, lead-212, bismuth-212, and polonium-212.

(156) "Working level month" (WLM) means an exposure to one working level for 170 hours (2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.)

(157) "Year" means the period of time beginning in January used to determine compliance with the provisions of these rules. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

[ED. NOTE: Tables and Appendices referenced are available from the agency.]

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 10-1987, f. & ef. 7-28-87; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; Administrative Reformatting 12-8-97; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 4-2013, f. & cert. ef. 1-29-13; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-100-0010
Additional Definitions

Other definitions used only in a certain division of these rules will be found in that division.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; PH 4-2007, f. & cert. ef. 3-1-07

333-100-0015
Interpretations

Except as specifically authorized by the Agency in writing, no interpretation of the meaning of these rules by any officer or employee of the Agency, other than a written interpretation, will be recognized to be binding upon the Agency.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 4-2007, f. & cert. ef. 3-1-07

333-100-0020
Prohibited Uses

(1) Hand-held fluoroscopic screens shall not be used unless they have been listed in the Registry of Sealed Source and Devices or accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health.

(2) Shoe-fitting fluoroscopic devices shall not be used.

(3) Sources of radiation shall not be used to expose any individual solely for training or demonstration purposes.

(4) Sources of radiation shall not be used for the purpose of screening or inspecting individuals for concealed weapons, hazardous materials, stolen property, illegal goods or contraband.

(5) No person shall intentionally apply or allow to be applied, either directly or indirectly, ionizing radiation to human beings except by, or under the supervision of, persons licensed by the State of Oregon to practice the healing arts and who are authorized to use radiation on humans. Notwithstanding this restriction, the Authority recognizes practitioners of the healing arts to be as outlined in ORS 676.110, that is:

(a) Podiatrists, Chiropractors, Dentists, Naturopath, Osteopaths, Medical Doctors, and Veterinarians;

(b) Nurse Practitioners and Physician Assistants may prescribe X-ray when doing so within the bounds of their independent rules;

(c) Dental Professionals are permitted to prescribe and review intraoral radiographs, in accordance with the Oregon Board of Dentistry administrative rules, chapter 818.

(d) No person shall be allowed to use X-ray producing equipment without first meeting the requirements of OAR 333-106-0045(16) or 333-106-0055.

(6) No person shall intentionally or unintentionally expose another individual to radiation other than ionizing radiation in such a way as to adversely affect the health or safety of that individual. Notwithstanding this restriction, the use of radiation other than ionizing radiation by persons licensed by the State of Oregon to practice the healing arts and who are authorized to use radiation shall be allowed.

(7) Dental units with a Kilovolt peak (kVp) of 50 and below are prohibited from being sold, leased, transferred or lent.

(a) Existing diagnostic dental X-ray systems less than 55 kVp shall not be used on minors.

(b) After October 1, 2011, registrants may not use diagnostic dental X-ray systems with a fixed, nominal kVp of less than 55.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 24-2014, f. & cert. ef. 8-15-14

333-100-0025
Exemptions

(1) General Provision. The Agency may, upon application or upon its own initiative, grant such exemptions or exceptions from the requirements of these rules as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

(2) U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors. Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this state is exempt from these rules to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:

(a) Prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

(b) Prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;

(c) Prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and

(d) Any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the state and the U.S. Nuclear Regulatory Commission jointly determine:

(A) That the exemption of the prime contractor or subcontractor is authorized by law; and

(B) That, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 4-2007, f. & cert. ef. 3-1-07

333-100-0030
Additional Requirements

The Agency may, by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in these rules as it deems appropriate or necessary to minimize danger to public health and safety or property.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 4-2007, f. & cert. ef. 3-1-07

333-100-0035
Violations

An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any rule or order issued thereunder. Any person who willfully violates any provision of the Act or any rule or order issued thereunder may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by ORS 453.990.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85 ; HD 1-1991, f. & cert. ef. 1-8-91; PH 4-2007, f. & cert. ef. 3-1-07

333-100-0040

Impounding

Sources of radiation shall be subject to impounding pursuant to Section 453.705 of the Act.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; PH 4-2007, f. & cert. ef. 3-1-07

333-100-0045

Communications

All communications and reports concerning these rules, and applications filed thereunder, should be addressed to Radiation Protection Services, Center for Health Protection, 800 NE Oregon Street, Suite 640, Portland, OR 97232.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 15-1994, f. & cert. ef. 5-6-94; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-100-0050
Severability

Should any section, subsection, paragraph, sentence, clause or phrase of these rules be declared unconstitutional or invalid for any reason, the remainder of these rules shall not be affected thereby.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; PH 4-2007, f. & cert. ef. 3-1-07

333-100-0055
Records

Each licensee and registrant must maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in these rules.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-100-0057
Maintenance of Records

Each record required by this division must be legible throughout the retention period. For the purposes of these rules and unless otherwise specified, records must be retained a minimum of five years. The record may be the original or a reproduced copy or a microfilm provided that the copy or microfilm is authenticated by authorized personnel and that the microfilm is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability of producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee must maintain adequate safeguards against tampering with and loss of records.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-100-0060
Inspections

(1) Each licensee and registrant must afford to the Agency at all reasonable times opportunity to inspect sources of radiation and radioactive material and the premises and facilities wherein such sources of radiation and radioactive material are used or stored.

(2) Each licensee and registrant must make available to the Agency for inspection, upon reasonable notice, records maintained pursuant to the rules in this chapter.

(3) Within the available resources of the Agency, X-Ray Machine Registrants must be inspected at the following frequency based upon the class of x-ray machine(s) registered:

(a) Every Year: Hospitals and Radiologists.

(b) Every Two Years: Chiropractors, Medical and Osteopaths.

(c) Every Three Years: Academic, Dental, Industrial, Podiatry, and Veterinary.

(4) Not withstanding the above, the Agency may inspect more frequently as deemed necessary to protect public health and safety.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 16-1994, f. & cert. ef. 6-27-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-100-0065
Tests

Each licensee and registrant must perform, or permit the Authority to perform, such tests as the Authority deems appropriate or necessary for the administration of the rules in this division and divisions 101, 105, 106, 108, 109, 112, 113, 115, 116, 117, 119, 121, 122, and 123 of this chapter including, but not limited to, tests of:

(1) Sources of radiation and radioactive material;

(2) Facilities wherein sources of radiation and radioactive material are used or stored;

(3) Radiation detection and monitoring instruments; and

(4) Other equipment and devices used in connection with the utilization or storage of licensed or registered sources of radiation and radioactive material.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-81-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10

333-100-0070
Units of Exposure and Dose

The Metric Conversion Act of 1975 (PL 94-168) urged the increasing awareness and use of the International System of Units (SI). The generally accepted regulatory values in the narrative portions of this document are followed by the SI equivalents in parentheses. Where appropriate, schedules and appendices are provided with notes concerning conversion factors. The inclusion of the SI equivalent is for informational purposes only.

(1) The unit of exposure is the coulomb per kilogram (C/kg). One roentgen is equal to 2.58×10^{-4} coulomb per kilogram of air.

(2) The units of radiation dose are:

(a) Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule per kilogram (100 rad);

(b) Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 Gy);

(c) Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).

(d) Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

(e) As used in these regulations, the quality factors for converting absorbed dose to dose equivalent are shown in 10 CFR 20 Part 20.1004 Table 1004(b).1.

(3) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rem per hour or sieverts per hour, as provided in (2)(c) of this rule, one rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of the regulations in this part, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee may use the fluence rate per unit dose equivalent or the appropriate Q value from 10 CFR 20 part 20.1004 Table 1004(b).2 (at the end of this division) to convert a measured tissue dose in gray or rad to dose equivalent in sievert rem.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-100-0080
Deliberate Misconduct

(1) Any licensee or any employee of a licensee; and any contractor (including a supplier or consultant), subcontractor, or any employee of a contractor or subcontractor, of any licensee, who knowingly provides to any licensee, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's activities subject to this part; may not:

(a) Engage in deliberate misconduct that causes or, but for detection, would have caused, a licensee to be in violation of any rule, regulation, or order, or any term, condition, or limitation of any license, issued by the Authority; or

(b) Deliberately submit to the Authority, a licensee, or a licensee's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Authority.

(2) A person who violates subsection (1)(a) or (1)(b) of this rule may be subject to enforcement action in accordance with OAR 333-100-0035.

(a) For purposes of subsection (1)(a) of this rule, deliberate misconduct by a person means an intentional act or omission that the person knows:

(A) Would cause a licensee to be in violation of any rule, regulation, or order, or any term, condition, or limitation, of any license issued by the Authority; or

(B) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order or policy of a licensee, contractor, or subcontractor.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.625 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

DIVISION 101

REGISTRATION OF RADIATION MACHINES, GENERAL LICENSE RADIOACTIVE MATERIALS, LICENSING OF RADIATION SERVICES, AND ACCREDITATION OF HOSPITAL RADIOLOGY INSPECTORS

333-101-0001
Purpose and Scope

(1) This division provides for the registration of radiation machines, general license radioactive materials, and for the licensing of persons providing radia-tion machine, radioactive material, or tanning installation, consultation, servicing, and/or services, and hospital radiology inspectors performing hospital X-ray machine inspections, unless such activities are subject to other divisions of these Rules.

(2) In addition to the requirements of this division, all licensees, registrants, and accredited individuals are subject to the applicable provisions of other portions of these rules.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; HD 3-1996, f. & cert. ef. 8-9-96; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04

333-101-0003
Definitions

(1) "Facility" means the location, building, vehicle, or complex under one administrative control, at which one or more devices or sources of radiation (X-ray, radioactive materials, or non-ionizing radiation) are installed.

(2) "Health Physics Consultant" means a person, business, facility, or institution providing health physics knowledge and skills for a fee. A health physics consultant may not use or possess radioactive material without specific license authorization pursuant to OAR 333-102-0200.

(3) "Inoperable" means disabling equipment such that ionizing radiation cannot be produced. This is accomplished by removing the X-ray tube, removal of the control unit, removal of the power supply or physical removal of the power cord on a free standing unit.

(4) "Storage" means a condition in which a device or source is not being used for an extended period of time, and has been made inoperable.

(5) "Vendor" means a person, business, facility, or institution providing a product or service for a fee. Radiation vendors include, but are not limited to, machine salespersons, repair and technical personnel, training providers or marketing representatives who sell, demonstrate, or market X-ray machines or tanning beds and provide advice, consultation, service, or technical information to registrants.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.685 & 453.761
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 24-2014, f. & cert. ef. 8-15-14

333-101-0005
Application for Registration of Radiation Machines

No X-ray machine shall be operated unless the registration application has been submitted by the registrant to the Authority. Each person having a radiation machine must:

(1) Apply, in writing, for registration of such machines with the Authority prior to the operation of a radiation machine. All operable radiation machines must be registered and the appropriate fee, which is listed in division 103 of these rules, must be paid. Registration fees received by the Authority shall be refundable up to 10 calendar days if the application is withdrawn. Hospitals wishing to register any radiation machine must meet the additional requirements of OAR 333-101-0200. To avoid radiation machine registration and fees, the X-ray tube must be removed or the machine must be disassembled. Application for registration must be completed on forms furnished by the Authority and must contain the following information or such other information as may be required:

(a) Name of the owner or person having administrative control and responsibility for use. "Person" is defined in OAR 333-100-0005 to include "organization";

(b) Address and telephone number where the machine is located and used except that a central headquarters address may be given for a mobile machine used at various temporary field locations;

(c) A description of the type, model and control panel serial number of the radiation machine (state I.D. number if issued) and its rated capacity in peak kilovolts and maximum milliamperes;

(d) A description of the use (dental, medical, industrial, veterinary, research, etc.) of the machine;

(e) Date of application and signature of registrant;

(f) The individual and the signature of the individual designated under section (3) of this rule;

(g) If the facility is mobile, the geographic areas within the state to be covered; and

(h) Name of the radiation machine supplier, installer and service agent.

(2) The registrant must notify the Authority within 30 days of any change which increases the radiation output or rating of the radiation machine or of any other change which renders the information required in section (1) of this rule no longer accurate.

(3) When required by the Authority, the registrant must designate an individual who will be responsible for radiation protection for the machine. Such individual must:

(a) Be qualified by training and experience concerning all hazards and precautions involved in operating the machine for which he or she is responsible;

(b) Recommend a detailed program of radiation safety for effective compliance with the applicable requirements of these rules;

(c) Give instructions concerning hazards and safety practices to individuals who may be occupationally exposed to radiation from the machine; and

(d) Make surveys and carry out other procedures as required by these rules.

(4) When, in the opinion of the Authority, the individual designated to be responsible for radiation safety does not have qualifications sufficient to insure safe use of the machine for which he or she is responsible, the Authority may order the registrant to designate another individual who meets the requirements of this division.

(5) Each registrant must prohibit any person from furnishing radiation machine servicing or services as described in OAR 333-101-0020(4) to his radiation machine facility until such person pro-

vides evidence that he has been licensed with the Authority as a provider of services in accordance with 333-101-0020.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - ORS 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 3-1996, f. & cert. ef. 8-9-96; PH 12-2006, f. & cert. ef. 6-16-06; PH 25-2016, f. 8-26-16, cert. ef. 9-1-16

333-101-0007
Application for General License Registration for Radioactive Materials Gauges, In Vitro Testing, Source Material, Reference and Calibration Sources, and Reciprocal Recognition of Specific Radioactive Materials License

Except for specific licensees granted a general license under OAR 333-102-0340 for reciprocal use of specific license radioactive material, each person, pursuant to 333-102-0103, 333-102-0115(1), 333-102-0125, or 333-102-0130, having general license radioactive material must:

(1) Apply for registration of such materials with the Authority within thirty (30) days of possession of such device, in vitro radioactive material used for testing, or source material. Application for registration must be completed on forms furnished by the Authority and must include the name of the general license supplier, installer, and service agent.

(2) The general license registrant must notify the Authority within thirty (30) days of any change in information required in section (1) of this rule.

(3) Each general license registrant must prohibit any person from furnishing servicing or services to any general license device until such person provides evidence that the servicing agent has been registered with the Authority as a provider of services in accordance with OAR 333-101-0020.

(4) Each general license granted pursuant to OAR 333-102-0340 must provide the specific information required pursuant to that rule.

Stat. Auth.: ORS 453.605 - ORS 453.807
Stats. Implemented: ORS 453.605 - ORS 453.807
Hist.: HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06

333-101-0010
Exemptions

(1) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this division, providing dose equivalent rate averaged over an area of 10 square centimeters does not exceed 5 microSv (0.5 millirem) per hour at five centimeters from any accessible surface of such equipment. The production, testing or factory servicing of such equipment is not exempt.

(2) Radiation machines while in transit or inoperable are exempt from the requirements of this division. For the purposes of registration and fees, the Authority considers an X-ray unit to be inoperable only if the machine's X-ray tube (insert) has been removed or the machine disassembled. With the X-ray tube in place, and the machine assembled, the unit is considered to be operable. If a machine is "in storage," it must be registered and charged a registration fee. However, an "inoperable" machine need not be registered or assessed a fee.

(3) Domestic television receivers are exempt from the requirements of this division.

(4) Electron microscopes are exempt from the requirements of this division, provided that the dose equivalent rate, averaged over an area of 10 square centimeters, does not exceed 5 microSv (0.5 millirem) per hour at five centimeters from any accessible surface of the equipment.

NOTE: Electron microscope: A type of microscope which uses electrons to produce magnified images and may therefore produce ionizing radiation incidental to its use.

(5) Electron beam welding machines and electron beam furnaces are exempt from the requirements of this division, provided that the dose equivalent rate, averaged over an area of 10 square centimeters, does not exceed 5 microSv (0.5 millirem) per hour at five centimeters from any accessible surface of the equipment.

(6) Persons licensed under OAR 333-102-0200 or equivalent specific licenses rules under an Agreement State or the U.S. Nuclear Regulatory Commission are exempt from this requirement.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06

333-101-0015
Transfer or Disposal of Radiation Producing Machines or Equipment

Whenever radiation producing machines or equipment, including general license devices containing radioactive material, are transferred or disposed of, the Authority must be notified in writing by the registrant within 30 days of the date of such transfer or disposal, and include the name and address of the person to whom it was transferred or its final disposition.

NOTE: General License radioactive materials can only be transferred pursuant to requirements in OAR 333-102.

Stat. Auth.: ORS 453.605 - 453.755
Stats. Implemented: ORS 453.605 - 453.755
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06

333-101-0020
Application for License of Sales, Services, Consultation, and Servicing For Radiation Machines

(1) Each person who is engaged in the business of training, selling, leasing, transferring, lending, installing or offering to install radiation machines or tanning beds, or is engaged in the business of furnishing or offering to furnish radiation machines, X-ray automatic film processor, X-ray processing chemicals, radioactive material (unless such activities are authorized under a specific license), or tanning servicing or services in this state, must apply for license of such services with the Authority within 30 days following the effective date of this rule or thereafter prior to furnishing or offering to furnish any such services.

(2) Application for a license must be completed on forms furnished by the Authority and must contain the following information or such other information as may be required:

(a) Name, address and telephone number of the following:

(A) The individual or the company to be licensed; and

(B) The owner(s) of the company.

(b) The services that shall be provided;

(c) The area of the state and other states to be covered;

(d) A list of the individuals qualified to provide these services; and

(e) The date of application and signature of the individual responsible for the company, beneath a statement of the items specified in OAR 333-101-0020(3).

(3) Each person applying for license under this division must specify:

(a) That they have read and understand the requirements of these rules;

(b) The services for which they are applying for license;

(c) The training and experience that qualify them or their technical staff to discharge the services for which they are applying for license;

(A) Training for radiation machine vendors must include, but must not be limited to, a minimum of one day of training in radiation use and safety.

(B) The training specified in OAR 333-101-0020(3)(c)(A) must be taught by an Authority approved instructor. Approval shall be based upon the following criteria;

(i) Current Radiologic Technologist license with the Oregon Board of Radiologic Technology and a minimum of two years of work experience in Radiologic Technology; and

(ii) Experience in the use of radiation measurement instruments; or

(iii) "Qualified Expert" as defined in OAR 333-100-0005; or

(iv) "Health Physics Consultant" as defined in OAR 333-101-0003.

(C) Subjects to be covered must include but not be limited to:
(i) Nature of X-rays;
(ii) Radiation units;
(iii) Biological effects of X-ray radiation;
(iv) Principals of radiation protection;
(v) Radiation survey instruments;
(vi) Personnel monitoring equipment; and
(vii) Applicable federal and state radiation regulations.

(d) The type of measurement instruments to be used, frequency of calibration, source of calibration; and

(e) The type of personnel dosimeters supplied, frequency of reading and replacement or exchange schedule.

(4) All radiation machine vendors who install or repair radiation machines must have measurement instruments that assure compliance with all X-ray machine, or tanning bed installation requirements according to all applicable federal standards, as well as instruments to properly check items such as collimation, HVL, kVp, mA, time, and radiation output, or assure these tests are made by a qualified expert as needed, and that the information is included in the installation report.

(5) For the purpose of OAR 333-101-0020, services may include but must not be limited to:

(a) Sales or leasing of radiation machines, installation and servicing of radiation machines and associated radiation machine components;

(b) Calibration of radiation machines;

(c) Calibration and use of radiation measurement instruments or devices;

(d) Radiation protection or health physics consultations or surveys;

(e) Personnel dosimetry services (not otherwise licensed under these rules);

(f) Installation and servicing of automatic X-ray film processors; and

(g) Providing X-ray film processing chemicals.

(6) No individual shall perform services that are not specifically stated for that individual on the notice of licensure (certificate of validation or acknowledgment of validation) issued by the Authority.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06; PH 24-2014, f. & cert. ef. 8-15-14

333-101-0023
Application for License of Sales, Consulting Services, and Servicing for Radioactive Materials Devices under General License

(1) Each person who is engaged in the business of selling, installing, surveying, consulting, training, or servicing radioactive material in general license measuring, gauging, or controlling devices, or selling In Vitro testing kits, or source material, or is engaged in the business of furnishing or offering to furnish radioactive material consulting services in this state, must apply for license of such services with the Authority within 30 days following the effective date of this rule or thereafter prior to furnishing or offering to furnish any such services.

(2) Application for a license must be completed on forms furnished by the Authority.

(3) Each person applying for license under this division must specify:

(a) That they have read and understand the requirements of these rules;

(b) The services for which they are applying for license; and

(c) The training and experience that qualify them or their technical staff to discharge the services for which they are applying for license.

(4) All vendors must have measurement instruments that will assure compliance with all applicable standards, as well as instruments to properly check items such as collimation, time, and radiation output, or assure these tests are made by a qualified expert, and that the information is included in the installation report.

(5) For the purpose of OAR 333-101-0020, services may include but must not be limited to:

(a) Installation and/or servicing of radiation machines and associated radiation machine components;

(b) Calibration of general license radioactive material used for measuring, gauging, or controlling;

(c) Radiation protection or health physics consultations or surveys; and

(d) Personnel dosimetry services (not otherwise licensed under these rules).

(6) No individual shall perform services that are not specifically stated for that individual on the license application (certificate of validation or acknowledgement of validation) issued by the Authority.

(7) Persons licensed under OAR 333-102-0200 (specific radioactive materials license) are exempt from these requirements.

Stat. Auth.: ORS 453.605 - ORS 453.807
Stats. Implemented: ORS 453.605 - ORS 453.807
Hist.: HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06

333-101-0025
Out-of-State Radiation Machines

(1) Whenever any radiation machine is to be brought into the state for any temporary use (a period not in excess of 30 days), the person proposing to bring such machine into the state must give written notice to the Authority (at least two working days) before such machine is to be used in the state. The notice must include:

(a) The type of radiation machine;

(b) The nature, duration and scope of use;

(c) The exact locations where the radiation machine is to be used; and

(d) The States in which this machine is registered.

(2) If for a specific case, the two working-day period would impose an undue hardship on the person, upon application to the Authority, permission to proceed sooner may be granted.

(3) The person referred to in section (1) of this rule must:

(a) Comply with all applicable rules of the Authority;

(b) Supply the Authority with such other information as the Authority may reasonably request; and

(c) Not operate within the state on a temporary basis in excess of 180 calendar days per year.

(4) Notwithstanding sections (1), (2) and (3) of this rule, registered general licenses for out-of-state radioactive material under specific license may be brought into the state for use at temporary jobsites only under the provisions of OAR 333-102-0340.

Stat. Auth.: ORS 453.605 - ORS 453.807
Stats. Implemented: ORS 453.605 - ORS 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06

333-101-0035
Issuance of Notice of Registration for X-ray Machines

(1) Upon a determination that an applicant meets the requirements of the rules, the Authority must issue a registration and/or a validation certificate.

(2) The Authority may incorporate in the notice of registration at the time of issuance or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of radiation machines as it deems appropriate or necessary.

(3) Prior to issuance of an X-ray machine registration to a hospital, the X-ray machine will be approved by an X-ray machine inspector employed by the Authority, or inspected by an accredited radiology inspector.

(4) Prior to issuance of an X-ray machine registration to a facility other than a hospital, the X-ray machine must be approved by an X-ray machine inspector employed by the Authority.

Stat. Auth.: ORS 453.605 - ORS 453.807
Stats. Implemented: ORS 453.605 - ORS 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 3-1996, f. & cert. ef. 8-9-96; PH 12-2006, f. & cert. ef. 6-16-06

333-101-0040
Expiration of Notice of Registration

(1) Except as provided by OAR 333-101-0045(2) each notice of registration shall expire at the end of the specified day in the month and year stated therein.

(2) An X-ray machine registration shall terminate if the X-ray machine is relocated for use in a physical surrounding other than the physical surrounding it occupied when originally registered.

Stat. Auth.: ORS 453.761
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 3-1996, f. & cert. ef. 8-9-96

333-101-0045
Renewal of Notice of Registration

(1) Application for renewal of registration must be filed in accordance with OAR 333-101-0005 or 333-101-0020.

(2) In any case in which a registrant has filed an application in proper form for renewal, not less than 30 days prior to the expiration of his existing notice of registration, such existing notice of registration shall not expire until the application status has been determined by the Authority.

Stat. Auth.: ORS 453.605 - ORS 453.807
Stats. Implemented: ORS 453.605 - ORS 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 12-2006, f. & cert. ef. 6-16-06

333-101-0050
Report of Changes

The registrant must notify the Authority in writing before making any change which would render the information contained in the application for registration and/or the notice of registration no longer accurate.

Stat. Auth.: ORS 453.605 - ORS 453.807
Stats. Implemented: ORS 453.605 - ORS 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06

333-101-0055
Approval Not Implied

(1) No person, in any advertisement, shall refer to the fact that their facility is registered with the Authority pursuant to the provisions of OAR 333-101-0005 or 333-101-0020 and no person shall state or imply that any activity under such registration has been approved by the Authority.

(2) No person shall refer to any rule, or state or imply rules in any advertisement without citing the exact wording of the rule in its entirety.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

333-101-0060
Assembler and/or Transfer Obligation

(1) Any person who sells, leases, transfers, lends, disposes, assembles or installs radiation machines in this state must notify the Authority within 15 days of:

(a) The name and address of persons who have received these machines;

(b) The manufacturer, model and serial number of each radiation machine transferred; and

(c) The date of the transfer of each radiation machine.

(2) No person shall make, sell, lease, transfer, lend, assemble or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and used must meet the requirements of these rules.

(3) In the case of diagnostic x-ray systems which contain certified components, a copy of the assembler's report prepared in compliance with requirements of the federal diagnostic X-ray standard (21 CFR 1020.30(d)) must be submitted to the Authority within 15 days following completion of the assembly. Such report must suffice in lieu of any other report by the assembler.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 453.605 - ORS 453.807
Stats. Implemented: ORS 453.605 - ORS 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06

333-101-0065
Additional Requirements

(1) No person shall use a radiation machine unless that machine is registered with the Oregon Health Authority in accordance with OAR 333-101-0005 or is exempt from the registration under OAR 333-101-0010 or 333-101-0025.

(2) No registrant shall use a radiation machine unless a current certificate of validation has been issued for that machine.

(3) The registrant must comply with any additional requirements or conditions listed on the then current certificate of validation on which the Authority has deemed appropriate or necessary to minimize danger to public health and safety or property.

Stat. Auth.: ORS 453.605 - ORS 453.807
Stats. Implemented: ORS 453.605 - ORS 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-81-91; Renumbered from 333-101-0030; PH 12-2006, f. & cert. ef. 6-16-06; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-101-0070
X-ray Machine Registration Fee Proration

(1) Not withstanding the registration requirements of division 103 of these rules, the Authority must, at the written request of the X-ray machine owner, adjust the registration expiration date of any X-ray machine to coincide with the registration expiration date of other X-ray machines currently registered to the machine owner.

(2) When requested in writing the Authority must prorate the registration fee according to the following:

(a) If a machine is registered for 19 to 24 months in a biennium, the registration fee shall be 100 percent;

(b) If a machine is registered for 13 to 18 months in a biennium the registration fee shall be 75 percent;

(c) If a machine is registered for 7 to 12 months in a biennium the registration fee shall be 50 percent;

(d) If a machine is registered for 1 day to 6 months in a biennium the registration fee shall be 25

Stat. Auth.: ORS 453.605 - ORS 453.807
Stats. Implemented: ORS 453.605 - ORS 453.807
Hist.: HD 3-1996, f. & cert. ef. 8-9-96; PH 12-2006, f. & cert. ef. 6-16-06

333-101-0080
X-ray Machine Registration Denial

(1) The Authority may deny the registration or may grant a provisional registration permitting temporary operation pending compliance with Authority standards for any of the following:

(a) The X-ray machine does not comply with one or more standards adopted by rule by the Authority;

(b) The equipment associated with the operation of the X-ray machine does not comply with one or more standards adopted by rule by the Authority;

(c) The physical surroundings associated with the operation of the X-ray machine does not comply with one or more standards adopted by rule by the Authority.

(2) The Authority may deny, condition, suspend or revoke a X-ray machine registration if the Authority believes that the X-ray machine or the physical surroundings or the equipment used in conjunction with the operation of the X-ray machine presents a danger to the health or safety of the operator or the public.

Stat. Auth.: ORS 453.761
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 3-1996, f. & cert. ef. 8-9-96

333-101-0090
Investigation and Civil Penalty

(1) If after an investigation by an Authority-employed X-ray machine inspector, the Authority has reason to believe that an act prohibited by division 101 of these rules has been committed, the Authority may impose a civil penalty not to exceed $5,000. The Authority reserves the right to pursue other remedies against alleged violators and may take any other disciplinary action at its discretion that it finds proper.

(2) In establishing the amount of the penalty for each violation, the Authority must consider, but not be limited to, the following factors:

(a) The gravity and magnitude of the violation;

(b) The person's, as defined in OAR 333-100-0005, previous record of complying or failing to comply with division 101 of these rules;

(c) The person/company's history in taking all feasible steps or in following all procedures necessary or appropriate to correct the violation; and

(d) Such other considerations as the Authority may consider appropriate.

(3) Civil penalties must be imposed in the manner provided by ORS 183.090.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - ORS 453.807
Hist.: HD 3-1996, f. & cert. ef. 8-9-96; PH 12-2006, f. & cert. ef. 6-16-06

333-101-0200
Hospital X-ray Machine Registration

(1) Prior to issuance of an X-ray machine registration to a hospital, the X-ray machine must be approved by an X-ray machine inspector employed by the Authority or inspected by an Authority-accredited hospital radiology inspector; and

(2) If inspection is performed by an accredited hospital radiology inspector, the test results must be reviewed and approved by the Authority; and

(3) All standards adopted by rule of the Authority are met; and

(4) A properly completed registration application has been submitted by the X-ray machine owner; and

(5) All required fees have been paid.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - ORS 453.807
Hist.: HD 3-1996, f. & cert. ef. 8-9-96; PH 12-2006, f. & cert. ef. 6-16-06

333-101-0210
Hospital Radiology Inspector

An accredited hospital radiology inspector is an individual who has a combination of education and experience as indicated in OAR 333-101-0220. This individual must have been tested on knowledge of Authority radiation rules governing the X-ray machine inspection program, including but not limited to, safety requirements and inspection procedures. Those individuals with current accreditation are then allowed at a participating hospital's request, to complete the annual Authority radiation inspection.

Stat. Auth.: ORS 453.780 - 453.785
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 3-1996, f. & cert. ef. 8-9-96

333-101-0220
Hospital Radiology Inspector Qualifications

(1) All applicants for licensure as hospital radiology inspectors must possess at a minimum one of the following combinations of education and experience:

(a) One year of experience using X-ray machines and associated auxiliary equipment, and at least one of the following:

(A) Certification by the American Board of Radiology or the American Board of Health Physics;

(B) A doctoral degree in a physical or biological science; or

(C) A doctor of medicine degree or a degree recognized by the Authority as an equally qualified health professional degree.

(b) Two years of experience using X-ray machines and associated auxiliary equipment, and a master's degree in a physical or biological science.

(c) Four years of experience using X-ray machines and associated auxiliary equipment, and a bachelor's degree in a physical or biological science.

(d) Six years of experience using X-ray machines and associated auxiliary equipment, and an associate's degree in a physical or biological science.

(2) Experience of an applicant includes, but is not limited to, measuring ionizing radiation, evaluating radiation safety and documenting radiation protection needs in a diagnostic radiology setting.

(3) In addition to meeting the education and experience requirements of this section, applicants must be tested on knowledge of Authority rules governing the X-ray machine inspection program, including but not limited to, safety requirements and inspection procedures.

(4) Applicants must also complete such additional written or practical testing as the Authority may require.

(5) An accreditation must not be issued or renewed to an applicant unless the applicant has paid all required fees.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - ORS 453.807
Hist.: HD 3-1996, f. & cert. ef. 8-9-96; PH 12-2006, f. & cert. ef. 6-16-06

333-101-0230
Hospital Radiology Inspector Testing

(1) The Authority must offer quarterly examinations for licensure. A schedule of examination dates and times will be available upon request. The Authority reserves the right to alter or adjust examination dates, times and locations as it deems necessary and will notify applicants whenever possible.

(2) Testing will be done by the Authority or the Authority's representative and upon passing the test, the Authority will issue a radiology inspector accreditation.

(3) Applicants must qualify for examination upon compliance with all applicable provisions of OAR 333-101-0020. Applicants must not be allowed to sit for the examination if documentation is incomplete or incorrect.

(4) Documentation must be submitted to the Authority office within seven days of the examination date. No accreditation will be issued without proper documentation.

(5) Applicants providing documentation to the Authority must submit the official transcript in a sealed envelope, issued from the school or training organization. The school must attest to the documents authenticity and accuracy.

(6) Applicants taking the examination must present photographic identification, such as a driver's license, before sitting for the examination.

(7) Each applicant must complete a written examination to test the applicant's knowledge in the following subjects:

(a) Licensure and registration requirements and applicable radiation rules including:

(A) Registrant's administrative responsibilities;

(B) Registrant's X-ray machine operator responsibilities;

(C) Registrant's X-ray machine responsibilities;

(D) Registrant's responsibilities regarding film, film processing, and all quality control related to the hospital radiology department; and

(E) Hospital radiology inspector responsibilities.

(b) Authority inspection procedures and practice application;

(c) The basic principles of radiation safety; and

(d) Inspection equipment and tools.

(8) The applicant must pass the examination by a score of at least 75 percent.

(9) All examinations must be prescheduled.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807.
Hist.: HD 3-1996, f. & cert. ef. 8-9-96; PH 12-2006, f. & cert. ef. 6-16-06

333-101-0240
Hospital Radiology Inspector Accreditation

(1) Accreditation as a radiology inspector shall be valid for two years and shall expire in the second year on the last day of the month of issuance unless renewed.

(2) An accreditation may be renewed if the radiology inspector has complied with the continuing education requirements specified in OAR 333-101-0260 and has paid the renewal fee.

(3) An accreditation for the current period must be provided by the Authority.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 3-1996, f. & cert. ef. 8-9-96; PH 12-2006, f. & cert. ef. 6-16-06

333-101-0250
Hospital Radiology Inspector Accreditation Revocation

The Authority may condition, suspend, revoke, or refuse to renew accreditation of a radiology inspector for the following reasons:

(1) Knowingly falsifying information included on the inspection report form supplied by the Authority.

(2) Substantially failing to comply with Authority procedures.

(3) Failing to meet Authority accuracy requirements.

Stat. Auth.: ORS 453.790
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 3-1996, f. & cert. ef. 8-9-96

333-101-0260
Hospital Radiology Inspector Continuing Education

(1) Each radiology inspector requesting an accreditation renewal must complete 10 clock hours of continuing education every two years from the date of accreditation to qualify for renewal of accreditation.

(2) Accreditation will not be renewed without receipt of the required continuing education report, by the Authority.

(3) Accredited hospital radiology inspectors failing to obtain 10 clock hours of continuing education every two years, must reapply, complete 5 hours of continuing education for the current year, and successfully pass a written examination.

(4) Continuing education includes attendance or participation at a radiology instructional program presented, organized or under the auspices of any organization or association. For example, lectures, post-secondary school, or post-graduate courses, scientific sessions at conventions, or correspondence courses.

(5) Subject matter must be related to the law and rules regulating hospital radiology inspectors, and the regulatory concept pertaining to radiation machines and their use in the State of Oregon.

(6) Documentation must include the name of the sponsoring institution/association or organization, title of presentation, description of content, name of instructor or presenter, date, clock hours, and a statement of attendance or completion provided by the sponsor.

(7) Submission to the Authority of proof of participation in continuing education is the responsibility of the hospital radiology inspector. Such proof must be held by the hospital accredited radiology inspector until submitted to the Authority biennially at the time of renewal.

(8) Hours obtained in excess of the 10 required for each two-year period must not be carried forward as credit for the subsequent two-year continuing education requirement.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 3-1996, f. & cert. ef. 8-9-96; PH 12-2006, f. & cert. ef. 6-16-06

333-101-0270
Hospital Responsibilities Re: X-ray Machines

Each hospital that is utilizing the services of an accredited radiology inspector must comply with the following and any other applicable sections of these rules:

(1) Contact the Authority, in writing, for information and authorization to allow the hospital to use the services of an accredited radiology inspector:

(a) Contact must be made three months prior to the facility's one year inspection due date or before March 1 of each renewal year by the registrant;and

(b) Contact with the Authority must be remade and a new authorization given by the Authority for every renewal period.

(2) Continually have available the services of an accredited radiology inspector or notify the Authority if they have terminated the services of the accredited radiology inspector.

(3) Records of safety inspections must be dept for two years after completion of the last inspection.

(4) Have procedures in place and followed which comply with all applicable parts of divisions 100, 101, 106, 109, 111, and 120 of these rules.

(5) Have an inspection and safety program in place which complies with all applicable parts of divisions 100, 101, 106, 109, 111 and 120 of these rules.

(6) Make records, X-ray machines, and related equipment available for inspection by the Authority during normal working hours.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 3-1996, f. & cert. ef. 8-9-96; PH 12-2006, f. & cert. ef. 6-16-06

333-101-0280
Authority Responsibilities Regarding the Radiology Inspection

The Authority responsibilities must include the following as well as other applicable sections of these rules:

(1) Do annual audits of hospital programs to monitor accredited radiology inspector results and to monitor changes in the performance of registered X-ray machines during the registration period.

(2) Evaluate registrant test results provided by the accredited radiology inspectors.

(3) Grant or deny X-ray machine registrations, accreditation of hospital radiology inspectors and issue documents of registration and accreditation.

(4) Deny, condition, suspend, or revoke an X-ray machine registration or radiology inspector accreditation.

(5) Grant a provisional registration permitting temporary operation pending compliance with Authority standards.

(6) Investigate any alleged prohibited act and resolve complaints against accredited radiology inspectors and their employers.

(7) Impose civil penalties.

(8) Develop programs to evaluate hazards associated with the use of X-ray machines.

(9) Develop testing, training and continued education standards for accreditation of radiology inspectors.

(10) Promulgate standards and make regulations relating to the registration of X-ray machines, accreditation of radiology inspectors, X-ray machine operation, physical surroundings and equipment related to the operation of the X-ray machines, operator training, and approved X-ray machine operating practices.

(11) Test applicants for radiology inspector accreditation.

(12) Collect and disseminate information relating to X-ray machine users.

(13) Provide technical assistance and safety information to X-ray machine users.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 3-1996, f. & cert. ef. 8-9-96; PH 12-2006, f. & cert. ef. 6-16-06

333-101-0290
Accredited Hospital Radiology Inspector Responsibilities

The accredited radiology inspector's responsibilities must include the following and compliance with any other applicable sections of these rules:

(1) Be currently accredited by the Authority as an accredited hospital radiology inspector.

(2) Each accredited hospital radiology inspector conducting a registration inspection on a hospital X-ray machine must collect information and do tests in the manner required by the Authority.

(3) Each accredited hospital radiology inspector must make calculations in the manner prescribed by the Authority and must enter the results and such other information as the Authority may require, on a form provided by the Authority.

(4) Each accredited hospital radiology inspector must make all inspection records and results available for audit or investigation by Authority inspectors.

(5) Accredited hospital radiology inspectors must not misrepresent in any way, a device identifying an X-ray machine registration.

(6) Accredited hospital radiology inspectors must not alter, obscure, deface, or remove a device identifying registration of an X-ray machine.

(7) Accredited hospital radiology inspectors must possess equipment appropriate and capable of doing the testing, monitoring, etc., required by applicable Authority standards.

(8) Assure all X-ray output and scatter radiation monitoring equipment have been calibrated within the past 12 months with X-rays in the same energy range as the diagnostic equipment being evaluated. Such calibration must be traceable to the National Institute of Standards and Technology (NIST).

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 3-1996, f. & cert. ef. 8-9-96; PH 12-2006, f. & cert. ef. 6-16-06

DIVISION 102

LICENSING OF RADIOACTIVE MATERIAL

333-102-0001
Purpose and Scope

(1) This division prescribes rules applicable to all persons in the State of Oregon governing licensing of radioactive material, and for exemptions from licensing requirements. No person may receive, produce, possess, use, transfer, own or acquire byproduct material except as authorized in a specific or general license pursuant to this division or divisions 105, 113, 115, 116, 117, or 121 of this chapter.

(2) In addition to the requirements of division 102, all licensees are subject to applicable requirements in divisions 100, 103, 111, 118, and 120 of this chapter. The requirements of this division are in addition to, and not in substitution for, other requirements of this chapter. In any conflict between the requirements in this division and a specific requirement in another division of the rules in this chapter, the specific requirement governs.

(3) This division establishes general licenses for the possession and use of source material and depleted uranium, for radioactive material contained in certain items, and for ownership of radioactive material.

(4) This division gives notice to all persons who knowingly provide to any licensee, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's activities subject to this division, that they may be individually subject to Authority actions pursuant to OAR 333-100-0035 or 333-100-0040.

(5) This division prescribes requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing radioactive material for sale or distribution to persons granted a general license by this division or to persons authorized by the US Nuclear Regulatory Commission to distribute to persons exempted from licensing requirements, and it prescribes certain rules governing holders of these licenses. In addition, this division prescribes requirements for the issuance of specific licenses to persons who introduce radioactive material into a product or material owned by or in the possession of the licensee or another and rules governing holders of such licenses. Further, this division describes procedures and prescribes requirements for the issuance of certificates of registration (governing radiation safety information about a product) to manufacturers or initial transferors of sealed source or devices containing sealed sources, which are to be used by persons specifically licensed under this division or equivalent regulations of an Agreement State or the US Nuclear Regulatory Commission.

(6) The Authority may engage the services of qualified persons in order to assist the Authority in meeting the requirements of this chapter, including, but not limited to, evaluating information that may be required under OAR 333-102-0200(6).

(7) Information provided to the Authority by an applicant for a license or by a licensee or information required by statute or by the Authority's rules, orders, or license conditions to be maintained by the applicant or the licensee must be complete and accurate in all material respects.

(8) Each applicant or licensee must notify the Authority of information identified by the applicant or licensee as having for the regulated activity a significant implication for public health and safety. An applicant or licensee violates this rule only if the applicant or licensee fails to notify the Authority of information that the applicant or licensee has identified as having a significant implication for public health and safety. Notification must be provided to the Authority within two working days of identifying the information. This requirement is not applicable to information that already is required to be provided to the Authority by other reporting or updating requirements.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.625 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 20-2010, f. & cert. ef. 9-1-10

Exemptions

333-102-0005
Unimportant Quantities of Source Material

(1) Any person is exempt from this division to the extent that such person receives, possesses, uses, owns or transfers source material in any chemical mixture, compound, solution or alloy in which the source material is by weight less than 1/20 of one percent (0.05 percent) of the mixture, compound, solution or alloy.

(2) Any person is exempt from this division to the extent that such person receives, possesses, uses or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person must not refine or process such ore.

(3) Any person is exempt from this division and divisions 111 and 120 to the extent that such person receives, possesses, uses or transfers:

(a) Any quantities of thorium contained in:

(A) Incandescent gas mantles;

(B) Vacuum tubes;

(C) Welding rods;

(D) Electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium;

(E) Germicidal lamps, sun lamps and lamps for outdoor or industrial lighting provided that each lamp does not contain more than two grams of thorium;

(F) Rare earth metals and compounds, mixtures and products containing not more than 0.25 percent by weight thorium, uranium or any combination of these; or

(G) Personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium.

(b) Source material contained in the following products:

(A) Glazed ceramic tableware manufactured before August 27, 2013, provided that the glaze contains not more than 20 percent by weight source material;

(B) Piezoelectric ceramic containing not more than two percent by weight source material;

(C) Glassware containing more than two percent by weight source material or , for glassware manufactured before August 27, 2013, not more than ten percent by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass or ceramic used in construction; or

(D) Glass enamel or glass enamel frit containing not more than ten percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983.

(c) Photographic film, negatives and prints containing uranium or thorium;

(d) Any finished product or part fabricated of, or containing tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed four percent by weight and that this exemption must not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such product or part;

(e) Uranium contained in counterweights installed in aircraft, rockets, projectiles and missiles or stored or handled in connection with installation or removal of such counterweights, provided that:

(A) Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM";

NOTE: The requirements specified in paragraphs (3)(e)(A) and (3)(e)(B) of this rule need not be met by counterweights manufactured prior to December 31, 1969 provided, that such counterweights were manufactured under a specific license issued by the Atomic Energy Commission and are impressed with the legend required by paragraph(3)(e)(B) of this rule in effect on June 30, 1969.

(B) Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED"; and

(C) This exemption must not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering.

(f) Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:

(A) The shipping container is conspicuously and legibly impressed with the legend "CAUTION — RADIOACTIVE SHIELDING — URANIUM"; and

(B) The uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of 1/8 inch (3.2 mm).

(g) Thorium or uranium contained in finished optical lenses and mirrors, provided that each lens does not contain more than 10 percent by weight of thorium or uranium or, for lenses manufactured before August 27, 2013, 30 percent by weight of thorium; and that this exemption must not be deemed to authorize either:

(A) The shaping, grinding or polishing of such lens or mirrors or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror; or

(B) The receipt, possession, use or transfer of uranium or thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

(h) Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

(A) The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide); and

(B) The thorium content in the nickel-thoria alloy does not exceed four percent by weight.

(4) The exemptions in section (3) of this rule do not authorize the manufacture of any of the products described.

(5) No person may initially transfer for sale or distribution a product containing source material to persons exempt under this rule, U.S. Nuclear Regulatory Commission or equivalent regulations of an Agreement State, unless authorized by a license issued under OAR 333-102-0300 and 333-102-0305 to initially transfer such products for sale or distribution.

(a) Persons initially distributing source material in products covered by the exemptions in this rule before August 27, 2013, without specific authorization may continue such distribution for one year beyond this date. Initial distribution may also be continued until the Authority takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than one year beyond this date.

(b) Persons authorized to manufacture, process, or produce these materials or products containing source material by an Agreement State, and persons who import finished products or parts, for sale or distribution must be authorized by a license issued under OAR 333-102-0300 and 333-102-0305 for distribution only and are exempt from the requirements of divisions 111 and 120 of this chapter, and OAR 333-102-0200(2) and (3).

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 10-1987, f. & ef. 7-28-87; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15; PH 25-2016, f. 8-26-16, cert. ef. 9-1-16

Exemptions — Byproduct Material Other than Source Material

333-102-0010
Exempt Concentrations

(1) Except as provided in sections (3) or (4) of this rule, any person is exempt from this division to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in 10 CFR Part 30.70.

(2) This section shall not be deemed to authorize the import of byproduct material or products containing byproduct material.

(3) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license outlined in OAR 333-102-0005 to the extent that transfers of radioactive material contained in a product or material in concentrations not in excess of those specified in 10 CFR Part 30.70 and introduced into the product or material by a licensee holding a specific license issued by an Agreement State, or the Nuclear Regulatory Commission, expressly authorizing such introduction. This exemption does not apply to the transfer of byproduct material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(4) No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under section (1) of this rule or equivalent regulations of the U.S. Nuclear Regulatory Commission, any Agreement State, or Licensing State except in accordance with a specific license issued pursuant to OAR 333-102-0245 or the general license granted by OAR 333-102-0340.

NOTE: 10 CFR Part 30.70 Schedule A is available from the Public Health Division, Radiation Protection Services.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10

Exempt Items

333-102-0015
Certain Items Containing Byproduct Material

(1) Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from these rules to the extent that he or she receives, possesses, uses, transfers, owns or acquires the following products:

NOTE: Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(a) Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:

(A) 25 millicuries (925 MBq) of tritium per timepiece;

(B) Five millicuries (185 MBq) of tritium per hand;

(C) 15 millicuries (555 MBq) of tritium per dial (when used, bezels must be considered as part of the dial);

(D) 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of promethium-147 per any other timepiece;

(E) 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) of promethium-147 per other timepiece hand;

(F) 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) of promethium-147 per other timepiece dial (when used, bezels must be considered as part of the dial);

(G) 0.15 microcurie (5.55 kBq) of radium per timepiece;

(H) 0.03 microcurie (1.11 kBq) of radium per hand;

(I) 0.09 microcurie (3.33 kBq) of radium per dial (when used, bezels must be considered as part of the dial);

(J) The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(i) For wrist watches, 0.1 millirad (one Gy) per hour at 10 centimeters from any surface;

(ii) For pocket watches, 0.1 millirad (one Gy) per hour at one centimeter from any surface; and

(iii) For any other timepiece, 0.2 millirad (two Gy) per hour at 10 centimeters from any surface.

(K) One microcurie (37 kBq) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

(b) Precision balances containing not more than one millicurie (37 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part manufactured before December 17, 2007;

(c) Marine compasses containing not more than 750 millicuries (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas manufactured before December 17, 2007;

(d) Electron tubes: Provided, that each tube does not contain more than one of the following specified quantities of radioactive material:

(A) 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries (370 MBq) of tritium per any other electron tube;

(B) One microcurie (37 kBq) of cobalt-60;

(C) Five microcuries (185 kBq) of nickel-63;

(D) 30 microcuries (1.11 MBq) of krypton-85;

(E) Five microcuries (185 kBq) of cesium-137; or

(F) 30 microcuries (1.11 MBq) of promethium-147.

(G) And provided further, that the radiation dose rate from each electron tube containing radioactive material will not exceed one millirad (10 Gy) per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber.

NOTE: For purposes of, subsection (1)(d) of this rule "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or control electrical currents.

(e) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:

(A) Each source contains no more than one exempt quantity set forth in 10 CFR Part 30.71 Schedule B; and

(B) Each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in 10 CFR Part 30.71 Schedule B provided that the sum of such fractions must not exceed unity.

(C) For americium-241, 0.05 microcuries (1.85 kBq) is considered an exempt quantity under paragraph (1)(e)(A) of this rule. Ionization chamber smoke detectors containing not more than one microcurie (uCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

(f) Static elimination devices that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium 210 per device.

(g) Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 500 millicuries(18.5 MBq) of polonium 210 per device or of a total of not more than 50 millicuries (1.85 GBq) of hydrogen 3 (tritium) per device.

(h) Such devices authorized before October 23, 2012 for use under the general license then provided in 10 CFR Part 31.3 and equivalent regulations of Agreement States and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Nuclear Regulatory Commission.

(2) The exemptions contained in this rule must not authorize any of the following:

(a) The manufacture of any product listed;

(b) The application or removal of radioactive luminous material to or from meters and timepieces or hands and dials therefore;

(c) The installation into automobile locks of illuminators containing tritium or promethium-147 or the application of tritium to balances of precision or parts thereof;

(d) Human use, or the use in any device or article, except timepieces, which is intended to be placed on or in the human body;

(e) As applied to radioactive material exempted under section (1) of this rule, the production, packaging, repackaging or transfer of radioactive material for purposes of commercial distribution or the incorporation of radioactive material into products intended for commercial distribution.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10; PH 20-2010, f. & cert. ef. 9-1-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-102-0025

Gas and Aerosol Detectors Containing Byproduct Material

(1) Except for persons who manufacture, process, produce or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license and from the rules in this division and in divisions 105, 113, 115, 116, 117, 120, and 121 of this chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires byproduct material in gas and aerosol detectors designed to protect health, safety, or property and manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Parts 32.26 of; or a Licensing State pursuant to OAR 333-102-0260, which authorizes the initial transfer of the product for use under this rule. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by a state under comparable provisions to OAR 333-102-0260 authorizing distribution to persons who are exempt from regulatory requirements.

(2) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct materials, or to initially transfer such products for use under section (1) of this rule shall apply for a license under OAR 333-102-0260 and for a certificate of registration in accordance with 10 CFR Part 32.210.

(3) Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a Licensing State must be considered exempt under section (1) of this rule, provided that the device is labeled in accordance with the specific license authorizing distribution and provided further that they meet the requirements of OAR 333-102-0260.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 20-2010, f. & cert. ef. 9-1-10; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-102-0030

Self-Luminous Products Containing Tritium, Krypton-85, or Promethium-147

(1) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, and except as

provided in section (3) of this rule, any person is exempt from the requirements for a license set forth in divisions 105, 113, 115, 116, 117, 120, 121 and 124 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, produced, or initially transferred in accordance with a specific license issued pursuant to OAR 333-102-0245, which authorizes the initial transfer of the product for use under this section.

(2) Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under section (1) of this rule, shall apply for a license under OAR 333-102-0245 and for a certificate of registration in accordance with 10 CFR Part 32.210.

(3) The exemption in section (1) of this rule does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 20-2010, f. & cert. ef. 9-1-10; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-102-0032
Self Luminous Products and Sources Containing Radium-226

(1) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer in accordance with the provisions of sections (1), (2), and (3) of this rule, radium-226 contained in the following products manufactured prior to November 30, 2007.

(a) Antiquities originally intended for use by the general public. For the purposes of this subsection, antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

(b) Intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

(c) Luminous items installed in air, marine, or land vehicles.

(d) All other luminous products provided that no more than 100 items are used or stored at the same location at any one time.

(e) Small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of radium-226. For the purposes of this subsection, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the Nuclear Regulatory Commission.

(2) Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in section (1) of this rule are exempt from the provisions of the rules in this division and in divisions 105, 113, 115, 116, 117, 120, 121 and 124 of this chapter, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under this chapter.

(3) Any person who acquires, receives, possesses, uses or transfers byproduct material in accordance with the general license in section (1) of this rule:

(a) Shall notify the Authority should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Authority within 30 days.

(b) Shall not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to 10 CFR Part 20.2008 or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the Nuclear Regulatory Commission.

(c) Shall not export products containing radium-226 except in accordance with 10 CFR Part 110.

(d) Shall dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any federal or state solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific licensee or equivalent regulations of an Agreement State, or as otherwise approved by the Authority.

(e) Shall respond to written requests from the Authority to provide information relating to the general licensee within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by a written authorization to the Authority

(f) The general license in section (1) of this rule does not authorize the manufacture, assembly, disassembly, repair or import of products containing radium-226, except that timepieces may be disassembled and repaired.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 20-2010, f. & cert. ef. 9-1-10

333-102-0033
Certain Industrial Devices

(1) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license set forth in rules in this division and in divisions 105, 113, 115, 116, 117, 120, and 121 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under this division, which authorizes the initial transfer of the device for use under this section. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

(2) Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under section (1) of this rule shall apply for a license under this division and for a certificate of registration in accordance with 10 CFR Part 32.210.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-102-0035
Exempt Quantities

(1) Except as provided in sections (2), (3) and (5) of this rule, any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in individual quantities, each of which does not exceed the applicable quantity set forth in 10 CFR Part 30.71 Schedule B.

(2) This rule does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution or the incorporation of radioactive material into products intended for commercial distribution.

(3) Any person who possesses radioactive material received or acquired under the general license formerly provided in OAR 333-102-0015(1)(g) is exempt from the requirements for a license set forth in this rule to the extent that such person possesses, uses, transfers or owns such byproduct material. .

(4) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in 10 CFR Part 30.71 Schedule B, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under this rule or equivalent regulations of the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to section 32.18 of 10 CFR Part 32 or by the Authority pursuant to OAR 333-102-0255, which license states that the radioactive material may be transferred by the licensee to persons exempt under this rule or the equivalent regulations of the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State.

(5) No person may, for purposes of producing an increased radiation level, combine quantities of byproduct material covered by this exemption so that the aggregate quantity exceeds the limits set forth in 10 CFR Part 30.71, Schedule B, except for byproduct material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the regulations in this rule.

NOTE: Authority to transfer possession or control by the manufacturer, processor or producer or any equipment, device, commodity or other product containing byproduct material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-2985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10; PH 20-2010, f. & cert. ef. 9-1-10; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-102-0040
In Vivo Testing in Humans for H. Pylori Using Carbon-14 Labeled Urea

(1) Except as provided in sections (3) and (4) of this rule, any person is exempt from the requirements for a specific license pursuant to this division and divisions 116 of this chapter provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1 microcurie) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

NOTE: "Nominal variation" as used in this context means + 10% of the reported per capsule dose.

(2) Any person who desires to use the capsules for research involving human subjects must apply for and receive a specific license pursuant to division 102 of this chapter.

(3) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules must apply for and receive a specific license pursuant to 10 CFR 32.21.

(4) Nothing in this rule relieves persons from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

Licenses

333-102-0075
Types of Licenses

Licenses for radioactive materials are of two types: General and specific.

(1) General licenses provided in this division are granted as being effective without the filing of applications with the Authority or the issuance of licensing documents to particular persons, except Depleted Uranium subject to OAR 333-102-0106, Measuring, Gauging, and Controlling devices subject to OAR 333-102-0115, and In Vitro Clinical or Laboratory Testing subject to OAR 333-102-0130.

(2) Specific licenses require the submission of an application to the Authority and the issuance of a specific licensing document by the Authority. The licensee is subject to all applicable portions of these rules as well as any limitations specified in the licensing document. Specific licenses are issued to named persons upon applications filed pursuant to OAR 333-102-0200 and divisions 105, 113, 115, 116, 117, and 121 of this chapter.

(3) General licenses granted by OAR 333-102-0101, 333-102-0106, 333-102-0115, and 333-102-0130 require the submission of an application to the Authority for registration pursuant to 333-101-0007, payment of a fee in accordance with 333-103-0015, and the issuance of a registration (licensing document or general license acknowledgment) by the Authority.

(4) General licenses are subject to OAR 333-100-0005 (Definitions), 333-100-0025 (Exemptions), 333-100-0030 (Additional Requirements), 333-100-0055 (Records), 333-100-0060(1) and 333-100-0060(2) (Inspections), 333-100-0065 (Tests), 333-102-0305(1) through 333-102-0305(8) (Terms and Conditions of Licenses), 333-102-0330 (Transfers), 333-102-0335 (Modification, Revocation, and Termination of Licenses), and divisions 103, 111, 118, and 120 of this chapter unless indicated otherwise in the language of the general license.

NOTE: Attention is directed particularly to the provisions of the regulations in division 120 of this chapter that relate to the labeling of containers and notification of incidents.

(5) Any record required by this division must be legible throughout the retention period specified by each Authority rule. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as letters, stamps, initials, and signatures. The licensee must maintain adequate safeguards against tampering with and loss of records.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

General Licenses

333-102-0101
General Licenses — Small Quantities of Source Material

(1) A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local government agencies to use and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operations purposes in the following forms and quantities:

(a) No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms such as gaseous, liquid, or powder, at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year. Persons possessing source material in excess of these limits as of August 27, 2013, may continue to possess up to 7 kg (15.4 lb) of uranium and thorium at any one time for one year beyond this date, or until the Commission takes final action on a pending application submitted on or beforeAugust 27, 2014, for a specific license for such material; and receive up to 70 kg (154 lb) of uranium or thorium in any one calendar year until December 31, 2014, or until the Commission takes final action on a pending application submitted on or before August 27, 2014, for a specific license for such material; and

(b) No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under this section may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under this section unless it is accounted for under the limits of subsection (1)(a) of this rule; or

(c) No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under this section; or

(d) No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under this section may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.

(2) Any person who receives, possesses, uses, or transfers source material in accordance with the general license in section (1) of this rule:

(a) Is prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the Authority in a specific license.

(b) Shall not abandon such source material. Source material may be disposed of as follows:

(A) A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of this paragraph is exempt from the requirements to obtain a license under this rule to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued under this chapter; or

(B) In accordance with OAR 333-120-0500, Waste Disposal – General Requirements.

(c) Is subject to the provisions in OAR 333-100-0080, 333-102-0001, 333-102-0005, 333-102-0075, 333-102-0101, 333-102-0305, 333-102-0330, 333-102-0350, and 333-102-0353.

(d) Shall not export such source materials except in accordance with 10 CFR Part 110.

(3) Any person who receives, possesses, uses, or transfers source material in accordance with section (1) of this rule shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the Authority about such contamination and may consult with the Authority as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in 10 CFR Parts 20.1402.

(4) Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in section (1) of this rule is exempt from the provisions of division 111 and 120 of this chapter and 10 CFR Part 21 to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of CFR 10 Parts 20.1402 and 20.2001 to the extent necessary to meet the provisions of subsection (2)(b) and section (3) of this rule. However, this exemption does not apply to any person who also holds a specific license issued under this division.

(5) No person may initially transfer or distribute source material to persons generally licensed under subsection (1)(a) or section (2) of this rule, or equivalent regulations of an Agreement State, unless authorized by a specific license issued in accordance with OAR 333-102-0102 or equivalent provisions of an Agreement State. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally licensed by section (1) of this rule before August 27, 2013 without specific authorization may continue for one year beyond this date. Distribution may also be continued until the Commission takes final action on a pending application for license or license amendment to specifically authorize distribution submitted on or before August 27, 2014.

(6) A general license is hereby granted authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use or transfer source material.

(7) Persons who receive, acquire, possess or use source material pursuant to the general license granted by section (1) of this rule must develop and maintain procedures to establish physical control over the source material and prevent transfer of such source material to persons not authorized to receive the source material.

(8) A person who receives, acquires, possesses or uses source material pursuant to the general license granted by section (1) of this rule:

(a) Must not introduce such source material, in any form, into a chemical, physical, or metallurgical treatment or process;

(b) Must not abandon such source material; and

(c) Must transfer or dispose of such source material only by transfer in accordance with the provisions of OAR 333-102-0330 or 333-120-0500.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 10-1987, f. & ef. 7-28-87; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-102-0102
Requirements for License to Initially Transfer Source Material for Use Under the Small Quantities of Source Materials General License

An application for a specific license to initially transfer source material for use under OAR 333-102-0101, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State shall be approved if:

(1) The applicant satisfies the general requirements specified in OAR 333-102-0200; and

(2) The applicant submits adequate information on, and the Authority approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15; PH 25-2016, f. 8-26-16, cert. ef. 9-1-16

333-102-0103 [Renumbered to **333-102-0106**]

333-102-0104
Conditions of Licenses to Initially Transfer Source Material for Use Under the 'Small Quantities of Source Material' General License: Quality Control, Labeling, Safety Instructions, and Records and Reports

(1) Each person licensed under OAR 333-102-0102 shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words "radioactive material".

(2) Each person licensed under OAR 333-102-0102 shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

(3) Each person licensed under OAR 333-102-0102 shall provide the information specified in this rule to each person to whom source material is transferred for use under OAR 333-102-0101, equivalent provisions in Agreement State or the U.S. Nuclear Regulatory Commission's regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

(a) A copy of OAR 333-102-0101 and OAR 333-102-0330, or relevant equivalent regulations of the Agreement State or the U.S. Nuclear Regulatory Commission; and

(b) Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

(4) Each person licensed under OAR 333-102-0102 shall report transfers as follows:

(a) File a report with the Authority. The report shall include the following information:

(A) The name, address, and license number of the person who transferred the source material;

(B) For each general licensee under OAR 333-102-0101:

(i) Equivalent Agreement State provisions or the Nuclear Regulatory Commission regulations to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter;

(ii) The name and address of the general licensee to whom source material is distributed:

(iii) A responsible agent, by name and position, and phone number, of the general licensee to whom the material was sent; and

(iv) The type, physical form, and quantity of source material transferred.

(C) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

(b) File a report with each responsible Agreement State or U.S. Nuclear Regulatory Commission agency that identifies all persons, operating under provisions equivalent to OAR 333-102-0101, to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the Agreement State being reported to:

(A) The name, address, and license number of the person who transferred the source material; and

(B) The name and address of the general licensee to whom source material was distributed; a responsible agent, by name or position and phone number of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred.

(C) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the Agreement State or U.S. Nuclear Regulatory Commission's jurisdiction.

(c) Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under OAR 333-102-0101 or equivalent Agreement State or U.S. Nuclear Regulatory Commission's provisions during the current period, a report shall be submitted to the Authority indicating so. If no transfers have been made to general licensees in a particular Agreement State or U.S. Nuclear Regulatory Commission's jurisdiction during the reporting period, this information shall be reported to the responsible Agreement State agency upon request of the agency

(5) Each person licensed under OAR 333-102-0102 shall maintain all information that supports the reports required by this rule concerning each transfer to a general licensee for a period of one year after the event is included in a report to the Authority, Agreement State agency, or the U.S. Nuclear Regulatory Commission.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15; PH 25-2016, f. 8-26-16, cert. ef. 9-1-16

333-102-0106
General Licenses — Depleted Uranium in Industrial Products and Devices

(1) A general license is hereby granted to receive, acquire, possess, use or transfer, in accordance with the provisions of sections (2), (3), (4) and (5), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(2) The general license in section (1) of this rule applies only to industrial products or devices that have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to OAR 333-102-0235 or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State that authorizes manufacture of the products or devices for distribution to persons granted a general license by the U.S. Nuclear Regulatory Commission or an Agreement State.

(3) Persons who receive, acquire, possess or use depleted uranium pursuant to the general license established by section (1) of this rule must apply for registration of the general license pursuant to OAR 333-101-0007, and submit the required fee pursuant to 333-103-0015. Applicants will receive a validation certificate from the Authority. Application for registration must be submitted within 30 days after the first receipt or acquisition of such depleted uranium.

(a) The general licensee must provide the following information in accordance with the registration application required by OAR 333-101-0007 and such other information as may be required by that form:

(A) Name and address of the general licensee;

(B) A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in section (1) of this rule and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(C) Name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in subsection (3)(b) of this rule.

(b) The general licensee possessing or using depleted uranium under the general license established by section (1) of this rule must report any changes in information in writing to the Authority within 30 days after the effective date of such change.

(4) A person who receives, acquires, possesses or uses depleted uranium pursuant to the general license established by section (1) of this rule:

(a) Must not introduce such depleted uranium, in any form, into a chemical, physical or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

(b) Must not abandon such depleted uranium;

(c) Must transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of OAR 333-102-0330. In the case where the transferee receives the depleted uranium pursuant to the general license granted by section (1) of this rule, the transferor must furnish the transferee a copy of this rule and a copy of the general license registration application required by 333-101-0007. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to section (1) of this rule, the transferor must furnish the transferee a copy of this rule and a copy of the general license registration application required by 333-101-0007 accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in this rule;

(d) Must report in writing to the Authority, within 30 days of any transfer, the name and address of the person receiving the depleted uranium pursuant to such transfer; and

(e) Must not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(5) Any person receiving, acquiring, possessing, using or transferring depleted uranium pursuant to the general license established by section (1) of this rule is exempt from the requirements of divisions 111 and 120 of this chapter with respect to the depleted uranium covered by that general license.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; Renumbered from 333-102-0103, PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

General Licenses — Radioactive Material Other than Source Material

333-102-0110
Luminous Safety Devices for Aircraft

(1) A general license is hereby granted to own, receive, acquire, possess and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

(a) Each device contains not more than 370 GBq (10 curies) of tritium or 11.1 GBq (300 millicuries) of promethium-147; and

(b) Each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the Authority or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in 10 CFR Part 32.53.

(2) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in section (1) of this rule are exempt from the requirements of divisions 111 and 120 of this chapter except that they must comply with the provisions of 333-120-0700 and 333-120-0710.

(3) This general license does not authorize the manufacture, assembly or repair of luminous safety devices containing tritium or promethium-147.

(4) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

(5) This general license is subject to the provisions of OAR 333-100-0005 (Definitions), 333-100-0025 (Exemptions), 333-100-0030 (Additional Requirements), 333-100-0055 (Records), 333-100-0060(1) and 333-100-0060(2) (Inspections), 333-100-0065 (Tests), 333-102-0305(1) through 333-102-0305(7) (Terms and Conditions of Licenses), 333-102-0330 (Transfer of Material), 333-102-0335 (Modification, Revocation, and Termination of Licenses), and division 118 of this chapter.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10

333-102-0115
Certain Measuring, Gauging and Controlling Devices

(1) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of OAR 333-103-0015 and sections (2), (3) and (4) of this rule, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(2) The general license in section (1) of this rule applies only to radioactive material contained in devices that have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued by the Authority pursuant to OAR 333-102-0200 or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, that authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.

(3) The devices must have been received from one of the specific licensees described in section (2) of this rule or through a transfer made in accordance with subsection (4)(i) of this rule.

NOTE: Regulations under the Federal Food, Drug and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.

(4) Any person who owns, receives, acquires, possesses, uses or transfers radioactive material in a device pursuant to the general license in section (1) of this rule:

(a) Must assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and must comply with all instructions and precautions provided by such labels;

(b) Must assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; however:

(A) Devices containing only krypton need not be tested for leakage of radioactive material; and

(B) Devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta or gamma emitting material or

10 microcuries (0.37 MBq) of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose.

(c) Must assure that tests required in subsection (4)(b) of this rule and other testing, installation servicing and removing from installation involving the radioactive materials, its shielding or containment, are performed:

(A) In accordance with the instructions provided by the labels; or

(B) By a person holding an applicable specific license from the Authority, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform such activities.

(d) Must maintain records showing compliance with the requirements of subsections (4)(b) and (4)(c) of this rule. The records must show the results of tests. The records also must show the dates of performance of, and the names of persons performing, testing, installation servicing and removal from installation concerning the radioactive material, its shielding or containment. The licensee must retain these records as follows:

(A) Records of tests for leakage of radioactive material required by subsection (4)(b) of this rule must be maintained as required in OAR 333-100-0057.

(B) Records of tests of the on-off mechanism and indicator required by subsection (4)(b) of this rule must be maintained as required in OAR 333-100-0057.

(C) Records which are required by subsection (4)(c) of this rule must be maintained as required in OAR 333-100-0057.

(e) Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more of removable radioactive material, the licensee must immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the Authority, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to repair such devices. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the Authority. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be submitted to the Authority within 30 days. Under these circumstances, the criteria set out in OAR 333-120-0190, as determined by the Authority, on a case-by-case basis;

(f) Must not abandon the device containing radioactive material;

(g) Except as provided in subsection (4)(i) of this rule, must transfer or dispose of the device containing radioactive material only by export as provided by subsection (4)(l) of this rule, by transfer to another general licensee as authorized in subsection (4)(i) of this rule, or by transfer to a specific licensee of the Authority, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State whose specific license authorizes the individual to receive the device; and

(A) Must furnish to the Authority, within 30 days after transfer of a device to a specific licensee or export, a report containing identification of the device by manufacturer's name, model number, serial number, the date of transfer, and the name, address and license number of the person receiving the device;

(B) The general licensee must obtain written Authority approval before transferring the device to any other specific licensee not specifically identified in subsection (4)(g) of this rule.

(h) A holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if the holder:

(A) Verifies that the specific license authorized the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(B) Removes, alters, covers, or clearly and unambiguously augments the existing label so that the device is labeled in compliance with OAR 333-120-0430, however the manufacturer model and serial numbers must be retained;

(C) Obtains manufacturer's or initial transferor's information concerning maintenance that are applicable under the specific license (such as leak testing procedures); and

(D) Reports the transfer under OAR 333-102-0115(4)(g)(A).

(i) Must transfer the device to another general licensee only:

(A) Where the device remains in use at a particular location. In such case the transferor must give the transferee a copy of this rule and any safety documents identified in the label on the device and within 30 days of the transfer, report to the Authority the manufacturer's (or initial transferor's) name, model number, serial number of the device transferred, the date of transfer, the name and address of the transferee and the location of use, and the name, title and phone number of the individual who is a point of contact between the Authority and the transferee. This individual must have the knowledge and authority to take actions to ensure compliance with the appropriate rules and requirements concerning the possession and use of these devices; or

(B) Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee.

(j) Must comply with the provisions of OAR 333-120-0700 and 333-120-0710 for reporting radiation incidents, theft or loss of licensed material but shall be exempt from the other requirements of divisions 111 and 120 of this chapter;

(k) Must submit the required Authority form and receive from the Authority a validated registration certificate acknowledging the general license and verifying that all provisions of these rules have been met. The form must be submitted within 30 days after the first receipt or acquisition of such device. The general licensee must develop and maintain procedures designed to establish physical control over the device as described in this rule and designed to prevent transfer of such devices in any form, including metal scrap, to persons not authorized to receive the devices.

(l) Shall not export a device containing radioactive material except in accordance with 10 CFR Part 110.

(5) The general license in section (1) of this rule does not authorize the manufacture of devices containing radioactive material.

(6) The general license provided in section (1) of this rule is subject to the provisions of OAR 333-100-0040 through 333-100-0055, 333-102-0335, 333-103-0015 and 333-118-0050.

(7) The general licensee possessing or using devices licensed under the general license established by section (1) of this rule must report in writing to the Authority any changes in information furnished by the licensee on the required Authority form. The report must be submitted within 30 days after the effective date of such change.

(8) The licensee must appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, must ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

(9)(a) A device distributed or otherwise received as a generally licensed device must be registered with the Authority. Each address for a location of use, as described under subsection (9)(b) of this rule, represents a separate general licensee and requires a separate registration and fee. Devices containing more than 37 MBq (1 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, any quantity of americium-241, 3.7 MBq (0.1 mCi) of radium 226 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on

the activity indicated on the label are required to have a specific license.

(b) In registering devices, the general licensee must furnish the following information and any other information specifically requested by the Authority:

(A) Name and mailing address of the general licensee;

(B) Information about each device. The manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label);

(C) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under section (8) of this rule.

(D) Address or location at which the device(s) are used and stored. For portable devices, the address of the primary place of storage.

(E) Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.

(F) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

(10) General licensees must report changes to their mailing address or the location of use (including a change in name of general licensee) to the Authority within 30 days of the effective date of the change.

(11) Generally licensed devices that are not in use for longer than two years must be transferred to an authorized recipient or disposed of as radioactive waste. Shutters must be locked in the closed position on devices that are not being used or are in storage. The testing required by subsection (4)(b) of this rule need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use.

(12) Persons generally licensed by an Agreement State with respect to devices meeting the criteria in section (9) of this rule are not subject to registration requirements if the devices are used in areas subject to NRC jurisdiction for a period less than 180 consecutive days in any calendar year. The Nuclear Regulatory Commission does not require registration information from such licensees.

(13) The general license in section (1) of this rule does not authorize the manufacture or import of devices containing radioactive material.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 20-2010, f. & cert. ef. 9-1-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 4-2013, f. & cert. ef. 1-29-13

333-102-0120
Ownership of Radioactive Material

A general license is hereby granted to own radioactive material without regard to quantity. Notwithstanding any other provisions of this division, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

333-102-0125
Calibration and Reference Sources

(1) A general license is hereby granted to those persons listed in subsections (1)(a) and (1)(b) of this rule to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of sections (4) and (5) of this rule, americium-241, plutonium, or radium-226, in the form of calibration or reference sources:

(a) Any person who holds a specific license issued by the Authority that authorizes receipt, possession, use, and transfer of radioactive material; and

(b) Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission that authorizes receipt, possession, use, and transfer of special nuclear material.

(2) A general license is hereby granted to own, receive, possess, use and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of sections (4) and (5) of this rule to any person who holds a specific license issued by the Authority that authorizes receipt, possession, use, and transfer of radioactive material.

(3) A general license is hereby granted to own, receive, possess, use and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of sections (4) and (5) of this rule to any person who holds a specific license issued by the Authority that authorizes receipt, possession, use, and transfer radioactive material.

(4) The general licenses in sections (1), (2), and (3) of this rule apply only to calibration or reference sources that have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to section 32.57 of 10 CFR Part 32 or section 70.39 of 10 CFR Part 70 or that have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Authority, any Agreement State or Licensing State pursuant to licensing requirements equivalent to those contained in section 32.57 of 10 CFR Part 32, or section 70.39 of 10 CFR Part 70.

(5) The general licenses provided in sections (1), (2) and (3) of this rule are subject to the provisions of OAR 333-100-0005 (Definitions), 333-100-0025 (Exemptions), 333-100-0030 (Additional Requirements), 333-100-0055 (Records), 333-100-0060(1) and 333-100-0060(2) (Inspections), 333-100-0065 (Tests), 333-102-0305(1) through 333-102-0305(8) (Terms and Conditions of Licenses), 333-102-0330 (Transfers), 333-102-0335 (Modification, Revocation, and Termination of Licenses), and divisions 111, and 120 of this chapter. In addition, persons who own, receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to these general licenses:

(a) Must not possess at any one time, at any one location of storage or use, more than five microcuries (185 kBq) each of americium-241, of plutonium-238, plutonium-239, or of radium-226 in such sources; and

(b) Each license issued under this rule shall affix to each source or source storage container a label containing sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement that contains the information called for in the following statement:

The receipt, possession, use, and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL -THIS SOURCE CONTAINS (AMERICIUM-241) (PLUTONIUM) or (RADIUM 226) DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE. _____ Name of manufacturer or importer

NOTE: Show only the name of the appropriate material.

(c) Must not transfer, abandon or dispose of such source except by transfer to a person authorized by a specific license from the Authority, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to receive the source;

(d) Must store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 that might otherwise escape during storage; and

(e) Must not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(6) These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

(7) Each licensee licensed under the provisions of 10 CFR Part 32.57 shall perform a dry wipe test as outlined in 10 CFR Part 32.59.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1085, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 20-2010, f. & cert. ef. 9-1-10

333-102-0130
General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing

(1) A general license is hereby granted to any physician, veterinarian, clinical laboratory, or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with sections (2), (3), (4), (5) and (6) of this rule, the following radioactive materials in prepackaged units for use in In Vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

(a) Iodine-125 in units not exceeding ten microcuries (370 kBq) each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals;

(b) Iodine-131, in units not exceeding ten microcuries (370 kBq) each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals;

(c) Carbon-14, in units not exceeding ten microcuries (370 kBq) each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals;

(d) Hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals;

(e) Iron-59 in units not exceeding 20 microcuries (740 kBq) each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals;

(f) Selenium-75, in units not exceeding ten microcuries (370 kBq) each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals;

(g) Mock iodine-125 reference or calibration sources, in units not exceeding 0.05 microcuries (1.85 kBq) of iodine-129 and 0.005 microcuries (185 Bq) of americium-241 each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(2) A person may not receive, acquire, possess, use or transfer radioactive material under the general license granted by section (1) of this rule unless that person:

(a) Has filed the required Authority application for registration pursuant to OAR 333-101-0007 and submitted the registration fee pursuant to 333-103-0015 and received from the Authority a validated license with certification number assigned; or

(b) Has a license that authorizes the medical use of radioactive material that was issued under OAR chapter 333, division 116.

(3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by section (1) of this rule must comply with the following:

(a) The general licensee must not possess at any one time, at any one location of storage or use a total amount of iodine-125, iodine-131, selenium-75, cobalt-57 and/or iron-59 in excess of 200 microcuries (7.4 MBq);

(b) The general licensee must store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection;

(c) The general licensee must use the radioactive material only for the uses authorized by section (1) of this rule;

(d) The general licensee must dispose of the mock iodine-125 reference or calibration sources described in subsection (1)(g) of this rule as required by OAR 333-120-0500 and section (6);

(e) The general licensee must not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Authority, the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(4) The general licensee must not receive, acquire, possess or use radioactive material pursuant to section (1) of this rule:

(a) Except as prepackaged units that are labeled in accordance with the provisions of an applicable specific license issued by the U.S. Nuclear Regulatory Commission, any Agreement State or any Licensing State that authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, cobalt-57, iron-59 or mock iodine-125 for distribution to persons generally licensed under section (1) of this rule or its equivalent; and

(b) Unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(A) This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation there from, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the United States Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____

Name of Manufacturer

(B) This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation there from, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a Licensing State.

_____

Name of Manufacturer

(5) The registrant possessing or using radioactive material granted by the general license of section (1) of this rule must report in writing to the Authority any changes in the information furnished on the required Authority form. The report must be furnished within 30 days after the date of such change.

(6) Any person using radioactive material pursuant to the general license granted by section (1) of this rule is exempt from the requirements of divisions 111 and 120 of this chapter with respect to radioactive material covered by that general license, except that such persons using mock iodine-125 described in subsection (1)(g) of this rule must comply with provisions of OAR 333-120-0500, 333-120-0700 and 333-120-0710.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-102-0135
Ice Detection Devices

(1) A general license is hereby issued to own, receive, acquire, possess, use and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries (1.85 MBq) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the Authority or an Agreement State to the manufacturer of such device pursuant to licensing requirements equivalent to those in section 32.61 of 10 CFR Part 32.

(2) Persons who own, receive, acquire, possess, use or transfer strontium-90 contained in ice detection devices pursuant to the general license granted by section (1) of this rule:

(a) Must, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the Authority, the U.S. Nuclear Regulatory Commission or any other Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of OAR 333-120-0500;

(b) Must assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

(c) Are exempt from the requirements of divisions 111 and 120 of this chapter except that such persons must comply with the provisions of OAR 333-120-0500, 333-120-0700, and 333-120-0710.

(3) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.

(4) This general license is subject to the provisions of OAR 333-100-0005 (Definitions), 333-100-0025 (Exemptions), 333-100-0030 (Additional Requirements), 333-100-0055 (Records), 333-100-0060(1) and 333-100-0060(2) (Inspections), 333-100-0065 (Tests), 333-102-0305(1) through 333-102-0305(8) (Terms and Conditions of Licenses), 333-102-0330 (Transfer of material), 333-102-0335 (Modification, Revocation, and Termination of Licenses) and division 118 of this chapter.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. &ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-102-0190
Application for Specific Licenses

(1) Applications for specific licenses must be filed on a form prescribed by the Authority. Information contained in previous applications, statements or reports filed with the Authority, the US Nuclear Regulatory Commission, or an Agreement State or a Licensing State or the Atomic Energy Commission may be incorporated by reference, provided that the reference is clear and specific.

(2) The Authority may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Authority to determine whether the application shall be granted or denied or whether a license shall be modified or revoked.

(3) Each application must be signed by the applicant or licensee or a person duly authorized to act for and on the applicant's or licensee's behalf.

(4) Each applicant for a specific license is required to have a permanent in-state office with a copy of all required records available for inspection by the Authority.

(5) An application for a license filed pursuant to the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter will be considered also as an application for licenses authorizing other activities for which licenses are required by the Act, provided that the application specifies the additional activities for which licenses are requested and complies with rules of the Authority and the US Nuclear Regulatory Commission as to applications for such licenses.

(6) Each new application for a radioactive material license must be accompanied by the fee prescribed by OAR 333-103-0010. Fees received by the Authority shall be refundable up to 10 calendar days if the application is withdrawn. No fee will be required to accompany an application for renewal or amendment of a license, except as provided in OAR 333-103-0010.

(7) An application for a license to receive and possess radioactive material for the conduct of any activity that the Authority has determined, pursuant to Subpart A of Part 51 of 10 CFR (Environmental Protection Regulations applicable to materials licensing), will significantly affect the quality of the environment, must be filed at least nine months prior to commencement of con-

struction of the plant or facility in which the activity will be conducted and must be accompanied by any Environmental Report required pursuant to Subpart A of 10 CFR Part 51.

(8) An application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either:

(a) Identify the source or device by manufacturer and model number as registered with the US Nuclear Regulatory Commission under 10 CFR Part 32.210 or with an Agreement State; or for a source or a device containing radium-226 or accelerator-produced radioactive material with a state under provisions comparable to 10 CFR Parts 32.210; or

(b) Contain the information identified in 10 CFR Part 32.210(c); or

(c) For sources or devices manufactured prior to October 23, 2012 that are not registered with the Nuclear Regulatory Commission or an Agreement State which the applicant is unable to provide all categories of information specified in 10 CFR Part 32.210(c) the applicant must provide:

(A) All available information identified in 10 CFR Part 32.210(c) concerning the source and if applicable the device; and

(B) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Information must include a description of the source or device, description of radiation safety features, intended use and associated operating experience and the results of a recent leak test:

(i) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 CFR Part 32.210(g)(1), the applicant may supply only the manufacturer, model number, and radionuclide and quantity; or

(ii) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

(9) As provided by OAR 333-102-0200, certain applications for specific licenses filed under this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning as follows:

(10)(a) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in 10 CFR 30.72, "Schedule C — Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," must contain either:

(A) An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials shall not exceed one rem effective dose equivalent or five rems to the thyroid; or

(B) An emergency plan for responding to a release of radioactive material.

(b) One or more of the following factors may be used to support an evaluation submitted under paragraph (10)(a)(A) of this rule:

(A) The radioactive material is physically separated so that only a portion could be involved in an accident;

(B) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(C) The release fraction in the respirable size range shall be lower than the release fraction shown in 10 CFR Part 30.72 (Schedule C — Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release) due to the chemical or physical form of the material;

(D) The solubility of the radioactive material shall reduce the dose received;

(E) Facility design or engineered safety features in the facility shall cause the release fraction to be lower than shown in 10 CFR Part 30.72;

(F) Operating restrictions or procedures shall prevent a release fraction as large as that shown in 10 CFR Part 30.72; or

(G) Other factors appropriate for the specific facility.

(c) An emergency plan for responding to a release of radioactive material submitted under paragraph (10)(a)(B) of this rule must include the following information:

(A) Facility description. A brief description of the licensee's facility and area near the site.

(B) Types of accidents. An identification of each type of radio-active materials accident for which protective actions may be needed.

(C) Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

(D) Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

(E) Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(F) Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

(G) Responsibilities. A brief description of the responsibilities of licensee personnel if an accident occurs, including identification of personnel responsible for promptly notifying offsite response organizations and the Authority; also responsibilities for developing, maintaining, and updating the plan.

(H) Notification and coordination. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee also must commit to notify the Authority immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

NOTE: These reporting requirements do not supersede or release licensees of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499 or other state or federal reporting requirements.

(I) Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the Authority.

(J) Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee can offer to fire, police, medical and other emergency personnel. The training must familiarize personnel with site-specific emergency procedures. Also, the training must thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

(K) Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

(L) Exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee must invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios must not be known to most exercise participants. The licensee must critique each exercise using individuals not having direct implementation responsibility

for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

(M) Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the byproduct material.

(N) An application from a medical facility, educational institution, or federal facility to produce Positron Emission Tomography (PET) radiopharmaceutical drugs for noncommercial transfer to licensees in its consortium authorized for medical use under 10 CFR Part 35 or division 116 of this chapter or equivalent Agreement State requirements shall include:

(i) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under 10 CFR Part 30 or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(ii) Evidence that the applicant is qualified to produce radiopharmaceutical drugs for medical use by meeting one of the criteria in 10 CFR 32.72(a)(2).

(iii) Identification of individual(s) authorized to prepare the PET radiopharmaceutical drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in OAR 333-116-0880 and 333-116-0910.

(iv) Information identified in 10 CFR Part 32.72(a)(3) on the PET radiopharmaceutical to be non-commercially transferred to members of its consortium.

(v) Each applicant for a license for byproduct material shall protect Safeguards Information against unauthorized disclosure in accordance with the requirements in 10 CFR Parts 73.21, 73.22 and 73.23 as applicable.

(d) The licensee must allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the Authority. The licensee must provide any comments received within the 60 days to the Authority with the emergency plan.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 20-2010, f. & cert. ef. 9-1-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15; PH 25-2016, f. 8-26-16, cert. ef. 9-1-16

333-102-0200
General Requirements for the Issuance of Specific Licenses

An application for a specific license, will be approved if:

(1) The application is for a purpose authorized by the Act;

(2) The applicant is qualified by training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to life or property;

(3) The applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property;

(4) The applicant satisfies any applicable special requirements contained in divisions 102, 105, 113, 115, 116, 117, or 121 of this chapter; and

(5) In the case of an application for a license to receive and possess radioactive material for the conduct of any activity which the Authority determines will significantly affect the quality of the environment, the Authority Manager or designee, before commencement of construction of the plant or facility in which the activity will be conducted, on the basis of information filed and evaluations made pursuant to Subpart A of Part 51 of 10 CFR, has concluded, after weighing the environmental, economic, technical, and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion must be grounds for denial of a license to receive and possess byproduct material in such plant or facility. As used in this rule, the term "commencement of construction" means any clearing of land, excavation, or other substantial action that can adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values. Upon a determination that an application meets the requirements of the Act, and the rules of the Authority, the Authority will issue a specific license authorizing the possession and use of radioactive material ("Radioactive Materials License").

(6) Financial assurance and recordkeeping for decommissioning following the specific requirements listed below:

(a) 10 CFR 30.35 and 30.36 for radioactive material that is not source or special nuclear material; or

(b) 10 CFR 40.36 for source material; or

(c) 10 CFR 70.25 for special nuclear material.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-102-0203
Definitions

The following definitions apply for Radioactive Material Licenses issued pursuant to this division and divisions 105, 113, 115, 117, and 121 of this chapter:

NOTE: Unless otherwise specified in this rule, the licenses described in this rule are limited by conditions of the radioactive materials license issued pursuant to OAR 333-102-0200, and other applicable rules in this chapter.

(1) "Analytical Leak Test" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(a), authorizing possession of environmental samples, sealed source leak-test, contamination wipe and samples for radioanalytical measurements. This license does not authorize collection of samples, or decommissioning or decontamination activities.

(2) "Assets" means anything of material value or usefulness. In the context of a materials license, assets include all existing capital, effects, possessions, and belongings and all probable future economic benefits obtained or controlled by a particular entity.

(3) "Basic License" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(b) authorizing the receipt, possession, use, transfer, and disposal of sources of radiation or radioactive materials incident to gauge service, teletherapy service, medical afterloader service, and other licensed service activities; pre-packaged waste pickup (not packaging), storage of materials prior to license termination, instrument quality control servicing or calibration (excluding activities authorized by 333-103-0010(2)(m)), or other minor activities not otherwise specified in these rules, such as authorization for "systems," as defined in these rules, pursuant to that definition.

(4) "Beneficiating" means subjecting a product to any process that can increase or concentrate any component (including the radioactive materials) to benefit the product.

(5) "Brachytherapy" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(c) authorizing the use of brachytherapy sources for in vivo application of radiation in accordance with 333-116-0420. Brachytherapy includes radioactive material sealed sources in seeds, needles, plaques, or other localized medical devices, but excludes remote afterloaders.

(6) "Broad Scope A" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(d), authorizing activities in 333-102-0900(1)(a), under the authority of a Radiation Safety Committee.

(7) "Broad Scope B" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(e) authorizing activities described in 333-102-0900(1)(b), under the authority of a Radiation Safety Officer.

(8) "Broad Scope C" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(f) authorizing activities described in 333-102-0900(1)(c), under the authority of an authorized user.

(9) "Commencement of construction" means taking any action defined as "construction" or any other activity at the site of a facility subject to the regulations in this division that has a reasonable nexus to radiological health and safety.

(10) "Construction" means the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to the regulations in this division that are related to radiological safety or security. The term "construction" does not include:

(a) Changes for temporary use of the land for public recreational purposes;

(b) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

(c) Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

(d) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this division;

(e) Excavation;

(f) Erection of support buildings (for example, construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

(g) Building of service facilities (for example, paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);

(h) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or

(i) Taking any other action that has no reasonable nexus to radiological health and safety.

(11) "Current assets" means cash or other assets or resources commonly identified as those which are reasonably expected to be realized in cash or sold or consumed during the normal operating cycle of the business.

(12) "Decontamination and Decommissioning" means:

(a) A facility specific license issued pursuant to OAR 333-103-0010(2)(w) authorizing activities that result in returning a site to its original pre-license condition prior to termination of licensed activities; and

(b) Activities performed pursuant to OAR 333-102-0335 on any portion of a site prior to license termination.

(13) "Diagnosis" means examination, determination, identification, study, or analysis of a medical condition.

(14) "Distribution" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(g), authorizing transfer or distribution (sale) of general or specific license radioactive material to persons granted a general license or issued a specific license, or, in the case of NARM, to persons exempt from the rules in this chapter.

(15) "Exempt Source" means radioactive material, exempt from the rules in this chapter.

(16) "Facility" means location of licensed activities under the direct control of licensee management. If a "facility," as used in this division, includes multiple separate addresses, the Authority may determine how the scope of licensed activities, pursuant to OAR 333-102-0190, 333-102-0300, 333-102-0305, 333-102-0315, 333-102-0320, or 333-102-0325, is authorized.

(17) "Fixed Gauge" means a source-specific license for measuring, gauging, or controlling devices pursuant to OAR 333-103-0010(2)(h). The fixed gauge license also includes X-ray & Hybrid Gauges pursuant to division 115 of this chapter that contain either an X-ray source or a radioactive sealed source.

(18) "General License" means a granted license, as opposed to an issued license, effective under these rules, to acquire, own, possess, use, or transfer radioactive material or a device that contains radioactive material.

(19) "General License Depleted Uranium" means the general license granted subject to receipt of the registration application pursuant to OAR 333-101-0007, and fee, pursuant to 333-103-0015, for depleted uranium used for shielding or counter weights and issued pursuant to 333-102-0106.

(20) "General License Device" means the general license for in vitro materials granted subject to receipt of the registration application pursuant to OAR 333-101-0007, and fee, pursuant to 333-103-0015, for measuring, gauging.

(21) "General License In Vitro Laboratory" means the general license granted by OAR 333-102-0130, subject to receipt of the registration application pursuant to 333-101-0007, and fee, pursuant to 333-103-0015, for in vitro materials granted a general license by 333-102-0130.

(22) "General License Source Material" means the general license granted for use and possession of source material pursuant to OAR 333-102-0101.

(23) "General License for Certain Devices and Equipment" means the general license granted for use and possession of devices consisting of not more than 500 microcuries of polonium-210 or not more than 50 millicuries of tritium (H-3) per device, pursuant to 10 CFR 31.3.

(24) "General License for Luminous Devices for Aircraft" means the general license granted for use and possession of devices containing not more than ten curies of tritium or not more than 300 millicuries of promethium-147.

(25) "General License for Ownership of Radioactive Material and Limits of Possession" means the general license granted to own material that is not necessarily possessed; conversely, material that is possessed is, by grant of general license, not necessarily owned, pursuant to the general license in OAR 333-102-0120.

(26) "General License for Calibration and Reference Sources" means the general license granted to possess not more than five microcuries (185 kBq) of americium-241, plutonium-238, plutonium-239, or radium-226, pursuant to the general license in OAR 333-102-0125.

(27) "General License for Ice Detection Devices" means the general license granted to possess not more than 50 microcuries (1.85 MBq) of strontium-90, pursuant to the general license in OAR 333-102-0135.

(28) "Generators and Kits" means "Imaging and Localization."

(29) "Healing Arts Specific License" means a specific license authorizing activities in division 116 of this chapter.

(30) "High Doserate Remote Afterloader" means a source-specific license issued pursuant to OAR 333-103-0010(2)(i) authorizing the use of sources in accordance with 333-116-0475, which may be either mobile or stationary, and which deliver a doserate in excess of two Gray (200 rad) per hour at the point or surface where the dose is prescribed. A device may be designated as being high, medium, or pulsed dose remote afterloader or mobile high, medium, or pulsed doserate remote afterloader.

(31) "Hybrid Gauge" means a fixed gauging device that contains both a sealed source and an X-ray source, pursuant to division 115 of this chapter.

(32) "In Vitro Laboratory" means a Healing Arts facility-specific license, under management of a physician or Healing Arts specialist, issued pursuant to OAR 333-103-0010(2)(k) authorizing the use of prepackaged radioactive materials in quantities greater than those authorized by the General License granted by 333-102-0130(2).

(33) Imaging and Localization means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(j) authorizing the use of generators and kits for nuclear medicine imaging and localization in accordance with 333-116-0320 or positron emission tomography studies in accordance with 333-116-0800 through 333-116-0880.

(34) "Industrial Radiography" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(l) authorizing activities in division 105 of this chapter.

(35) "Instrument Calibration" means a source-specific radioactive materials license issued pursuant to OAR 333-103-0010(2)(m) for sources of radiation used to calibrate instruments.

(36) "Investigational New Drug" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(n) authorizing the use of any investigational product or device approved by the US Food and Drug Administration (FDA) for human use research, diagnosis, or therapy, in accordance with the rules in this chapter.

(37) "Irradiator-Other" means an irradiator with greater than 10,000 curies (370 TBq) licensed pursuant to OAR 333-103-0010(2)(w) and 333-103-0010(7), designed to produce extremely high dose rates as authorized by division 121 of this chapter.

(38) "Irradiator Self-shielded or Other — Less than 10,000 Curies" means a source-specific license issued pursuant to OAR 333-103-0010(2)(o) authorizing self-shielded irradiators, including blood irradiators, panoramic irradiators, and converted teletherapy units, with less than 10,000 Ci (370 TBq) activity.

(39) "Liabilities" means probable future sacrifices of economic benefits arising from present obligations to transfer assets or provide services to other entities in the future as a result of past transactions or events.

(40) "Lot Tolerance Percent Defective" means, expressed in percent defective, the poorest quality in an individual inspection lot that can be accepted.

(41) "Low Doserate Remote Afterloader Device" means a Healing Arts source-specific license issued pursuant to OAR 333-103-0010(2)(b) authorizing devices 333-116-0475, which remotely deliver a doserate of less than two Gray (200 rad) per hour at the point or surface where the dose is prescribed.

(42) "Manufacturing or Compounding" means a facility-specific radioactive materials license issued pursuant to OAR 333-103-0010(2)(p) authorizing manufacture, fabrication, assembly, construction, combining, processing, concentrating, beneficiating, or processing items or products using or containing radioactive materials into a finished product containing radioactive material in accordance with applicable requirements in division 102 of this chapter.

(43) "Manufacturing or Compounding and Distribution" means activities performed as defined in sections (14) and (42) of this rule and require separate specific licenses for each activity.

(44) "Mobile Nuclear Medicine Service" means a facility-specific Healing Arts license issued pursuant to OAR 333-116-0120 authorizing the medical use of radioactive material at specified temporary locations.

(45) "Nationally Tracked Source" means a sealed source containing a quantity equal to or greater than Category 1 or 2 levels of any radioactive material listed in 10 CFR 20 Appendix E.

(46) "Naturally occurring radioactive material (NORM)" means radioactive material in the uranium or thorium decay series existing in nature in concentrations less than 0.05 percent source material.

(47) "Net working capital" means current assets minus current liabilities.

(48) "Net worth" means total assets minus total liabilities and is equivalent to owner's equity.

(49) "Neutron Howitzer" means a device that contains a sealed source containing Special Nuclear Material (see definition in OAR 333-100-0005) that generates neutrons that are used for analytical, teaching, or research purposes.

(50) "Neutron Production" denotes a process in which neutrons are produced, either by natural or artificial means.

(51) "NORM (no processing)" means a facility-specific license pursuant to OAR 333-103-0010(2)(r) authorizing possession, use, and transfer of NORM in accordance with division 117 of this chapter.

NOTE: NORM licenses authorize licensable quantities of radioactive material in the uranium or thorium decay series. Licensable quantities of NORM are derived from disposal limits in OAR chapter 345, division 50. Any material that contains NORM requires a specific license unless exempted in OAR chapter 345, division 50. Zircon sand is used as the NORM model for licensing purposes. Quantities of zircon sand in excess of 20,000 pounds in a year constitute a licensable quantity of NORM. NORM materials that are not zircon are based on the zircon model.

(52) "Nuclear Laundry" means a laundry facility designed specifically to clean or launder clothing contaminated with licensed radioactive materials. Nuclear Laundry facilities must have process and waste management control procedures to prevent reconcentrating of licensed materials in sewers, drains, premises, and the environment. Nuclear Laundry activities are authorized pursuant to OAR 333-103-0010(2)(w), "Radioactive Material Not Otherwise Specified Facility," see 333-102-0203(61).

(53) "Nuclear Pharmacy" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(s) for activities authorized by 333-102-0285 and the Oregon Board of Pharmacy rules, to compound Radiopharmaceutical and distribute (sell or transfer) to persons specifically licensed to receive such compounds or products.

NOTE: Nuclear Pharmacies, pursuant to policy provisions of chapter 345 division 50 may collect syringes containing residual licensed material from spent patient doses, since the syringe is considered to be a transport device under the administrative control of the pharmacy rather than the licensed material transferred as the dose. Residual licensed material may be considered either to be exempt pursuant to Table 1 of division 50 or under the authority of a division license if the receding licensee stores syringes for decay. In either case, the division license specifies which disposal method is being used by the pharmacy and licensee to avoid compatibility conflicts with division 50 requirements.

(54) "Other Measuring Device" means a source-specific license issued pursuant to OAR 333-103-0010(2)(t), authorizing analytical instruments, gas chromatograph electron capture detectors, and other non-portable analytical instruments, including those devices that contain multiple sources but are configured and used as a "system," in accordance with the definition in this rule.

NOTE: General license gas chromatograph detectors that formerly were granted a general license by OAR 333-102-0115, but which required a registration fee pursuant 333-103-0015(2)(b), now are subject to the specific license in 333-103-0010(2)(t).

(55) "Pool-type Irradiator" means an irradiator with greater than 10,000 curies (370 TBq) in which water provides the radiation shielding, authorized in accordance with division 121 of this chapter.

(56) "Portable Gauge" means a source-specific license issued pursuant to OAR 333-103-0010(2)(u) for sources used in devices that can be transported and used at temporary job sites.

NOTE: Any device that meets the definition of "portable gauge" and is transported or used at temporary job sites within the state of Oregon, requires an application for and issuance of an Oregon specific license subject to OAR 333-103-0010(2)(u).

(57) "Positron Emission Tomography" (PET) means a licensed healing arts activity authorized by OAR 333-116-0800 and included in the facility specific license issued pursuant to 333-103-0010(2)(j). PET nuclides, which are NARM, are subject to all Oregon rules.

(58) "Possession or Storage of Industrial Wastes Containing Radioactive Material" means activities subject to division 110 of this chapter for the production or storage of wastes that are exempt from division 50 of chapter 345 facility siting requirements, and were generated under a current NRC, Agreement State, or Licensing State specific radioactive materials license.

(59) "Possession or Storage of Uranium Tailings" means activities incident to uranium processing or milling operations resulting in the production of tailings.

(60) "Principal Activities" means activities authorized by the license that are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

(61) "Processing" means chemically or physically changing a licensed material from one physical form to another form or specie (for example, breaking an ore down into its components resulting in "tailings"; milling a raw licensed material and combining to form another product or material. See "Beneficiating"; "Manufacturing or Compounding").

(62) "Radiation Source" means source of radiation (see definition of "Source of radiation" in OAR 333-100-0005).

(63) "Radioactive Material Not Otherwise Specified Facility" means a license issued pursuant to OAR 333-103-0010(2)(w) authorizing activities that includes, but are not limited to, complex licensable activities such as facility decontamination and decommissioning, nuclear laundry activities, uranium mill tailings storage, storage of industrial wastes containing radioactive materials, large irradiator management, and other complex activities not otherwise specified in these rules.

(64) "Radioactive Materials License" means the document, pursuant to OAR 333-102-0300, issued after an application, pursuant to 333-102-0190, has been accepted as adequate, that specifies radioactive materials, use authorizations, safety procedures, and use locations.

(65) "Radiopharmaceutical Therapy" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(v) authorizing the use of Radiopharmaceutical for therapy in accordance with 333-116-0360.

(66) "Remote Afterloader" means a medical device that moves a sealed source to an interstitial (in vivo) location without exposing the practitioner to the radiation dose. Remote afterloader sources may be manipulated using computer software and engineering techniques.

(67) "Research & Development" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(x) authorizing research and development activities, as defined in 333-100-0005, but does not authorize additional specific sources of radiation, which must be licensed separately pursuant to 333-103-0010 and 333-103-0015.

(68) "Responsible Representative" means

(a) The person designated as having responsibility for general license device or general license material;

(b) The person management has selected to certify general license inventory; and

(c) The individual responsible to the Authority and to management to ensure that all regulatory elements are adequate.

(69) "Sealed Source/Device Evaluation" means the review of a licensee's prototype source or device prior to registration by the Nuclear Regulatory Commission in the Sealed Source and Device Catalog.

NOTE: The Authority no longer has authority to review sources or devices. All source or device reviews must be forwarded to the NRC for review. Authority to conduct device or source evaluations was rescinded by the NRC in 1998.

(70) "Site Area Emergency" means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

(71) "Sealed Sources for Diagnosis" means a Healing Arts source-specific license issued pursuant to OAR 333-103-0010(2)(y) authorizing the use of sealed sources for diagnosis in accordance with 333-116-0400.

(72) "Special Nuclear Material" means:

(a) Plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the NRC, pursuant to the provisions of section 51 of the act, determines to be special nuclear material, but does not include source material; or

(b) Any material artificially enriched by any of the foregoing but does not include source material.

(73) "Specific License Radioactive Material" means radioactive material that requires authorization in a specific license document pursuant to OAR 333-102-0075(2) where materials must be annotated on the specific license, and validated with a specific license fee pursuant to 333-103-0010(2)(a) through 333-103-0010(2)(hh) (see "Radioactive Materials License").

(74) "System," as used in this division, means multiple separate (individual) sources of radiation (sealed radioactive sources), which together, rather than independently, achieve a desired functionality. Such "system" is subject to one specific license fee or general license registration fee, as the case may be.

(75) "Tangible Net Worth" means the tangible assets that remain after deducting liabilities; such assets may not include intangibles such as goodwill and rights to patents or royalties.

(76) "Teletherapy" means a Healing Arts source-specific license issued pursuant to OAR 333-103-0010(2)(cc) authorizing teletherapy procedures in accordance with OAR 333-116-0480. This license also includes other high dose rate external beam therapy devices such as the "gamma knife."

(77) "Temporary Job Site" means any location, where specific license material is used that is either:

(a) Not the specific location of the licensee if an in-state licensee; or

(b) Any location in the state if an out-of-state specific licensee pursuant to a specific radioactive materials license.

NOTE: Persons authorized for temporary jobsites in Oregon must have a specific license for such activities.

(78) "Therapy" means a process that is meant to be restorative, promotes healing, or is beneficial to a patient in a healing arts context.

(79) "Unique" means a specific license issued pursuant to OAR 333-103-0010(2)(dd) to agencies in the Oregon Health Authority.

(80) "Uptake and Dilution" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(ee) authorizing activities in 333-116-0300 for uptake, dilution, and excretion studies.

(81) "Use and Possession of Source Material " means a facility-specific radioactive materials license issued pursuant to OAR 333-103-0010(2)(z) to possess, use, process, or transfer source material, as defined in OAR 333-100-0005, in quantities greater than general license quantities or in concentrations greater than 0.05 percent source material.

NOTE: This definition was amended to avoid confusion between the definition of "source material" in division 100 of this chapter and the specific license (billable object) in division 103 of this chapter.

(82) "Use of Xenon Gas" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(ff) authorizing the use of Xe-133 for diagnosis pursuant to 333-116-0280.

(83) "Waste Packaging" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(gg), authorizing packaging, collection, storage, and transfer of radioactive waste. This specific license does not authorize storage of radioactive wastes, but does authorize temporary job sites.

(84) "Well Logging" means a license issued pursuant to OAR 333-103-0010(2)(hh) authorizing the possession, use, transfer, or disposal of sources of radiation used for well logging activities authorized by division 113 of this chapter.

NOTE: Unless specifically authorized in this rule or in a radioactive materials license that authorizes temporary job sites, specific licenses must be used only at one authorized site.

[ED. NOTE: Appendices referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1995, f. & cert. ef. 4-26-95; HD 2-1995(Temp), f. & cert. ef. 7-11-95; HD 4-1995, f. & cert. ef. 9-8-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 11-2011, f. & cert. ef. 10-27-11; PH 4-2013, f. & cert. ef. 1-29-13; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-102-0235

Requirements for License to Manufacture, or Initially Transfer Radioactive Material Contained in Devices Granted a General License Under OAR 333-102-0115

(1) An application for a specific license to manufacture, or initially transfer devices containing radioactive material, excluding

special nuclear material, to persons granted a general license by OAR 333-102-0115 or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State will be approved if:

(a) The applicant satisfies the general requirements of OAR 333-102-0200;

(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(A) The device can be safely operated by persons not having training in radiological protection;

(B) Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device; and it is unlikely that any person will receive in one year a dose in excess of ten percent of the annual limits specified in OAR 333-120-0100; and

(C) Under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any person may receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column IV of the table in 10 CFR Part 32.24:

(i) Whole body, head and trunk, active blood-forming organs, gonads, or lens of eye 150 mSv (15 rem);

(ii) Hands and forearms, feet and ankles, localized areas of skin averaged over areas no larger than one square centimeter two Sv (200 rem);

(iii) Other organs 500 mSv (50 rem).

(c) Each device bears a durable, legible, clearly visible label or labels approved by the Authority, which contain in a clearly identified and separate statement:

(A) Instructions and precautions necessary to assure safe installation, operation and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

(B) The requirements, or lack of requirement, for leak testing, or for testing of any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

(C) The information called for in the following statement in the same or substantially similar form:

> The receipt, possession, use and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label must be maintained on the device in a legible condition. Removal of this label is prohibited.
>
> CAUTION — RADIOACTIVE MATERIAL
>
> _____
>
> (Name of manufacturer or initial transferor)

(D) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, "Caution-Radioactive Material," the radiation symbol described in OAR 333-120-0400, and the name of the manufacturer or initial distributor.

(E) Each device meeting the criteria of OAR 333-102-0115(9)(a), bears a permanent label, such as being embossed, etched, stamped, or engraved, affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in OAR 333-120-0400.

(F) The device has been registered in the Sealed Source and Device Registry

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or both, the applicant must include in this application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices, and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Authority will consider information that includes, but is not limited to:

(a) Primary containment (source capsule);

(b) Protection of primary containment;

(c) Method of sealing containment;

(d) Containment construction materials;

(e) Form of contained radioactive material;

(f) Maximum temperature withstood during prototype tests;

(g) Maximum pressure withstood during prototype tests;

(h) Maximum quantity of contained radioactive material;

(i) Radiotoxicity of contained radioactive material; and

(j) Operating experience with identical devices or similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee under OAR 333-102-0115, or under equivalent rules of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant must include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and the bases for these estimates. The submitted information must demonstrate that performance of this activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of ten percent of the annual limits specified in OAR 333-120-0100.

(4) Prior to transfer of a device to a person granted a general license by OAR 333-102-0115(1), the licensee must:

(a) Furnish a copy of the general license contained in OAR 333-102-0115 to each person to whom the licensee directly, or through an intermediate person, transfers radioactive material in a device for use pursuant to the general license contained in 333-102-0115;

(b) Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission, Agreement State or Licensing State's rules equivalent to OAR 333-102-0115. Alternatively, a copy of the general license contained in 333-102-0115 must be furnished to each person to whom directly, or through an intermediate person, is transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission, the Agreement State or the Licensing State. If a copy of the general license in 333-102-0115 is furnished to such person, it must be accompanied by a note explaining that the use of the device is regulated by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State under requirements substantially the same as those in 333-102-0115;

(c) Report to the Authority all transfers of such devices to persons for use under the general license in OAR 333-102-0115. Such report must identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the Authority and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report must include identification of each intermediate person by name, address, contact and relationship to the intended user. If no transfers have been made to persons granted a general license by 333-102-0115 during the reporting period, the report must so indicate. The report must cover each calendar quarter and must be filed within 30 days after the end of each quarter;

(d) Furnish reports to other agencies:

(A) Report to the U.S. Nuclear Regulatory Commission all transfers of such devices to persons for use under the U.S. Nuclear Regulatory Commission general license in section 31.5 of 10 CFR Part 31. Reports must be submitted on the NRC form "Transfers of Industrial Devices Report" or on a clear and legible report containing all of the data required by the form. The required information includes:

(i) The identity of each general licensee by name and address;

(ii) The name and phone number of the person designated by the general licensee to be responsible for ensuring compliance with the appropriate regulations and requirements;

(iii) The date of transfer;

(iv) The type, model number, and serial number of the device transferred; and

(v) The quantity and type of byproduct material contained in the device.

(B) If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report must include the same information for each intermediate person, and clearly designate that person as an intermediate person.

(C) If the device transferred replaced another returned by the general licensee, report also the type, model number, and serial number of the one returned.

(D) If no transfers have been made to persons generally licensed under 10 CFR 31.5 or OAR 333-102-0115 during the reporting period, the report must so indicate.

(E) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(F) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(e) Report to the responsible Agreement or Licensing State Authority all transfers of such devices to persons for use under a general license in an Agreement State's regulations equivalent to OAR 333-102-0115. Such reports must identify all of the information in 333-102-0235(4)(d) of this rule, including each general licensee by name and address, an individual by name or position who may constitute a point of contact between the Authority and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report must include identification of each intermediate person by name, address, contact and relationship to the intended user. The report must be submitted within 30 days after the end of each calendar quarter in which such device is transferred to the person granted a general license;

(f) If no transfers have been made to U.S. Nuclear Regulatory Commission's licensees during the reporting period, this information must be reported to the U.S. Nuclear Regulatory Commission;

(g) If no transfers have been made to persons granted a general license within a particular Agreement State during the reporting period, this information must be reported to the responsible Agreement State Agency upon request of the Authority;

(h) Keep records showing the name, address and the point of contact for each general licensee to whom directly, or through an intermediate person is transferred radioactive material in devices for use pursuant to the general license provided in OAR 333-102-0115 or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. The records must show the date of each transfer, the isotope and the quantity of radioactive material in each device transferred, the identity of any intermediate person and compliance with the reporting requirements of subsection (4)(h) of this rule. Records required by this rule must be maintained for a period of three years following the estimated useful life of the device or the date of final disposition, if known;

(i) Furnish a list of the services that only can be performed by a specific licensee, and information on acceptable disposal options, including estimated costs of disposal, to each person to whom he directly, or through an intermediate person, transfers radioactive material in a device for use under the general license granted in OAR 333-102-0115;

(j) Furnish the name, address, and phone number of the contact at the Agreement State regulatory agency from which additional information may be obtained. If a copy of the general license in OAR 333-102-0115 is furnished to such person, it must be accompanied by a note explaining that use of the device is regulated by the Agreement State.

(k) Label each device transferred if more than one year after the effective date of this rule in accordance with the labeling requirements in 10 CFR Part 32.51(a)(3) through (5).

(l) If a notification of bankruptcy has been made under 10 CFR Part 30.34(h) or the license is to be terminated, provide, upon request, to the NRC and to any appropriate Agreement State, records of final disposition required under 10 CFR Part 32.52(c).

(5) License Conditions.

(a) If a device containing radioactive material is to be transferred for use under the general license contained in OAR 333-102-0115, each person that is licensed under this rule must provide the information specified in this section to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(A) A copy of the general license contained in OAR 333-102-0115; if 333-102-0115(4)(b) through (d) or 333-102-0115(8) do not apply to the particular device, those sections may be omitted;

(B) A copy of OAR 333-102-0115, 333-100-0055, 333-100-0057, 333-120-0700 and 333-120-0710;

(C) A list of the services that can only be performed by a specific licensee;

(D) Information on acceptable disposal options including estimated costs of disposal; and

(b) If radioactive material is to be transferred in a device for use under an equivalent general license of an Agreement State, each person that is licensed under this rule must provide the information specified in this section to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(A) A copy of the Agreement State's regulations equivalent to OAR 333-102-0115, 333-100-0055, 333-100-0057, 333-120-0700 and 333-120-0710 or a copy of 10 CFR Secs. 31.5, 31.2, 30.51, 20.2201, and 20.2202. If a copy of the Nuclear Regulatory Commission regulations is provided to a prospective general licensee in lieu of the Agreement State's regulations, it must be accompanied by a note explaining that use of the device is regulated by the Agreement State. If certain sections of the regulations do not apply to the particular device, those sections may be omitted;

(B) A list of the services that can only be performed by a specific licensee;

(C) Information on acceptable disposal options including estimated costs of disposal; and

(D) The name or title, address, and phone number of the contact at the Agreement State regulatory agency or the Nuclear Regulatory Commission from which additional information may be obtained.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

Special Requirement for a Specific License to Manufacture, Assemble, Repair or Distribute Commodities, Products or Devices Which Contain Radioactive Material

333-102-0245
Introduction of Radioactive Material in Exempt Concentrations into Products or Materials, and Transfer of Ownership or Possession: Requirements for License

An application for a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another and the transfer of ownership or possession of the product or material containing the radioactive material: will be approved if the applicant:

(1) Satisfies the general requirements specified in OAR 333-102-0200, provided however, that the requirements of OAR 333-102-0200(2) and (3) do not apply to an application for a license to introduce byproduct material into a product or material owned by or in the possession of the licensee or another and the transfer of ownership or possession of the product.

(2) Provides a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material, and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioiosotopes in the product or material at the time of transfer.

(3) Provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in 10 CFR Part 30.70 Schedule A, that reconcentrating of the radioactive material in concentrations exceeding those in 10 CFR Part 30.70 Schedule A is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(4) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under 10 CFR Part 30.14 or equivalent regulations of an Agreement State, except in accordance with a license issued pursuant to 10 CFR Part 32.11, or the general license provided in 10 CFR Part 150.20 (reciprocity).

(5) Each person licensed under this rule must maintain records of transfer of material and file reports with the Authority as required in OAR 333-102-0247.

(6) Each licensee who manufactures a nationally tracked source shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10

333-102-0247
Records and Material Transfer Reports

Each person licensed under OAR 333-102-0235 to initially transfer devices to generally licensed persons must comply with the requirements of this rule.

(1) The licensee must report on a quarterly basis all transfers of devices to persons for use under the general license in OAR 333-102-0115 and all receipts of devices from persons licensed under 333-102-0115 to the Authority.

(a) The required information for transfers to general licensees includes:

(A) The identity of each general licensee by name and mailing address for the location of use. If there is no mailing address for the location of use, an alternate address for the general licensee must be submitted along with information on the actual location of use;

(B) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(C) The date of transfer;

(D) The type, model number, and serial number of the device transferred; and

(E) The quantity and type of byproduct material contained in the device.

(b) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(c) For devices received from an OAR 333-102-0115 general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(d) If the licensee makes changes to a device possessed by an OAR 333-102-0115 general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(e) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(f) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(g) If no transfers have been made to or from persons generally licensed under OAR 333-102-0115 during the reporting period, the report must so indicate.

(2) The licensee must report all transfers of devices to persons for use under a general license in an Agreement State's regulations that are equivalent to OAR 333-102-0115 and all receipts of devices from general licensees in the Agreement State's jurisdiction to the responsible Agreement State Agency.

(a) The required information for transfers to general licensees includes:

(A) The identity of each general licensee by name and mailing address for the location of use. If there is no mailing address for the location of use, an alternate address for the general licensee must be submitted along with information on the actual location of use.

(B) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(C) The date of transfer;

(D) The type, model number, and serial number of the device transferred; and

(E) The quantity and type of byproduct material contained in the device.

(b) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(c) For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(d) If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(e) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(f) The report must clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.

(g) If no transfers have been made to or from a particular Agreement State during the reporting period, this information must be reported to the responsible Agreement State Agency upon request of the Authority.

(3) The licensee must maintain all information concerning transfers and receipts of devices that supports the reports required by this section. Records required by this section must be maintained in accordance with OAR 333-100-0057.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-102-0250
Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under a General License

An application for a specific license to manufacture or distribute radioactive material for use under the general license specified in OAR 333-102-0130 or equivalent may be approved if:

(1) The applicant satisfies the general requirements specified in OAR 333-102-0200.

(2) The radioactive material is to be prepared for distribution in prepackaged units of:

(a) Carbon-14 in units not exceeding ten microcuries (370 kBq) each;

(b) Cobalt-57 in units not exceeding ten microcuries (370 kBq) each;

(c) Hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each;

(d) Iodine-125 in units not exceeding ten microcuries (370 kBq) each;

(e) Mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each;

(f) Iodine-131 in units not exceeding ten microcuries (370 kBq) each;

(g) Iron-59 in units not exceeding 20 microcuries (740 kBq) each;

(h) Selenium-75 in units not exceeding ten microcuries (370 kBq) each;

(i) Cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries) each.

(3) Each prepackaged unit bears a durable, clearly visible label:

(a) Identifying the radioactive contents as to chemical form and radionuclide and indicating that the amount of radioactivity does not exceed ten microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57 or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each or colbalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries); and

(b) Displaying the radiation caution symbol described in OAR 333-120-0400 and the words, CAUTION, RADIOACTIVE MATERIAL and Not for Internal or External Use in Humans or Animals.

(4) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(a) This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation there from, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of manufacturer

(b) This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation there from, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a Licensing State.

_____
Name of manufacturer

(5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements in OAR 333-120-0500.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 20-2010, f. & cert. ef. 9-1-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 4-2013, f. & cert. ef. 1-29-13

333-102-0255
Licensing the Distribution of Radioactive Material in Exempt Quantities

(1) An application for a specific license to distribute NARM to persons exempted from these rules pursuant to OAR 333-102-0035 will be approved if:

(a) The radioactive material is not contained in any food, beverage, cosmetic, drug or other commodity designed for ingestion or inhalation by, or application to, a human being;

(b) The radioactive material is in the form of processed chemical elements, compounds or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product or device intended for commercial distribution; and

(c) The applicant submits copies of prototype labels and brochures and the Authority approves such labels and brochures.

(2) The license issued under this rule is subject to the following conditions:

(a) No more than ten exempt quantities may be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions must not exceed unity;

(b) Each exempt quantity must be separately and individually packaged. No more than ten such packaged exempt quantities must be contained in any outer package for transfer to persons exempt pursuant to OAR 333-102-0035. The outer package must be such that the dose rate at the external surface of the package does not exceed 0.5 millirem (5 microSv) per hour;

(c) The immediate container of each quantity or separately packaged fractional quantity of radioactive material must bear a durable, legible label which:

(A) Identifies the radionuclide and the quantity of radioactivity; and

(B) Bears the words Radioactive Material.

(d) In addition to the labeling information required by subsection (2)(c) of this rule, the label affixed to the immediate container, or an accompanying brochure, must:

(A) State that the contents are exempt from Licensing State requirements;

(B) Bear the words, Radioactive Material — Not for Human Use — Introduction into Foods, Beverages, Cosmetics, Drugs or Medicinals or into Products Manufactured for Commercial Distribution is Prohibited — Exempt Quantities Should Not Be Combined; and

(C) Set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage and disposal of the radioactive material.

(3) Each person licensed under this rule must maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under OAR 333-102-0035 or the equivalent rules of any Agreement State or Licensing State and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license must be filed with the Authority. Each report must cover the year ending June 30, and must be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to this rule during the reporting period, the report must so indicate.

NOTE: Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity or other product containing byproduct material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-102-0260
Licensing the Incorporation of Naturally Occurring and Accelerator-Produced Radioactive Material into Gas and Aerosol Detectors

An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under OAR 333-102-0025 will be approved if the application satisfies requirements equivalent to those contained in section 32.26 of 10 CFR Part 32. The maximum quantity of radium-226 in each device must not exceed 0.1 microcurie (3.7 kBq).

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-102-0265
Special Requirements for the Manufacture, Assembly or Repair of Luminous Safety Devices for Use in Aircraft

An application for a specific license to manufacture, assemble or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons granted a general license by OAR 333-102-0110 will be approved if:

(1) The applicant satisfies the general requirements specified in OAR 333-102-0200; and

(2) The applicant satisfies the requirements of sections 32.53, 32.54, 32.55, 32.56, 32.101, and 32.110 of 10 CFR Part 32 or their equivalent.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

333-102-0270
Special Requirements for License to Manufacture Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Granted a General License by OAR 333-102-0125

An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons granted a general license by OAR 333-102-0125 will be approved if:

(1) The applicant satisfies the general requirement of OAR 333-102-0200; and

(2) The applicant satisfies the requirements of sections 32.57, 32.58, 32.59, and 32.102 of 10 CFR Part 32 and section 70.39 of 10 CFR Part 70 or their equivalent.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

333-102-0275
Licensing the Manufacture and Distribution of Ice Detection Devices

An application for a specific license to manufacture and distribute ice detection devices to persons granted a general license by OAR 333-102-0135 will be approved if:

(1) The applicant satisfies the general requirements of OAR 333-102-0200;

(2) The criteria of sections 32.61, 32.62, 32.103, and 32.110 of 10 CFR Part 32 are met.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

333-102-0285
Manufacture, Preparation, or Transfer for Commercial Distribution of Radiopharmaceutical Drugs Containing Byproduct Material for Medical Use Under Division 116

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radiopharmaceutical drugs containing radioactive material for use by persons authorized pursuant to division 116 of this chapter may be approved if:

(a) The applicant satisfies the general requirements specified in OAR 333-102-0200;

(b) The applicant submits evidence that the applicant is at least one of the following:

(A) Registered or licensed with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

(B) Registered or licensed with a state agency as a drug manufacturer;

(C) Licensed as a pharmacy by a state Board of Pharmacy;

(D) Operating as a nuclear pharmacy within a federal medical institution; or

(E) A Positron Emission Tomography (PET) drug production facility registered with a state agency.

(c) The applicant submits information on the radionuclide, chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radiopharmaceutical drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radiopharmaceutical drugs by medical use licensees; and

(d) The applicant satisfies the following labeling requirements:

(A) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radiopharmaceutical drug to be transferred for commercial distribution. The label must include the radiation symbol and the words CAUTION, RADIOACTIVE MATERIAL or DANGER, RADIOACTIVE MATERIAL; the name of the radiopharmaceutical drug or its abbreviation; and the quantity of radioactivity at a spec-

ified date and time. For radiopharmaceutical drugs with a half-life greater than 100 days, the time may be omitted.

(B) A label is affixed to each syringe, vial, or other container used to hold a radiopharmaceutical drug to be transferred for commercial distribution. The label must include the radiation symbol and the words CAUTION, RADIOACTIVE MATERIAL or DANGER, RADIOACTIVE MATERIAL and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(2) A licensee described by paragraphs (1)(b)(C) or (D) of this rule:

(a) May prepare radiopharmaceutical drugs for medical use, as defined in OAR 333-116-0020, provided that the radiopharmaceutical drug is prepared either by an authorized nuclear pharmacist, as specified in subsections (2)(b) and (2)(d) of this rule, or an individual under the supervision of an authorized nuclear pharmacist as specified in OAR 333-116-0100.

(b) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(A) This individual qualifies as an authorized nuclear pharmacist as defined in OAR 333-116-0020;

(B) This individual meets the requirements specified in OAR 333-116-0910, 333-116-0760, 333-116-0915 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(C) This individual is designated as an authorized nuclear pharmacist in accordance with subsection (2)(d) of this rule.

(c) The actions authorized in subsections (2)(a) and (2)(b) of this rule are permitted in spite of more restrictive language in license conditions.

(d) May designate a pharmacist (as defined in OAR 333-116-0020) as an authorized nuclear pharmacist if:

(A) The individual was a nuclear pharmacist preparing only radiopharmaceutical drugs containing accelerator-produced radioactive material; and

(B) The individual practiced at a pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the Nuclear Regulatory Commission.

(e) Shall provide to the Authority a copy of:

(A) Each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in OAR 333-116-0910 with the written attestation signed by a preceptor as required by OAR 333-116-0680(2)(b); or

(B) The Commission or Agreement State license; or

(C) Commission master materials licensee permit; or

(D) The permit issued by a licensee or Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

(E) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

(F) A copy of the state pharmacy licensure or registration no later than 30 days after the date that the licensee allows pursuant to paragraphs (2)(b)(A) and (2)(b)(C) of this rule, which allows the individual to work as an authorized nuclear pharmacist.

(3) A licensee shall possess and use instrumentation to measure the radioactivity of radiopharmaceutical drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radiopharmaceutical drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(a) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument and make adjustments when necessary; and

(b) Check each instrument for constancy and proper operation at the beginning of each day of use.

(4) Nothing in this rule relieves the licensee from complying with applicable FDA, other federal and state requirements governing radiopharmaceutical drugs.

NOTE: Although the Authority does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radio pharmaceuticals containing radioactive material as a part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material, who desires to have the reagent kits approved by the Authority for use by persons licensed for medical use pursuant to OAR chapter 333, division 116 or by persons authorized under a group license, or equivalent, by the U.S. Nuclear Regulatory Commission or any other Agreement State, may submit the pertinent information specified in this rule.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 20-2010, f. & cert. ef. 9-1-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 4-2013, f. & cert. ef. 1-29-13; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-102-0290

Manufacture and Distribution of Sources or Devices Containing Byproduct Material for Medical Use

(1) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed pursuant to division 116 of this chapter for use as a calibration, transmission, or reference source, or for the uses listed in OAR 333-116-0400, 333-116-0420, 333-116-0480 and 333-116-0485 will be approved if:

(a) The applicant satisfies the general requirements in OAR 333-102-0200.

(b) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(A) The radioactive material contained, its chemical and physical form and amount;

(B) Details of design and construction of the source or device;

(C) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;

(D) For devices containing radioactive material, the radiation profile of a prototype device;

(E) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;

(F) Procedures and standards for calibrating sources and devices;

(G) Legend and methods for labeling sources and devices as to their radioactive content; and

(H) Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device. Provided, that instructions that are too lengthy for such a label may be summarized on the label and printed in detail on a brochure that is referenced on the label.

(c) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, date of assay and a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the (name of source or device) to persons licensed to use radioactive material identified in OAR 333-116-0190, 333-116-0400, or 333-116-0420, as appropriate, and to persons who hold an equivalent license issued by an Agreement State or the US Nuclear Regulatory Commission. However, labels worded in accordance with requirements that were in place on March 30, 1987 may be used until March 30, 1989.

(d) The source or device has been registered in the Sealed Source and Device Registry.

(2) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months:

(a) The applicant must include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and

(b) In determining the acceptable interval for test of leakage of radioactive material, the Authority will consider information that includes, but is not limited to:

(A) Primary containment or source capsule;

(B) Protection of primary containment;

(C) Method of sealing containment;

(D) Containment construction materials;

(E) Form of contained radioactive material;

(F) Maximum temperature withstood during prototype tests;

(G) Maximum pressure withstood during prototype tests;

(H) Maximum quantity of contained radioactive material;

(I) Radiotoxicity of contained radioactive material; and

(J) Operating experience with identical sources or devices similarly designed and constructed sources or devices.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-102-0293

Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications

(1) An application for a specific license to manufacture industrial products or devices containing depleted uranium for use pursuant to OAR 333-102-0106 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

(a) The applicant satisfies the general requirements specified in OAR 333-102-0200;

(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses and potential hazards of the industrial product or device to provide reasonable assurance that possession, use or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of ten percent of the limits specified in OAR 333-120-0100; and

(c) The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of an industrial product or device whose unique benefits are questionable, the Authority will approve an application for a specific license under this rule only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The Authority may deny any application for a specific license under this rule if the end use(s) of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to section (1) of this rule must:

(a) Maintain the level of quality control required by the license in the manufacture of the industrial product or device; and in the installation of the depleted uranium into the product or device;

(b) Label or mark each unit to:

(A) Identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium and the quantity of depleted uranium in each product or device; and

(B) State that the receipt, possession, use and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an Agreement State.

(c) Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: Depleted Uranium.

(A) Furnish a copy of the general license contained in OAR 333-102-0106 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in 333-102-0106; or

(B) Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to OAR 333-102-0106 and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in 333-102-0106 to each person to whom depleted uranium in a product or device is transferred for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in 333-102-0106.

(d) Report to the Authority all transfers of industrial products or devices to persons for use under the general license in OAR 333-102-0106. Such report must identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the Authority and the general licensee, the type and model number of device transferred and the quantity of depleted uranium contained in the product or device. The report must be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons granted a general license by OAR 333-102-0106 during the reporting period, the report must so indicate.

(e) Report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in section 40.25 of 10 CFR Part 40.

(A) Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to OAR 333-102-0115 for use under a general license in that state's regulations equivalent to 333-102-0106.

(B) Such report must identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the Authority and the general licensee, the type and model number of the device transferred and the quantity of depleted uranium contained in the product or device. The report must be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person.

(C) If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information must be reported to the U.S. Nuclear Regulatory Commission.

(f) If no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information must be reported to the responsible Agreement State Agency upon the request of that Agency.

(g) Keep records showing the name, address and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in OAR 333-102-0101(4) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records must be maintained until inspection

by the Authority and must show the date of each transfer, the quantity of depleted uranium in each product or device transferred and compliance with the report requirements of section (9) of this rule.

(h) Licensees required to submit emergency plans by OAR 333-102-0190(10) must follow the emergency plan approved by the Commission. The licensee may change the plan without Commission approval if the changes do not decrease the effectiveness of the plan. The licensee must furnish the change to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease the effectiveness of the approved emergency plan may not be implemented without application to and prior approval by the Authority.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-102-0297
Sealed Source or Device Evaluation

No sealed source or device containing radioactive material may be authorized on a specific license or general license until radiation safety information for that sealed source or device has been evaluated by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-102-0300
Issuance of Specific Licenses

(1) Upon a determination that an application meets the requirements of the Act and these rules, the Authority shall issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(2) The Authority may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to this division as it deems appropriate or necessary in order to:

(a) Minimize danger to public health and safety or property;

(b) Require such reports and the keeping of such records and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(c) Prevent loss or theft of material subject to this division.

(3) Whenever the Authority denies an application for a new license or a license renewal, the Authority shall notify the applicant in writing stating the grounds for denial. Upon denial, the applicant may request a hearing pursuant to OAR 333-102-0345.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 24-2014, f. & cert. ef. 8-15-14

333-102-0305
Specific Terms and Conditions of License

(1) Each license issued pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120, 121 and 124 of this chapter are subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations and orders of the Authority.

(2) No license issued or granted pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter nor any right may be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Authority, after securing full information, shall find that the transfer is in accordance with the provisions of the Act, and shall give its consent in writing.

(3) An application for transfer of license must include:

(a) The identity, technical and financial qualification of the proposed transferee; and

(b) Financial assurance for decommissioning as required by 10 CFR Part 30.35.

(4) Each person licensed by the Authority pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter must confine the use and possession of the radioactive material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter shall carry with it the right to receive, acquire, own, and possess radioactive material. Preparation for shipment and transport of radioactive material must be in accordance with the provisions of division 118 of this chapter.

(5) Each license issued pursuant to the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter shall be deemed to contain the provisions set forth in section 183b.-d., inclusive, of the Atomic Energy Act of 1954, as amended, whether or not these provisions are expressly set forth in the license.

(6) The Authority may incorporate, in any license issued pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter, at the time of issuance, or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material as it deems appropriate or necessary in order to:

(a) Promote the common defense and security;

(b) Protect health or to minimize danger to life or property;

(c) Protect restricted data; and

(d) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and regulations thereunder.

(7) Licensees required to submit emergency plans by OAR 333-102-0190(10) must follow the emergency plan approved by the Authority. The licensee may change the approved plan without Authority approval only if the changes do not decrease the effectiveness of the plan. The licensee must furnish the change to the Authority and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the Authority.

(8) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators must test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85, respectively, in accordance with OAR 333-116-0330. The licensee must record the results of each test and retain each record for three years after the record is made.

(9)(a) Each general licensee subject to the registration requirement in OAR 333-101-0007 and each specific licensee must notify the Authority in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(A) The licensee;

(B) An entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

(C) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

(b) This notification must indicate:

(A) The bankruptcy court in which the petition for bankruptcy was filed; and

(B) The date of the filing of the petition.

(10) Sealed sources or detector cells containing licensed material must not be opened or sources removed from source holders or detector cells by the licensee.

(11) No licensee may acquire licensed radioactive material in a sealed source or in a device that contains a sealed source unless the source or device has been registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.

(12) Any sealed source fabricated by a licensee must be registered, inspected, and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source in accordance with requirements in 10 CFR 32.210.

(13) Each licensee must conduct a physical inventory at intervals not to exceed six months to account for all radioactive material received and possessed by licensee. Inventories must include the types and quantities of radioactive material, location of materials, date of receipt, and the date of the inventory; and for sealed sources, the inventory must include the types and quantities of sealed sources, sealed source manufacturer, model number, serial number, date of receipt, condition of sealed sources, and the date of the inventory. Records of the inventories required by this section must be kept until inspection by the Authority.

(14) Each licensee must transport radioactive material or deliver radioactive material to a carrier for transport in accordance with the provisions of Parts 170 through 189 of Title 49, Code of Federal Regulations and in accordance with division 118 of this chapter, "Transportation of Radioactive Material."

(15) Each licensee possessing a device licensed pursuant to OAR 333-103-0010(2)(h) must perform an inspection of all devices at intervals not to exceed six months. Inspections must include condition of labeling and posting of each radiation device, and corrective actions taken if any; condition of shutter operation, if applicable, of each device, and corrective actions taken if any; and location of each device. Records of the inspections required by this section must be kept until inspection by the Authority.

(16) No licensee may open or remove radioactive material from sealed sources or detector cells containing licensed radiation sources.

(17) No person may repair, modify, dismantle, or effect any change in licensed devices or radiation sources, nor modify nor alter labels affixed to licensed devices by the manufacturer

(18) Installation, initial radiation survey, relocation, removal from service, maintenance, and repair of fixed gauging devices containing radioactive sealed sources, and installation, replacement, and disposal of sealed sources must be performed only by persons specifically authorized by the Authority, the U.S. Nuclear Regulatory Commission, or another Agreement state to perform such services. Records of all surveys must be maintained for inspection by the Radiation Protection Services section.

(19) If the licensee has previously determined that monitoring for internal exposure pursuant to OAR 333-120-0130, 333-120-0210, or 333-120-0320 is required, the data and results of this evaluation must be placed in the worker's exposure records and included the worker's Oregon Form Z report.

(20) Testing for leakage or contamination of sealed sources must be in accordance with requirements in OAR 333-120-0460. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source or detector cell received from another person must not be put into use until tested.

(21) Detector cells must be used only in conjunction with a properly operating temperature control mechanism that prevents foil temperatures from exceeding manufacturer's specifications. Exhaust from detector cells must be vented to keep exposures to personnel and the public as low as reasonably achievable pursuant to OAR 333-120-0180.

(22) Licensees who possess sealed sources used for testing at field sites must possess at such locations transport documents, a current copy of the specific radioactive materials license, specific license validation certificates, the current leak test certificate, and the licensee's operating and emergency procedures. Licensed materials stored in an unrestricted area must be secured from unauthorized removal from the place of storage in accordance with provisions of OAR 333-120-0250 and 333-120-0260.

(23) Any specific licensee is authorized to receive, possess, use, transfer, and import up to 999 kilograms of uranium contained as shielding for specific licensed radioactive material authorized by license.

(24) A licensee may store, pursuant to OAR 333-120-0500, radioactive waste for decay in storage before disposal in accordance with 333-116-0290.

(25) Licensed materials in an unrestricted area and not in storage must be tended under the constant surveillance and immediate control of the licensee.

(26) Except as otherwise specified in a radioactive materials license, the licensee must have available and follow the instructions contained in the manufacturer's instruction manual for the chromatography device.

(27) In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in OAR 333-120-0400(2), the licensee is hereby authorized to label detector cells and cell baths, containing licensed radioactive material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.

(28) If a radiography licensee plans to use, during normal industrial radiographic operations subject to division 105 of this chapter, two or more exposure devices at one jobsite, the licensee must require at least one Radiographer or Radiographer Instructor authorized user for each exposure device, and the total number of authorized personnel (radiographers and assistant radiographers) at the temporary jobsite must not be less than n+1 where n=the number of cameras.

(29) Security requirements for portable devices containing licensed radioactive materials. Each portable device containing licensed radioactive materials must be secured using a minimum of two independent physical controls that form two separate tangible barriers to prevent unauthorized removal or use, whenever the portable device is not under the direct control and constant surveillance of the licensee.

(30) Authorization under OAR 333-102-0190(10)(c)(N) to produce Positron Emission Tomography (PET) radiopharmaceutical drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other federal, and state requirements governing radiopharmaceutical drugs.

(31) Each licensee authorized under OAR 333-102-0190(10)(c)(N) to produce PET radiopharmaceutical drugs for noncommercial transfer to medical use licensees in its consortium shall:

(a) Satisfy the labeling requirements in OAR 333-102-0285(1)(d) for each PET radiopharmaceutical drug transport radiation shield and each syringe, vial, or other container used to hold a PET radiopharmaceutical drug intended for noncommercial distribution to members of its consortium.

(b) Possess and use instrumentation to measure the radioactivity of the PET radiopharmaceutical drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in OAR 333-102-0285(3).

(32) A licensee that is a pharmacy authorized under OAR 333-102-0190(10)(c)(N) to produce PET radiopharmaceutical drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radiopharmaceutical drugs shall be:

(a) An authorized nuclear pharmacist who meets the requirements in OAR 333-116-0910; or

(b) An individual under the supervision of an authorized nuclear pharmacist as specified in OAR 333-116-0100.

(33) A pharmacy, authorized under OAR 333-102-0190(10)(c)(N) to produce PET radiopharmaceutical drugs for noncommercial transfer to medical use licensees in its consortium

that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of 333-116-0910.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10; PH 20-2010, f. & cert. ef. 9-1-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-102-0310
Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas

(1)(a) Except as provided in subsection (1)(b) of this rule, each specific license must expire at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under OAR 333-102-0315 before the expiration date stated in the existing license (or, for those licenses subject to subsection (1)(b) of this rule, before the deemed expiration date in that section). If an application for renewal has been filed before the expiration date stated in the existing license (or, for those licenses subject to subsection (2)(a) of this rule, before the deemed expiration date in that section), the existing license expires at the end of the day on which the Authority makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(b) Each specific license that has an expiration date after July 1, 1995, and is not one of the licenses described in subsection (1)(c) of this rule, shall be deemed to have an expiration date that is five years after the expiration date stated in the current license.

(c) The following specific licenses are not subject to, or otherwise affected by, the provisions of subsection (1)(b) of this rule:

(A) Specific licenses for which, on February 15, 1996, an evaluation or an emergency plan is required in accordance with OAR 333-102-0190(10);

(B) Specific licenses whose holders are subject to the financial assurance requirements specified in OAR 333-102-0200(6), and on February 15, 1996, the holders either:

(i) Have not submitted a decommissioning funding plan or certification of financial assurance for decommissioning; or

(ii) Have not received written notice that the decommissioning funding plan or certification of financial assurance for decommissioning is acceptable;

(C) Specific licenses who need an environmental assessment or environmental impact statement pursuant to OAR 333-102-0200(5);

(D) Specific licenses whose holders have not had at least one Authority inspection of licensed activities before February 15, 1996;

(E) Specific licenses whose holders, as the result of the most recent Authority inspection of licensed activities conducted before February 15, 1996, have been:

(i) Cited for a serious health and safety noncompliance;

(ii) Subject to an Order issued by the Authority; or

(iii) Subject to a Confirmatory Action Letter issued by the Authority.

(F) Specific licenses with expiration dates before July 1, 1995, for which the holders have submitted applications for renewal under OAR 333-102-0315.

(2) Each specific license revoked by the Authority expires at the end of the day on the date of the Commission's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Authority Order.

(3) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material or source material until the Authority notifies the licensee in writing that the license is terminated. During this time, the licensee must:

(a) Limit actions involving material to those related to decommissioning; and

(b) Continue to control entry to restricted areas until they are suitable for release in accordance with Authority requirements.

(4) Within 60 days of the occurrence of any of the following, consistent with the administrative directions in OAR 333-100-0045, each licensee must provide notification to the Authority in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Authority requirements, or submit within 12 months of notification a decommissioning plan, if required by subsection (7)(a) of this rule, and begin decommissioning upon approval of that plan if:

(a) The license has expired pursuant to sections (1) or (2) of this rule; or

(b) The licensee has decided to permanently cease principal activities, as defined in OAR 333-102-0203, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Authority requirements; or

(c) No principal activities under the license have been conducted for a period of 24 months; or

(d) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Authority requirements.

(5) Coincident with the notification required by section (4) of this rule, the licensee must maintain in effect all decommissioning financial assurances established by the licensee pursuant to OAR 333-102-0200(6) in conjunction with a license issuance or renewal or as required by this rule. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to paragraph (7)(d)(E) of this rule.

(a) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan must do so when this rule becomes effective November 24, 1995.

(b) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Authority.

(6) The Authority may grant a request to extend the time periods established in section (4) of this rule if the Authority determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to section (4) of this rule. The schedule for decommissioning set forth in section (4) of this rule may not commence until the Authority has made a determination on the request.

(7)(a) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Authority and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(A) Procedures may involve techniques not applied routinely during cleanup or maintenance operations;

(B) Workers that may be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(C) Procedures could result in significantly greater airborne concentrations of radioactive material or source material than are present during operation; or

(D) Procedures could result in significantly greater releases of radioactive material or source material to the environment than those associated with operation.

(b) The Authority may approve an alternate schedule for submittal of a decommissioning plan required pursuant to section (4) of this rule if the Authority determines that the alternative schedule is necessary to the effective conduct of decommissioning operations

and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(c) Procedures such as those listed in subsection (7)(a) of this rule with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(d) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(A) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(B) A description of planned decommissioning activities;

(C) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(D) A description of the planned final radiation survey; and

(E) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(F) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan must include a justification for the delay based on the criteria in section (9) of this rule.

(e) The proposed decommissioning plan will be approved by the Authority if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

(8)(a) Except as provided in section (9) of this rule, licensees must complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

(b) Except as provided in section (9) of this rule, when decommissioning involves the entire site, the licensee must request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(9) The Authority may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Authority determines that the alternative is warranted by consideration of the following:

(a) Whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(b) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(c) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(d) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(e) Other site-specific factors which the Authority may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, groundwater treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(10) As the final step in decommissioning, the licensee must:

(a) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314 or equivalent information; and

(b) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR Part 20, Subpart E. The licensee must, as appropriate:

(A) Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters — removable and fixed — for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(B) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(11) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Authority determines that:

(a) Radioactive material or source material has been properly disposed;

(b) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(c)(A) A radiation survey has been performed that demonstrates that the premises are suitable for release or establishes the level of residual activity in accordance with the criteria for decommissioning in 10 CFR Part 20, Subpart E; or

(B) The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

(i) Funds placed into an account separate from the licensee's assets and outside of the licensee's control before the start of decommissioning operations; or

(ii) A statement of intent containing a cost estimate for decommissioning or an amount based on the table in paragraph (d) of 10 CFR section 30.35(d), and indicating that funds for decommissioning will be obtained when necessary; or

(iii) An arrangement deemed acceptable by the governmental entity that is assuming custody and ownership of a site.

(C) Alternate criteria for license termination. The Authority will terminate a license using alternate criteria greater than the dose criterion of OAR 333-102-0310, if the licensee:

(i) Provides assurance that public health and safety shall continue to be protected and that it is unlikely that the total effective dose equivalent from all combined man-made sources other than medical sources shall be more than 100 millirem per year (1 millisievert per year) by submitting an analysis of possible sources of exposure;

(ii) Has employed restrictions on site use in minimizing exposures at the site;

(iii) Reduces doses to ALARA levels considering any detriments such as traffic accidents potentially expected to result from decontamination and waste disposal; and

(D) Has submitted a decommissioning or license termination plan to the Authority indicating the licensee's intent to decommission as specified in OAR 333-102-0310, and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the license termination or decommissioning plan how the advice of individuals and institutions in the community who could be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice in:

(i) Participation by representatives of a broad cross section of community interests who could be affected by the decommissioning;

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement on the issues.

(E) The use of alternate criteria to terminate a license requires the approval of the Authority after consideration of any comments provided by the U. S. Environmental Protection Agency and any public comments submitted.

(F) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR Part 20, Subpart E.

(d) The licensee has kept records of receipt, transfer, and disposal of radioactive material or source material, pursuant to OAR 333-100-0055 that meet the following criteria:

(A) The licensee must retain each record of receipt of radioactive material or source material as long as the material is possessed and for three years following transfer or disposal of the material.

(B) The licensee who transferred the material must retain each record of transfer for three years after each transfer unless a specific requirement in another part of the rules in this chapter dictates otherwise.

(C) The licensee who disposed of the material must retain each record of disposal of byproduct material until the Authority terminates each license that authorizes disposal of the material.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-102-0315
Application for Renewal of Licenses

(1) Application for renewal of a specific license must be filed in accordance with OAR 333-102-0190.

(2) In any case in which a licensee, not less than 30 days prior to expiration of the existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the Authority.

(3) Unless otherwise specified, specific licenses shall expire after five years.

(4) The Authority shall require reapplication when the license expires.

(5) The Authority may grant, upon written request from a licensee, extension of the license expiration date up to five years from the original expiration date. Notwithstanding any licensee request, the Authority is not required, and may deny, any license extension, based on review of licensed activities.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

333-102-0320
Amendment of Licenses at Request of Licensee

Application for amendment of a license must be filed in accordance with OAR 333-102-0190 and must specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-102-0325
Authority Action on Applications to Renew and Amend

In considering an application by a licensee to renew or amend the license, the Authority will apply the criteria set forth in OAR 333-102-0200 through 0290, as applicable.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10

333-102-0327
Specifically Licensed Items — Registration of Product Information

(1) Any manufacturer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific license may submit a request to the U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards for evaluation of radiation safety information about its product and for its registration.

(2) The request for review must be made in duplicate and sent to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

NOTE: The U.S. Nuclear Regulatory Commission charges a fee for processing a sealed source or device evaluation request. Contact the U.S. Nuclear Regulatory Commission directly for current fee structure.

(3) The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

(4) The U.S. Nuclear Regulatory Commission normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. The U.S. Nuclear Regulatory Commission uses criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.

(5) After completion of the evaluation, the U.S. Nuclear Regulatory Commission, issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product.

(6) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:

(a) The statements and representations, including quality control program, contained in the request; and

(b) The provisions of the registration certificate.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-102-0330
Transfer of Material

(1) No licensee may transfer radioactive material except as authorized pursuant to this rule.

(2) Except as otherwise provided in the license and subject to the provisions of sections (3) and (4) of this rule, any licensee may transfer radioactive material:

(a) To the Authority;

NOTE: A licensee may transfer radioactive material to the Authority only after receiving prior approval in writing from the Authority.

(b) To the U.S. Department of Energy;

(c) To any person exempt from the rules in this division to the extent permitted under such exemption;

(d) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Authority, the U.S. Nuclear Regulatory Commission, any Agreement State or any Licensing State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Authority, an Agreement State or a Licensing State; or

(e) As otherwise authorized by the Authority in writing.

(3) Before transferring radioactive material to a specific licensee of the Authority, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, or to a general licensee who is required to register with the Authority, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State prior to receipt of the radioactive material, the licensee transferring the material must verify that the transferee's license authorizes the receipt of the type, form and quantity of radioactive material to be transferred.

(4) Any of the following methods for the verification required by section (3) of this rule are acceptable:

(a) The transferor may possess and read a current copy of the transferee's specific license or registration certificate;

(b) The transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date;

(c) For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date; provided, that the oral certification is confirmed in writing within 10 days;

(d) The transferor may obtain other information compiled by a reporting service from official records of the Authority, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State regarding the identity of licensees and the scope and expiration dates of licenses and registration;

(e) When none of the methods of verification described in subsections (4)(a) through (4)(d) of this rule are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Authority, the U.S. Nuclear Regulatory Commission, the licensing agency of an Agreement State or a Licensing State that the transferee is licensed to receive the radioactive material.

(5) Shipment and transport of radioactive material must be in accordance with the provisions of division 118 of this chapter.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-102-0335
Modification, Revocation and Termination of Licenses

(1) The terms and conditions of each license issued pursuant to the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter shall be subject to amendment, revision or modification or by reason of amendments to the Act, or by reason of rules, regulations and orders issued in accordance with the terms of the Act by the Authority.

(2) Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application or any statement of fact required under section 182 of the Act, or because of conditions revealed by such application or statement of fact or any report, record or inspection or other means that would warrant the Authority to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act or of any rule, regulation or order of the US Nuclear Regulatory Commission or the Authority.

(3) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended or revoked unless, prior to the institution of proceedings therefore, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

(4) The Authority may terminate a specific license upon request submitted by the licensee to the Authority in writing.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-102-0340
Reciprocal Recognition of Licenses

(1) Subject to these rules, any person who holds a specific license from the U.S. Nuclear Regulatory Commission, an Agreement State, or a licensing state, and issued by the Authority having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 consecutive days in any calendar year, provided that:

(a) The licensing document does not limit the activity authorized by such document to specified installations or locations;

(b) The out-of-state licensee has notified the Authority using the Notification of Entry to Perform Activities Under Oregon Reciprocity Application form at least three days prior to engaging in such activity and has paid the applicable registration fee pursuant to OAR 333-103-0030. Such notification shall indicate the location, period and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three-day period imposes an undue hardship on the out-of-state licensee, the licensee may, upon application to the Authority, obtain permission to proceed sooner. The Authority may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license granted by subsection (1)(a) of this rule;

(c) The out-of-state licensee complies with all applicable rules of the Authority and with all the terms and conditions of the licensing document, except any such terms and conditions that may be inconsistent with applicable rules of the Authority or laws of the State of Oregon;

(d) The out-of-state licensee supplies such other information as the Authority may request; and

(e) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in subsection (1)(a) of this rule except by transfer to a person:

(A) Specifically licensed by the Authority or by the U.S. Nuclear Regulatory Commission to receive such material; or

(B) Exempt from the requirements for a license for such material under OAR 333-102-0010(2).

(2) Notwithstanding the provisions of section (1) of this rule, any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission, pursuant to 10 CFR 31.6 or equivalent regulations of an Agreement State, authorizing the holder of the license to manufacture, transfer, install or service a device described in OAR 333-102-0115(1) within the State of Oregon is hereby granted a general license to install, transfer, demonstrate or service such a device in this state provided that:

(a) Such person shall register the general license pursuant to OAR 333-101-0007;

(b) File a report with the Authority within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred and the quantity and type of radioactive material contained in the device;

(c) Ensure that the device has been manufactured, labeled, installed and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an Agreement State;

(d) Ensure that any labels required to be affixed to the device under rules of the licensing authority also include the statement "Removal of this label is prohibited"; and

(e) The holder of the specific license shall furnish to each general licensee to whom such device is transferred, or on whose premises such a device is installed, a copy of the general license contained in OAR 333-102-0115 or in equivalent rules of the Authority having jurisdiction over the manufacture and distribution of the device.

(3) The Authority may withdraw, limit or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an Agreement State, or any product distributed pursuant to such licensing document,

upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property. The Authority may deny the licensee to perform activities under Oregon reciprocity.

(4) The out-of-state licensee shall at all times during work at any work location within the state have available the pertinent licensing document, the applicable sections of the State of Oregon radiation regulations, a complete source inventory, pertinent U.S. Department of Transportation documentation, leak test records, instrument calibration records, personnel training records, and necessary documentation required by applicable special requirements of these regulations.

(5) While working in Oregon, the out-of-state licensee shall notify the Authority (in writing, indicating date and court) immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (bankruptcy) of the United States code by or against:

(a) The licensee;

(b) An entity (as that term is defined in II U.S.C 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

(c) An affiliate (as that term is defined in II U.S.C. 101(2)) of the license.

(6) If multiple work crews or persons work concurrently at more than one work location under a general license granted pursuant to this rule, each day worked at each location shall count toward the limit of 180 consecutive days in a calendar year.

(7) Each general licensee granted authorization to conduct activities within the State of Oregon pursuant to this rule, based upon an acceptable licensing document, will receive acknowledgment from the Authority. This acknowledgment shall be kept at the site of use.

(8) Each general licensee granted authorization to conduct activities within the State of Oregon pursuant to this rule based upon an acceptable licensing document is subject to the reciprocity fee and may be inspected by the Authority. The fee for the general license granting reciprocity shall:

(a) Be charged as provided by division 103 of this chapter; and

(b) Shall not be charged more often than once during each calendar year.

(9) Each general licensee operating within the state under reciprocity in areas of exclusive federal jurisdiction shall comply with the applicable provisions of 10 CFR 150.20.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 20-2010, f. & cert. ef. 9-1-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 4-2013, f. & cert. ef. 1-29-13

333-102-0345
Special Procedures in Regulatory Review

(1) The provisions of ORS Chapter 183 governing contested cases are applicable in any case where the Authority proposes to refuse to issue, renew, modify, amend, revise, revoke or suspend a general or specific license or to find noncompliance with or to refuse to grant exemption from a regulation of the Authority.

(2) In any case where the Authority proposes to grant, issue, renew, modify, amend or revise a general or specific license, or to find compliance or to grant exemption from a regulation of the Authority and the Assistant Director of the Public Health Division determines that such action would first merit public notice and opportunity for hearing, the following procedures shall be applicable:

(a) Notice of the proposed action shall be published in the Secretary of State's bulletin or a newspaper of general circulation in the state, which notice shall provide that within 15 days of the day of publication of the notice, any person whose interest may be affected by the outcome of the proceeding, or who represents a public interest in the results of the proceeding, may file a petition to be made a party and given an opportunity for hearing in the matter. The notice of proposed action shall set forth:

(A) The nature of the action proposed;

(B) The manner in which and the location at which inspection may be made of the Authority records pertaining to the proposed action; and

(C) A reference of the Authority's rules governing institution and conduct of hearings in radiation control proceedings.

(b) If no request for hearing is filed within the time prescribed in the notice, the proposed action shall be taken;

(c) If a hearing is requested, the person requesting to participate as a party must file a petition requesting party status and opportunity for hearing, setting forth the same information required of a person requesting party status in a contested case when the Authority has given notice that it intends to hold a contested case hearing pursuant to OAR 137-003-0005(6). The same procedures for determining party status under OAR 137-003-0005 shall be followed upon receipt of the petition;

(d) If the Authority allows party status, it shall in the same order set the time for a contested case hearing and provide notice of the order to the petitioner and all parties;

(e) A contested case shall proceed in accordance with the provisions of ORS Chapter 183 governing contested cases.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-102-0350
Reporting Requirements

(1) Immediate report. Each licensee must notify the Authority as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

(2) Twenty-four hour report. Each licensee must notify the Authority within 24 hours after the discovery of any of the following events involving licensed material:

(a) An unplanned contamination event that:

(A) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(B) Involves a quantity of material greater than five times the lowest annual limit on intake specified in appendix B of Secs. 20.1001–20.2401 of 10 CFR part 20 for the material; and

(C) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(b) An event in which equipment is disabled or fails to function as designed when:

(A) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(B) The equipment is required to be available and operable when it is disabled or fails to function; and

(C) No redundant equipment is available and operable to perform the required safety function.

(c) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

(d) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(A) The quantity of material involved is greater than five times the lowest annual limit on intake specified in appendix B of Secs. 20.1001–20.2401 of 10 CFR part 20 for the material; and

(B) The damage affects the integrity of the licensed material or its container.

(3) Preparation and submission of reports. Reports made by licensees in response to the requirements of this rule must be made as follows:

(a) Licensees must make reports required by sections (1) and (2) of this rule by telephone to the Authority. To the extent that the information is available at the time of notification, the information provided in these reports must include:

NOTE: The 24-hour telephone number for the Authority is 971-673-0490.

(A) The caller's name and call back telephone number;

(B) A description of the event, including date and time;

(C) The exact location of the event;

(D) The isotopes, quantities, and chemical and physical form of the licensed material involved; and

(E) Any personnel radiation exposure data available.

(b) Written report. Each licensee who makes a report required by sections (1) or (2) of this rule must submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be faxed or sent to the Department with Attention to Manager, Radiation Protection Services, Center for Health Protection, 800 NE Oregon Street, Suite 640, Portland, OR 97232. The reports must include the following:

(A) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(B) The exact location of the event;

(C) The isotopes, quantities, and chemical and physical form of the licensed material involved;

(D) Date and time of the event;

(E) Corrective actions taken or planned and the results of any evaluations or assessments; and

(F) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

(4) The provisions of this rule apply to licensees subject to the notification requirements in OAR 333-102-0200(5).

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-102-0355
Records

(1) Each person who receives radioactive material pursuant to a license issued in accordance with the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter must keep records showing the receipt, transfer, and disposal of the radioactive material as follows:

(a) The licensee must retain each record of receipt of radioactive material as long as the material is possessed and for three years following transfer or disposal of the material.

(b) The licensee who transferred the material must retain each record of transfer for three years after each transfer unless a specific requirement in another division of the rules in this chapter dictates otherwise.

(c) The licensee who disposed of the material must retain each record of disposal of radioactive material until the Authority terminates each license that authorizes disposal of the material.

(2) The licensee must retain each record that is required by the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter or by license condition for the period specified by the appropriate rule or license condition. If a retention period is not otherwise specified by rule or license condition, the record must be retained until the Authority terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(3)(a) Records that must be maintained pursuant to this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Authority rules. The record also may be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, or specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee must maintain adequate safeguards against tampering with and loss of records.

(b) If there is a conflict between the Authority's rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter, license condition, or other written Authority approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter for such records must apply unless the Authority, pursuant to OAR 333-102-0003, has granted a specific exemption from the record retention requirements specified in the rules in this division or divisions 105, 113, 115, 116, 117, and 121 of this chapter.

(4) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, must forward the following records to the program office:

(a) Records of disposals of licensed material made prior to January 28, 1981; and

(b) Records required by OAR 333-120-0620(2)(d).

NOTE: Prior to Oregon Department of Energy's Energy Facility Siting Council rules for burial of small quantities of licensed materials in soil was permitted without specific Authority authorization.

(5) If licensed activities are transferred or assigned in accordance with OAR 333-102-0305(2), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, must transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(a) Records of disposal of licensed material made under OAR 333-120-0510 (including burials authorized before January 28, 1981), 333-120-0520, 333-120-0530, 333-120-0540; and

(b) Records required by OAR 333-120-0620(2)(d).

(6) Prior to license termination, each licensee must forward the records required by OAR 333-102-0200(6) to the Authority.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-102-0360
Right to Cause the Withholding or Recall of Byproduct Material

The Authority may cause the withholding or recall of byproduct material from any licensee who is not equipped to observe or fails to observe such safety standards to protect health as may be established by the Authority, or who uses such materials in violation of law or regulation of the Authority, or in a manner other than as disclosed in the application therefore or approved by the Authority.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

333-102-0365
Third Party Method

If the applicant consents, the Authority may enter into third party agreements for the applicant to engage and pay for the services of a third party contractor to prepare an environmental impact analysis required by OAR 333-102-0190 and/or to furnish an opinion of independent experts, satisfactory to the Authority, in respect to the completeness and adequacy of any information or data furnished by the applicant and on any aspect of the applicant's project or effects thereof.

(1) When the license applicant pays for a third party agreement, the monies paid for the consultant must not be considered as specific license fees, pursuant to OAR 333-103-0010 of this chapter.

(2) In proceeding under the third party agreement, the Authority shall carry out the following practices:

(a) Such contractor shall be chosen solely by the Authority.

(b) The Authority shall manage the contract.

(c) The consultant must be selected based on the consultant's ability and relevant and applicable work experience and an absence of conflict of interest. Third party contractors shall be required to execute a disclosure statement showing that they have no financial or other conflicting interest in the outcome of the project.

(d) The Authority shall specify the information to be developed and supervise the gathering, analysis and presentation of the information. The Authority shall have sole authority for approval and modification of the statement, analysis, and conclusions included in third party's report.

(e) The Authority has the single right of refusal of the final application and the Authority is not obligated to approve the application or issue a license.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

Transport

333-102-0900

Special Requirements for Specific Licenses of Broad Scope

This rule prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain rules governing holders of such licenses.

(1) The different types of broad scope licenses are set forth below:

(a) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range;

(b) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in 10 CFR, Part 33.100, Schedule A, for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in 10 CFR, Part 33.100, Schedule A, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR, Part 33.100, Schedule A Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license must not exceed unity;

(c) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in 10 CFR, Part 33.100, Schedule A, for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in 10 CFR, Part 33.100, Schedule A, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR, Part 33.100, Schedule A, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license must not exceed unity.

(2) An application for a Type A specific license of broad scope will be approved if:

(a) The applicant satisfies the general requirements specified in OAR 333-102-0200;

(b) The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

(c) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting and management review that are necessary to assure safe operations, including:

(A) The establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management and persons trained and experienced in the safe use of radioactive material;

(B) The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(C) The establishment of appropriate administrative procedures to assure:

(i) Control of procurement and use of radioactive material;

(ii) Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user and the operating or handling procedures; and

(iii) Review, approval and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with subparagraph (2)(c)(C)(ii) of this rule prior to use of the radioactive material.

(3) An application for a Type B specific license of broad scope will be approved if:

(a) The applicant satisfies the general requirements specified in OAR 333-102-0200; and

(b) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(A) The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(B) The establishment of appropriate administrative procedures to assure:

(i) Control of procurement and use of radioactive material;

(ii) Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user and the operating or handling procedures; and

(iii) Review, approval and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with subparagraph (3)(b)(B)(ii) of this rule prior to use of the radioactive material.

(4) An applicant for a Type C specific license of broad scope will be approved if:

(a) The applicant satisfies the general requirements specified in OAR 333-102-0200;

(b) The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

(A) A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

(B) At least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used.

(c) The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.

(5) Specific licenses of broad scope are subject to the following conditions:

(a) Unless specifically authorized, persons licensed pursuant to this rule must not:

(A) Conduct tracer studies in the environment involving direct release of radioactive material;

(B) Receive, acquire, own, possess, use or transfer devices containing 100,000 curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;

(C) Conduct activities for which a specific license issued by the Authority under OAR 333-102-0235, 333-102-0245, 333-102-0250, 333-102-0255, 333-102-0260, 333-102-0265, 333-102-0270, 333-102-0275, 333-102-0285, 333-102-0290, 333-102-0293, or chapter 333 divisions 105, 110, 113, 115, 116, or 117 is required; or

(D) Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug or other product designed for ingestion or inhalation by, or application to, a human being.

(b) Each Type A specific license of broad scope issued under this division shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee;

(c) Each Type B specific license of broad scope issued under this division shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer;

(d) Each Type C specific license of broad scope issued under this division shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of section (4) of this rule.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 13-1988, f. 6-7-88, cert. ef. 7-1-88; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 20-2010, f. & cert. ef. 9-1-10

333-102-0910
Specific Terms and Conditions for Broad Licenses

(1) No licensee may use radioactive material in or on human beings or in field applications where radioactive material is released except as specifically authorized by license.

(2) Experimental animals administered radioactive materials or their products must not be used for human consumption.

(3) Licensees must conduct a physical inventory every six months to account for all radioactive material received and possessed under the license. The records of the inventories must be maintained until inspection by the Radiation Protection Services Section, and must include the quantities and kinds of radioactive material, location of sealed sources and the date of the inventory.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2007, f. & cert. ef. 3-1-07

DIVISION 103

FEES

333-103-0001
Purpose and Scope

(1) The rules in this division establish fees for sources of radiation and provide for their payment. Sources of radiation, as defined in OAR 333-100-0005, include, but are not limited to, radiation facilities, radiation producing machines, radiation producing devices, radioactive material in sealed and unsealed form (normal form and special form), and radioactive material uses.

(2) Except as otherwise specifically provided, the rules in this division apply as follows:

(a) Radiation producing machines, radiation facility registration, radiation machine vendors and/or services, accredited hospital radiology inspectors, and non-ionizing sources of radiation are subject to OAR chapter 333, divisions 101, 105, 106, 108, 109, 111, 112, 115, 119, 122 or 123;

(b) Radioactive materials pursuant to OAR chapter 333 divisions 102, 105, 110, 113, 115, 116, 117 or 121;

(c) General licenses and registrations pursuant to divisions 101 and 102 of this chapter;

(d) Microwave Oven Service Licensees;

(e) Radiological Analyses; and

(f) Tanning Device Registrations.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 2-1995(Temp), f. & cert. ef. 7-11-95; HD 4-1995, f. & cert. ef. 9-8-95; HD 3-1996, f. & cert. ef. 8-9-96; DOA 13-2006, f.& cert. ef. 6-21-06; PH 11-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10

333-103-0003
Definitions

As used in this division, the following definitions apply:

(1) "License" ("Acknowledgment of Validation," "Validation Certificate," "Certificate of Validation") means the document issued that validates receipt of payment for a specific license or registration fee.

(2) "Registration Fee" means:

(a) The fee paid to the Authority for registering Radiation Producing Machines; or

(b) The fee paid to the Authority to validate a general license registration issued pursuant to OAR 333-102-0101, 333-102-0103, 333-102-0115, 333-102-0130 or 333-102-0340

(3) "Specific License Fee" means:

(a) The annual fee payable, to validate specific licenses for sources of radiation; or

(b) The fee paid upon application to the Authority for an Oregon Radioactive Materials License to license specific licensed sources of radiation pursuant to OAR 333-103-0010; or

(c) The fee paid to license additional sources of radiation pursuant to OAR 333-103-0010.

Stat. Auth.: ORS 453.757

Stats. Implemented: ORS 453.757

Hist.: HD 2-1995(Temp), f. & cert. ef. 7-11-95; HD 4-1995, f. & cert. ef. 9-8-95; HD 3-1996, f. & cert. ef. 8-9-96; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 20-2010, f. & cert. ef. 9-1-10; PH 24-2014, f. & cert. ef. 8-15-14

333-103-0005
Biennial Fee for Radiation Machines

(1) For the purpose of this division, a radiation machine is defined under OAR 333-100-0005.

(2) Each radiation machine shall be validated biennially by a radiation machine fee in the following amounts:

(a) Hospital, radiologist, chiropractic, osteopathic or medical X-ray machine, $285;

(b) Hospital X-ray machine when X -ray machine inspection is performed by an accredited hospital radiology inspector rather than an Authority inspector, $145;

(c) Industrial or podiatry X-ray machine, $190;

(d) Dental, academic or veterinary X-ray machine, $140.

(3) The radiation machine fee shall be due and payable for each radiation machine on or before October 1 of each biennium.

(4) A certificate of validation or acknowledgment of validation for the current biennium must be posted on or near the radiation machine by the registrant.

(5) In any case in which a registrant has submitted the proper fee prior to the expiration of a validation certificate, such existing validation certificate shall not expire until the issuance of a new validation certificate for the current biennium.

(6) Upon written request and approval by the Authority, fees for new licenses or additional machines may be prorated on a biennial quarterly basis for the current biennium.

Stat. Auth.: ORS 453.757, 453.761

Stats. Implemented: ORS 453.757, 453.761

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 13-1988, f. 6-7-88, cert. ef. 7-1-88; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 2-1995(Temp), f. & cert. ef. 7-11-95; HD 4-1995, f. & cert. ef. 9-8-95; HD 3-1996, f. & cert. ef. 8-9-96; PH 11-2006, f. & cert. ef. 6-

16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-103-0010
Annual Fee for Specific Licenses

(1)(a) Each specific license listed in section (2) of this rule, as defined in OAR 333-102-0203, shall be licensed pursuant to sections (2), (3), (4), (5) and (6) of this rule by a specific license fee.

(b) Upon written request and approval by the Authority, fees for new licenses or additional sources may be prorated on a quarterly basis for the current fiscal year.

(2) Each specific license type appearing in the following fee schedule shall be licensed separately with a specific license fee as indicated:

(a) Analytical/Leak Test/Fixed X-ray Fluorescence, $690(F);
(b) Basic License, $1,220(F);
(c) Brachytherapy, $2,755(F);
(d) Broad Scope A, $3,000(F);
(e) Broad Scope B, $2,755(F);
(f) Broad Scope C, $1,370(F);
(g) Distribution, $1,370(F);
(h) Fixed Gauge, $345(S);
(i) High, medium and low doserate brachytherapy, $3,000(S);
(j) Imaging and Localization, $1,370(F);
(k) In Vitro Laboratory, $455(F);
(l) Industrial Radiography:
(A) Fixed Facility, $3,000(F);
(B) Field Use, $3,000(F);
(m) Instrument Calibration, $1,035(S);
(n) Investigational New Drug, $2,065(F);
(o) Irradiator Self-Shielded, $1,370(S);
(p) Manufacturing/Compounding, $3,000(F);
(q) Mobile Nuclear Medicine, $3,000(F);
(r) NORM (no processing), $920(F);
(s) Nuclear Pharmacy, $3,000(F);
(t) Other Measuring Device, $200(S). Six sources or more, for attenuation purposes, may apply for a basic license;
(u) Portable Gauge:
(A) X-ray Fluorescence, $690(S);
(B) All other portable gauges, $920(S);
(v) Radiopharmaceutical Therapy, $2,065(F);
(w) RAM/NOS Facility, $3,000(F);
(x) Research & Development, $2,065(F);
(y) Sealed Sources for Diagnosis, $690(S);
(z) Source Material, $3,000(F);
(aa) Special Nuclear Material (sealed), $1,370(S);
(bb) Special Nuclear Material (unsealed), $3,000(F);
(cc) Teletherapy (external beam), $3,000(S);
(dd) Unique, No Fee;
(ee) Uptake and Dilution, $920(F);
(ff) Use of Xenon Gas, $920(F);
(gg) Waste Packaging, $3,000(F);
(hh) Well Logging, $2,065(S);

NOTE: (F) means facility; (S) means source.

(3) Each specific license validation fee shall be due and payable:

(a) Based on the following fee schedule:

(A) Validation fees for licenses expiring July through September are due by October 1 each year.

(B) Validation fees for licenses expiring October through December are due by January 1 each year.

(C) Validation fees for licenses expiring January through March are due by April 1 each year; and,

(D) Validation fees for licenses expiring April through June are due by July 1 each year.

(b) For each specific license source of radiation listed in section (2) of this rule for which application pursuant to OAR 333-102-0190 for an Oregon Radioactive Materials License has been made;

(c) For each additional specific license source of radiation in an amendment to an existing Oregon Radioactive Materials License pursuant to OAR 333-102-0320.

(4) A license for each specific license issued pursuant to section (3) of this rule shall be provided by the Authority. The certificate of validation for the current fiscal year shall be retained by the licensee and attached to the license pursuant to requirements in OAR 333-111-0005.

(5) The specific license fee that validates specific sealed sources also validates possession of one additional sealed source during source exchange (one new source and one spent source) for a period not to exceed 30 calendar days.

(6) Sealed sources manufactured and distributed as reference sources that do not exceed 100 times the quantity in 30.71 Schedule B of 10 CFR Part 30 are exempt from specific license fees and validation if used pursuant to a specific license listed in section (2) of this rule. The license validation fee for reference sources that exceed 100 times the quantity in 30.71 Schedule B of 10 CFR Part 30 or reference sources authorized alone without additional licensed radioactive material shall be $1,220, pursuant to subsection (2)(b) of this rule.

Stat. Auth.: ORS 453.757
Stats. Implemented: ORS 453.757
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 13-1988, f. 6-7-88, cert. ef. 7-1-88; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 2-1995(Temp), f. & cert. ef. 7-11-95; HD 4-1995, f. & cert. ef. 9-8-95; HD 3-1996, f. & cert. ef. 8-9-96; PH 11-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 20-2010, f. & cert. ef. 9-1-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 24-2014, f. & cert. ef. 8-15-14; PH 25-2016, f. 8-26-16, cert. ef. 9-1-16

333-103-0015
Annual Registration Fee for General Licenses and Devices

(1) Any general license granted by the Authority must be validated annually by the general license registration fee listed in section (2) of this rule, unless otherwise exempted by subsection (2)(e) of this rule. Validation must be confirmed by verifying, correcting, and adding to the information provided in a request for registration received from the Authority. General License registration fees as defined in OAR 333-103-0003 shall:

(a) Validate each general licensed source of radiation due October 1 of each year for sources of radiation; and

(b) Validate each new application to register general license material pursuant to OAR 333-101-0007.

(2) The general licenses appearing in the following fee schedule shall be registered on the appropriate Authority form and shall be validated annually by a general license registration fee:

(a) Each healing arts facility that uses radioactive material for In Vitro laboratory or clinical testing authorized by OAR 333-102-0130, $200;

(b) Each radiation source in a generally licensed measuring, gauging or controlling device authorized pursuant to OAR 333-102-0115(1), $200;

(c) For radioactive material contained in devices designed and manufactured for the purpose of producing light, except Tritium exit signs, or an ionized atmosphere that exceed the limits in OAR 333-102-0105, $82 per device for the first 12 devices after which a Basic Specific License is required.

(d) Each general licensee possessing or using depleted uranium for the purpose of providing a concentrated mass in a small volume of the product or device pursuant to OAR 333-102-0103, $200;

(e) Each General Licensee possessing or using source material for research, development, educational, commercial or operational purpose pursuant to OAR 333-102-0101, $300;

(f) General licenses not specifically identified in subsections (2)(a), (2)(b), (2)(c) and (2)(d) of this rule are exempt from the payment of an annual general license registration fee.

(g) Each out-of-state or NRC specific licensee granted a general license pursuant to OAR 333-102-0340 to conduct activities within the State of Oregon for a period not to exceed 180 consecutive days in a calendar year must pay a registration validation fee as required by OAR 333-103-0030(1).

(h) State and local government agencies are required to register each generally licensed device but are exempt from the fees required in this rule.

(3) Notwithstanding subsection (2)(g) of this rule, the general license fee shall be due and payable on or before October 1 of each year.

(4) A certificate of validation for the then current fiscal year shall be provided by the Authority. The certificate for the then current fiscal year must be retained by the licensee and attached to the general license.

(5) Upon written request and approval by the Authority, fees for new licenses or additional sources may be prorated on a quarterly basis for the fiscal year.

Stat. Auth.: ORS 453.757

Stats. Implemented: ORS 453.757

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 13-1988, f. 6-7-88, cert. ef. 7-1-88; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1991, f. & cert. ef. 10-1-91; HD 2-1995(Temp), f. & cert. ef. 7-11-95; HD 4-1995, f. & cert. ef. 9-8-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 11-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 20-2010, f. & cert. ef. 9-1-10; PH 24-2014, f. & cert. ef. 8-15-14

333-103-0020

Biennial Fee for Microwave Oven Service Licensees

(1) Each license issued by the Authority for microwave oven service shall be subject to a biennial $112 specific license fee.

(2) The license fee shall be due and payable on or before October 1 of each biennium.

(3) A certificate of validation or acknowledgement of validation for the then current fiscal biennium shall be provided by the Authority. The current certificate of validation must be retained by the licensee.

(4) Unless validated by the biennial fee, each license shall be deemed to expire on September 30 of each biennium.

(5) Upon written request and approval by the Authority, fees for new licenses may be prorated on a biennial quarterly basis for the current biennium.

Stat. Auth.: ORS 453.757, 453.761

Stats. Implemented: ORS 453.757, 453.761

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 15-1994, f. & cert. ef. 6-5-94; HD 2-1995(Temp), f. & cert. ef. 7-11-95; HD 4-1995, f. & cert. ef. 9-8-95; PH 11-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-103-0025

Annual Fee for Tanning Devices

(1) Each tanning device must be validated annually by a tanning device fee of $150.

(2) The tanning device fee shall be due and payable for each tanning device on or before January 1 of each year.

(3) A certificate of validation or acknowledgment of validation for the then current fiscal year must be posted on or near the tanning device, by the registrant.

(4) In any case in which a registrant has submitted the proper fee prior to the expiration of a validation certificate, such existing validation certificate shall not expire until the issuance of a new validation certificate for the then current fiscal year.

(5) Upon written request and approval by the Authority, fees for new licenses or additional tanning devices may be prorated on a quarterly basis for the current fiscal year.

Stat. Auth.: ORS 453.729

Stats. Implemented: ORS 453.729

Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 13-1993, f. & cert. ef. 9-27-93; HD 15-1994, f. & cert. ef. 5-6-94; PH 11-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 34-2015, f. 12-29-15, cert. ef. 1-1-16

333-103-0030

Reciprocal Recognition Fee

(1) Any radiation machine or radioactive material source brought into the state for use under reciprocity must pay a fee equal to 100 percent of the appropriate license or registration validation fee, listed in OAR 333-103-0005 or 333-103-0010, not to exceed $3,000 in a year.

(2) Reciprocal fees shall be due and payable prior to entry into the state.

(3) An acknowledgment of fee payment, such as a certificate of validation, shall be provided by the Authority. The acknowledgment of fee payment must be retained by the licensee or registrant and attached to the license or registration.

(4) Reciprocal fees shall not be transferred or refunded.

(5) Reciprocal fees shall expire 12 months from the issue date.

(6) Any use of radioactive material in Oregon pursuant to OAR 333-102-0340 exceeding 180 consecutive days may be required to apply for an Oregon specific radioactive materials license pursuant to OAR 333-102-0190.

Stat. Auth.: ORS 453.757

Stats. Implemented: ORS 453.757

Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 2-1995(Temp), f. & cert. ef. 7-11-95; HD 4-1995, f. & cert. ef. 9-8-95; PH 11-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 20-2010, f. & cert. ef. 9-1-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 24-2014, f. & cert. ef. 8-15-14

333-103-0035

Fees For Radiological Analyses

(1) An individual, agency, or company that requests that the Authority's Radiation Laboratory perform radiological analyses on samples must pay a fee to the Authority in accordance with the schedule in section (2) of this rule. The responsible individual submitting the sample(s) must first obtain a request form from the Authority. This form contains the fee schedule and the types of radiological analyses offered. That individual must then submit the completed form along with the sample and the appropriate fee to the Authority. The Authority submits the results by return mail in accordance with the estimated time as per section (3) of this rule.

(2) Fee Schedule:

(a) Gamma Isotopic:

(A) Liquid — $310;

(B) Solid — $355;

(b) Low-level Iodine-131 — $265;

(c) Tritium (H-3) — $115.

(3) The analyses results shall be available in approximately five working days for Gamma Isotopic analyses.

NOTE: If the Authority cannot complete the analyses according to the schedule in section (3) of this rule, the Authority must notify the customer as soon as possible.

(4) A $100 surcharge shall be added to the fee for a one-day completion schedule for a Gamma Isotopic analysis.

Stat. Auth.: ORS 453.757

Stats. Implemented: ORS 453.757

Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 2-1995(Temp), f. & cert. ef. 7-11-95; HD 4-1995, f. & cert. ef. 9-8-95; PH 11-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 20-2010, f. & cert. ef. 9-1-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 24-2014, f. & cert. ef. 8-15-14

333-103-0050

Fees for Accredited Hospital Radiology Inspectors

(1) Each accreditation for a radiology inspector shall be subject to an accreditation fee of $264.

(2) Each accreditation issued by the Authority for a radiology inspector shall be subject to a biennial renewal fee of $264.

(3) Each accreditation shall expire in the second year on the last day of the month of issuance unless renewed.

Stat. Auth.: ORS 453.757

Stats. Implemented: ORS 453.757

Hist.: HD 3-1996, f. & cert. ef. 8-9-96; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

DIVISION 105

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

333-105-0001
Purpose

This division prescribes requirements for the industrial use of sources of radiation and radiation safety requirements for persons using these sources of radiation in industrial radiography.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0003
Scope

The provisions and requirements of this division are in addition to, and not in substitution for, other requirements of these rules. In particular, the general requirements of divisions 100, 102, 111, 118, and 120 of this chapter apply to applicants and licensees, subject to this division. Divisions 102 and 118 of these rules apply to licensing and transportation of radioactive material, respectively. This rule does not apply to medical uses addressed in division 116.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0005
Definitions

As used in this division, the following definitions apply:

(1) "Annual refresher safety training" means a review conducted or provided by the licensee for its employees on radiation safety aspects of industrial radiography. The review must include, as a minimum, a review of radiation safety aspects of industrial radiography, any results of internal audits, Authority inspections, new procedures or equipment, new or revised regulations, and accidents or errors that have been observed. The review must also provide opportunities for employees to ask safety questions.

(2) "ANSI" means the American National Standards Institute.

(3) "Associated equipment" means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source, (e.g., guide tube, control tube, control (drive) cable, removable source stop, "J" tube and collimator when it is used as an exposure head.

(4) "Camera" see "Radiographic exposure device".

(5) "Certifying entity" means an independent certifying organization meeting the requirements in Appendix A of division 105 or an Agreement State regulatory program meeting the requirements in **Appendix A**, Sections II and III.

(6) "Collimator" means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size, shape, and direction of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

(7) "Control drive cable" means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

(8) "Control drive mechanism" means a device that enables the source assembly to be moved into and out of the exposure device.

(9) "Control tube" means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

(10) "Drive cable" see "Control cable".

(11) "Exposure head" means a device that locates the gamma radiography sealed source in the selected working position. An exposure head also is known as a source stop or end cap.

(12) "Field station" means a facility from which sources of radiation may be stored or used and from which equipment is dispatched.

(13) "Guide tube" (projection sheath) means a flexible or rigid tube, or "J" tube, for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

(14) "Hands-on experience" means experience in all of those areas considered to be directly involved in the radiography process, and includes taking radiographs, calibration of survey instruments, operational and performance testing of survey instruments and devices, film development, posting of radiation areas, preparing radiographic sources for transport, set-up of radiography equipment, posting of records and radiation area surveillance, etc., as applicable. In addition the Radiation Safety Officer experience must include source exchange and source retrieval. Excessive time spent in only one or two of these areas, such as film development or radiation area surveillance, should not be counted toward the 2000 hours of hands-on experience required for a radiation safety officer in 333-105-0520 or the hands-on experience for a radiographer as required by 333-105-0530.

(15) "Independent certifying organization" means an independent organization that meets all of the criteria of Appendix A of this part.

(16) "Industrial radiography" means a nondestructive examination of the structure of materials using ionizing radiation to make radiographic images.

(17) "Lay-barge radiography" means industrial radiography performed on any water vessel used for laying pipe.

(18) "Lixiscope" means a portable light-intensified imaging device using a sealed source.

(19) "Offshore platform radiography" means industrial radiography conducted from a platform over a body of water.

(20) "Permanent radiographic installation" means an enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed.

(21) "Personal supervision" means supervision in which the radiographer is physically present at the site where sources of radiation and associated equipment are being used, watching the performance of the radiographer's assistant and in such proximity that immediate assistance can be given if required.

(22) "Pigtail" see "Source assembly".

(23) "Pill" see "Sealed source".

(24) "Practical examination" means a demonstration through application of the safety rules and principles in industrial radiography including use of all procedures and equipment to be used by radiographic personnel.

(25) "Projection sheath" see "Guide tube".

(26) "Projector" see "Radiographic exposure device".

(27) "Radiation safety officer for industrial radiography" means an individual with the responsibility for the overall radiation safety program on behalf of the licensee and who meets the requirements of 333-105-0520.

(28) "Radiographer" means any individual who performs or who, in attendance at the site where sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee for assuring compliance with the requirements of these rules and the conditions of the license or registration.

(29) "Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met the radiation safety, testing, and experience criteria in 333-105-0530.

(30) "Radiographer's assistant" means any individual who, under the direct supervision of a radiographer, uses radiographic exposure devices, sources of radiation, related handling tools or radiation survey instruments in industrial radiography.

(31) "Radiographer instructor" means any radiographer who has been authorized by the Authority to provide on-the-job training to radiographer trainees in accordance with OAR 333-105-0530(3).

(32) "Radiographer trainee" means any individual who, under the direct supervision of a radiographer instructor, uses sources of radiation, related handling tools or radiation survey instruments during the course of his instruction.

(33) "Radiographic exposure device" (also called a camera or a projector) means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved or otherwise changed from a shielded to unshielded position for purposes of making a radiographic exposure.

(34) "Radiographic operations" means all activities performed with a radiographic exposure device. Activities include using, transporting (except when being transported by common or contract carriers), storing at a temporary job site, performing surveys to confirm the adequacy of boundaries, setting up equipment, and any activity inside restricted area boundaries. Transporting a radiation machine is not considered a radiographic operation.

(35) "Radiographic personnel" means any radiographer, radiographer's assistant, radiographer instructor or radiographer trainee.

(36) "Radiography" see "Industrial radiography".

(37) "Residential location" means any area where structures in which people lodge or live are located and the grounds on which such structures are located including, but not limited to, houses, apartments, condominiums and garages.

(38) "S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.

(39) "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

(40) "Shielded position" means the location within the radiographic exposure device, source changer, or storage container that, by manufacturer's design, is the proper location for storage of the sealed source.

(41) "Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a stop ball used to secure the source in the shielded position.

(42) "Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices. They also may be used for transporting and storing sealed sources.

(43) "Storage area" means any location, facility or vehicle that is used to store and secure a radiographic exposure device, a radiation machine, or a storage container when it is not used for radiographic operations. Storage areas are locked or have a physical barrier to prevent accidental exposure, tampering with or unauthorized removal of the device, container, source, or machine.

(44) "Storage container" means a device in which sealed sources are secured and stored.

(45) "Temporary jobsite" means any location where radiographic operations are performed and where sources of radiation may be stored other than those location(s) of use authorized on the license or registration.

(46) "Transport container" means a package that is designed to provide radiation safety and security when sealed sources are transported and which meets all applicable requirements of the U.S. Department of Transportation.

(47) "Underwater radiography" means radiographic operations performed when the radiographic exposure device or radiation machine and/or related equipment are beneath the surface of the water.

[ED. NOTE: Appendices referenced are available from the agency.]

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0050
Exemptions

Industrial uses of lixiscopes are exempt from the requirements of this division if the dose rate 18 inches from the source of radiation to any individual does not exceed two millirem per hour. Devices that exceed this limit must meet the applicable requirements of this division and the licensing or registration requirements of division 101 or division 102 of these rules, as applicable.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0075
Licensing and Registration Requirements for Industrial Radiography Operations

The Authority will approve an application for a specific license for the use of licensed material if the applicant meets the following requirements:

(1) The applicant satisfies the general requirements specified in 333-102-0200 for radioactive material and any special requirements contained in this division;

(2) The applicant submits an adequate program for training radiographers and radiographer's assistants that meets the requirements of 333-105-0530:

(a) After July 1, 2003, the applicant need not describe the initial training and examination program for radiographers in the subjects outlined in 333-105-0530(7).

(b) From December 1, 2002 to July 1, 2003, the applicant may affirm that all individuals acting as industrial radiographers will be certified in radiation safety by a certifying entity before commencing duty as radiographers. This affirmation substitutes for a description of its initial training and examination program for radiographers in the subjects outlined in 333-105-0530(7).

(3) The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid;

(4) The applicant submits written operating and emergency procedures as described in 333-105-0540;

(5) The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer's assistant at intervals not to exceed 6 months as described in 333-105-0530(5);

(6) The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation of authority and responsibility;

(7) The applicant submits the qualifications of the individual(s) designated as the radiation safety officer as described in 333-105-0520(1);

(8) If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing the test. The description must include the:

(a) Methods of collecting the samples;

(b) Qualifications of the individual who analyzes the samples;

(c) Instruments to be used; and

(d) Methods of analyzing the samples.

(9) If the applicant intends to perform calibrations of survey instruments and alarming ratemeters, the applicant must describe methods to be used and the experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in 333-105-0450 and 333-105-0560(7)(d);

(10) The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations;

(11) The applicant identifies the location(s) where all records required by this and other divisions of these rules will be maintained;

(12) If a license application includes underwater radiography, a description of:

(a) Radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography;

(b) Radiographic equipment and radiation safety equipment unique to underwater radiography; and

(c) Methods for gas-tight encapsulation of equipment; and

(13) If an application includes offshore platform and/or lay-barge radiography, a description of:

(a) Transport procedures for radioactive material to be used in industrial radiographic operations;

(b) Storage facilities for radioactive material; and

(c) Methods for restricting access to radiation areas.

(14) A license will be issued if sections (1) through (13) of this rule, as applicable, are met.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

Equipment Control

333-105-0420
Performance Requirements for Industrial Radiography Equipment

Equipment used in industrial radiographic operations must meet the following minimum criteria:

(1) Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standard Institute, N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981). This publication may be purchased from the American National Standards Institute, Inc., 25 West 43rd Street, New York, New York 10036, Telephone (212) 642-4900.

(2) In addition to the requirements specified in section (1) of this rule, the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources:

(a) The licensee must ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the:

(A) Chemical symbol and mass number of the radionuclide in the device;

(B) Activity and the date on which this activity was last measured;

(C) Model or product code and serial number of the sealed source;

(D) Name of the manufacturer of the sealed source; and

(E) Licensee's name, address, and telephone number.

(b) Radiographic exposure devices intended for use as Type B packages must meet the applicable transportation requirements of division 118 of these rules.

(c) Modification of radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless approved by the Authority or other approval body.

(3) In addition to the requirements specified in sections (1) and (2) of this rule, the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operations or to source changers;

(a) The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

(b) The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

(c) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

(d) Each sealed source or source assembly must have attached to it or engraved on it, a durable, legible, visible label with the words:

"DANGER – RADIOACTIVE."

The label may not interfere with the safe operation of the exposure device or associated equipment.

(e) The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.

(f) Guide tubes must be used when moving the source out of the device.

(g) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during industrial radiography operations.

(h) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980.

(i) Source changers must provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

(4) All radiographic exposure devices and associated equipment in use after January 10, 1996, must comply with the requirements of this division; and

(5) As an exception to section (1) of this rule, equipment used in industrial radiographic operations need not comply with 8.9.2(c) of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can reasonably exert on the lever or crankshaft of the drive mechanism.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-105-0430
Limits on External Radiation Levels From Storage Containers and Source Changers

The maximum exposure rate limits for storage containers and source changers are two millisieverts (200 mrem) per hour at any exterior surface, and 0.1 millisieverts (10 mrem) per hour at one meter from any exterior surface with the sealed source in the shielded position.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0440
Locking of Sources of Radiation, Storage Containers and Source Changers

(1) Each radiographic exposure device must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device and/or its container must be kept locked (If a keyed lock, the key must be removed at all times) when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in 333-105-0580. In addition, during radiographic operations the sealed source assembly must be secured in the shielded position each time the source is returned to that position.

(2) Each sealed source storage container and source changer must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers must be kept locked (If a keyed lock, the key must be removed at all times) when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

(3) The control panel of each radiation machine must be equipped with a lock that will prevent the unauthorized use of an x-ray system or the accidental production of radiation. The radiation

machine must be kept locked and the key removed at all times except when under the direct visual surveillance of a radiographer or a radiographer's assistant.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0450
Radiation Survey Instruments

(1) The licensee must keep sufficient calibrated and operable radiation survey instruments at each location where sources of radiation are present to make the radiation surveys required by this division and by division 120 of these rules. Instrumentation required by this section must be capable of measuring a range from 0.02 millisieverts (2 mrem) per hour through 0.01 sievert (1 rem) per hour.

(2) The licensee must have each radiation survey instrument required under section (1) of this rule calibrated:

(a) At energies appropriate for use and at intervals not to exceed six months or after instrument servicing, except for battery changes;

(b) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at three points between 0.02 and ten millisieverts (2 and 1000 mrem) per hour; and

(c) So that an accuracy within plus or minus 20 percent of the true radiation dose rate can be demonstrated at each point checked.

(3) The licensee must maintain records of the results of the instrument calibrations in accordance with 333-105-0620.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0460
Leak Testing and Replacement of Sealed Sources

(1) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source must be performed by persons authorized to do so by the Authority, the Nuclear Regulatory Commission, or another Agreement State.

(2) The opening, repair, or modification of any sealed source must be performed by persons specifically authorized to do so by the Authority, the Nuclear Regulatory Commission, or another Agreement State.

(3) Testing and recordkeeping requirements.

(a) Each licensee who uses a sealed source must have the source tested for leakage at intervals not to exceed six months. The leak testing of the source must be performed using a method approved by the Authority, the Nuclear Regulatory Commission, or by another Agreement State. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 185 becquerel (0.005 microCurie) of radioactive material on the test sample and must be performed by a person specifically authorized by the Authority, the Nuclear Regulatory Commission, or another Agreement State to perform the analysis.

(b) The licensee must maintain records of the leak tests in accordance with 333-105-0630.

(c) Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within six months before the transfer, it may not be used by the licensee until tested for leakage. Sealed sources that are in storage and not in use do not require leak testing, but must be tested before use or transfer to another person if the interval of storage exceeds six months. Leak test results must be received prior to use or transfer.

(4) Any test conducted pursuant to section (2) and (3) of this rule that reveals the presence of 185 Becquerel (0.005 microCurie) or more of removable radioactive material must be considered evidence that the sealed source is leaking. The licensee must immediately withdraw the equipment involved from use and must have it decontaminated and repaired or disposed of in accordance with Authority rules. A report must be filed with the Authority within five days of any test with results that exceed the threshold in this paragraph, describing the equipment involved, the test results, and the corrective action taken.

(5) Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration must be tested for DU contamination at intervals not to exceed 12 months. The analysis must be capable of detecting the presence of 185 becquerel (0.005 microCurie) of radioactive material on the test sample and must be performed by a person specifically authorized by the Authority, the Nuclear Regulatory Commission, or another Agreement State to perform the analysis. Should such testing reveal the presence of DU contamination, the exposure device must be removed from use until an evaluation of the wear of the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while not in use and in storage. Before using or transferring such a device, however, the device must be tested for DU contamination, if the interval of storage exceeds 12 months. A record of the DU leak-test must be made in accordance with 333-105-0630.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0470
Quarterly Inventory

(1) Each licensee must conduct a quarterly physical inventory to account for all sources of radiation, and for devices containing depleted uranium received and possessed under the license.

(2) The licensee must maintain records of the quarterly inventory in accordance with 333-105-0640.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0480
Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments

(1) The licensee must perform visual and operability checks on survey meters, radiation machines, radiographic exposure devices, transport and storage containers, associated equipment and source changers before each day's use, or work shift, to ensure that:

(a) The equipment is in good working condition;

(b) The sources are adequately shielded; and

(c) Required labeling is present.

(2) Survey instrument operability must be performed using check sources or other appropriate means.

(3) If equipment problems are found, the equipment must be removed from service until repaired.

(4) Each licensee must have written procedures for and perform inspection and routine maintenance of radiation machines, radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed three months or before the first use thereafter to ensure the proper functioning of components important to safety. If equipment problems are found, the equipment must be removed from service until repaired.

(5) The licensee's inspection and maintenance program must include procedures to assure that Type B packages are shipped and

maintained in accordance with the certificate of compliance or other approval.

(6) Records of equipment problems and of any maintenance performed under this rule must be made in accordance with 333-105-0660.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0490
Permanent Radiographic Installations

(1) Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation must have either:

(a) An entrance control of the type described in OAR 333-120-0220 that causes the radiation level upon entry into the area to be reduced; or

(b) Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal must be actuated by radiation whenever the source is exposed. The audible signal must be actuated when an attempt is made to enter the installation while the source is exposed or the machine is energized.

(2) The alarm system must be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test must include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry as designated in section (1)(a) of this rule must be tested monthly. If an entrance control device or an alarm is operating improperly, it must be immediately labeled as defective and repaired within seven calendar days. The facility may continue to be used during this seven-day period, provided the licensee implements the continuous surveillance requirements of 333-105-0580 and uses an alarming rate-meter. Test records for entrance controls and audible and visual alarms must be maintained in accordance with 333-105-0670.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0500
Labeling, Storage, and Transportation

(1) The licensee may not use a source changer or a container to store radioactive material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol conventional colors, i.e., magenta, purple or black on a yellow background, having a minimum diameter of 25 mm, and the wording:

CAUTION RADIOACTIVE MATERIAL
NOTIFY CIVIL AUTHORITIES
or "DANGER"

(2) The licensee may not transport radioactive material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with rules set out in division 118.

(3) Radiographic exposure devices, source changers, storage containers, and radiation machines, must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee must store radioactive material in a manner that will minimize danger from explosion or fire.

(4) The licensee must lock and physically secure the transport package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

(5) The licensee's name and city or town where the main business office is located must be prominently displayed with a durable, clearly visible label(s) on both sides of all vehicles used to transport radioactive material or radiation machines for temporary job site use.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

Radiation Safety Requirements

333-105-0510
Conducting Industrial Radiographic Operations

(1) Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of 333-105-0530(3). The additional qualified individual must observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present.

(2) All radiographic operations must be conducted in a permanent radiographic installation unless otherwise specifically authorized by the Authority.

(3) Except when physically impossible, collimators must be used in industrial radiographic operations that use radiographic exposure devices that allow the source to be moved out of the device.

(4) A licensee may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the Authority, the Nuclear Regulatory Commission, or by another Agreement State.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0520
Radiation Safety Officer

The radiation safety officer must ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's program.

(1) The minimum qualifications, training, and experience for radiation safety officers for industrial radiography are as follows:

(a) Completion of the training and testing requirements of 333-105-0530(1);

(b) 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

(c) Formal training in the establishment and maintenance of a radiation protection program.

(2) The Authority will consider alternatives when the radiation safety officer has appropriate training and experience in the field of ionizing radiation, and in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

(3) The specific duties and authorities of the radiation safety officer include:

(a) Establishing and overseeing all operating, emergency, and ALARA procedures as required by division 120 of these rules and reviewing them regularly to ensure that they conform to Authority rules and to the license or registration conditions;

(b) Overseeing and approving the training program for radiographic personnel to ensure that appropriate and effective radiation protection practices are taught;

(c) Ensuring that required radiation surveys and leak tests are performed and documented in accordance with the rules, including any corrective measures when levels of radiation exceed established limits;

(d) Ensuring that personnel monitoring devices are calibrated, if applicable, and used properly; that records are kept of the monitoring results; and that timely notifications are made as required by division 120 of these rules; and

(e) Ensuring that operations are conducted safely and for implementing corrective actions including terminating operations.

(4) Licensees will have two years from the effective date of this rule to meet the requirements of section (1) and (2) of this rule.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0530
Training

(1) The licensee may not permit any individual to act as a radiographer until the individual:

(a) Has received training in the subjects outlined in section (7) of this rule, in addition to on the job training consisting of hands-on experience under the supervision of a radiographer and is certified through a radiographer certification program. . The on the job training must include a minimum of two months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material and/or one month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines. Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of the on the job training (3 months or 480 hours); or

(b) The licensee may, until July 1, 2003, allow an individual who has not met the requirements of subsection (1)(a) of this rule, to act as a radiographer after the individual has received at least 40 hours of training in the subjects outlined in section (7) of this rule and demonstrated an understanding of these subjects by successful completion of a written examination that was previously submitted to and approved by the Authority, the Nuclear Regulatory Commission, or another Agreement State, in addition to on the job training consisting of hands-on experience under the supervision of a radiographer. The on the job training must include a minimum of two months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material and/or one month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines. Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of the on the job training (3 months or 480 hours).

(2) In addition, the licensee may not permit any individual to act as a radiographer until the individual:

(a) Has received copies of and instruction in the requirements described in the rules contained in this division, and applicable sections of divisions 120, 111, and 118 of these rules, in the license or registration under which the radiographer will perform industrial radiography, and the licensee's operating and emergency procedures;

(b) Has demonstrated an understanding of items in subsection (2)(a) of this rule by successful completion of a written or oral examination;

(c) Has received training in the use of the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and

(d) Has demonstrated understanding of the use of the equipment described in subsection (2)(c) of this rule by successful completion of a practical examination.

(3) The licensee may not permit any individual to act as a radiographer's assistant until the individual:

(a) Has received copies of and instruction in the requirements described in the rules contained in this, and applicable sections of divisions 120, 111, and 118 of these regulation, in the license or registration under which the radiographer's assistant will perform industrial radiography, and the licensee's operating and emergency procedures;

(b) Has demonstrated an understanding of items in subsection (3)(a) of this rule by successful completion of a written or oral examination;

(c) Under the personal supervision of a radiographer, has received training in the use of the licensee's radiographic exposure devices and sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and

(d) Has demonstrated understanding of the use of the equipment described in subsection (3)(c) of this rule by successful completion of a practical examination.

(4) The licensee must provide annual refresher safety training, as defined in OAR 333-105-0005, for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

(5) Except as provided in subsection (5)(d) of this rule, the radiation safety officer or designee must conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Authority's rules, license requirements, and operating and emergency procedures are followed. The inspection program must:

(a) Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed six months; and

(b) Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than six months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of subsection (2)(c) of this rule and the radiographer's assistant must demonstrate knowledge of the training requirements of subsection (3)(c) of this rule by a practical examination before these individuals can next participate in a radiographic operation.

(c) The Authority may consider alternatives in those situations where the individual serves as both radiographer and radiation safety officer.

(d) In those operations where a single individual serves as both radiographer and radiation safety officer, and performs all radiography operations, an inspection program is not required.

(6) The licensee must maintain records of the above training to include certification documents, written, oral and practical examinations, refresher safety training and inspections of job performance in accordance with OAR 333-105-0680.

(7) The licensee must include the following subjects required in section (1) of this rule:

(a) Fundamentals of radiation safety including:

(A) Characteristics of gamma and x-radiation;

(B) Units of radiation dose and quantity of radioactivity;

(C) Hazards of exposure to radiation;

(D) Levels of radiation from sources of radiation; and

(E) Methods of controlling radiation dose (time, distance, and shielding);

(b) Radiation detection instruments including:

(A) Use, operation, calibration, and limitations of radiation survey instruments;

(B) Survey techniques; and

(C) Use of personnel monitoring equipment;

(c) Equipment to be used including:

(A) Operation and control of radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtails);

(B) Operation and control of radiation machines;

(C) Storage, control, and disposal of sources of radiation; and

(D) Inspection and maintenance of equipment.

(d) The requirements of pertinent state and federal rules; and

(e) Case histories of accidents in radiography.

(8) Licensees will have one year from the effective date of this rule to comply with the additional training requirements specified in subsections (2)(a) and (3)(a) of this rule.

[ED. NOTE: Appendices referenced are available from the agency.]
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-105-0540
Operating and Emergency Procedures

(1) Operating and emergency procedures must include, as a minimum, instructions in the following:

(a) Appropriate handling and use of sources of radiation so that no person is likely to be exposed to radiation doses in excess of the limits established in division 120 of these rules;

(b) Methods and occasions for conducting radiation surveys;

(c) Methods for posting and controlling access to radiographic areas;

(d) Methods and occasions for locking and securing sources of radiation;

(e) Personnel monitoring and the use of personnel monitoring equipment;

(f) Transporting equipment to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when required, and control of the equipment during transportation as described in division 118 of these rules;

(g) The inspection, maintenance, and operability checks of radiographic exposure devices, radiation machines, survey instruments, alarming ratemeters, transport containers, and storage containers;

(h) Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarming ratemeter alarms unexpectedly;

(i) The procedure(s) for identifying and reporting defects and noncompliance, as required by 333-105-0740;

(j) The procedure for notifying proper persons in the event of an accident or incident;

(k) Minimizing exposure of persons in the event of an accident or incident, including a source disconnect, a transport accident, or loss of a source of radiation;

(l) Source recovery procedure if licensee will perform source recoveries; and

(m) Maintenance of records.

(2) The licensee must maintain copies of current operating and emergency procedures in accordance with 333-105-0690 and 333-105-0730.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0550
Supervision of Radiographer's Assistants

The radiographer's assistant must be under the direct visual supervision of a radiographer when using radiographic exposure devices, associated equipment or sources of radiation, or when conducting radiation surveys required by 333-105-0570(2) to determine that the sealed source has returned to the shielded position or the radiation machine is off after an exposure. The personal supervision must include:

(1) The radiographer's physical presence at the site where the sources of radiation are being used;

(2) The availability of the radiographer to give immediate assistance if required; and

(3) The radiographer's direct observation of the assistant's performance of the operations referred to in this section.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0560
Personnel Monitoring

(1) The licensee may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a combination of direct reading dosimeter, an alarming ratemeter, and a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. At permanent radiographic installations where other appropriate alarming or warning devices are in routine use, or during radiographic operations using radiation machines, the use of an alarming ratemeter is not required.

(a) Pocket dosimeters must have a range from zero to two millisieverts (200 mrem) and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

(b) Each personnel dosimeter must be assigned to and worn by only one individual.

(c) Film badges must be exchanged and processed at periods not to exceed one month and other personnel dosimeters processed and evaluated by an accredited NVLAP processor must be replaced at periods not to exceed three months.

(d) After replacement, each personnel dosimeter must be returned to the supplier for processing within 14 calendar days of the end of the monitoring period, or as soon as practicable. In circumstances that make it impossible to return each personnel dosimeter in 14 calendar days, such circumstances must be documented and available for review by the Authority.

(2) Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with 333-105-0700.

(3) Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed 12 months for correct response to radiation, and records must be maintained in accordance with 333-105-0700(1). Acceptable dosimeters must read within plus or minus 20 percent of the true radiation exposure.

(4) If an individual's pocket dosimeter is found to be off-scale, or the electronic personal dosimeter reads greater than two millisieverts (200 mrem), the individual's personnel dosimeter must be sent for processing within 24 hours. In addition, the individual may not resume work associated with the use of sources of radiation until a determination of the individual's radiation exposure has been made. This determination must be made by the radiation safety officer or the radiation safety officer's designee. The results of this determination must be included in the records maintained in accordance with 333-105-0700.

(5) If a personnel dosimeter is lost or damaged, the worker must cease work immediately until a replacement personnel dosimeter is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter. The results of the calculated exposure and the time period for which the personnel dosimeter was lost or damaged must be included in the records maintained in accordance with 333-105-0700.

(6) Dosimetry reports received from the accredited NVLAP personnel dosimeter processor must be retained in accordance with 333-105-0700.

(7) Each alarming ratemeter must:

(a) Be checked to ensure that the alarm functions properly before using at the start of each shift;

(b) Be set to give an alarm signal at a preset dose rate of five millisieverts (500 mrem per hour) with an accuracy of plus or minus 20 percent of the true radiation dose rate;

(c) Require special means to change the preset alarm function; and

(d) Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee must maintain records of alarming ratemeter calibrations in accordance with 333-105-0700(2).

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0570
Radiation Surveys

The licensee must:

(1) Conduct all surveys with a calibrated and operable radiation survey instrument that meets the requirements of 333-105-0450;

(2) Conduct a survey of the radiographic exposure device and the guide tube after each exposure when approaching the device or the guide tube. The survey must determine that the sealed source has returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment. Radiation machines must be surveyed after each exposure to determine that the machine is off;

(3) Conduct a survey of the radiographic exposure device whenever the source is exchanged and whenever a radiographic exposure device is placed in a storage area as defined in 333-105-0005, to ensure that the sealed source is in its shielded position; and

(4) Maintain records in accordance with 333-105-0710.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0580
Surveillance

During each radiographic operation, the radiographer must ensure continuous direct visual surveillance of the operation to protect against unauthorized entry into a radiation area or a high radiation area, as defined in division 100 of these rules, except at permanent radiographic installations where all entryways are locked and the requirements of 333-105-0490 are met.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0590
Posting

All areas in which industrial radiography is being performed must be conspicuously posted as required by OAR 333-120-0410. The exceptions listed in 333-120-0420 do not apply to industrial radiographic operations.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

Recordkeeping Requirements

333-105-0600
Records for Industrial Radiography

Each licensee must maintain a copy of its license, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the Authority, or until the Authority terminates the license.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0610
Records of Receipt and Transfer of Sources of Radiation

(1) Each licensee must maintain records showing the receipts and transfers of sealed sources, devices using Depleted Uranium (DU) for shielding, and radiation machines, and retain each record for three years after it is made.

(2) These records must include the date, the name of the individual making the record, radionuclide, number of Becquerel (Curies) or mass (for DU), and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0620
Records of Radiation Survey Instruments

Each licensee must maintain records of the calibrations of its radiation survey instruments that are required under 333-105-0450 and retain each record for three years after it is made.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0630
Records of Leak Testing of Sealed Sources and Devices Containing DU

Each licensee must maintain records of leak test results for sealed sources and for devices containing DU. The results must be stated in units of Becquerels (microcuries). The licensee must retain each record for three years after it is made or until the source in storage is removed.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0640
Records of Quarterly Inventory

(1) Each licensee must maintain records of the quarterly inventory of sources of radiation, including devices containing DU as required by 333-105-0470, and retain each record for three years.

(2) The record must include the date of the inventory, name of the individual conducting the inventory, radionuclide, number of Becquerel (curies) or mass (for DU) in each device, location of sources of radiation and/or devices, and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0650
Utilization Logs

(1) Each licensee must maintain utilization logs showing for each source of radiation the following information:

(a) A description, including the make, model, and serial number of the radiation machine or the radiographic exposure device, transport, or storage container in which the sealed source is located;

(b) The identity and signature of the radiographer to whom assigned;

(c) The location and dates of use, including the dates removed and returned to storage; and

(d) For permanent radiographic installations, the dates each radiation machine is energized.

(2) The licensee must retain the logs required by section (1) of this rule for three years.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0660
Records of Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments

(1) Each licensee must maintain records specified in 333-105-0480 of equipment problems found in daily checks and quarterly inspections of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source

changers, and survey instruments; and retain each record for three years after it is made.

(2) The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was performed.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0670
Records of Alarm System and Entrance Control Checks at Permanent Radiographic Installations

Each licensee must maintain records of alarm system and entrance control device tests required by 333-105-0490 and retain each record for three years after it is made.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0680
Records Of Training and Certification

Each licensee must maintain the following records for three years after the individual terminates employment:

(1) Records of training of each radiographer and each radiographer's assistant. The record must include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, the names of individuals conducting and receiving the oral and practical examinations, and a list of items tested and the results of the oral and practical examinations; and

(2) Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any non-compliance observed by the radiation safety officer or designee.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0690
Copies of Operating and Emergency Procedures

Each licensee must maintain a copy of current operating and emergency procedures until the Authority terminates the license or registration. Superseded material must be retained for three years after the change is made.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0700
Records of Personnel Monitoring

Each licensee must maintain the following exposure records specified in 333-105-0560:

(1) Direct reading dosimeter readings and yearly operability checks required by 333-105-0560(2) and 333-105-0560(3) for three years after the record is made;

(2) Records of alarming ratemeter calibrations for three years after the record is made;

(3) Reports received from the film badge or TLD processor until the Authority terminates the license or registration; and

(4) Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged film badges or TLD's, until the Authority terminates the license or registration.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0710
Records of Radiation Surveys

Each licensee must maintain a record of each exposure device survey conducted before the device is placed in storage as specified in 333-105-0570(3). Each record must be maintained for three years after it is made.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0720
Form of Records

Each record required by this division must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee must maintain adequate safeguards against tampering with and loss of records.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0730
Location Of Documents and Records

(1) Each licensee must maintain copies of records required by this division and other applicable divisions of these rules at the location specified in 333-105-0410(11).

(2) Each licensee must also maintain current copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary job site:

(a) The license or registration authorizing the use of sources of radiation;

(b) A copy of divisions 100, 120, 105 & 111 of this chapter;

(c) Utilization logs for each source of radiation dispatched from that location as required by 333-105-0650.

(d) Records of equipment problems identified in daily checks of equipment as required by 333-105-0660(1);

(e) Records of alarm system and entrance control checks required by 333-105-0670, if applicable;

(f) Records of dosimeter readings as required by 333-105-0700;

(g) Operating and emergency procedures as required by 333-105-0690;

(h) Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by 333-105-0620;

(i) Evidence of the latest calibrations of alarming ratemeters and operability checks of dosimeters as required by 333-105-0700;

(j) Survey records as required by 333-105-0710 and 333-120-0620 as applicable, for the period of operation at the site;

(k) The shipping papers for the transportation of radioactive materials required by division 118 of these rules; and

(l) When operating under reciprocity pursuant to OAR 333-102-0340, a copy of the applicable State license or registration, or Nuclear Regulatory Commission license authorizing the use of sources of radiation.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

Notifications

333-105-0740
Notifications

(1) In addition to the reporting requirements specified in 10 CFR 30.50 and in division 120 of these rules, each licensee must provide a written report to the Authority within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

(a) Unintentional disconnection of the source assembly from the control cable;

(b) Inability to retract the source assembly to its fully shielded position and secure it in this position;

(c) Failure of any component, which is critical to safe operation of the device, to properly perform its intended function; or

(d) An indicator on a radiation machine fails to show that radiation is being produced.

(2) The licensee must include the following information in each report submitted under section (1) of this rule, and in each report of overexposure submitted under OAR 333-120-0720 which involves failure of safety components of radiography equipment:

(a) Description of the equipment problem;

(b) Cause of each incident, if known;

(c) Name of the manufacturer and model number of equipment involved in the incident;

(d) Place, date, and time of the incident;

(e) Actions taken to establish normal operations;

(f) Corrective actions taken or planned to prevent recurrence; and

(g) Names and qualifications of personnel involved in the incident.

(3) Any licensee conducting radiographic operations or storing sources of radiation at any location not listed on the license or registration for a period in excess of 180 days in a calendar year, must notify the Authority prior to exceeding the 180 days.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0750
Reciprocity

(1) All reciprocal recognition of licenses and registrations by the Authority will be granted in accordance with OAR 333-102-0340.

(2) Reciprocal recognition by the Authority of an individual radiographer certification will be granted provided that:

(a) The individual holds a valid certification in the appropriate category issued by a certifying entity, as defined in 333-105-0005;

(b) The requirements and procedures of the certifying entity issuing the certification affords the same or comparable certification standards as those afforded by 333-105-0530(1);

(c) The applicant presents the certification to the Authority prior to entry into the state; and

(d) No escalated enforcement action is pending with the Nuclear Regulatory Commission or in any other state.

(3) Certified individuals who are granted reciprocity by the Authority must maintain the certification upon which the reciprocal recognition was granted, or prior to the expiration of such certification, must meet the requirements of 333-105-0530(1).

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-105-0760
Specific Requirements for Radiographic Personnel Performing Industrial Radiography

(1) At a job site, the following must be supplied by the licensee:

(a) At least one operable, calibrated survey instrument for each exposure device or radiation machine in use;

(b) A current whole body personnel monitor (TLD or film badge) for each person performing radiographic operations;

(c) An operable, calibrated pocket dosimeter with a range of zero to 200 milliroentgens for each person performing radiographic operations;

(d) An operable, calibrated, alarming ratemeter for each person performing radiographic operations using a radiographic exposure device; and

(e) The appropriate barrier ropes and signs.

(2) Each radiographer at a job site must have on their person a valid certification ID card issued by a certifying entity.

(3) Industrial radiographic operations must not be performed if any of the items in section (1) and (2) of this rule are not available at the job site or are inoperable.

(4) During an inspection, the Authority may terminate an operation if any of the items in section (1) and (2) of this rule are not available or operable, or if the required number of radiographic personnel are not present. Operations must not be resumed until all required conditions are met.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

DIVISION 106

X-RAYS IN THE HEALING ARTS

333-106-0001
Purpose and Scope

This Division establishes requirements, for which a registrant is responsible, for use of X-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The provisions of this Division are in addition to, and not in substitution for, other applicable provisions of these rules.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

333-106-0005
Definitions

As used in this division, the following definitions apply:

(1) "Accessible Surface" means the external surface of the enclosure or housing provided by the manufacturer.

(2) "Added Filtration" means any filtration that is in addition to the inherent filtration.

(3) "Aluminum Equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

NOTE: The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

(4) "Applications Training" means a vendor or manufacturer providing training for specific X-ray equipment.

(5) "A.R.R.T." means the American Registry of Radiologic Technologists.

(6) "Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an X-ray system or subsystem. The term includes the owner of an X-ray system or his or her employee or agent who assembles components into an X-ray system that is subsequently used to provide professional or commercial services.

(7) "Attenuation Block" means a block or stack, having dimensions 20 centimeters (cm) by 20 cm by 3.8 cm, of type 1100 aluminum alloy or other materials having equivalent attenuation.

(8) "Authority approved instructor" means an individual who has been evaluated and approved by the Authority to teach Radiation Safety.

(9) "Authority approved training course" means a course of training that has been evaluated and approved by the Authority.

(10) "Automatic Exposure Control (AEC)" means a device that automatically controls one or more technique factors in order to obtain at a pre-selected location(s) a required quantity of radiation. (See also "Photo timer".)

(11) "Barrier" (see "Protective Barrier").

(12) "Beam Axis" means a line from the source through the centers of the X-ray fields.

(13) "Beam-Limiting Device" means a device that provides a means to restrict the dimensions of the X-ray field.

(14) "Beam Monitoring System" means a system designed to detect and measure the radiation present in the useful beam.

(15) "C-arm X-ray system" means an X-ray system in which the image receptor and X-ray tube housing are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

(16) "Cephalometric Device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

(17) "Certified Components" means components of X-ray systems that are subject to the X-ray Equipment Performance Standards promulgated under Public Law 90-602, the Radiation Control Agency for Health and Safety Act of 1968.

(18) "Certified System" means any X-ray system that has one or more certified component(s).

(19) "Changeable Filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical or physical process.

(20) "Coefficient of Variation (C)" means the ratio of the standard deviation to the mean value of a set of observations.

(21) "Computed tomography (CT)" means the production of a tomogram by the acquisition and computer processing of X-ray transmission data.

(22) "Computed radiography (CR)" means creating an X-ray image using plates consisting of a photo stimulable phosphor (PSP) that when exposed to radiation and then processed by a scanner, provides the information to a computer for display and manipulation.

(23) "Contact Therapy System" means an X-ray system used for therapy with the tube port placed in contact with or within five centimeters of the surface being treated.

(24) "Control Panel" means that part of the X-ray control upon which are mounted the switches, knobs, pushbuttons and other hardware necessary for manually setting the technique factors.

(25) "Cooling Curve" means the graphical relationship between heat units stored and cooling time.

(26) "Dead-Man Switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

(27) "Detector" (see "Radiation detector").

(28) "Diagnostic X-ray imaging system" means an assemblage of components for the generation, emission, and reception of X-rays and the transformation, storage, and visual display of the resultant X-ray image.

(29) "Diagnostic Source Assembly" means the tube housing assembly with a beam-limiting device attached.

(30) "Diagnostic-Type Protective Tube Housing" means a tube housing so constructed that the leakage radiation measured at a distance of one meter from the source does not exceed 100 milliroentgens (mR) in one hour when the tube is operated at its leakage technique factors.

(31) "Diagnostic X-ray System" means an X-ray system designed for irradiation of any part of the human body or animal body for the purpose of diagnosis or visualization.

(32) "Direct Digital Radiography (DR)"" means creating an X-ray image by sending signals directly from a digital image receptor to a computer for display and manipulation.

(33) "Direct Scattered Radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (see "Scattered radiation").

(34) "Entrance Exposure Rate" means the exposure free in air per unit of time.

(35) "Field Emission Equipment" means equipment which uses a tube in which electron emission from the cathode is due solely to the action of an electric field.

(36) "Filter" means material placed in the useful beam to absorb preferentially selected radiations.

(37) "Fluoroscopic Benchmark" means a standard based upon the average cumulative fluoroscopic on-time normally found to be used for a specific fluoroscopic procedure at the site.

(38) "Fluoroscopic Imaging Assembly" means a subsystem in which X-ray photons produce a visible image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

(39) "Fluoroscopic X-ray equipment operator" means any individual who, adjusts technique factors, activates the exposure switch or button of a fluoroscopic X-ray machine or physically positions patients or animals. Human holders, used solely for immobilization purposes (example being veterinarian human holders) are excluded from this rule.

(40) "Focal Spot" means the area projected on the anode of the tube by the electrons accelerated from the cathode and from which the useful beam originates.

(41) "General Purpose Radiographic X-ray System" means any radiographic X-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

(42) "Gonad Shield" means a protective barrier for the testes or ovaries.

(43) "Half-Value Layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

(44) "Healing arts screening" means the testing of human beings using X-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by an Oregon licensed practitioner of the healing arts legally authorized to prescribe such X-ray tests for the purpose of diagnosis or treatment.

(45) "Heat Unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes and seconds, example being kVp x mA x second.

(46) "HVL" (see "Half-value layer").

(47) "Image Intensifier" means a device, installed in its housing, which instantaneously converts an X-ray pattern into a corresponding light image of higher energy density.

(48) "Image Receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident photons either into a visible image or into another form which can be made into a visible image by further transformations.

(49) "Inherent Filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

(50) "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

(51) "Irradiation" means the exposure of matter to ionizing radiation.

(52) "Kilovolt-Peak" (see "Peak tube potential").

(53) "kV" means kilovolts.

(54) "kVp" (see "Peak tube potential").

(55) "kWs" means kilowatt second.

(56) "Lead Equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

(57) "Leakage Radiation" means radiation emanating from the diagnostic or therapeutic source assembly except for:

(a) The useful beam; and

(b) Radiation produced when the exposure switch or timer is not activated.

(58) "Leakage Technique Factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

(a) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, example being 10 milliampere seconds (mAs), or the minimum obtainable from the unit, whichever is larger.

(b) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of X-ray pulses in an hour for operation at the maximum-rated peak tube potential.

(c) For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

(59) "Light Field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

(60) "Line-Voltage Regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential.

(61) "mA" means milliampere.

(62) "mAs" means milliampere second.

(63) "Maximum Line Current" means the root-mean-square current in the supply line of an X-ray machine operating at its maximum rating.

(64) "Mobile Equipment" (see "X-ray Equipment").

(65) "Non-radiologist practitioner" means an individual who practices medicine as a medical doctor (M.D.), doctor of osteopathic medicine (D.O), doctor of chiropractic medicine (D.C.), doctor of podiatric medicine (D.P.M.) or doctor of veterinary medicine (D.V.M.); and

(a) Are not specifically certified in diagnostic or therapeutic use of X-rays; and

(b) Are currently licensed by their respective Oregon licensing board.

(66) "Operator" means an individual who, under the supervision of a practitioner of the healing arts, handles ionizing radiation equipment, physically positions patients or animals, determines exposure parameters or applies the radiation for the diagnostic or therapeutic purposes intended.

(67) "Patient" means an individual subjected to healing arts examination, diagnosis, or treatment.

(68) "Peak Tube Potential" means the maximum value of the potential difference across the X-ray tube during an exposure.

(69) "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

(70) "Photo timer" means a method for controlling radiation exposures to image receptors by measuring the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is a part of an electronic circuit which controls the duration of time the tube is activated (see also "Automatic exposure control").

(71) "PID" (see "Position indicating device").

(72) "Portable Equipment" (see "X-ray Equipment").

(73) "Position Indicating Device" means a device on dental X-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

(74) "Primary Dose Monitoring System" means a system which will monitor useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been acquired.

(75) "Primary Protective Barrier" (see "Protective barrier").

(76) "Protective Apron" means an apron made of radiation absorbing materials used to reduce radiation exposure.

(77) "Protected Area" means an area shielded with primary or secondary protective barriers or an area removed from the radiation source such that the exposure rate within the area due to normal operating procedures and workload does not exceed any of the following limits:

(a) 2 milliroentgens (mR) in any one hour; or

(b) 100 mR in any one year.

(c) See OAR 333-120-0180 for additional information.

(78) "Protective Barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

(a) "Primary protective barrier" means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure;

(b) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

(79) "Protective Glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

(80) "Qualified Expert" means an individual, approved by the Authority, who has demonstrated, pursuant to these rules, that he/she possesses the knowledge, skills, and training to measure ionizing radiation, to evaluate radiation parameters, to evaluate safety techniques, and to advise regarding radiation protection needs. The individual shall:

(a) Be certified in the appropriate field by the American Board of Radiology, the American Board of Health Physics, the American Board of Medical Physics or the American Board of Nuclear Medicine Science; or

(b) Hold a master's or doctor's degree in physics, biophysics, radiological physics, health physics, or medical physics and have completed one year of documented, full time training in the appropriate field and also one year of documented, full time work experience under the general supervision of a qualified expert in the appropriate field. To meet this requirement, the individual shall have performed the tasks required of a qualified expert during the year of work experience; or

(c) Receive approval from the Authority for specific activities.

(81) "Quality Control Program" means a program directed at film processing and radiographic image quality whereby periodic monitoring of film processing is performed. Test films are compared against control film, either visually or by use of a densitometer, to determine if density or contrast have changed. Steps can then be taken to investigate such change and correct the problem. The X-ray machine itself can also be involved in the quality control program, as can other components of the imaging chain.

(82) "Radiation Detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

(83) "Radiation Therapy Simulation System" means a radiographic or fluoroscopic system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

(84) "Radiograph" means an image receptor on which the image is created directly or indirectly by a pattern and results in a permanent record.

(85) "Radiographic Imaging System" means any system whereby a permanent or semipermanent image is recorded on an image receptor by the action of ionizing radiation.

(86) "Radiological Physicist" means an individual who:

(a) Is certified by the American Board of Radiology in therapeutic radiological physics, radiological physics, or x- and gamma-ray physics; or

(b) Has a bachelor's degree in one of the physical sciences or engineering and three years full-time experience working in therapeutic radiological physics under the direction of a physicist certified by the American Board of Radiology. The work duties

must include duties involving the calibration and spot checks of a medical accelerator or a sealed source teletherapy unit; or

(c) Has a master's or a doctor's degree in physics, biophysics, radiological physics, health physics, or engineering; has had one year's full-time training in therapeutic radiological physics; and has had one year's full-time work experience in a radiotherapy facility where the individual's duties involve calibration and spot checks of a medical accelerator or a sealed source teletherapy unit.

(87) "Radiologist" or "Oral Radiologist" means a physician or dentist trained in the diagnostic use of X-rays and who is;

(a) Currently licensed by their respective Oregon licensing board; and

(b) Board certified by the American Board of Radiology (ABR) or American Osteopathic Board of Radiology (AOBR) or American Chiropractic Board of Radiology (DACBR) or Royal College of Physicians and Surgeons of Canada (RCPSC) or the American Board of Oral and Maxillo-Facial Radiology (ABOMFR) and currently licensed to practice medicine or dentistry in Oregon; or

(c) ABR board eligible after successfully completing the Accreditation Council for Graduate Medical Education accredited diagnostic radiology residency program.

(88) "Radiology Physician's Assistant" (R.P.A.)/ "Registered Radiology Assistant" (R.R.A.).

(a) An R.P.A. means an American Registry of Radiologic Technologists (A.R.R.T.) technologist who has successfully completed an advanced training program and is certified by the Certification Board for Radiology Practitioner Assistants (CBRPA).

(b) An R.R.A means an A.R.R.T. technologist who has successfully completed an advanced training program and is certified by A.R.R.T.

(89) "R.T." means a radiologic technologist certified in radiography and currently licensed by the Oregon Board of Medical Imaging.

(90) "Rating" means the operating limits as specified by the component manufacturer.

(91) "Recording" means producing a permanent form of an image resulting from X-ray photons.

(92) "Registrant," as used in this division, means any person who owns or possesses and administratively controls an X-ray system which is used to deliberately expose humans, animals or materials to the useful beam of the system and is required by the provisions contained in divisions 100 and 101 of this chapter to register with the Authority.

(93) "Response Time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero, sufficient to provide a steady state midscale reading.

(94) "Scattered Radiation" means radiation that, during passage through matter, has been deviated in direction (see "Direct Scattered Radiation").

(95) "Screening" means the use of a systematic approach to obtain cursory examinations of a person or group of persons without regard to specific clinical indications.

(96) "Secondary Dose Monitoring System" means a system which will terminate irradiation in the event of failure of the primary system.

(97) "Secondary Protective Barrier" (see "Protective barrier").

(98) "Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

(99) "SID" (see "Source-image receptor distance").

(100) "Source" means the focal spot of the X-ray tube.

(101) "Source-Image Receptor Distance" means the distance from the source to the center of the input surface of the image receptor.

(102) "Spot Check" means a procedure which is performed to assure that a previous calibration continues to be valid.

(103) "Spot Film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

(104) "Spot-Film Device" means a device intended to transport or position a radiographic image receptor between the X-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

(105) "SSD" means the distance between the source and the skin of the patient.

(106) "Stationary Equipment" (see "X-ray Equipment").

(107) "Stray Radiation" means the sum of leakage and scattered radiation.

(108) "Supervision" means the supervising individual routinely reviews and monitors the work being performed. There are three categories of supervision:

(a) "General Supervision" means that the supervisor is not required to be on-site, but must be available for direct communication, either in person, by telephone, or other electronic means.

(b) "Direct Supervision" means that the supervisor is physically present in the building and immediately available to furnish assistance as needed.

(c) "Personal Supervision" means that the supervisor is physically present in the room during the performance of the procedure at all times.

(109) "Technique Factors" means the conditions of operation. They are specified as follows:

(a) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

(b) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of X-ray pulses;

(c) For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

(110) "Termination of Irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

(111) "Traceable to a National Standard" means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

(112) "Tube" means an X-ray tube, unless otherwise specified.

(113) "Tube Housing Assembly" means the tube housing with tube installed. It includes high-voltage and filament transformers and other appropriate elements when such are contained within the tube housing.

(114) "Tube Rating Chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

(115) "Unprotected Area" means any area in which the exposure rate, due to the use of the radiation machine under normal operating procedures and workload, exceeds any of the following limits:

(a) Two mR in any one hour;

(b) 100 mR in any seven consecutive days; or

(c) 500 mR in any one year.

(116) "Useful Beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the system to produce radiation.

(117) "Variable-Aperture Beam-Limiting Device" means a beam-limiting device which has capacity for stepless adjustment of the X-ray field size at a given SID.

(118) "Visible Area" means that portion of the input surface of the image receptor over which the incident X-ray photons are producing a visible image.

(119) "Wedge Filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

(120) "X-ray Control" means a device which controls input power to the X-ray high-voltage generator and the X-ray tube. It includes equipment such as exposure switches (control), timers,

photo timers, automatic brightness stabilizers and similar devices, which control the technique factors of an X-ray exposure.

(121) "X-ray Equipment" means an X-ray system, subsystem, or component thereof. Types of equipment are as follows:

(a) "Mobile equipment" means X-ray equipment mounted on a permanent base with wheels and casters for moving while completely assembled and intended to be taken from one geographical location to another or from one room to another;

(b) "Portable equipment" means X-ray equipment designed to be hand-carried but not hand-held during operations.

(c) "Stationary equipment" means X-ray equipment which is installed in a fixed location; such as bolted to the floor or wall;

(d) "Transportable" means X-ray equipment installed in a vehicle or trailer;

(e) "Hand-held unit" means a self-contained X-ray machine designed so that it can be held in one or two hands to perform intraoral radiography or other Authority approved radiography.

(122) "X-ray equipment operator" means any individual who handles, adjusts technique factors, activates the exposure switch/or button of an X-ray machine, or physically positions patients or animals for a radiograph (see "Operator").

(123) "X-ray Field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

(124) "X-ray High-Voltage Generator" means a device which transforms electrical energy from the potential supplied by the X-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the X-ray tube(s), high-voltage switches, electrical protective devices and other appropriate elements.

(125) "X-ray System" means an assemblage of components for the controlled production of X-rays. It includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

(126) "X-ray Subsystem" means any combination of two or more components of an X-ray system for which there are requirements specified in this division.

(127) "X-ray Tube" means any electron tube which is designed to be used primarily for the production of X-rays.

[ED. NOTE: Equations referenced are available from the agency.]

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 20-2010, f. & cert. ef. 9-1-10; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15; PH 25-2016, f. 8-26-16, cert. ef. 9-1-16

General Requirements

333-106-0010
Administrative Controls

(1) Registrants shall be responsible for directing the operation of the X-ray system(s) under their administrative control. The registrant or the registrant's agent shall assure that the requirements of this rule are met in the operation of the X-ray system(s).

(2) An X-ray system and/or the operation of the X-ray system which does not meet the provisions of these rules shall not be operated for diagnostic or therapeutic purposes.

(3) For X-ray equipment manufactured after July 31, 1974, the registrant shall assure that the equipment will remain in compliance with the **Code of Federal Regulations**, **Title 21**.

Stat. Auth.: ORS 453.605 - 453.755

Stats. Implemented: ORS 453.605 - 453.755

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 14-2008, f. & cert. ef. 9-15-08

333-106-0015
Technique Chart

A useable up-to-date chart shall be provided in the vicinity of the diagnostic X-ray system's control panel which specifies, for all examinations performed with that system, the following information:

(1)(a) Patient's anatomical size in centimeters versus technique factors to be utilized.

(b) For veterinary X-rays, the patient's anatomical size in centimeters or weight in pounds versus technique factors to be used.

(2) Film-screen combination to be used.

(3) Type and focal distance of the grid to be used, if any.

(4) Source to image receptor distance to be used.

(5) Indication of radiographic examinations requiring gonad shielding, except in the case of veterinary use.

(6) Units utilizing phototimers shall have a chart indicating cell choice, optimum kVp and density setting as well as other applicable requirements of this rule.

(7) Units utilizing automatic techniques that are incorporated in the X-ray machine are considered to meet the requirements of sections (1), (2), (3) and (4) of this rule.

(8) In cases where machine use is restricted to intraoral radiography, or one operator and less than three techniques, the registrant is exempt from the requirements of this rule.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 24-2014, f. & cert. ef. 8-15-14

333-106-0020
Written Rules and Procedures

For safe operation of the registrants X-ray system the following apply when required in writing by the Authority:

(1) Written safety procedures:

(a) Shall be mandatory for hospitals and radiologists;

(b) Shall include any equipment limitations or restrictions;

(c) Shall include any restrictions of the operating technique required for the safe operation of the X-ray system.

(2) Written procedures shall be available for review at any time to all individuals operating X-ray equipment.

(3) The operator shall be able to demonstrate familiarity with these procedures.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.752 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

333-106-0025
Protection of Patients and Personnel

(1) Except for patients who cannot be moved out of the unprotected area, only the staff and ancillary personnel required for the medical procedure or training shall be in the unprotected area during the radiographic exposure.

(2) Other than the patient being examined, all individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter (mm) lead equivalent.

(3) Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 mm lead equivalent.

(4) Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 mm lead equivalent or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-106-0030
Gonad Shielding

(1) Gonad shielding of not less than 0.5 mm lead equivalent shall be used for patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the

useful beam, except for cases in which this would interfere with the diagnostic procedure. In addition:

(a) Collimation shall not be used as a substitute for proper shielding;

(b) Should the situation arise where by gonadal shielding would compromise the diagnosis, a sticker stating "Gonadal shielding would interfere with the diagnostic procedure" (or the equivalent) shall be placed on the film to identify the reason this procedure does not comply with section (1) of this rule.

(2) A written policy regarding gonad shielding shall be provided to each individual operating X-ray equipment. This policy shall include but not be limited to:

(a) Definition of age of patients requiring gonad shielding;

(b) A listing of radiographic procedures requiring gonad shielding for both males and females; and

(c) Other pertinent data that would help insure compliance, such as type and location of placement of gonad shielding.

(3) The registrant shall provide a means to assure that the requirements of section (1) of this rule are followed.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06

333-106-0035
Deliberate Exposures Restricted

Persons shall not be exposed to the useful beam except for healing art purposes until the patient has been evaluated, and a medical need for the X-ray/s is determined, and has been authorized by a physician or Dental Professional licensed to practice the healing arts. Any useful diagnostic information obtained from each exposure shall be reviewed by a practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

(1) Exposure of an individual for training, demonstration or other purposes unless there are also healing arts requirements and proper prescription has been provided.

(2) Exposure of an individual for the purpose of healing arts screening:

(a) Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Authority;

(b) When requesting such approval, that person shall submit the following information.

(A) Name and address of the applicant and, where applicable, the names and addresses of agents within this state;

(B) Diseases or conditions for which the X-ray examinations are to be used in diagnoses;

(C) A detailed description of the X-ray examinations proposed in the screening program to include the estimated total radiation dose received by the individual(s) participating in the screening program;

(D) Description of the population to be examined in the screening program, i.e., age, sex, physical conditions, and other appropriate information;

(E) An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the X-ray examinations;

(F) An evaluation by a qualified expert of the X-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of these rules;

(G) A description of the diagnostic film quality control program;

(H) A copy of the technique chart for the X-ray examination procedures to be used;

(I) The qualifications of each individual who will be operating the X-ray system(s);

(J) The qualifications of the individual who will be supervising the operators of the X-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified;

(K) The name and address of the individual who will interpret the radiograph(s);

(L) A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated;

(M) A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the X-ray examinations.

(3) If any information submitted to the Authority under subsection (2)(b) changes, the Authority shall be immediately notified.

(4) Mammography screening shall be exempt from the requirements of section (2) of this rule if the following conditions are met:

(a) The requirements set forth in OAR 333-106-0700 to 333-106-0750 of these rules are satisfied.

(b) All other applicable rules are met.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 25-2016, f. 8-26-16, cert. ef. 9-1-16

333-106-0040
Patient Holding and Restraint

(1) When a patient or film must be provided with auxiliary support during a radiation exposure:

(a) Mechanical holding devices shall be provided and used when the technique permits. The safety rules, required by OAR 333-106-0020, shall list individual projections where holding devices cannot be used.

(b) Written safety procedures, as required by OAR 333-106-0020, shall indicate the requirements for selecting a holder and the procedure the holder shall follow.

(c) The human holder shall be protected, as required by OAR 333-106-0025.

(2) No individual shall be used routinely to hold film or patients.

(3) Occupationally exposed personnel are prohibited from holding human patients during radiographic examination.

(4) The Authority may require a separate record to be maintained which would include the name of the human holder, date of the examination, number of exposures and technique factor used for the exposure(s).

(5) In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest exposed to the useful beam shall be protected by not less than 0.5 mm lead equivalent material.

(6) Holding of patients shall be permitted only when it is otherwise impossible to obtain the necessary radiograph.

(7) Individuals stressing joints shall be exempt from section (3) of this rule.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-106-0045
Use of Best Procedures and Equipment

(1) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

(2) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.

(3) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality, see Tables 1, 2 and 3. The referenced tables are available on the Program's website: www.healthoregon.org/rps.

(4) Portable or mobile X-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a

stationary X-ray installation due to the medical status of the patient or the inability of the patient to be left alone during the imaging procedure except as permitted under section (5) of this rule.

(5) Hand-held dental units may be used at facilities or programs as defined in ORS 680.205(1) and (2).

(6) X-ray systems subject to OAR 333-106-0301 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters (cm).

(7) Cardboard cassettes without screens shall not be used (dental intraoral excluded).

(8) The number of radiographs taken for any radiographic examination should be the minimum number needed to adequately diagnose the clinical condition.

(9) Use of techniques designed to compensate for anatomical thickness variations after the primary beam has exited the patient is specifically prohibited. This includes "split screen" imaging techniques whereby multiple speed intensifying screens are placed in the same cassette, or any techniques which rely on attenuation of secondary (remnant) radiation for compensatory purposes. Lead lined grids, which are designed to reduce scattered radiation are excluded from this provision.

(10) Filter slot covers shall be provided for the X-ray operator's protection.

(11) Facilities shall determine or cause to be measured the typical patient exposure for their most common radiographic examinations. The exposures shall be recorded as milliroentgens measured in free air at the point of skin entrance for an average patient. These exposure amounts must then be compared to existing guidelines and rules, and if they exceed such guidelines or rules, action must be taken to reduce the exposure while at the same time maintaining or improving diagnostic image quality. In addition, typical patient exposure values shall be posted in the radiographic examination rooms so that they are readily available to administrators, X-ray operators, patients and practitioners.

(12) Protective equipment including aprons, gloves and shields shall be checked annually for defects, such as holes, cracks and tears to assure reliability and integrity. A record of this test shall be made and maintained for inspection by the Authority. If such defect is found, equipment shall be replaced or removed from service until repaired. Fluoroscopy shall only be used for this purpose if a visual and manual check indicated a potential problem.

(13) Dental X-ray machines designed and manufactured to be used for dental purposes shall be restricted to dental use only.

(14) An X-ray quality control program shall be implemented when required by the Authority.

(15) All X-ray equipment must be capable of functioning at the manufacturer's intended specifications.

(16) All patients' radiographic images or copies shall be made available for review by any practitioner of the healing arts, currently licensed by the appropriate Oregon licensing board, upon request of the patient.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 4-2013, f. & cert. ef. 1-29-13; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-106-0050
Personnel Monitoring

All individuals who are associated with the operation of an X-ray system are subject to the requirements of OAR 333-120-0100 and 333-120-0210. In addition:

(1) When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:

(a) When an apron is worn, the monitoring device shall be worn at the collar outside of the apron;

(b) The dose to the whole body based on the maximum dose attributed to the most critical organ (which are the gonads, the blood-forming organs, head and trunk or lens of the eye), shall be recorded in the reports required by OAR 333-120-0650(3). If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.

(2) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

Stat. Auth.: ORS 453.605 - 453.755

Stats. Implemented: ORS 453.605 - 453.755

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94; PH 14-2008, f. & cert. ef. 9-15-08

333-106-0055
X-ray Operator Training

(1) The registrant shall assure that individuals who will be operating the X-ray equipment by physically positioning patients or animals, determining exposure parameters, or applying radiation for diagnostic purposes shall have adequate training in radiation safety.

(a) Radiation safety training records shall be maintained by the registrant for each individual who operates X-ray equipment. Records must be legible and meet the requirements in OAR 333-120-0690.

(b) When requested by the Authority, radiation safety training records shall be made available.

(2) Dental X-ray operators who meet the following requirements are considered to have met the requirements in section (1) of this rule:

(a) Currently licensed by the Oregon Board of Dentistry as a dentist or dental hygienist; or

(b) Is a dental assistant who is certified by the Oregon Board of Dentistry in radiologic proficiency.

(c) Dental radiology students in an approved Oregon Board of Dentistry dental radiology course are permitted to take dental radiographs on human patients during their clinical training, under the direct supervision of a dentist or dental hygienist currently licensed, or a dental assistant who has been certified in radiologic proficiency by the Oregon Board of Dentistry.

(3) Veterinary X-ray operators who meet the following requirements are considered to have met the requirements in section (1) of this rule:

(a) Currently licensed by the Oregon Veterinary Medical Examining Board as a veterinarian or a certified veterinary technician.

(b) Veterinary students enrolled in a radiology course approved by the Oregon Veterinary Medical Examining Board are permitted to take radiographs on animal patients during their clinical training under the direct supervision of a veterinarian or a certified veterinary technician who is currently licensed.

(4) Diagnostic medical X-ray operators who meet the following requirements are considered to have met the requirements of section (1) of this rule:

(a) Holds a current license from the Oregon Board of Medical Imaging; or

(b) Holds a current limited X-ray machine operator permit from the Oregon Board of Medical Imaging; or

(c) Is a student in an approved school of Radiologic Technology as defined in ORS 688.405 while practicing Radiologic Technology under the direct supervision of a radiologist who is currently licensed with the Oregon Medical Board or a radiologic technologist who is licensed with the Oregon Board of Medical Imaging; or

(d) Is a student in an Oregon Board of Medical Imaging approved limited permit program under a radiologic technologist who is licensed by the Oregon Board of Medical Imaging.

(5) All other types of X-ray operators must have completed an Authority approved radiation use and safety course.

(6) At a minimum, an Authority approved training course shall cover the following subjects:

(a) Nature of X-rays:

(A) Interaction of X-rays with matter;
(B) Radiation units;
(C) X-ray production;
(D) Biological effects of X-rays; and
(E) Risks of radiation exposure.
(b) Principles of the X-ray machine:
(A) External structures and operating console;
(B) Internal structures:
(i) Anode; and
(ii) Cathode.
(C) Operation of an X-ray machine;
(D) Tube warm up;
(E) Factors affecting X-ray emission:
(i) mA;
(ii) kVp;
(iii) Filtration; and
(iv) Voltage waveform.
(c) Principles of radiation protection:
(A) Collimation;
(B) Types of personal protection equipment and who must wear it;
(C) ALARA;
(D) Time, distance, shielding;
(E) Operator safety;
(F) Personal dosimetry:
(i) Types of dosimetry;
(ii) Proper placement of dosimetry; and
(iii) Situations that require dosimetry.
(G) Occupational and non-occupational dose limits.
(d) Radiographic technique:
(A) Factors affecting technique choice:
(i) Thickness of part;
(ii) Body composition;
(iii) Pathology; and
(iv) Film versus computed radiography (CR) and digital radiography (DR).
(B) How to develop an accurate chart;
(C) Low dose techniques;
(D) Pediatric techniques (does not apply to veterinary); and
(E) AEC Techniques.
(e) Darkroom:
(A) Safelights;
(B) Chemical storage;
(C) Film storage; and
(D) Darkroom cleanliness.
(f) Image processing:
(A) Automatic film processing;
(B) Dip tank film processing;
(C) Computed radiography (CR) processing; and
(D) Digital radiography (DR) processing.
(g) Image critique:
(A) Reading room conditions;
(B) Light box conditions;
(C) Image identification;
(D) Artifacts;
(E) Exposure indicators for CR and DR;
(F) Technical parameter evaluation; and
(G) Positioning evaluation.
(h) Veterinary X-ray use (for veterinary courses only):
(A) Types of animal restraints;
(B) Small animal versus large animal;
(C) Film holders; and
(D) Portable X-ray machine safety.
(i) Applicable federal and state radiation regulations including those portions of chapter 333, divisions 100, 101, 103, 106, 111, 120, and 124.

(7) In addition to the training outlined in section (6) of this rule, medical X-ray equipment operators using diagnostic radiographic equipment on human patients, and who are not regulated by the Oregon Board of Medical Imaging, must have 100 hours or more of instruction in radiologic technology including, but not limited to:

(a) Anatomy physiology, patient positioning, exposure and technique; and

(b) Appropriate types of X-ray examinations that the individual will be performing; and in addition

(c) Receive 200 hours or more of X-ray laboratory instruction and practice in the actual use of an energized X-ray unit, setting techniques and practicing positioning of the appropriate diagnostic radiographic procedures that they intend to administer.

(8) All X-ray operators shall be able to demonstrate competency in the safe use of the X-ray equipment and associated X-ray procedures.

(9) When required by the Authority, applications training must be provided to the operator before use of X-ray equipment on patients.

(a) Records of this training must be maintained and made available to the Authority for inspection.

(b) The training may be in any format such as hands-on training by a manufacturer's representative, video or DVD instruction, or a training manual.

(10) X-ray equipment operators who have received their radiation safety training outside of Oregon will be considered to have met the training requirements in section (5) of this rule, if the Authority's or applicable Oregon Licensing Board's evaluation of their training or training and experience, reveals that they substantially meet the intent of section (6) of this rule.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 20-2010, f. & cert. ef. 9-1-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 24-2014, f. & cert. ef. 8-15-14; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-106-0060
Radiation Use and Safety Instructor Qualifications

The training required in OAR 333-106-0055(1) must be taught by an Authority approved instructor. Approval will be based upon the following criteria.

(1) A medical use and safety instructor is an individual who is currently:

(a) Licensed as a Radiologic Technologist and approved as an education provider by the Oregon Board of Medical Imaging; or

(b) A dental radiation use and safety instructor is an individual who is currently licensed by the Oregon Board of Dentistry as a Dentist, a Hygienist, or has been approved by the Oregon Board of Dentistry as a radiation use and safety instructor.

(2) A veterinarian radiation use and safety instructor is an individual who is currently:

(a) Licensed by the Oregon Veterinary Medical Examining board as a Veterinarian, or a Veterinary Technician; or

(b) Is currently licensed as a Radiologic Technologist by the Oregon Board of Medical Imaging, and has completed training specific to veterinarian radiography, including training in animal restraint, and has a minimum of two years of experience in taking veterinary radiographs.

(3) On a case by case basis, if an evaluation by the Authority reveals the individual has alternative qualifications that are substantially equivalent to the qualifications listed in subsections (1)(a), (1)(b), (2)(a) or (2)(b) of this rule or is an individual who is qualified under OAR 333-106-0005(80) as a qualified expert, or OAR 333-101-0230 as a Hospital Radiology Inspector.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-106-0101
Diagnostic X-ray Systems

In addition to other requirements of this division, all diagnostic X-ray systems shall meet the following requirements:

(1) Warning Label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(2) The state shall attach an identification number to each X-ray control panel or an appropriate location:

(a) Identification numbers shall not be removed without written permission of the Authority;

(b) Identification numbers shall not be defaced.

(3) Mobile and portable X-ray systems shall meet the requirements of a stationary system when used for greater than seven consecutive days in the same location.

(4) Battery Charge Indicator. On battery-powered X-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(5) Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 100 mR (25.8 C/kg) in one hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

(6) Radiation from Components Other Than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 mR (0.516 C/kg) in one hour at 5 cm from any accessible surface of the component when it is operated in an assembled X-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

(7) Beam Quality:

(a) Half-Value Layer (HVL): The HVL of the useful beam for a given X-ray tube potential shall not be less than the values shown in Table 4. If it is necessary to determine such HVL at an X-ray tube potential which is not listed in Table 4, linear interpolation or extrapolation may be made; The referenced table is available on the Program's website: www.healthoregon.org/rps.

(A) The HVL required in subsection (7)(a) of this rule is considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table 5. The referenced table is available on the Program's website: www.healthoregon.org/rps.

(B) In addition to the requirements of section (5) of this rule, all intraoral dental radiographic systems manufactured on and after December 1, 1980, shall have a minimum HVL not less than 1.5 mm aluminum (Al) equivalent filtration permanently installed in the useful beam;

(C) Beryllium window tubes shall have a minimum of 0.5 mm Al equivalent filtration permanently installed in the useful beam;

(D) For capacitor energy storage equipment, compliance with the requirements of section (5) of this rule shall be determined with the maximum quantity of charge per exposure;

(E) The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials, which are always, present between the source and the patient.

(b) Filtration Controls. For X-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by subsection (5)(a) of this rule is in the useful beam for the given kVp, which has been selected.

(8) Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes, which have been selected, shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the X-ray control panel and at or near the tube housing assembly, which has been selected.

(9) Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly remains stable during an exposure unless the tube housing movement is a designed function of the X-ray system.

(10) Technique Indicators:

(a) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors, which are set prior to the exposure, shall be indicated;

(b) The requirement of subsection (10)(a) of this rule may be met by permanent marking on equipment having fixed technique factors.

(11) There shall be provided for each X-ray machine a means for determining the proper SID.

(12) X-ray film developing requirements. Compliance with this section is required of all healing arts registrants and is designed to ensure that patient and operator exposure is minimized and to produce optimum image quality and diagnostic information:

(a) Manual processing of films.

(A) The relationship between temperature of the developer and development time indicated in Table 6 or the manufacturer's recommendations must be used with standard developing chemistry. The referenced table is available on the Program's website: www.healthoregon.org/rps.

(B) Processing of film. All films shall be processed in such a fashion as to achieve adequate sensitometric performance. This criterion shall be adjudged to have been met if:

(i) Film manufacturer's published recommendations for time and temperature are followed; or

(ii) Each film is developed in accordance with the time-temperature chart (see subsection (12)(a) of this rule).

(C) Chemical-film processing control.

(i) Chemicals shall be mixed in accordance with the chemical manufacturer's recommendations;

(ii) Developer replenisher shall be periodically added to the developer tank based on the recommendations of the chemical or film manufacturer. Solution may be removed from the tank to permit the addition of an adequate volume of replenisher.

(D) All processing chemicals shall be completely replaced at least every two months or as indicated by the manufacturer.

(E) Devices shall be available which will:

(i) Give the actual temperature of the developer; and

(ii) Give an audible or visible signal indicating the termination of a preset development time (in minutes or seconds).

(b) Automatic film processing. Films shall be processed in such a manner that the degree of film development is the same as being achieved by proper adherence to subsection (12)(a) of this rule (manual processing).

(c) Darkrooms. Darkrooms shall be constructed so that film being processed, handled, or stored will be exposed only to light which has passed through an appropriate safelight filter.

(d) Safelights shall be mounted in accordance with manufacturer's recommendations.

(e) Light bulbs used in safelights shall be the type and wattage recommended by the manufacturer.

(f) Safelight lenses shall be the type recommended for use by the film manufacturer.

(g) Rapid film processing. Special chemicals have been designed for use in Endodontics. These chemicals have special development requirements and do not permit as large of a margin of error in darkroom technique as do standard developing chemicals. Failure to precisely follow manufacturer's recommendations can easily lead to overexposure and underdevelopment. Darkroom procedures shall include:

(A) The manufacturer's time temperature development is crucial and shall be followed exactly;

(B) Caution: A timer capable of accurately measuring the short development times required shall be used;

(C) If rapid chemical processing is used for general radiography all applicable requirements of section (12) of this rule shall be followed.

(h) The Authority shall make such tests as may be necessary to determine compliance with this section.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-

2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 11-2011, f. & cert. ef. 10-27-11; PH 4-2013, f. & cert. ef. 1-29-13

333-106-0105
Information and Maintenance Record and Associated Information

(1) The registrant shall maintain the following information for each X-ray and automatic film processing system for inspection by the Authority:

(a) Model, serial numbers and manufacturer's user manuals for all X-ray systems and automatic film processors;

(b) Tube rating charts and cooling curves;

(c) Records of surveys, calibrations maintenance, and modification performed on the X-ray system(s) with names of persons who perform such services;

(d) A scale drawing of the room in which a stationary X-ray system is located with such drawing indicating the current use of areas adjacent to the room and an estimate of the extent of occupancy by individuals in such areas. In addition, the drawing shall include:

(A) The result of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or

(B) The type and thickness of materials, or lead equivalency, of each protective barrier.

(e) A copy of all correspondence with this Authority regarding that X-ray system;

(f) Provisions in section (1) of this rule shall pertain to X-ray systems placed in service after the effective date of these rules.

(2) X-ray Log. Each facility shall maintain an X-ray log containing the patient's name, the type of examinations, and the dates the examinations were performed and the name of the X-ray operator. The X-ray log must have a cover page containing the printed names of all X-ray operators and a sample of their signed initials. The following facilities are exempt from these requirements:

(a) Dental facilities that maintain patient records showing the type and date of the examination and the operator's name;

(b) Industrial facilities doing industrial X-ray only;

(c) Veterinary facilities;

(d) Hospitals or clinics who employ only fully licensed X-ray operators;

(e) Doctors' offices or clinics with only 1 X-ray operator, or 1 X-ray exam;

(f) Academic, when not X-raying humans.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08

333-106-0110
Plan Review

When required by the Authority, and:

(1) Prior to construction, the floor plans and equipment arrangement of all new installations, or modifications of existing installations, utilizing X-rays for diagnostic or therapeutic purposes must be submitted to the Authority for review and approval. The required information is as set out in division 120.

(2) The Authority may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

(3) The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in division 120.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08

333-106-0120
Information on Radiation Shielding for Plan Reviews — Optional

In order to provide an evaluation or technical advice on shielding requirements for a radiation installation, the following information must be submitted:

(1) The plans should show, as a minimum, the following:

(a) The normal location of the X-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the X-ray control panel;

(b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;

(c) The dimensions of the room(s) concerned;

(d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present;

(e) The make and model of the X-ray equipment and the maximum technique factors;

(f) The type of examination(s) or treatment(s) which will be performed with the equipment.

(2) Information on the anticipated workload of the X-ray system(s).

(3) If the services of a qualified expert have been utilized to determine the shielding requirements, a report, including all basic assumptions used, shall be submitted with the plans.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.775
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

333-106-0130
Design Requirements for an Operator's Booth

(1) Space Requirements when required by OAR 333-106-0110 of these rules:

(a) The operator shall be allotted not less than 7.5 square feet (0.697 m2) of unobstructed floor space in the booth;

(b) The operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.61 m);

(c) The space shall be allotted excluding any encumbrance by the X-ray control panel, such as overhang, cables, or other similar encroachments;

(d) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette not reach the operator's station in the booth.

(2) Structural Requirements:

(a) The booth walls shall be permanently fixed barriers of at least seven feet (2.13 m) high;

(b) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed;

(c) Shielding shall be provided to meet the requirements of division 120 of these rules.

(3) X-ray Exposure Control Placement: The X-ray exposure control for the system shall be fixed within the booth and:

(a) Shall be at least 40 inches (1.02 m) from any open edge of the booth wall which is nearest to the examining table;

(b) Shall allow the operator to use the majority of the available viewing windows.

(4) Viewing System Requirements:

(a) Each booth shall have at least one viewing device which will:

(A) Be so placed that the operator can view the patient during any exposure; and

(B) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then that door must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.

(b) When the viewing system is a window, the following requirements also apply:

(A) The viewing area shall be at least one square foot (0.0929 m2);

(B) The design of the booth shall be such that the operator's expected position when viewing the patient and operating the X-ray system is at least 18 inches (0.457 m) from the edge of the booth;

(C) The material constituting the window shall have the same lead equivalence as that required in the booth's wall in which it is mounted.

(c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of subsection (4)(a) of this rule;

(d) When the viewing system is by electronic means:

(A) The camera shall be so located as to accomplish the general requirements of subsection (4)(a) of this rule;

(B) There shall be an alternate viewing system as a backup for the primary system.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08

Fluoroscopic X-ray Systems Requirements

333-106-0201
Fluoroscopic X-ray Systems

All fluoroscopic X-ray systems shall meet the following requirements:

(1) Primary Barrier:

(a) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID;

(b) The X-ray tube used for fluoroscopy shall not produce X-rays unless the barrier is in position to intercept the entire useful beam.

(2) Nonimage intensified types of fluoroscopes shall not be used.

(3) Image-Intensified Fluoroscopy and Spot Filming:

(a) For image-intensified fluoroscopic equipment, neither the length nor the width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent of the SID. The sum of the excess length and the excess width shall be no greater than four percent of the SID. In addition:

(A) Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or a visible area of greater than 300 square cm shall be provided with means for stepless adjustment of the X-ray field;

(B) All equipment with a fixed SID and a visible area of 300 square cm or less shall be provided with either stepless adjustment of the X-ray field or with means to further limit the X-ray field size at the plane of the image receptor to 125 square cm or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of 5 cm by 5 cm or less;

(C) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor; and

(D) Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular X-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor.

(b) Spot-film devices which are certified components shall meet the following additional requirements:

(A) Means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the X-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

(B) It shall be possible to adjust the X-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 cm by 5 cm;

(C) The center of the X-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent of the SID; and

(D) On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(c) If a means exists to override any of the automatic X-ray field size adjustments required in section (3) of this rule, that means:

(A) Shall be designed for use only in the event of system failure;

(B) Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and

(C) Shall be clearly and durably labeled as follows: "FOR X-RAY FIELD LIMITATION SYSTEM FAILURE"

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-106-0205
Activation of the Fluoroscopic Tube

(1) X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(2) Proper training in the operation of fluoroscopic X-ray equipment is required for all operators and shall include but not be limited to the following:

(a) Principles and operation of the fluoroscopic X-ray machine:

(A) Generating X-rays;

(B) kVp and mA;

(C) Image intensification;

(D) High level control versus standard operating mode;

(E) Magnification (multi-field);

(F) Automatic Brightness Control (ABC);

(G) Pulsed versus continuous X-ray dose rates;

(H) Image recording modes;

(I) Imaging Systems (TV and Digital); and

(J) Contrast, noise and resolution.

(b) Radiation units:

(A) Traditional units;

(B) SI units; and

(C) Dose Area Product.

(c) Typical fluoroscopic outputs:

(A) Patient skin entrance dose;

(B) Standard Roentgen per minute (R/min) dose rates; and

(C) High level/Boost enable Roentgen per minute (R/min) dose rates.

(d) Dose reduction techniques for fluoroscopy:

(A) Collimation;

(B) X-ray tube and image intensifier placement;

(C) Patient size versus technique selection;
(D) Grid use;
(E) Last image hold;
(F) Additional beam filtration;
(G) Gantry angles;
(H) Use of spacer cone; and
(I) Pulsed fluoroscopy.
(e) Factors affecting personnel dose:
(A) Patient dose;
(B) Scatter radiation;
(C) Tube and image intensifier placement; and
(D) Time, distance and shielding.
(f) Protective devices:
(A) Lead aprons and gloves;
(B) Thyroid collars;
(C) Protective glasses;
(D) Leaded drapes;
(E) Bucky slot cover; and
(F) Protective shields/barriers.
(g) Radiation exposure monitoring:
(A) Personnel monitors;
(B) Placement of personnel monitors; and
(C) Occupational and non-occupational dose limits.
(h) Biological effects of X-ray radiation:
(A) X-rays and particulate matter;
(B) Absorption variables (field size, dose rate, as an example);
(C) Scatter radiation;
(D) Cell sensitivity;
(E) Acute effects; and
(F) Latent effects.
(i) Applicable regulations:
(A) Federal; and
(B) Oregon Administrative Rules for the Control of Radiation to include, but not limited to, chapter 333, divisions 101, 103, 106, 111 and 120.

(3) The operation of fluoroscopic equipment shall be performed by a properly trained operator. The following categories of operators are considered to have met the training requirements in section (2) of this rule:

(a) Radiologists currently licensed in Oregon;

(b) Non-Radiologist practitioners who have successfully completed a training program from an Authority approved resource or have been operating fluoroscopic equipment prior to April 11, 2005;

(c) Radiologic Technologists who have a permanent or temporary license from the Oregon Board of Medical Imaging (OBMI) to practice radiography;

(d) Physician assistants who have a fluoroscopy permit from the Oregon Board of Medical Imaging;

(e) R.P.A.s and R.R.A.s who are licensed by the OBMI; and

(f) Students currently enrolled in an approved school of Radiologic Technology as defined in ORS 688.405.

(4) Supervision requirements for operators of fluoroscopic equipment. The operation of fluoroscopic equipment by properly trained operators must comply with the following supervisory requirements:

(a) Radiologists may operate fluoroscopic equipment with no supervision.

(b) Non-radiologist practitioners who have had proper training in the use and operation of fluoroscopic X-ray equipment may operate fluoroscopic equipment without supervision provided that the registrant arranges to have a radiologist or medical or health physicist assist in:

(A) Developing fluoroscopic and radiation safety policies and procedures;

(B) Conducting an on-site practical evaluation of the Non-Radiologist practitioner's knowledge of radiation safety practices and ability to operate the fluoroscopic equipment; and

(C) At least annually, review the registrant's fluoroscopy program. The review includes an evaluation of the fluoroscopic on-times Quality Assurance reports, condition of fluoroscopic equipment and compliance with current rules. The registrant shall correct any deficiencies noted by the review.

(c) Radiologic Technologists who have a permanent or temporary license from the OBMI to practice radiography may operate fluoroscopic equipment under the personal or direct supervision of a radiologist or a non-radiologist practitioner who has had proper training in the use and operation of fluoroscopic X-ray equipment.

(d) Physician assistants with fluoroscopy permits may operate fluoroscopic equipment if:

(A) The supervising physician with whom the physician assistant has entered into a practice agreement is in the room where the fluoroscopic procedure is taking place at the time that the procedure is taking place; or

(B) The supervising physician with whom the physician assistant has entered into a practice agreement is in the building where the fluoroscopic procedure is taking place, and a radiographer with a license from the Oregon Board of Medical Imaging is in the room where the procedure is taking place, at the time that the procedure is taking place.

(e) R.R.A.s or R.P.A.s may operate fluoroscopic equipment under the direct supervision of a radiologist.

(f) Physician assistants licensed with the Oregon Medical Board while completing specific clinical experience pre-requisites to become eligible to take the OBMI fluoroscopy permit examination, may operate fluoroscopy equipment under personal supervision of the physician assistant's supervising physician, licensed radiologist, licensed radiographer or medical physicist.

(g) Students currently enrolled in an approved school of Radiologic Technology as defined in ORS 688.405, may operate fluoroscopic equipment under the personal supervision of a radiologist or an R.T. while in the clinical phase of training.

(5) The operation of fluoroscopic equipment is restricted to the healing arts exclusively for the purpose of localization and to assist physicians in obtaining images for diagnostic purposes.

(6) Overhead fluoroscopy is not to be used as a positioning tool for radiographic examinations except for those fluoroscopic examinations specified in the registrant's written policies/procedures for fluoroscopy.

(7) All images formed by the use of fluoroscopy shall be viewed, directly or indirectly, and interpreted by a radiologist, cardiologist, non-radiologist practitioner or other qualified specialist. R.R.A.s and R.P.A.s may issue a preliminary report; however, the final report must be issued by their supervising radiologist.

(8) Written procedures for fluoroscopic X-ray equipment operators shall be available at the worksite and include:

(a) A list of all individuals who are permitted to operate fluoroscopic X-ray equipment at the facility;

(b) A list of the fluoroscopic X-ray equipment that each operator is qualified to operate;

(c) Written procedures regarding the set up and operation of each fluoroscopic X-ray machine registered to the facility;

(d) Written radiation safety procedures pertaining to the use and operation of fluoroscopy; and

(e) The name and title of the individual who is responsible for overseeing the fluoroscopy program.

(9) Facilities shall determine, or cause to be determined, the typical patient entrance exposure rate for their most common fluoroscopic examinations. The determination shall be made using an attenuation block as described in OAR 333-106-0005(7) using measurement protocol in compliance with OAR 333-106-0210 and expressed in Roentgens per minute (R/min.) or milliRoentgens per minute (mR/min.). In addition, these entrance exposure rates shall be posted in the room where fluoroscopic examinations are conducted so that they are readily available to administrators, X-ray operators, patients and practitioners.

(10) Facilities that utilize fluoroscopy shall maintain a record of the cumulative fluoroscopic exposure time used for each examination. The record must indicate the patient's name, the type of examination, the date of the examination, the fluoroscopist's name, the fluoroscopic room in which the examination was done and the

total cumulative fluoroscopic on-time for each fluoroscopic examination and:

(a) Established cumulative fluoroscopic on-time benchmarks for at least two (if applicable) of the most common types of fluoroscopic examinations performed at the facility's site in each of the following categories:

(A) Routine procedures performed on adults;

(B) Routine procedures performed on children;

(C) Orthopedic procedures performed in surgery;

(D) Urologic procedures performed in surgery;

(E) Angiographic procedures performed; and

(F) Interventional cardiac studies.

(b) Develop and perform periodic (not to exceed 12 month intervals) quality assurance studies to determine the status of each individual fluoroscopist's cumulative on-time in relation to the fluoroscopic benchmarks established for individual fluoroscopic examinations;

(c) Take appropriate action when the established benchmarks are consistently exceeded. The Radiation Safety Committee (RSC) must review the results of the cumulative fluoroscopic on-time Quality Assurance Study and take corrective action regarding those individuals who have exceeded the benchmarks established by the facility for a particular procedure more than 10 percent of the total times the individual performed the procedure during the study period. Documentation of the RSC review, as well as any corrective actions taken, must be available for Authority review. Corrective actions, at a minimum, include:

(A) Notification of the individual; and

(B) Recommendation that the individual undergo additional coaching and training in the safe use of fluoroscopic equipment in order to assist them in reducing their cumulative fluoroscopic on-times.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15; PH 25-2016, f. 8-26-16, cert. ef. 9-1-16

333-106-0210
Fluoroscopic Entrance Exposure Rates

(1) Fluoroscopic equipment manufactured before May 19, 1995 that is provided with Automatic Exposure Rate Control (AERC) shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 10 roentgens (R) (2.58 mC/kg) per minute, at a point where the center of the useful beam enters the patient, except:

(a) During the recording of fluoroscopic images; or

(b) When optional high-level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 5 R (1.29 mC/kg) per minute at a point where the center of the useful beam enters the patient, unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(2) Fluoroscopic equipment that is not provided with AERC shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 5 R (1.29 mC/kg) per minute at a point where the center of the useful beam enters the patient, except:

(a) During the recording of fluoroscopic images; or

(b) When optional high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(3) Equipment with both an AERC mode and a manual mode. Fluoroscopic equipment that is provided with both an AERC and a manual mode shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 10 R (2.58 mC/kg) per minute in either mode at a point where the center of the useful beam enters the patient, except:

(a) During the recording of fluoroscopic images; or

(b) When the mode or modes have an optional high-level control, in which case that mode or modes shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 5 R (1.29 mC/kg) per minute at a point where the center of the useful beam enters the patient, unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(4) Exemptions. Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in sections (1), (2), and (3) of this rule.

(5) For fluoroscopic equipment manufactured on and after May 19, 1995, the following requirements will apply:

(a) Fluoroscopic equipment operable at any combination of tube potential and current that will result in an exposure rate in excess of 5 R (1.29 mC/kg) per minute at a point where the center of the useful beam enters the patient shall be equipped with AERC. Provision for manual selection of the technique factors may be provided.

(b) Fluoroscopic equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 10 R (2.58 mC/kg) per minute at a point where the center of the useful beam enters the patient except:

(A) During the recording of fluoroscopic images from an X-ray image-intensifier tube using photographic film or a video camera when the X-ray source is operated in a pulsed mode.

(B) When an optional high-level control is activated, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 20 R per minute at a point where the center of the useful beam enters the patient. Special means of activation of high-level

controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(6) Measuring compliance. Compliance with the requirements of this rule shall be determined as follows:

(a) Movable grids and compression devices shall be removed from the useful beam during the measurement;

(b) If the source is below the table, exposure rate shall be measured 1 cm above the tabletop or cradle;

(c) If the source is above the table, the exposure rate shall be measured at 30 cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;

(d) For a C-arm type of fluoroscope, the exposure rate shall be measured 30 cm from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 cm from the input surface of the fluoroscopic imaging assembly;

(e) For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 cm from the centerline of the X-ray table and in the direction of the X-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is moveable, it shall be positioned as closely as possible to the lateral X-ray source, with the end of the beam-limiting device or spacer no closer than 15 cm to the centerline of the X-ray table.

(7) Exemptions. Fluoroscopic radiation therapy simulation systems are exempt from the requirement set forth in section (5) of this rule.

(8) Periodic measurement of entrance exposure rate shall be performed as follows:

(a) Such measurement shall be made annually or after any maintenance of the system which might affect the exposure rate; and

(b) Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in OAR 333-106-0105(1)(c). The measurement results shall be stated in roentgens per minute and include the technique factors used in determining such results. The name of the person performing the measurements and the date the measurements were performed shall be included in the results; and

(c) Personnel monitoring devices may be used to perform the measurements required by subsection (8)(a) of this rule, provided the measurements are made as described in subsection (8)(d) of this rule;

(d) Conditions of periodic measurement of entrance exposure rate are as follows:

(A) The measurement shall be made under the conditions that satisfy the requirements of section (6) of this rule; and

(B) The kVp shall be the kVp typical of clinical use of the X-ray system; and

(C) The X-ray system(s) that incorporates automatic exposure control shall have sufficient material placed in the useful beam to produce a milliamperage typical of the use of the X-ray system or the worst case; and

(D) X-ray system(s) that do not incorporate an automatic exposure control shall utilize a milliamperage typical of the clinical use of the X-ray system.

NOTE: Materials should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-106-0215
Fluoroscopic Barrier Transmitted Radiation Rate Limits

(1) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed two mR (0.516 uC/kg) per hour at 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(2) Measuring Compliance of Barrier Transmission:

(a) The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm;

(b) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 cm above the tabletop;

(c) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 cm;

(d) Movable grids and compression devices shall be removed from the useful beam during the measurement; and

(e) The attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-106-0220
Fluoroscopic Indication of Potential and Current

During fluoroscopy and cinefluorography X-ray tube potential and current shall be continuously indicated. Deviation of X-ray tube potential and current from the indicated values shall not exceed the maximum deviation stated by the manufacturer.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635 & 453.695

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-106-0225
Fluoroscopic Source-to-Skin Distance

The source-to-skin distance shall not be less than:

(1) 38 cm on stationary fluoroscopes manufactured on or after August 1, 1974;

(2) 35.5 cm on stationary fluoroscopes manufactured prior to August 1, 1974;

(3) 30 cm on all mobile fluoroscopes; and

(4) 20 cm for image intensified fluoroscopes used for specific surgical application. The written safety procedures must provide precautionary measures to be adhered to during the use of this device.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-106-0230
Fluoroscopic Timer

(1) Means shall be provided to present the cumulative on-time of the fluoroscopic tube.

(2) The maximum cumulative time of the timing device shall not exceed five minutes without resetting.

(3) A signal audible to the fluoroscopist, or the appropriate operator, shall indicate the completion of any preset cumulative on-time; or if no audible signal is provided, the exposure shall terminate.

Stat. Auth.: ORS 453.752 - 453.775

Stats. Implemented: ORS 453.752 - 453.775

Hist.: HD 4-1985, f. & ef. 3-20-85; PH 14-2008, f. & cert. ef. 9-15-08

333-106-0235
Mobile Fluoroscopes

In addition to the other requirements of OAR 333-106-0201 through 333-106-0245 of these rules, mobile fluoroscopes shall provide intensified imaging.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06

333-106-0240
Fluoroscopic Control of Scattered Radiation

(1) Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall not be less than 0.25 mm lead equivalent.

(2) Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

(a) Is at least 120 cm from the center of the useful beam; or

(b) The radiation has passed through not less than 0.25 mm lead equivalent material including, but not limited to, drapes, Bucky-slot cover, sliding or folding panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in OAR 333-106-0025;

(c) Upon application to the Authority, providing adequate justification, exceptions to this section may be made in some special procedures where a sterile field will not permit the use of the normal protective barriers or where the protective barriers would interfere with the procedures.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-106-0245
Fluoroscopic Radiation Therapy Simulation Systems

Radiation therapy simulation systems shall be exempt from all the requirements of OAR 333-106-0201 through 333-106-0245 provided that:

(1) Such systems are designed and used in such a manner that no individual other than the patient is in the X-ray room during periods of time when the system is producing X-rays; and

(2) Systems which do not meet the requirements of OAR 333-106-0230 are provided with a means of indicating the cumulative time that an individual patient has been exposed to X-rays. Procedures shall require in such cases that the timer be reset between examinations.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

Additional Requirements for Radiographic Machines

333-106-0301
Beam Limitation for Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, Veterinary Systems, or Computed Tomography(CT)

(1) The useful beam shall be limited to the area of clinical interest.

(2) General Purpose Stationary and Mobile X-ray Systems:

(a) There shall be provided a means for stepless adjustment of the size of the X-ray field, where the adjustment of each dimension of the field is independent of the other;

(b) A method shall be provided for visually defining the perimeter of the X-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam;

(c) Evidence of compliance with subsections (2)(a) and (b) of this rule shall be shown on each radiograph taken, either by imaging part of the collimator on the radiograph or by imaging collimator nubs or pointers;

(d) Beam-defining lights used for visually defining perimeters of the X-ray field shall have an illumination great enough to be visualized by the operator under ambient light conditions;

(e) The Authority may grant an exemption on noncertified X-ray systems to subsections (2)(a) and (b) of this rule provided the registrant makes a written application for such exemption and in that application:

(A) Demonstrates it is impractical to comply with subsections (2)(a) and (b) of this rule; and

(B) The purpose of subsections (2)(a) and (b) of this rule will be met by other methods.

(3) In addition to the requirements of section (2) of this rule, all stationary general purpose X-ray systems shall meet the following requirements:

(a) A method shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, to align the center of the X-ray field with respect to the center of the image receptor to within two percent of the SID, and to indicate the SID to within two percent;

(b) The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

(c) Indication of field size dimensions and SID's shall be specified in inches or centimeters, and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within two percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(4) Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the X-ray field with the center of the image receptor to within two percent of the SID, or shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(5) Special Purpose X-ray Systems:

(a) Means shall be provided to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the X-ray beam is perpendicular to the plane of the image receptor;

(b) Means shall be provided to align the center of the X-ray field with the center of the image receptor to within two percent of the SID, or means shall be provided to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the X-ray beam perpendicular to the plane of the image receptor;

(c) Subsections (5)(a) and (b) of this rule may be met with a system that meets the requirements for a general purpose X-ray system as specified in section (2) of this rule or, when alignment means are also provided, may be met with either:

(A) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(B) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent,

clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-106-0305
Radiation Exposure Control Devices

(1) Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. In addition:

(a) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero;

(b) It shall not be possible to make an exposure when the timer is set to a zero or "off" position if either position is provided.

(2) X-ray Exposure Control:

(a) An X-ray exposure control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time except for:

(A) Exposure of 0.5 second or less; or

(B) During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

(b) Each X-ray exposure control shall be located in such a way as to meet the following requirements:

(A) Stationary X-ray systems shall be required to have the X-ray exposure control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and

(B) The operator's protected area shall provide visual indication of the patient during the X-ray procedure; and

(C) Mobile and portable X-ray systems which are:

(i) Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of paragraph (2)(b)(A) of this rule;

(ii) Used for greater than one hour and less than one week at the same location, i.e., a room or suite, shall meet the requirement of subparagraph (2)(b)(C)(i) of this rule or be provided with a 6.5 feet (1.98 m) high protective barrier which is placed at least 6 feet (1.83 m) from the tube housing assembly and at least 6 feet (1.83 m) from the patient; or

(iii) Used to make an exposure(s) of a patient at the use location shall meet the requirement of subparagraph (2)(b)(C)(i) or (ii) of this rule or be provided with a method of X-ray control which permits the operator to be at least 12 feet (3.66 m) from the tube housing assembly during an exposure.

(c) The X-ray control shall provide visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(3) Automatic Exposure Controls. When an automatic exposure control is provided:

(a) Indication shall be made on the control panel when this mode of operation is selected;

(b) If the X-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;

(c) The minimum exposure time for all equipment other than that specified in subsection (3)(b) of this rule shall be equal to or less than 1/60 second or a time interval required to deliver 5 mAs, whichever is greater;

(d) Either the product of peak X-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of X-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the X-ray tube potential is less than 50 kVp, the product of X-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

(e) A visible signal shall indicate when an exposure has been terminated at the limits required by subsection (3)(d) of this rule, and manual resetting shall be required before further automatically timed exposures can be made.

(4) Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period (T) shall be greater than or equal to five times the maximum exposure period (Tmax) minus the minimum exposure period (Tmin) when four timer tests are performed: (T)> 5 (Tmax - Tmin).

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2013, f. & cert. ef. 1-29-13

333-106-0310
Source-to-Skin Distance

(1) All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 cm. This is considered to have been met when the collimator or cone provides the required limits.

(2) Any device provided to limit the SSD must be durable and securely fastened to the system.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06

333-106-0315
Exposure Reproducibility

The coefficient of variation of exposure shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to five times the maximum exposure (Emax) minus the minimum exposure (Emin). E >5 (Emax - Emin).

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2013, f. & cert. ef. 1-29-13

333-106-0320
Radiation from Capacitor Energy Storage Equipment in Standby Status

Radiation emitted from the X-ray tube when the exposure switch or timer is not activated shall not exceed a rate of two milliroentgens (0.516 uC/kg) per hour at five centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

Stat. Auth.: ORS 453.605 - 453.755
Stats. Implemented: ORS 453.605 - 453.755
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10

333-106-0325
Intraoral Dental Radiographic Systems

In addition to the provisions of OAR 333-106-0010 through 333-106-0101, the requirements of this rule apply to X-ray equipment and facilities where intraoral dental radiography is conducted. Requirements for extraoral dental radiographic systems are covered in OAR 333-106-0301 through 333-106-0320. Intraoral dental radiographic systems must meet the following requirements:

(1) Source-to-Skin Distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance, to not less than 18cm.

(2) Beam Limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that:

(a) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the X-ray field, at the minimum SSD, shall be

containable in a circle having a diameter of no more than seven centimeters; or

(b) If the minimum SSD is less than 18 centimeters, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than six centimeters.

(3) Radiation Exposure Control (Timers). Means shall be provided to control the radiation exposure through the adjustment of exposure time in seconds, milliseconds (ms) or, number of pulses, or current/milliamps (mA), or the product of current and exposure time (mAs) or adjustment of kVp. In addition:

(a) Exposure Initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and

(b) It shall not be possible to make an exposure when the timer is set to a "0" or "off" position if either position is provided;

(c) Exposure Indication. Means shall be provided for visual indication, observable at or from the operator's protected position, whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(d) Timer Reproducibility. With a timer setting of 0.5 second or less, the average exposure time (T) shall be greater than or equal to five times the minimum exposure time (Tmax) minus the minimum exposure time (Tmin) when four timer tests are performed: (T) >5 (Tmax - Tmin).

(A) Means shall be provided to terminate the exposure at a preset, time interval, mAs, number of pulses, or radiation to the image receptor.

(B) An X-ray exposure control shall be incorporated into each system such that an exposure can be terminated by the operator at any time, except for exposures of 0.5 second or less.

(C) Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "0".

(4) Radiation Exposure Control Location and Operator Protection. Each X-ray control must be located in such a way as to meet the following requirements:

(a) The exposure switch shall be able to be operated in a protected area, as defined in OAR 333-106-0005(77), and the operator shall remain in that protected area during the entire exposure; and

(b) The operator's protected area shall provide visual indication of the patient during the X-ray procedure.

(c) Mobile and portable X-ray systems which are:

(A) Used for greater than one week in the same location, such as a room or suite, shall meet the requirements of subsections (4)(a) and (4)(b) of this rule.

(B) Used for less than one week at the same location, such as a room or suite, shall be provided with:

(i) Either a protective barrier of at least 6.5 feet (2 meters) high for operator protection; or

(ii) A means to allow the operator to be at least nine feet (2.7 meters) from the tube housing assembly while making exposures; or

(iii) A full length protective apron, of not less than 0.25 millimeter lead equivalent for operator protection, when using a hand-held dental intraoral X-ray machine.

(5) Exposure Reproducibility. The coefficient of variation shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to five times the maximum exposure (Emax) minus the minimum exposure (Emin): E >5 (Emax - Emin)

(6) Accuracy.

(a) Deviation of technique factors from the indicated values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer.

(b) kVp Limitations. Dental X-ray machines with a nominal fixed kVp of less than 55 kVp shall not be used to make diagnostic dental radiographs on humans.

(7) Administrative Controls.

(a) Patient and film holding devices shall be used when the techniques permit;

(b) The tube housing and the PID shall not be hand held during an exposure;

(c) The X-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of section (2) of this rule or its updated version;

(d) Dental fluoroscopy without image intensification shall not be used; and

(e) Pointed cones shall not be utilized unless specific authorization has been granted by the Authority.

(8) Hand-held X-ray systems.

(a) Registrants must provide for security and safe storage while not in use. A report must be filed with the Authority within 72 hours if the hand-held unit is lost or stolen.

(b) The image receptor used with hand-held dental X-ray systems must either be:

(A) A speed class of intra-oral film designated as "E/F", "F" or faster; or

(B) A digitally acquired image (CR or DR).

(c) The hand-held X-ray system must be equipped with a permanently attached backscatter shield of 0.25 mm Pb equivalent.

(d) The backscatter shield must be designed to appropriately protect the operator during an exposure. The manufacturer of the hand-held unit must provide documentation to the Authority of the design specifications of the backscatter shield's protection to the operator prior to sale and distribution in the State of Oregon.

(e) The hand-held unit must be capable of a minimum of 60 kVp and 2.0 mA.

(f) Hand-held units not meeting the requirements of subsections (8)(c), (8)(d) and (8)(e) of this rule may not be sold, distributed or used in the State of Oregon.

(9) Hand-held dental X-ray administrative controls.

(a) The hand-held unit shall not be used for patient examinations in hallways and waiting rooms.

(b) The unit can only be operated in an enclosed room when possible. All individuals except the X-ray operator and the patient must leave the room and stand behind a protective barrier or be at least six feet from the X-ray source if a protective barrier is not available during radiographic exposures.

(c) Operators must complete machine specific applications training as described in OAR 333-106-0055(9) before using a hand-held unit. Training on the safe use of the unit shall be documented and include at a minimum:

(A) Proper positioning of the unit to ensure an adequate protected position;

(B) Limitations on the use of position indicating devices that require longer distances to the patient's face;

(C) Diagrams such as drawings, illustrations, or schematics of protected position and location in relationship to the unit;

(D) Diagrams such as drawings, illustrations, or schematics of the effect of improper distance or removal of shielding device; and

(E) Diagrams such as drawings, illustrations, schematics of common examples of improper positioning of the unit and or location of the operator.

(d) An appropriate receptor holder must be used during the X-ray exposure.

(e) A PID must be used during the X-ray exposure.

(f) A hand-held unit shall be held without any motion during a patient examination. A tube stand may be utilized to immobilize the hand-held unit during a patient examination.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 20-2010, f. & cert. ef. 9-1-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 4-2013, f. & cert. ef. 1-29-13; PH 24-2014, f. & cert. ef. 8-15-14; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15; PH 25-2016, f. 8-26-16, cert. ef. 9-1-16

Computed Tomography X-ray Systems

333-106-0345
Purpose and Scope

(1) OAR 333-106-0350 through 333-106-0369 establishes requirements governing the use of computed tomography (CT) scanners in the healing arts; and

(2) Applies to all registrants who use a CT scanner for the intentional exposure of humans for diagnostic imaging.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 24-2014, f. & cert. ef. 8-15-14

333-106-0350
Definitions

In addition to the definitions provided in division 100 and 106 of these rules, the following definitions shall be applicable to OAR 333-106-0350 through 333-106-0369.

(1) "Annual" means a period of 12 consecutive months, not to exceed a period of 14 months.

(2) "Computed tomography (CT)" means the production of a tomogram by the acquisition and computer processing of X-ray transmission data. Computed tomography includes the capability of producing axial tomograms.

(3) "Computed Tomography Dose Index" means the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan. This definition assumes that the dose profile is centered around z = 0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

(4) "Contrast scale" or "CS" means the change in the linear attenuation coefficient per CTN relative to water.

(5) "CT conditions of operation" means all selectable parameters governing the operation of a CT X-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in OAR 333-106-0005.

(6) "CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

(7) "CT number" means the number used to represent the X-ray attenuation associated with each elemental area of the CT image.

(8) "CT scanner" means a CT machine capable of performing CT scans of the head, other body parts, or full body patient procedures including PET/CT and SPECT/CT hybrid scanners if used for diagnostic CT procedures.

(9) "CTDIvol" (see computed tomography dose index).

(10) CTN (see CT number).

(11) "Dose-length product (DLP)" is the CTDIvol multiplied by the scan length (image thickness multiplied by the number of adjacent, non-overlapped images in the acquisition in centimeters.

(12) "Dose profile" means the dose as a function of position along a line.

(13) "Elemental area" means the smallest area within a tomogram for which the X-ray attenuation properties of a body are depicted (see also picture element.)

(14) "Multiple tomogram system" means a computed tomography X-ray system which obtains X-ray transmission data simultaneously during a single scan to produce more than one tomogram.

(15) "Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water.

(16) "Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which X-ray transmission data are collected.

(17) "Picture element" means an elemental area of a tomogram.

(18) "Positron emission tomography (PET)" means an imaging technique that uses positron-emitting radionuclides to produce 3-dimensional images of functional processes in the body.

(19) "Qualified CT medical physicist" means an individual qualified in accordance with OAR 333-106-0367.

(20) "Reference plane" means a plane which is displaced from and parallel to the tomographic plane.

(21) "Scan" means the complete process of collecting X-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

(22) "Scan increment" means the amount of relative displacement of the patient with respect to the CT X-ray system between successive scans measured along the direction of such displacement.

(23) "Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

(24) "Scan time" means the period of time between the beginning and end of X-ray transmission data accumulation for a single scan.

(25) "Single photon emission computed tomography (SPECT)" means an imaging technique that uses radionuclides to produce 3-dimensional images of functional processes in the body.

(26) "Single Tomogram System" means a CT X-ray system which obtains X-ray transmission data during a scan to produce a single tomogram.

(27) "Tomogram" means the depiction of the attenuation properties of a section through a body.

(28) "Tomographic plane" means that geometric plane which is identified as corresponding to the output tomogram.

(29) "Tomographic section" means the volume of an object whose X-ray attenuation properties are imaged in a tomogram.

(30) "Traceable to a national standard" means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with the NIST at least once every two years and the results of the proficiency test conducted within 24 months of calibration show agreement within plus or minus three percent of the national standard in the appropriate energy range.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 24-2014, f. & cert. ef. 8-15-14

333-106-0355
CT Equipment Requirements

(1) CT equipment requirements shall comply with the Food and Drug Administration's 21 CFR in the following areas:

(a) Information to be provided for users — Part 1020.33(c);

(b) Quality Assurance — Part 1020.33(d);

(c) Control and indication of conditions of operation — Part 1020.33(f);

(d) Tomographic plane indication and alignment — Part 1020.33(g);

(e) Beam-on and status indicators — Part 1020.33(h);

(f) Scan increment accuracy — Part 1020.33(i); and

(g) CT number mean and standard deviation — Part 1020.33(j).

(2) CT equipment shall be maintained in compliance with the requirements of section (1) of this rule.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 24-2014, f. & cert. ef. 8-15-14

333-106-0360
Facility Design Requirements

(1) A fixed CT scanner room shall be a permanent part of the building or equipment. Portable shields shall not be used for permanent installations.

(2) The CT scanner shall be situated in a protected area and is subject to design approval by a qualified expert. National Council on Radiation Protection and measurements (NCRP) Report #147 shall be used as guidance for determining adequate shielding.

(3) The control panel for a fixed CT scanner shall be in a protected area.

(4) Movable barriers with electrical interlocks shall not be approved in lieu of compliance with section (3) of this rule.

(5) The operator of a fixed CT scanner shall be able to see and communicate with the patient from the protective area at the control panel. When an observation window is provided, it shall have a lead equivalence at least equal to that required of the control barrier in which it is installed.

(6) Mobile or portable CT scanners used routinely in one location shall be considered a fixed installation and shall comply with the requirements of sections (1) through (5) of this rule.

(7) CT scanners mounted in a vehicle or trailer must meet requirements of sections (1) through (5) of this rule.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.775
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 24-2014, f. & cert. ef. 8-15-14

333-106-0361
Radiation Protection Surveys

(1) The registrant must ensure that radiation protection surveys are performed at new facilities, at existing facilities not previously surveyed, and anytime the CT scanner is replaced, moved or structural changes are made in the room.

(2) In new facilities, a radiation protection survey must be completed prior to the first clinical use following installation.

(3) The radiation protection survey must be performed by a qualified CT medical physicist as defined in OAR 333-106-0367 or a qualified expert as defined in OAR 333-100-0005.

(4) Surveys must be conducted with an operable radiation survey instrument that has been calibrated according to manufacturer's specifications, not to exceed 24 months. If manufacturer specifications are not available, then the radiation survey instrument shall be calibrated every 12 months.

(5) The qualified CT medical physicist or qualified expert must verify that:

(a) Radiation levels in restricted areas are not likely to cause personnel to receive exposures in excess of the limits specified in OAR 333-120-0100(1); and

(b) Radiation levels in unrestricted areas do not exceed the limits specified in OAR 333-120-0180 and 333-120-0190.

(6) The radiation protection survey record must be documented and indicate all instances where the facility, in the opinion of the qualified medical physicist or qualified expert, is in violation of applicable regulations. The survey record must also include the:

(a) Date of the measurements;

(b) Reason the survey is required;

(c) Manufacturer's name, model number and serial number of the CT scanner;

(d) Manufacturer's name, model number and serial number of the instrument(s) used to measure radiation levels and the date last calibrated;

(e) Floor plan of the areas surrounding the exam room that were surveyed;

(f) Measured dose rate at several points in each area expressed in mSv/hr or mR/hr;

(g) Calculated maximum level of radiation over a period of one week for each restricted and unrestricted area;

(h) Signature of the individual responsible for conducting the survey; and

(i) The survey must be available for review at the time of inspection.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 24-2014, f. & cert. ef. 8-15-14

333-106-0362
Operating Procedures and Conditions of Operation

(1) Within six months following the effective date of these rules, the CT facility shall establish default scanning protocols in consultation with a qualified CT medical physicist.

(2) Default scanning protocols shall be password protected or a written policy shall be in place that prohibits anyone from changing protocols without documented approval from the CT medical director, lead CT technologist or supervising CT radiologist.

(a) Each facility shall establish a policy to review all of their default CT protocols at least annually to ensure they are correct and are the intended protocols.

(b) Written and signed documentation of this annual review shall be kept and made available for inspection for each CT unit at the facility.

(3) The CT operator shall ensure all technique factors and dose indices are appropriate for the protocol being used and the patient being imaged. This may be accomplished by reviewing dose indicator devices if available or dose indices such as the technique factors.

(4) The facility shall establish a written policy for retaking CT exams on patients.

(5) Staff shall not be required by the licensee or registrant to hold patients during CT examinations.

(6) When a patient must be held in position for a CT procedure, mechanical supporting or restraining devices shall be used unless contraindicated. If the patient must be held by an individual, this individual shall wear a protective apron of 0.5 millimeter minimum lead equivalence and be so positioned that no part of his or her body shall be in the path of the primary beam and that his or her body is as far as possible from the edge of the primary beam.

(7) Only individuals whose presence is necessary are allowed in a CT scan room during exposure. Each individual, except the patient, shall be protected by at least 0.5 millimeter lead equivalent aprons or a whole body protective barrier.

(8) A CT scanner shall not be left unattended without locking the apparatus, room, or building in some manner which must prevent use of the apparatus by unauthorized persons.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 24-2014, f. & cert. ef. 8-15-14

333-106-0363
Quality Control Program

(1) The registrant shall ensure that a CT quality assurance phantom is available for testing the CT system.

(2) Instructions on the use of the phantom shall be provided. The instructions shall include a schedule of tests appropriate for the CT system, the allowable variations for the test parameters, and a method to store the test results.

(3) Within six months following the effective date of these rules, a CT facility shall establish and implement a quality control program under the direction of a CT medical physicist.

(4) Evaluations and tests shall be performed following written procedures and methods.

(5) Corrective action shall be taken and documented according to instructions provided by the qualified CT medical physicist if the results of an evaluation or test fall outside the control limits.

(6) The qualified CT medical physicist shall determine the frequency of each test. An on-site CT Radiologic Technologist shall be identified to be responsible for the ongoing quality control testing.

(7) The ongoing quality control evaluation must include, at a minimum, the following:

(a) Water CT number accuracy check and standard deviation (noise);

(b) Artifact evaluation;

(c) Visual checklist; and

(d) Printer quality control (if used for primary interpretation).

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 24-2014, f. & cert. ef. 8-15-14

333-106-0364
Initial and Annual Qualified CT Medical Physicist Scanner Performance Evaluations

(1) A CT medical physicist shall complete an initial performance evaluation of the CT scanner before use on patients and annually thereafter.

(2) A performance evaluation of the CT system shall be performed after any change in the equipment which might cause a change in the radiation output or image quality.

(3) A calibrated dosimetry system shall be used to measure the radiation output of a CT scanner. Calibration of the dosimetry system shall be within the preceding 24 months, or per manufacturer's specifications, and shall be traceable to a national standard.

(4) A performance evaluation shall include the following, as a minimum:

(a) Alignment light accuracy;

(b) Alignment of table to gantry;

(c) Gantry tilt, as appropriate;

(d) Slice localization from scanned projection radiograph;

(e) Table travel accuracy;

(f) Image thickness;

(g) Radiation beam width;

(h) Image quality, including the following:

(A) Gray level performance of CT acquisition display monitors,

(B) Low-contrast performance,

(C) Image uniformity,

(D) Noise,

(E) Artifact evaluation, and

(F) Spatial resolution;

(i) CT number uniformity;

(j) Dosimetry, including the following:

(A) Dose indicator such as computed tomography dose index (CTDI¬vol), and

(B) Patient radiation dose for representative examinations.

(k) A safety evaluation, including the following:

(A) Visual inspection,

(B) Audible and visual signals, and

(C) Posting requirements.

(l) A review of clinical protocols shall include at a minimum:

(A) An evaluation of scanner features, including kV, mAs, detector configuration, reconstructed scan width, pitch, reconstruction algorithm, and other features such as dose reduction options, including automatic exposure controls, iterative reconstruction techniques, etc. to ensure they are being properly utilized; and

(B) A review of the following clinical protocols, if they are used on the CT scanner:

(i) Pediatric head (one year old);

(ii) Pediatric abdomen (five years old; 40–50 pounds or approximately 20 kilograms);

(iii) Adult head;

(iv) Adult abdomen (70 kilograms);

(v) High-resolution chest;

(vi) Brain perfusion; and

(vii) Low dose lung cancer screening exam.

(m) A review of the facility's ongoing quality control program, including test results and corrective action.

(5) Evaluations and tests shall be performed following written procedures and methods found in the latest ACR CT Quality Control Manual.

(6) The qualified CT medical physicist shall prepare a report that includes the following:

(a) A summary of the performance evaluation required under section (1) of this rule;

(b) Recommendations for necessary improvements; and

(c) The type of dosimetry system used, including the date of the last calibration.

(7) The report required under section (6) of this rule shall be provided to the CT facility within 30 days after completion of the evaluation and shall be made available to the Authority upon request.

(8) The facility shall keep written documentation of actions taken in response to the recommendations from the performance evaluation report.

(9) Records of preventive maintenance and repair shall be retained for each CT scanner and be made available to the Authority upon request.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 24-2014, f. & cert. ef. 8-15-14

333-106-0366
Dose Limits

The CTDIvol for the following CT examinations on standard phantoms shall not exceed the dose limits listed below:

(1) Adult head, 80 mGy;

(2) Adult abdomen, 30 mGy;

(3) Pediatric abdomen (five years of age or 40 pounds, 20 mGy; and

(4) Pediatric head, 40 mGy.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 24-2014, f. & cert. ef. 8-15-14

333-106-0367
Records and Report Retention

A facility with a CT scanner shall maintain records and reports on file and shall make the records and reports available for review by the Authority as follows:

(1) Records documenting the qualifications of all personnel who worked at the facility as an operator or CT medical physicist.

(2) Records of personnel no longer employed by the facility shall be kept on file until the next inspection following the employee's termination has been completed and the Agency has determined that the facility is in compliance with the CT personnel requirements.

(3) A report of a CT medical event required under OAR 333-106-0368 shall be maintained on file for at least seven years.

(4) Initial and annual CT medical physicist performance evaluation reports required under OAR 333-106-0364 shall be maintained on file for at least five years.

(5) Records of the results from the ongoing quality control evaluation required under OAR 333-106-0363 shall be maintained on file for at least three years.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 24-2014, f. & cert. ef. 8-15-14

333-106-0368
Qualified CT Medical Physicist

In order to perform a CT survey or provide consultative services on a CT unit, a person must be approved by the Authority, under the provisions of OAR 333-101-0020, as a provider of radiation services in CT. In addition, the qualified CT medical physicist shall meet the requirements outlined below:

(1) Initial qualifications. Before beginning to provide consultation to a CT facility, a medical physicist shall meet one of the following:

(a) Be certified in diagnostic radiological physics or radiological physics by the American Board of Radiology, or in diagnostic imaging physics by the American Board of Medical Physics, or in diagnostic radiology physics by the Canadian College of Physicists in Medicine; or

(b) Have a graduate degree in medical physics, radiological physics, physics, or other relevant physical science or engineering discipline from an accredited institution and have formal coursework in the biological sciences with at least one course in biology or radiation biology and one course in anatomy, physiology, or similar topics related to the practice of medical physics, and have three years of documented experience in a clinical CT environment. An accredited institution is a college or university accredited by a regional accrediting organization that has been recognized either by the U.S. department of education (USDE) or by the council for higher education accreditation (CHEA) or both. Individuals with non-U.S. degrees shall provide documentation that their foreign degrees are equivalent to those granted from an approved institution in the U.S. and that the granting institution is equivalent to a regionally accredited institution in the USA; or

(c) CT medical physicists who, prior to August 1, 2014, have been actively working in the area of CT in the State of Oregon and are specifically approved by the Authority to provide CT medical

physics services in Oregon, are exempt from the requirements in subsections (a) and (b) this section.

(2) Continuing experience. After the second anniversary of the date when the requirements of section (1) of this rule were completed, the medical physicist shall have evaluated at least two CT scanners in the prior 24-month period.

(3) Continuing education. After the third anniversary of the date when the requirements of section (1) of this rule were completed, the CT medical physicist shall have earned at least 15 continuing medical education units; at least half shall be category 1, in the prior 36-month period. The continuing education shall include credits pertinent to CT.

(4) Re-establishing qualifications. A CT medical physicist who fails to maintain the required continuing experience or continuing education requirements shall reestablish his or her qualifications before resuming the independent evaluation of CT scanners and facilities, as follows:

(a) A CT medical physicist who fails to meet the continuing experience requirements of section (2) of this rule shall evaluate two CT scanners under the supervision of a medical physicist, to meet the requirements of section (2) of this rule.

(b) A CT medical physicist who fails to meet the continuing education requirements of section (3) of this rule shall obtain a sufficient number of additional continuing education credits to meet the requirements of section (3) of this rule.

(5) Documentation of continuing education and continuing experience shall be kept on file and made available to an inspector upon request.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 24-2014, f. & cert. ef. 8-15-14

333-106-0369
Report and Notification of a CT Medical Event

(1) A CT facility shall notify the Authority within 48 hours of any CT medical event in which a patient who has undergone a CT study has incurred a deterministic radiation injury, such as epilation or erythema.

(2) The registrant shall submit a written report to the Authority within 30 days after the CT medical event is discovered.

(3) The written report shall include all of the following:

(a) The registrant's name, address, facility registration number, and machine registration tag number as they appear on the registration certificate;

(b) The name of the individual who determined a CT medical event occurred;

(c) The dates of occurrence and discovery of the CT medical event;

(d) A narrative description of the CT medical event, including an estimated dose to the patient, if possible, and body part involved;

(e) The cause of the CT medical event;

(f) The effect on the individual who received the exposure;

(g) A narrative detailing corrective action taken or planned to prevent a recurrence;

(h) Certification that the registrant notified the individual or the individual's responsible relative or guardian and, if not, why not; and

(i) The name and signature of the person preparing the report.

(4) The report shall not contain the name of the individual who is the subject of the CT medical event or any other information that could lead to identification of the individual.

(5) The registrant shall consult with the referring physician prior to notifying the individual that they were involved in a CT medical event.

(a) The registrant shall ensure that the individual was notified of the CT medical event no later than one week after the discovery unless unforeseen circumstances exist.

(b) The registrant shall not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the CT medical event.

(c) If verbal notification is necessary, the registrant shall inform the individual or legal guardian that a written description of the CT medical event can be obtained from the registrant.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 24-2014, f. & cert. ef. 8-15-14

333-106-0370
Operator Requirements

(1) Computed Tomography (CT) X-ray systems shall be operated by individuals who:

(a) Are registered with the American Registry of Radiologic Technologists (A.R.R.T); and

(b) Have received additional CT system training; and

(c) Meet the clinical experience requirements for CT established by A.R.R.T.; and

(d) Are currently licensed by the Oregon Board of Medical Imaging.

(2) Individuals who are registered with the A.R.R.T. and credentialed as an R.T. (R) and (CT) are considered to have met the CT training requirement in section (1) of this rule and clinical experience requirement in subsection (1)(c) of this rule.

(3) Those individuals who have met the requirements of section (1) of this rule prior to the effective date of this rule are considered to have met subsection (1)(a) of this rule.

(4) Technologists operating CT systems must do so under the direction of a radiologist.

(5) Positron Emission-Computed Tomography (PET/CT) or Single Photon Emission-Computed Tomography (SPECT/CT) systems shall be operated by a technologist licensed by the Oregon Board of Medical Imaging who is:

(a) Any registered radiographer with the credential R.T. (R); or

(b) Registered radiation therapist with the credential R.T. (T);

(c Registered certified nuclear medicine technologist with the credentials R.T. (N); or

(d) Certified Nuclear Medicine Technologist (CNMT) by the Nuclear Medicine Technologist Certification Board (NMTCB).

(6) The individuals mentioned in section (5) of this rule must also have successfully completed appropriate additional education and training and demonstrated competency in the use and operation of PET/CT or SPECT/CT systems.

(7) Appropriate additional training is considered training that covers the topic areas outlined in the PET/CT curriculum developed by the Multi-Organizational Curriculum Project Group sponsored by the American Society of Radiologic Technologists and the Society of Nuclear Medicine Technologists, or equivalent training approved by the Authority and:

(a) Includes the content specified in the PET/CT curriculum for the area(s) that the individual is not already trained or certified in; or

(b) Individuals meeting the requirements of section (5) of this rule and who have successfully completed training that the Authority has evaluated and judged to be substantially equivalent to that specified in subsection (7)(a) of this rule.

(8) R.T. (N)s or CNMTs who have become certified in Computed Tomography through the American Registry of Radiologic Technologists are considered to have met the training requirements in section (5) of this rule.

(9) Technologists operating PET/CT or SPECT/CT systems must do so under the direction of an authorized user licensed to perform imaging and localization studies in accordance with OAR 333-116-0320.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 4-2013, f. & cert. ef. 1-29-13

Veterinary X-ray Systems

333-106-0601
Veterinary Medicine Radiographic Installations Additional Requirements

(1) Equipment:

(a) The protective tube housing shall be of the diagnostic type;

(b) Collimating devices shall be provided and used for collimating the useful beam to the area of clinical interest;

(c) All X-ray equipment sold after October 1991 must be equipped with a variable adjustable collimator and beam-defining light that meets all of the requirements of OAR 333-106-0301(1), (2) and (3);

(d) The total filtration permanently in the useful beam shall not be less than 0.5 mm Al equivalent for machines operating up to 50 kVp, 1.5 mm Al equivalent for machines operating between 50 and 70 kVp, and 2.5 mm Al equivalent for machines operating above 70 kVp;

(e) A device shall be provided to terminate the exposure after a preset time or exposure;

(f) A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least 12 feet (3.66 m) from the animal during all X-ray exposures.

(2) Structural Shielding: All wall, ceiling and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with division 120.

(3) Operating Procedures:

(a) All individuals shall stand well away from the useful beam and the animal during radiographic exposures;

(b) No individual shall be in the X-ray room while exposures are being made unless such individual's assistance is required;

(c) When an animal must be held in position during radiography, mechanical supporting or restraining devices shall be available and used as appropriate.

(d) If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and that individual shall be so positioned that no part of the body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored with appropriate personnel monitoring devices.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

Mammography Requirements

333-106-0700
Mammography X-Ray Systems Definitions

In addition to the definitions provided in division 100 and 106 of this chapter, the following definitions shall be applicable to the rules in this division.

(1) "Air Kerma" means the sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a given mass of air. The unit used to measure the quantity of kerma is the gray (Gy). For X-rays with energies below 300 kiloelectronvolts (keV), 1Gy=100 rad and is equivalent to 114 (R) of exposure.

(2) "FDA" means the Food and Drug Administration.

(3) An "image receptor support surface" means that portion of the image receptor support which is the X-ray input surface and is used to support the patient's breast during mammography.

(4) "Interpreting physician" means a licensed physician who interprets mammographic images and meets the qualifications of OAR 333-106-0750(2).

(5) "Lead Interpreting Physician" means a physician who interprets mammographic images, meets the qualifications of OAR 333-106-0750(2), and who has the general responsibility for ensuring that the registrant's quality assurance program meets all applicable rules and regulations.

(6) "Mammographic screening" means the use of radiation to test women for the detection of diseases of the breast when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such tests for the purposes of diagnosis. Screening is considered as self-referral by asymptomatic women without physicians orders (see OAR 333-100-0020(5)(6) and 333-106-0035(3)).

(7) "Mammography" means radiography of the breast.

(8) "Mammography equipment evaluation" means an onsite assessment of a mammography unit(s) or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable state and federal standards.

(9) "Mammography unit(s)" means an assemblage of components for the production of X-rays for use during mammography, including, at a minimum; An X-ray generator, an X-ray control, a tube housing assembly, a beam limiting device, and the supporting structures for these components.

(10) "Medical Physicist" means a person trained in evaluating the performance of mammography equipment and quality assurance programs and meets the qualifications of OAR 333-106-0750(3).

(11) "MQSA" means the Mammography Quality Standards Act of 1992.

(12) "Phantom" means a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer. (The "FDA accepted phantom" meets this requirement.)

(13) "Quality Assurance" is a comprehensive concept that comprises all of the management practices instituted by the registrant or the registrant's representative/s to ensure that:

(a) Every imaging procedure is necessary and appropriate to the clinical problem at hand;

(b) The images generated contain information critical to the solution of that problem;

(c) The recorded information is correctly interpreted and made available in a timely fashion to the patient's physician;

(d) The examination results in the lowest possible radiation exposure, cost, and inconvenience to the patient, consistent with subsection (13)(b) of this rule.

(14) "Quality Assurance Program" includes such facets as efficacy studies, continuing education, quality control, preventive maintenance, and calibration of equipment.

(15) "Quality Control" means a series of distinct technical procedures that ensure the production of a satisfactory product,such as a high quality screening or diagnostic image.

(16) "Quality Control Technologist" means an individual who is qualified under MQSA, and who is responsible for those quality assurance responsibilities not assigned to the Lead Interpreting Physician or to the Medical Physicist.

(17) "Resting period" means the period of time necessary to bleed out air that has been trapped between the radiographic film and intensifying screen during the loading process in the darkroom. This period of time is usually measured in minutes and determined by the individual manufacturer of the intensifying screen/mammography cassette combination.

(18) "Standard Breast" means a 4.2 cm thick compressed breast, consisting of 50 percent adipose, and 50 percent glandular tissue.

(19) "Survey" means an onsite physics consultation and evaluation of a registrant's mammography equipment, and quality assurance program performed by a medical physicist.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-106-0710
Equipment Standards

Only x-ray systems meeting the design and performance standards required under Mammography Quality Standards Act (MQSA) shall be used, unless otherwise specified in the following rules.

(1) System design. The x-ray system shall be specifically designed for mammography.

(2) Image receptor.

(a) Image receptor systems shall be specifically designed, or appropriate for mammography.

(b) Systems using screen-film image receptors shall provide, at a minimum, image receptor sizes of 18 X 24 and 24 X 30 cm.

(c) An adequate number of image receptors shall be provided to accommodate the resting period recommended by the manufacturer.

(3) Target/filter. The x-ray system shall have the capability of providing kVp/target/filter combinations compatible with image receptor systems meeting the following requirements;

(a) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(b) When more than one target is provided, the system shall indicate, prior to exposure, the preselected target material.

(c) When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after exposure, the target material and/or focal spot actually used during the exposure.

(4) Beam quality: When used with screen-film image receptors, and the contribution to filtration made by the compression device is included, the useful beam shall have a minimum half-value layer (HVL). The minimum HVL, for mammography equipment designed to operate below 50 kVp, is determined by dividing the actual kVp by 100, and is expressed in mm Al equivalent.

(5) Resolution: Until October 28, 2002, focal spot condition shall be evaluated either by determining system resolution or by measuring focal spot dimensions. After October 28, 2002, facilities shall evaluate focal spot condition only by determining system resolution.

(a) Each x-ray system used for mammography, in combination with the mammography screen-film combination used, shall provide a minimum resolution of 11 Cycles/mm (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.

(b) The bar pattern shall be placed 4.5 cm above the image receptor support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor.

(6) Compression.

(a) All mammography systems shall incorporate a compression device capable of compressing the breast with a force of at least 25 pounds.

(b) Effective October 28, 2002, the maximum compression force for the initial power drive shall be between 25 pounds and 45 pounds.

(c) All mammography systems shall be equipped with different sized compression paddles that match the sizes of all full field image receptors provided for the system. The compression paddle shall:

(A) Be flat and parallel to the image receptor support and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied. If the compression paddle is not designed to be flat and parallel to the image receptor support during compression, it shall meet the manufacturer's design specifications and maintenance requirements;

(B) Have a chest wall edge that is straight and parallel to the edge of the image receptor support;

(C) Clearly indicate the size and available positions of the detector at the x-ray input surface of the compression paddle;

(D) Not extend beyond the chest wall edge of the image receptor support by more than 1 percent of the SID when tested with the compression paddle placed above the support surface at a distance equivalent to a standard breast thickness;

(E) Shall not be visible, at its vertical edge, on the image.

(d) When equipped with a compression paddle height digital display, the display shall accurately represent the actual height of the compression paddle to within +- 0.5 cms. Testing shall be performed according to manufacturer's specifications.

(7) System capabilities. A mammographic x-ray system utilizing screen-film image receptors shall:

(a) Be equipped with moving grids matched to all image receptor sizes provided.

(b) Provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, non-grid, magnification; and various target-filter combinations.

(A) The automatic exposure control shall be capable of maintaining film optical density (OD) within +0.30 of the mean optical density when thicknesses of a homogeneous material are varied over a range of 2 to 6 cms and the kVp is varied appropriately for such thicknesses over the kVp range used clinically. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different thicknesses and compositions that must be used so that optical densities within + 0.30 of the average under photo- timed conditions can be produced.

(B) After October 28, 2002, the AEC shall be capable of maintaining film optical density (OD) to within + 0.15 of the mean optical density when thicknesses of a homogeneous material are varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically.

(8) Breast entrance kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

(9) Collimation.

(a) All mammography systems shall have beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the X-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID. Under no circumstances, shall the x-ray field extend beyond the non-chest wall edges of the image receptor support.

(b) The total misalignment of the edges of the visually defined light field with the respective edges of the X-ray field either along the length or width of the visually defined field shall not exceed 2 percent of the SID.

(10) Kilovoltage peak (kVp) accuracy and reproducibility;

(a) The kVp, shall be accurate within + 5 percent of the indicated or selected kVp at the lowest clinical kVp that can be measured by a kVp test device, and the most commonly used, and highest available clinical kVp; and

(b) At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.

(11) Dose. The average glandular dose delivered during a single cranio-caudal view of an FDA accepted phantom simulating a standard breast, shall not exceed 250 millirad (mRad) (2.5 milliGy). The dose shall be determined with technique factors and conditions used, by the registrant, clinically for a standard breast. The testing protocol used shall be the same as used by MQSA.

(a) If the average glandular dose exceeds 250 mRad (2.5 milliGray) but is no greater than 275 mRad (2.75 milliGray), patient mammography may be continued until the cause of the problem is determined and corrected. Correction must be completed within 30 working days of when the registrant became aware of the problem. If correction has not been completed within 30 working days, and the registrant has not requested an extension in writing from the Authority, patient mammography must cease until correction of the dose problem has occurred.

(b) If the average glandular dose exceeds 275 mRad (2.5 milliGray), patient mammography must cease until the cause of the dose problem is determined and corrected.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06; PH 25-2016, f. 8-26-16, cert. ef. 9-1-16

333-106-0720
Quality Assurance Program

(1) The registrant shall have a written, on-going equipment quality assurance program specific to mammographic imaging, covering all components of the diagnostic X-ray imaging system. The quality assurance program shall include the testing required in section (5) of this rule, as well as the evaluation of the test results and corrective actions necessary to ensure consistently high-quality images with minimum patient exposure. Responsibilities under this requirement are as follows:

(a) The registrant shall identify in policy/procedure, by name, a Lead Interpreting Physician meeting the requirements of OAR 333-106-0750(2), whose responsibilities at a minimum must include:

(A) Ensuring that the registrant's quality assurance program meets all associated rules and regulations;

(B) Ensuring that an effective quality assurance program exists;

(C) Providing frequent feedback to mammography technologists regarding film quality and quality control procedures;

(D) Reviewing the Quality Control Technologist's test data at least every three months, or more if consistency has not been shown or problems are evident;

(E) Reviewing the Medical Physicist's annual survey report or equipment evaluation results.

(b) The registrant shall identify in policy/procedure, by name, and have the services of, a Medical Physicist who meets the requirements of OAR 333-106-0750(3). The Medical Physicist shall assist in overseeing the equipment quality assurance practices of the registrant. At a minimum, the Medical Physicist shall be responsible for the annual surveys, mammography equipment evaluations, and associated reports meeting all the requirements of MQSA.

(c) The registrant shall identify in policy/procedure, by name, a single qualified Quality Control Technologist meeting the requirements of OAR 333-106-0750(1), who shall be responsible for:

(A) Equipment performance monitoring functions;

(B) Analyzing the monitoring results to determine if there are problems requiring correction;

(C) Carrying out or arranging for the necessary corrective actions when results of quality control tests including those specified in section (5) of this rule, indicate the need; and

(D) The Quality Control Technologist may be assigned other tasks associated with the quality assurance program that are not assigned to the Lead Interpreting Physician or Medical Physicist. These additional tasks must be documented in written policy/procedure.

(2) Annual Survey. At intervals not to exceed 12 to 14 months, the registrant shall have a Medical Physicist meeting the requirements of OAR 333-106-0750(3) conduct a survey to evaluate the mammography equipment, and the effectiveness of the quality assurance program required in section (1) of this rule. Records of annual surveys shall be maintained for a minimum of two years, and shall be available on-site for Authority review.

(3) Annual survey/or equipment evaluation corrective actions. Corrective action shall be completed within 30 working days of when the registrant received written or verbal notice of recommendations or failures on their annual survey/or equipment evaluation report, unless otherwise noted in these rules or a written request for extension has been submitted to and approved by the Authority.

(a) Correction of equipment related failures or recommendations shall be demonstrated by a repeat test using the same test methodology and documentation, or a test accepted as the equivalent by the Authority, that was used to initially identify the problem.

(b) When the results of a quality control test/s fail to meet applicable action limits defined in these rules, the appropriate action regarding the suspension or continuation of mammography as defined in these rules or in MQSA, shall be taken.

(4) Quality assurance records. The registrant shall ensure that:

(a) Records concerning employee qualifications to meet assigned quality assurance tasks, mammography technique and procedures, policies, previous inspection findings, and radiation protection are maintained until inspected by the Authority.

(b) Quality control monitoring data and records, problems detected by the analysis of that data, corrective actions, and records of the Lead Interpreting Physician's periodic reviews of the Quality Control Technologist's monitoring data taken must be maintained for a minimum of two years.

(5) Equipment quality control tests frequency. The registrant shall ensure that the following quality control tests are performed when applicable equipment or components are initially installed or replaced and performed thereafter at least as often as the frequency specified in Table 7. The referenced table is available on the Program's website: www.healthoregon.org/rps.

(6) Testing methods and action limits for quality control tests shall meet the most current requirements of MQSA, in addition to the following:

(a) Screen/film contact. Screen film contact tests shall be performed on all screens used clinically, using a 40-mesh test tool and four cm thick sheet of acrylic. Screens demonstrating one or more areas of poor contact that are greater than one cm in diameter, that are not eliminated by screen cleaning, and remain in the same location during subsequent tests, shall not be used for mammography. Screen/film contact shall be such that any areas of poor contact, regardless of size, shall not detract from image quality.

(b) Processor performance. A processor performance test shall be performed by sensitometric means and evaluated daily, after the solution temperature in the processor has reached proper temperature, and just prior to processing any clinical mammograms. The test shall be an assessment of the base plus fog, mid-density, density difference, and developer temperature.

(A) Sensitometers and densitometers used to evaluate processor performance shall be calibrated per the manufacturer's recommended calibration procedures for such devices. A record of the calibration shall be maintained until inspected by the Authority. Densitometers shall be checked against the instrument control strip at least monthly.

(B) The mid-density and density difference action limits must be within + 0.15 of the control operating level.

(C) The base plus fog (B+F) action limit must be within + 0.03 of the control operating level.

(D) If the mid-density or the density difference fall outside of the + 0.10 control limit but within the + 0.15 control limit for a period of three days (a trend), steps must be taken to determine the cause and correct the problem;

(E) If the mid-density or the density difference falls outside of the + 0.15 control limit, mammograms must not be processed through the processor until the cause of the problem is determined, corrected, and a repeat test is done demonstrating that the mid-density aor density difference are within the + 0.15 control limit;

(F) Processor quality control graphs must be in the format of the registrant's accrediting body or equivalent, and indicate test date/s, mid-density and density difference action limits, base plus fog action limit, film brand, type and emulsion number in use, the date when chemistry changes occurred and corrective action(s) taken when limits are exceeded;

(G) Cross over records and calculations must be maintained until reviewed by the Authority during the annual inspection. New mid-density or density difference operating levels must be charted on a new graph page.

(H) Re-establishment of operating levels must be done in accordance with the accrediting body's protocol regarding the appropriateness of this procedure or at the specific direction of the facility's medical physicist.

(I) While re-establishing operating levels (five day average), the facility must chart each day's results against its old operating control levels. At the end of the five days, a new chart must be established, indicating the new calculated operating limits. During the five day average, the facility cannot be cited for having exceeded the old processor operating levels; and

(J) When collecting data for the five day average, a phantom image test shall be conducted each day to verify the adequacy of

image quality. Should the phantom image test exceed either the 0.20 background optical density limit or the + 0.05 density difference limit, mammography must be suspended until the cause of the problem is identified and corrected, and a repeat phantom image test is shown to be within limits.

(7) Primary/secondary barrier transmission evaluation must be conducted upon initial X-ray system installation and significant modification of the system or the facility.

(8) Image quality. The mammography system must be capable of producing an image of the phantom demonstrating the following:

(a) A minimum score of 4 fibers, 3 speck groups, and 3 masses (or the most current minimum score established by the accrediting body and accepted by the FDA);

(b) Background density action limits within ± 0.20 of the control level;

(c) Density difference action limits within ± 0.05 of the control level;

(d) Milliampere seconds (mAs) within ± 15 percent of the control level;

(e) Demonstrating a level of contrast sufficient enough to clearly help define fibril, speck, and mass edges;

(f) Without objectionable levels of image noise or quantum mottle that obscure the visualization of fibrils, specks, or masses;

(g) Demonstrating reasonably sharp fibril, and mass margins;

(h) With a minimum optical density (measured at the center of the phantom) of 1.20;

(i) Phantom image test records must be in the most current format of the registrant's accrediting body or the equivalent, and indicate the exposure mode, kVp, and photo-cell used for the test as well as remarks indicating the corrective action that was taken when limits were exceeded;

(j) When phantom image results do not meet the requirements defined in subsections (8)(a), (b), (c), (d), (e), (f), (g), or (h) of this rule, corrective action must occur, and a repeat phantom image test must be performed demonstrating compliance, before further mammography examinations are performed using the X-ray machine.

(11) Darkroom fog. Darkroom fog levels shall not exceed 0.05 in optical density difference when sensitized film is exposed to darkroom conditions with safelight on for two minutes. Film shall be sensitized by exposing it to sufficient light from an appropriate intensifying screen so that after processing, an optical density of at least 1.20 is achieved.

(a) If the darkroom fog optical density difference exceeds 0.05 but is less than 0.10, mammography may be continued until the problem is corrected.

(b) If the darkroom fog optical density difference exceeds 0.10, mammography must be curtailed until the problem is corrected and the density difference no longer exceeds 0.05.

(12) Repeat rate. Corrective actions shall be recorded and the results of these corrective actions shall be assessed if the reject rate exceeds five percent or changes by two percent from the previously measured rate. The reject rate shall be based on repeated clinical images.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2013, f. & cert. ef. 1-29-13

333-106-0730
Additional Requirements

(1) Masks. Masks shall be provided on the view boxes to block extraneous light from the viewer's eye when the illuminated surface of the view box is larger than the area of clinical interest.

(2) Film processors utilized for mammography shall be:

(a) Used with X-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.

(b) Use chemical solutions that are capable of developing the films used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer.

(c) Be adjusted to and operated at the specifications recommended by the mammographic film manufacturer, or at other settings such that the sensitometric performance is at least equivalent.

(3) Instruments and devices. The following instruments and devices shall be available and properly maintained;

(a) FDA accepted image quality phantom;

(b) 21 step sensitometer;

(c) Densitometer.

(4) Image retention. Clinical images shall be retained for a minimum of five years or not less than 10 years if no additional mammograms of the patient are performed.

(5) Mobile Mammography. In addition to meeting the requirements of this rule as well as OAR 333-106-0710, 333-106-0720, 333-106-0730, and 333-106-0750, registrants shall ensure that for a mammography system that is used at more than one location:

(a) The film processor is operated in accordance with the requirements of OAR 333-106-0720 of these rules, and is located where the mammography examinations are performed (batch processing is prohibited).

(b) The following tests are conducted, evaluated and documented after every move and before any mammography examinations are conducted, in order to verify that the unit's performance continues to meet quality requirements:

(A) Phantom image;

(B) The measured radiation output or the data from the post exposure mAs display does not deviate by more than 10 percent of the established operating level.

(6) Technique charts. Mammography technique charts shall posted in the vicinity of the mammography system's X-ray control. The technique chart shall indicate;

(a) Technique factors for 3, 3-5, 5-7, and > 7 cm compressed breast thicknesses for fatty, 50 percent fatty-50 percent dense, and dense breast tissue;

(b) The target/filter combination to be used;

(c) The kVp to be selected for the patient sizes and breast tissue compositions indicated in subsection (6)(a) of this rule, or if an auto-kVp mode is used, indicate the post kVp that is selected;

(d) The exposure mode to be used (i.e. auto-kVp, manual, etc.);

(e) The manual technique factors to be used for small, medium, and large sized breast tissue specimens, and Implanted breasts;

(f) The film/screen combination to be used;

(g) The date that the technique chart was last reviewed for accuracy and the name of the reviewer.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08

333-106-0735
Breast Density Notification

(1) As used in this rule:

(a) "Breast Density" refers to the relative amount of different tissues present in the breast. A dense breast has less fat than glandular and connective tissue. Mammogram films of breasts with higher density are harder to read and interpret than those of less dense breasts. (Source: National Cancer Institute).

(b) "Facility" has the meaning given that term in 42 U.S.C. 263b and includes but is not limited to a hospital, outpatient department, clinic, radiology practice, or mobile unit, an office of a physician, or other facility that conducts breast cancer screening or diagnosis through mammography activities. "Facility" does not include a facility of the Department of Veterans Affairs.

(c) "Mammography activities" means the operation of equipment to produce a mammogram, the processing of the film, the initial interpretation of the mammogram and the viewing conditions for that interpretation.

(2) In all cases where a mammogram shows a patient has extreme or heterogeneous breast density, the facility shall incorporate the following notification within the lay summary mammography report provided to the patient:

DENSE BREAST TISSUE NOTIFICATION

Your mammogram shows that your breast tissue is dense. Dense breast tissue is common and is not abnormal. However, dense breast tissue can make it harder to evaluate the results of your mammogram and may also be associated with an increased risk of breast cancer. This information about the results of your mammogram is given to you to raise your awareness and to promote discussion with your health care provider. Together, you can decide if you may benefit from further screening. A report of your results was sent to your health care provider.

(3) The Dense Breast Tissue Notification statement and guidelines shall be included in the facility's policy on how they communicate mammography results to the patient and their health care providers.

Stat. Auth.: ORS 413.042 & 431.823
Stats. Implemented: ORS 431.823
Hist.: PH 14-2013, f. 12-26-13, cert. ef. 1-1-14; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-106-0750
Mammography Personnel Qualifications

(1) Operator qualifications. In order to use any mammography X-ray machine the operator of the mammography X-ray unit must have the following qualifications:

(a) Have a current license issued by the Oregon Board of Medical Imaging; and

(b) Have prior to the effective date of these rules qualified as a radiologic technologist under the MQSA interim rules or completed 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not be limited to:

(A) Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging patients with breast implants;

(B) The performance of 25 examinations under the personal supervision of an individual qualified under this section; and

(C) At least eight hours of training in each mammography modality to be used by the technologist in performing mammography exams; and

(D) Be currently registered and in good standing with the American Registry of Radiologic Technologist (ARRT); and

(E) Be certified in mammography by the ARRT or the equivalent; or

(F) Provide documented evidence that an ARRT mammography certification test is scheduled. Technologists meeting the requirements of subsection (1)(a) and paragraphs (1)(b)(A), (B), (C), and (D) of this rule may work under the supervision (supervision means that a fully qualified technologist is on-site and readily available to answer questions or assist) of a technologist, meeting all of the requirements of this rule, for up to one year while waiting to take the certification test.

(2) Interpreting Physician qualifications. All physicians interpreting mammograms shall meet MQSA qualifications and hold a current license to practice medicine in the State of Oregon.

(3) Medical Physicist qualifications. All Medical Physicists conducting surveys and equipment evaluations of mammography facilities and providing oversight of their quality assurance programs shall;

(a) Meet MQSA requirements; and

(b) Be currently licensed as a vendor by the Authority.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

DIVISION 108

RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

333-108-0001
Purpose and Scope

This Division provides special requirements for analytical X-ray equipment. The requirements of this Division are in addition to, and not in substitution for, applicable requirements in other Divisions of these rules.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

333-108-0005
Definitions

As used in this Division, the following definitions apply:

(1) "Analytical X-ray equipment" means equipment used for X-ray diffraction or fluorescence analysis.

(2) "Analytical X-ray system" means a group of components utilizing X-rays or gamma-rays to determine the elemental composition or to examine the microstructure of materials.

(3) "Fail-safe characteristics" means a design features which cause beam port shutters to close, or otherwise prevent emergence of the primary beam, upon the failure of a safety or warning device.

(4) "Local components" mean part of an analytical X-ray system and include areas that are struck by X-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding, but do not include power supplies, transformers, amplifiers, readout devices and control panels.

(5) "Normal operating procedures" mean step-by-step instructions necessary to accomplish the analysis. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant or licensee and data recording procedures which are related to radiation safety.

(6) "Open-beam configuration" means an analytical X-ray system in which an individual could accidentally place some part of the body in the primary beam path during normal operation.

(7) "Primary beam" means radiation which passes through an aperture of the source housing by a direct path from the X-ray tube or a radioactive source located in the radiation source housing.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

Equipment Requirements

333-108-0010
Safety Device

A device which prevents the entry of any portion of an individual's body into the primary X-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant or licensee may apply to the Authority for an exemption from the requirement of a safety device. Such application shall include:

(1) A description of the various safety devices that have been evaluated;

(2) The reason each of these devices cannot be used; and

(3) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

Stat. Auth.: ORS 453.605 - 453.775
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

333-108-0015
Warning Devices

(1) Open-beam configurations shall be provided with a readily discernible indication of:

(a) X-ray tube "on-off" status located near the radiation source housing, if the primary beam is controlled in this manner; and/or

(b) Shutter "open-closed" status located near each port on the radiation source housing, if the primary beam is controlled in this manner.

(2) Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after January 1, 1978, warning devices shall have fail-safe characteristics.

Stat. Auth.: ORS 453.605 - 453.775
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

333-108-0020
Ports

Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

Stat. Auth.: ORS 453.605 - 453.775
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

333-108-0025
Labeling

All analytical X-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

(1) **CAUTION — HIGH INTENSITY X-RAY BEAM**, or words having a similar intent, on the X-ray source housing; and

(2) **CAUTION RADIATION — THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED**, or words having a similar intent, near any switch that energizes an X-ray tube if the radiation source is an X-ray tube; or

(3) **CAUTION — RADIOACTIVE MATERIAL**, or words having a similar intent, on the source housing in accordance with OAR 333-120-0400 if the radiation source is a radionuclide.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

333-108-0030
Shutters

On open-beam configurations installed after January 1, 1978, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85

333-108-0035
Warning Lights

(1) An easily visible warning light labeled with the words **X-RAY ON**, or words having a similar intent, shall be located:

(a) Near any switch that energizes an X-ray tube and shall be illuminated only when the tube is energized; or

(b) In the case of a radioactive source, near any switch that opens a housing shutter and shall be illuminated only when the shutter is open.

(2) On equipment installed after January 1, 1978, warning lights shall have fail-safe characteristics.

Stat. Auth.: ORS 453.605 - 453.775
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

333-108-0040
Radiation Source Housing

Each radiation source housing shall be subject to the following requirements:

(1) Each X-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.

(2) Each radioactive source housing or port cover or each X-ray tube housing shall be so constructed that, with all shutters closed, the radiation measured at a distance of five centi-meters from its surface is not capable of producing a dose in excess of 2.5 millirem (0.025 mSv) in one hour. For systems utilizing X-ray tubes, this limit shall be met at any specified tube rating.

Stat. Auth.: ORS 453.605 - 453.755
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

333-108-0045
Generator Cabinet

Each X-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of five centimeters from its surface such that it is not capable of producing a dose in excess of 0.25 millirem (2.5 μSv) in one hour.

Stat. Auth.: ORS 453.605 - 453.775
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

Area Requirements

333-108-0101
Radiation Levels

The local components of an analytical X-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in OAR 333-120-0180. For systems utilizing X-ray tubes, these levels shall be met at any specified tube rating.

Stat. Auth.: ORS 453.605 - 453.775
Stats. Implemented:Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

333-108-0105
Surveys

(1) Radiation surveys, as required by OAR 333-120-0200, of all analytical X-ray systems sufficient to show compliance with OAR 333-108-0101 shall be performed:

(a) Upon installation of the equipment and at least once every 12 months thereafter;

(b) Following any change in the initial arrangement, number or type of local components in the system;

(c) Following any maintenance requiring the disassembly or removal of a local component in the system;

(d) During the performance of maintenance and alignment procedures if the procedures require the presence of a primary X-ray beam when any local component in the system is disassembled or removed;

(e) Any time a visual inspection of the local components in the system reveals an abnormal condition; and

(f) Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in OAR 333-120-0100.

(2) Radiation survey measurements shall not be required if a registrant can demonstrate compliance with OAR 333-108-0101 to the satisfaction of the Authority.

Stat. Auth.: ORS 453.605 - 453.775
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

333-108-0110
Posting

Each area or room containing analytical X-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words **CAUTION — X-RAY EQUIPMENT**, or words having a similar intent in accordance with OAR 333-120-0400.

Stat. Auth.: ORS 453.605 - 453.775
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

333-108-0115
Operating Requirements

(1) Procedures. Normal operating procedures shall be written and available to all analytical X-ray equipment workers. No individual shall be permitted to operate analytical X-ray equipment in any manner other than that specified in the procedures unless such individual has obtained written approval of the radiation safety officer.

(2) Bypassing. No individual shall bypass a safety device or interlock unless such individual has obtained the approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device or interlock has been bypassed, a readily discernible sign bearing the words, **SAFETY DEVICE NOT WORKING**, or words having a similar intent, shall be placed on the radiation source housing.

(3) Repair or Modification of X-ray Tube Systems. Except as specified in OAR 333-108-0115(2), no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

(4) Radioactive Source Replacement, Testing or Repair. Radioactive source housings shall be opened for source replacement, leak testing or other maintenance or repair procedures only by individual authorized to specifically conduct such procedures under a license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.

Stat. Auth.: ORS 453.605 - 453.775
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

333-108-0201
Personnel Requirements

(1) Instruction. No individual shall be permitted to operate or maintain analytical X-ray equipment unless such individual has received instruction in and demonstrated competence as to:

(a) Identification of radiation hazards associated with the use of the equipment;

(b) Significance of the various radiation warning, safety devices and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

(c) Proper operating procedures for the equipment;

(d) Recognition of symptoms of an acute localized exposure; and

(e) Proper procedures for reporting an actual or suspected exposure.

(2) Each licensee or registrant shall maintain, for inspection by the Authority, records of training which demonstrate that the requirements of this rule have been met

Stat. Auth.: ORS 453.605 - 453.775
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

333-108-0205
Personnel Monitoring

(1) Finger or wrist dosimetric devices shall be provided to and shall be used by:

(a) Analytical X-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and

(b) Personnel maintaining analytical X-ray equipment if the maintenance procedures require the presence of a primary X-ray beam when any local component in the analytical X-ray system is disassembled or removed.

(2) Reported dose values shall not be used for the purpose of determining compliance with OAR 333-120-0100 of these rules unless evaluated by a qualified expert.

Stat. Auth.: ORS 453.605 - 453.775
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

DIVISION 109

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL AND MANUFACTURING USE OF PARTICLE ACCELERATORS

333-109-0001
Purpose and Scope

(1) This division establishes procedures for the registration and the use of particle accelerators.

(2) In addition to the requirements of this division, all registrants are subject to the requirements of divisions 100, 101, 120 and 111 of these rules. Registrants engaged in industrial radiographic operations are also subject to the requirements of divisions 105 and 108 of these rules, and registrants engaged in the healing arts are also subject to the requirements of division 106 of these rules. Registrants whose operations result in the production of radioactive material are also subject to the requirements of division 102 of these rules.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06

333-109-0002
Registration Requirements

No person may receive, possess, use, transfer, own, or acquire a particle accelerator unless they apply for, and are granted, a registration issued pursuant to division 333-101.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-109-0003
General Requirements for the Issuance of a Registration for Particle Accelerators

In addition to the requirements of division 101 of these rules, a registration application for use of a particle accelerator will be approved only if the Authority determines that:

(1) The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this division and divisions 120 and 111 of these rules in such a manner as to minimize danger to public health and safety or property;

(2) The applicant's equipment, facilities, operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;

(3) The issuance of the registration will not be harmful to the health and safety of the public;

(4) The applicant has appointed a qualified radiation safety officer;

(5) The applicant and/or the applicant's staff has substantial experience in the use of particle accelerators and training sufficient for application to its intended uses;

(6) The applicant has established a radiation safety committee to approve, in advance, proposals for uses of particle accelerators, whenever deemed necessary by the Authority;

(7) The applicant has an adequate training program for operators of particle accelerators;

(8) A shielding design, by a qualified expert licensed to do shielding design in Oregon, must be submitted with the registration application;

(9) For all new accelerators, a record indicating that a radiation safety survey has been conducted prior to the use of the accelerator, must be sent to the Authority as soon as practical after the registration application is submitted; and

(10) Copies of the facility's operating and emergency procedures must be submitted with the registration application.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06

333-109-0005
Equipment

(1) A label bearing essentially the words CAUTION — RADIATION — THIS MACHINE PRODUCES RADIATION WHEN ENERGIZED must be placed near any switch which energizes any portion of the machine. All labels must be the conventional colors (magenta or purple on yellow background) and bear the conventional radiation symbol.

(2) Any apparatus used in beam alignment procedures must be designed in such a way that excessive radiation will not strike the operator.

(3) Any switch or device which may cause the radiation machine to produce radiation when actuated must be located on a control panel or console, and must cause a warning light immediately adjacent to such switch or device to light; this light must remain lit when, and only when, the associated control circuit is energized.

(4) A lock must be provided on the control panel or console that prevents unauthorized operation of the accelerator.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06

333-109-0010
Administrative Responsibilities

(1) A person at each facility must be designated to be responsible for maintaining radiation safety. This person, designated the radiation safety officer, must be responsible for the following:

(a) Establishing and maintaining operational procedures so that the radiation exposure of each worker is kept as far below the maximum permissible dose as is practical;

(b) Instructing all personnel who work with or near radiation producing machines, in safety practices;

(c) Maintaining a system of personnel monitoring;

(d) Arranging for establishment of radiation control areas, including placement of appropriate radiation warning signs and/or devices;

(e) Providing for radiation safety inspection of radiation producing machines, including operation of all safety devices on a routine basis;

(f) Reviewing modifications to apparatus, shielding and safety interlocks;

(g) Investigating and reporting to proper authorities any case of excessive exposure to personnel and taking remedial action;

(h) Being familiar with all applicable rules for the control of ionizing radiation; and

(i) Terminating operations at the facility because of radiation safety considerations.

(2) No individual must be permitted to act as an operator of an accelerator until such person has:

(a) Received an acceptable amount of training in radiation safety as approved by the radiation safety officer;

(b) Has received copies of and instruction in this division, the applicable requirements of divisions 120 and 111 of these rules and:

(A) Pertinent registration conditions; and

(B) Operating and emergency procedures; and

(C) Must have demonstrated understanding of documents and information required in this rule;

(c) Demonstrated competence to in the use of the accelerator, related equipment and radiation survey instruments which will be employed; and

(d) Been approved by the radiation safety officer. Each operator must be responsible for:

(A) Keeping radiation exposure to all individuals as low as is practical;

(B) Being familiar with safety procedures as they apply to each machine;

(C) Wearing of personnel monitoring devices, if applicable; and

(D) Notifying the radiation safety officer of known or suspected excessive radiation exposures to any individual.

(3) The radiation safety committee or the radiation safety officer must have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to minimize danger to public health and safety or property.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06

333-109-0015
Operating Procedures

(1) Particle accelerators, when not in operation must be secured to prevent unauthorized use.

(2) Written operating procedures pertaining to radiation safety must be established for each accelerator facility by the radiation safety officer.

(3) Written emergency procedures pertaining to radiation safety must be established by the radiation safety officer. These must list the telephone number(s) of the radiation safety officer and must include the following actions to be taken in case of a known, or suspected, accident involving radiation exposures:

(a) Notifying the radiation safety officer; and

(b) Arranging for medical examination.

(4) Personnel must not expose any part of their body to the radiation beam.

(5) Accelerator must not be left unattended while energized unless access to radiation areas or high radiation areas is physically prevented.

(6) All safety and warning devices, including interlocks, must be checked for proper operation at intervals not to exceed three months. Results of such tests must be maintained at the accelerator facility for inspection by the Authority.

(7) Records of personnel monitoring results and safety device tests must be maintained for inspection by the Authority.

(8) An appropriate radiation monitor must be used within an accelerator target room and other high radiation areas. This may be:

(a) An area monitor with an easily observable indicator that warns of radiation levels above a predetermined limit in accessible areas; and/or

(b) A personal radiation monitor of the “chirpie” type carried into the room; and/or

(c) A portable survey instrument carried into the room.

(9) Personal radiation dosimeters that measure the expected radiations and are of sufficient range to be useful under normal and accident conditions shall be worn by all persons designated by the radiation safety officer.

(10) Records of all radiation protection surveys, inspections and maintenance performed on the accelerator and related components must be kept current and on file at each accelerator facility, and maintained for inspection by the Authority.

(11) The safety interlock system must not be used to turn off the accelerator beam except in an emergency.

(12) Electrical circuit diagrams of the accelerator and the associated safety interlock systems must be kept current and maintained for inspection by the Authority and must be available to the operator at each accelerator facility.

(13) If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action must be:

(a) Authorized by the radiation safety committee or radiation safety officer;

(b) Recorded in a permanent log and a notice posted at the accelerator control console; and

(c) Terminated as soon as possible.

(14) A copy of the current operating and the emergency procedures must be maintained at the accelerator control panel.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06

Radiation Safety Requirements for the Use of Particle Accelerators

333-109-0025
Shielding and Safety Design Requirements

(1) A qualified expert, acceptable to the Authority, must be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.

(2) Each particle accelerator installation must be provided with such primary and/or secondary barriers as are necessary to assure compliance with OAR 333-120-0100 and 333-109-0030.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06

333-109-0030
Particle Accelerator Controls and Interlock Systems

(1) Instrumentation, readouts and controls on the particle accelerator control console must be clearly identified and easily discernible.

(2) Each entrance into a target room or other high radiation area must be provided with a safety interlock that shuts down the machine under conditions of barrier penetration.

(3) Each safety interlock must be on a circuit which must allow it to operate independently of all other safety interlocks.

(4) All safety interlocks must be designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator.

(5) When a safety interlock system has been tripped, it must only be possible to resume operation of the accelerator by manually resetting controls at the position where the safety interlock has been tripped and, lastly, at the main control console.

(6) A scram button or other emergency power cutoff switch must be located and easily identifiable in all high radiation areas. Such a cutoff switch must include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

(7) All safety interlocks must not be dependent upon the operation of a single circuit; i.e., they must be of redundant or fail-safe design.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06

333-109-0035
Warning Devices

(1) Each location designated as a high radiation area, and each entrance to such location, must be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

(2) Except in facilities designed for human exposure, each high radiation area must have an audible warning device which must be activated for 15 seconds prior to the possible creation of such high radiation area. Such warning device must be clearly discernible in all high radiation areas.

(3) Barriers, temporary or otherwise and pathways leading to high radiation areas must be posted in accordance with OAR 333-120-0400.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06

333-109-0040
Radiation Monitoring Requirements

(1) There must be available at each particle accelerator facility appropriate portable monitoring equipment which is operable and has been appropriately calibrated for the radiations being produced at the facility. Such equipment must be tested for proper operation daily and calibrated at intervals not to exceed one year and after each servicing and repair.

(2) A radiation protection survey must be performed and documented by a qualified expert, acceptable to the Authority, when changes have been made in shielding, operation, equipment or occupancy of adjacent areas.

(3) Radiation levels in all high radiation areas must be continuously monitored. The monitoring devices must be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

(4) All area monitors must be calibrated at intervals not to exceed one year and after each servicing and repair.

(5) Whenever applicable, periodic surveys must be made to determine the amount of airborne particulate radioactivity present.

(6) Whenever applicable, periodic smear surveys must be made to determine the degree of contamination.

(7) All surveys must be made in accordance with the written procedures established by a qualified expert, acceptable to the Authority or the radiation safety officer.

(8) Records of all radiation protection surveys, calibrations and instrumentation tests must be maintained at the accelerator facility for inspection by the Authority.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06

333-109-0045
Ventilation Systems

(1) Ventilation systems must be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive materials in excess of those limits specified in 10 CFR Part 20 Table 1 of Appendix B to 20.1001 to 20.2401.

(2) A registrant, as required by OAR 333-120-0190, must not vent, release or otherwise discharge airborne radioactive material to an unrestricted area which exceed the limits specified in 10 CFR Part 20 **Table 2** Appendix B to 20.1001 to 20.2401, except as authorized pursuant to OAR 333-104-0035. For purposes of this rule concentrations may be averaged over a period not greater than one year. Every effort should be made to maintain releases of radioactive material to unrestricted areas as far below these limits as is reasonably achievable.

[ED. NOTE: Tables referenced are available from the agency.]
Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06

DIVISION 110

RADIATION SAFETY REQUIREMENTS FOR RADIOACTIVE TAILINGS AND PONDS

333-110-0001
Scope

The rules in this division establish requirements for radioactive tailings and ponds containing radioactive material from industrial processes. The provisions of this division are in addition to, and not in substitution for, other applicable provisions of these rules and any specific license issued pursuant to OAR 333-102-0300. The rules in this division do not apply to activities regulated by the Uranium Mill Tailings Radiation Control Act of 1978.

Stat. Auth.: ORS 453.605 - 453.745
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

333-110-0005
Definitions

As used in this division, these terms have the definitions as set forth below:

(1) "Radioactive" means:

(a) Concentrations of radioactive material in excess of those concentrations listed in **10 CFR Part 30.70**, **Schedule A**; or

(b) Concentrations of naturally occurring radioactive material or other radioactive material not listed in **10 CFR Part 30.70**,

Schedule A, which the Authority has determined to present a biological hazard to the occupational or public health and safety.

(2) "Tailings" means any material produced, other than the primary product, in any industrial activity including mining, milling, processing and production.

Stat. Auth.: ORS 453.605 - 453.745
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

333-110-0010
Specific Requirements for Tailings and Ponds

Unless specifically provided otherwise by the Authority, the following requirements for tailings and pond areas shall be fulfilled:

(1) Access to such areas shall be controlled and posted as specified by the Authority.

(2) These areas shall be maintained in such a manner that excessive erosion of, or environmental hazards from, radioactive material does not occur:

(a) Pile edges adjacent to a river, creek or other water course shall be stabilized to prevent erosion;

(b) Drainage ditches sufficient to prevent erosion from surface runoff water shall be provided.

(3) Prior written approval from the Authority shall be obtained before the surface area of the land shall be put to use.

(4) With the exception of reprocessing at the site, approval by the Authority must be obtained prior to removal of any material from these areas.

Stat. Auth.: ORS 453.605 - 453.745
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

333-110-0015
Sale or Transfer of the Site

The Authority shall be given written notice 30 days in advance of any contemplated transfer of right, title or interest in the site by deed, lease or other conveyance. The written notice shall contain the name and address of the proposed purchaser or transferee.

Stat. Auth.: ORS 453.605 - 453.745
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

333-110-0020
Abandonment of the Site

Prior to abandonment of the site, the requirements of this rule shall be fulfilled:

(1) Piles shall be stabilized against wind and water erosion and contoured in a manner which will prevent collection of water.

(2) In addition to the above requirements, any material which has been removed from the pile by natural forces shall be returned to the pile.

(3) Ponds shall be drained and covered with materials that prevent blowing of dust. Water drained from the ponds shall be disposed of in a manner approved by the Authority.

(4) Detailed plans for compliance with sections (1), (2) and (3) of this rule shall be submitted to the Authority for review and approval.

Stat. Auth.: ORS 453.605 - 453.745
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

333-110-0025
Waiver

Upon application to the Authority, certain requirements of this Division may be waived or modified if it can be shown that the requirements are unnecessary or impractical in specific cases.

Stat. Auth.: ORS 453.605 - 453.745
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

DIVISION 111

NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS

333-111-0001
Purpose and Scope

This division establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in activities under a license or registration and options available to such individuals in connection with Authority inspections of licensees or registrants to ascertain compliance with the provisions of the act and rules, orders and licenses issued thereunder regarding radiological working conditions. The rules in this division apply to all persons who receive, possess, use, own or transfer sources of radiation registered with or licensed by the Authority pursuant to divisions 100, 101 and 102 of this chapter.

Stat. Auth.: ORS 453.605 - 453.755
Stats. Implemented: ORS 453.605 - 453.755
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 14-2008, f. & cert. ef. 9-15-08

333-111-0005
Posting of Notices to Workers

(1) Each licensee or registrant shall post current copies of the following documents:

(a) The rules in this division and division 120 of this chapter;

(b) The license, certificate of validation, conditions or documents incorporated into the license by reference and amendments thereto;

(c) The operating procedures applicable to activities under the license or registration; and

(d) Any notice of noncompliance involving radiological working conditions, proposed imposition of civil penalty or order issued pursuant to division 100 of this chapter, and any response from the licensee or registrant.

(2) If posting of a document specified in subsection (1)(a), (b) or (c) of this rule is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined, provided that such document is readily available to workers at the licensee's or registrant's facility.

(3) Authority "Notice to Employees" shall be posted by each licensee or registrant as required by these rules.

(4) Documents, notices or forms posted pursuant to this rule shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous and shall be replaced if defaced or altered.

(5) Authority documents posted pursuant to subsection (1)(d) of this rule shall be posted within two working days after receipt of the documents from the Authority. The licensee's or registrant's response, if any, shall be posted within two working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

Stat. Auth.: ORS 453.605 - 453.755
Stats. Implemented: ORS 453.605 - 453.755
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 14-2008, f. & cert. ef. 9-15-08

333-111-0010
Instructions to Workers

All individuals working in or frequenting any portion of a restricted area:

(1) Shall be kept informed of the storage, transfer or use of sources of radiation in such portions of the restricted area;

(2) Shall be instructed in the health protection problems associated with exposure to radiation or radioactive material, in precautions or procedures to minimize exposure and in the purposes and functions of protective devices employed;

(3) Shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of

these rules and licenses for the protection of personnel from exposures to radiation or radioactive material occurring in such areas;

(4) Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to or cause a violation of Authority rules and licenses or unnecessary exposure to radiation or radioactive material;

(5) Shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and

(6) Shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to OAR 333-111-0015.

(7) Refresher training shall be provided at intervals not to exceed three years covering the topics identified in OAR 333-111-0010.

NOTE: The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.745

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 14-2008, f. & cert. ef. 9-15-08

333-111-0015
Notifications and Reports to Individuals

(1) Radiation exposure data for an individual and the results of any measurements, analyses and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in this rule. The information reported shall include data and results obtained pursuant to these rules, orders or license conditions, as shown in records maintained by the licensee or registrant pursuant to OAR 333-120-0650. Each notification and report shall:

(a) Be in writing;

(b) Include the appropriate identifying data such as the name of the licensee or registrant, the name of the individual and the individual's social security number;

(c) Include the individual's exposure information; and

(d) Contain the following statement: "This report is furnished to you under the provisions of rules entitled Oregon Rules for the Control of Radiation, division 111. You should preserve this report for further reference."

(2) Each licensee or registrant shall make dose information available to workers as shown in records maintained by the licensee or registrant under the provisions of OAR 333-120-0650. The licensee shall provide an annual report to each individual monitored under 333-120-0210 of the dose received in that monitoring year if:

(a) The individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue; or

(b) The individual requests his or her annual dose report.

(3) At the request of a worker formerly engaged in work controlled by the licensee or registrant, each licensee or registrant shall furnish to the worker a report of the worker's exposure to radiation or radioactive material. Such report shall be furnished within 30 days from the time the request is made or within 30 days after the exposure of the individual has been determined by the licensee or registrant, whichever is later; shall cover, within the period of time specified in the request, each calendar quarter in which the worker's activities involved exposure to radiation from radioactive material licensed by, or radiation machines registered with the Authority; and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

(4) When a licensee or registrant is required by OAR 333-120-0710, 333-120-0720 or 333-120-0730 to report to the Authority any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on the exposure data included in the report to the Authority. Such reports shall be transmitted at a time not later than the transmittal to the Authority.

(5) At the request of a worker who is terminating employment in a given calendar quarter with the licensee or registrant in work involving radiation dose, or of a worker who, while employed by another person, is terminating assignment to work involving radiation dose in the licensee's or registrant's facility in that calendar quarter, each licensee or registrant shall provide to each such worker, or to the worker's designee, at termination, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during that specifically identified calendar quarter or fraction thereof, or provide a written estimate of that dose if the finally determined personnel monitoring results are not available at that time. Estimated doses shall be clearly indicated as such.

Stat. Auth.: ORS 453.605 - 453.755

Stats. Implemented: ORS 453.605 - 453.755

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-111-0020
Presence of Representatives of Licensees or Registrants and Workers During Inspection

(1) Each licensee or registrant shall afford to the Authority at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises and records pursuant to these rules.

(2) During an inspection, Authority inspectors may consult privately with workers as specified in OAR 333-111-0025. The licensee or registrant may accompany Authority inspectors during other phases of an inspection.

(3) If, at the time of inspection, an individual has been authorized by the workers to represent them during Authority inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(4) Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in OAR 333-111-0010.

(5) Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(6) With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany Authority inspectors during the inspection of physical working conditions.

(7) Notwithstanding the other provisions of this rule, Authority inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

Stat. Auth.: ORS 453.605 - 453.755

Stats. Implemented: ORS 453.605 - 453.755

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 14-2008, f. & cert. ef. 9-15-08

333-111-0025
Consultation with Workers During Inspection

(1) Authority inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of these rules and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(2) During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of the Act, these rules or license condition, or any unnecessary exposure

of an individual to sources of radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of OAR 333-111-0030(1).

(3) The provisions of section (2) of this rule shall not be interpreted as authorization to disregard instructions pursuant to OAR 333-111-0010.

Stat. Auth.: ORS 453.605 - 453.755
Stats. Implemented: ORS 453.605 - 453.755
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 14-2008, f. & cert. ef. 9-15-08

333-111-0030
Requests by Workers for Inspections

(1) Any worker or representative of workers believing that a violation of the Act, these rules or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the Authority. Any such notice shall be in writing, shall set forth the specific grounds for the notice and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the Authority no later than at the time of inspection except that, upon the request of the worker giving such notice, their name and the name of individuals referred to therein shall not appear in such copy or on any record published, released or made available by the Authority, except for good cause shown.

(2) If, upon receipt of such notice, the Authority determines that the complaint meets the requirements set forth in section (1) of this rule, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to this rule need not be limited to matters referred to in the complaint.

(3) No licensee, registrant or contractor or subcontractor of a licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these rules or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself or others of any option afforded by this division.

Stat. Auth.: ORS 453.605 - 453.755
Stats. Implemented: ORS 453.605 - 453.755
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 14-2008, f. & cert. ef. 9-15-08

333-111-0035
Inspections Not Warranted; Informal Review

(1) If the Authority determines, with respect to a complaint under OAR 333-111-0030, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Authority shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the Assistant Director of the Public Health Division. The Authority will provide the licensee or registrant with a copy of such statement by certified mail, excluding at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the Assistant Director of the Public Health Division. The Authority will provide the complainant with a copy of such statement by certified mail.

(2) Upon the request of the complainant, the Assistant Director of the Public Health Division may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written or oral views presented, the Assistant Director of the Public Health Division shall affirm, modify or reverse the determination of the Authority and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefore.

(3) If the Authority determines that an inspection is not warranted because the requirements of OAR 333-111-0030(1) have not been met, the complainant shall be notified in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of OAR 333-111-0030(1).

Stat. Auth.: ORS 453.605 - 453.755
Stats. Implemented: ORS 453.605 - 453.755
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 14-2008, f. & cert. ef. 9-15-08

DIVISION 112

REQUIREMENTS FOR MICROWAVE OVEN USE AND SERVICE

333-112-0001
Purpose and Scope

(1) The purpose of this division is to assure adequate servicing and repair of microwave ovens and to prevent public and occupational exposure to microwave radiation from leaking microwave ovens which the Authority has determined to present a biological hazard to occupational and public health and safety.

(2) The requirements of this division apply to any person or facility that operates microwave ovens or that provides repair or other service for microwave ovens used in homes, restaurants, hospitals, schools or other establishments where the public could be exposed.

Stat. Auth.: ORS 453.605 - 453.745
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

333-112-0005
Definitions

As used in this division, these terms have the definitions set forth below:

(1) "Microwave oven" means an electronic product designed to heat or cook food through the application of electromagnetic energy at frequencies assigned by the Federal Communica-tions Commission in the normal industrial, scientific and medical heating bands ranging from 890 megahertz to 6,000 megahertz.

(2) "Cavity" means that portion of the microwave oven in which food may be heated or cooked.

(3) "Door" means the movable barrier which prevents access to the cavity during operation and the function of which is to prevent emission of microwave energy from the passage or opening which provides access to the cavity.

(4) "External surface" means the outside surface of the cabinet or enclosure provided by the manufacturer as part of the microwave oven, including doors, door handles, latches and control knobs.

(5) "Licensee" means any person (facility) that provides service for microwave ovens.

(6) "Service" means the testing, repair, maintenance, modification, replacement or adjustment of any microwave oven or any part or component thereof.

(7) "Stirrer" means that feature of a microwave oven which is intended to provide uniform heating of the load by constantly changing the standing wave pattern within the cavity or moving the load.

(8) "Technician" means any individual that performs service on microwave ovens

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85

333-112-0010
Licensing of Microwave Oven Repair Facilities

(1) No person or facility shall provide service for microwave ovens except as authorized by a specific license issued by the

Authority. A license application will be approved or an annual validation certificate issued when the Authority determines that:

(a) The applicant's proposed test equipment satisfies the requirements of OAR 333-112-0020;

(b) The applicant's proposed procedures pertaining to oven repair and instruction of personnel are adequate to ensure compliance with these rules.

(2) License applications shall be made on forms furnished by the Authority.

(3) In addition to the requirements of this division, all licensees are subject to the requirements of divisions 100 and 111 of these rules.

Stat. Auth.: ORS 453.605 - 453.745
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

Requirements for Microwave Oven Service Licensees

333-112-0015
Service Responsibilities

(1) The licensee shall test each microwave oven serviced for leakage in accordance with measurement and test procedures described in OAR 333-112-0020. The test shall be performed before, if the oven is operational, and after servicing of the oven has been completed.

(2) No licensee shall provide service for a microwave oven in such a manner as to cause leakage from the oven in excess of those limits specified in OAR 333-112-0040.

(3) The licensee shall notify the Authority within 20 days of any microwave oven that is found to be leaking microwave radiation in excess of the limits specified in OAR 333-112-0040. The notification shall include:

(a) The maximum power density measured with procedures described in OAR 333-112-0020;

(b) The name of the manufacturer of the oven;

(c) The date the leakage was corrected and the oven was brought into compliance with OAR 333-112-0040;

(d) The reason why the leakage was not corrected and brought into compliance with OAR 333-112-0040; or

(e) The name and address of the owner.

(4) A copy of the notification required by section (3) of this rule shall be supplied to the owner or user of the microwave oven at the time the notification is sent to the Authority.

Stat. Auth.: ORS 453.605 - 453.745
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

333-112-0020
Measurement and Test Procedures

(1) Leakage levels shall be determined by measurements of microwave power density made with an instrument system which:

(a) Reaches 90 percent of its steady-state reading within three seconds when the system is subjected to a stepped input signal;

(b) Has a radiation detector with an effective aperture of 25 square centimeters or less as measured in a plane wave, having no dimension exceeding ten centimeters;

(c) Is capable of measuring microwave oven leakage levels with an accuracy of plus 25 percent and minus 20 percent (plus or minus one decibel);

(d) Has been calibrated at least within the last 12 months.

(2) Measurements shall be made in accordance with the manufacturer's leakage test procedures or with the microwave oven operating at its maximum output and containing a load of 275 plus or minus 15 milliliters of tap water, initially at room temperature, placed within the cavity at the center of the load-carrying surface provided by the manufacturer. The water container for the latter procedure shall be a low form 600 milliliter beaker, or substantially similar vessel, having an inside diameter of approximately 8.5 centimeters and made of an electrically nonconductive material, such as glass or plastic.

(3) Measurements shall be made with the door fully closed, as well as with the door fixed in any other position which allows the oven to operate.

(4) Measurements shall be made at points five centimeters or less from external surfaces of the oven.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85

333-112-0025
Training of Service Personnel

The licensee shall ensure that each technician who services microwave ovens in his or her employ is instructed in the test procedures, compliance criteria and all requirements of this division.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85

333-112-0030
Personnel Monitoring for Cataracts

It is recommended that each individual who performs servicing of microwave ovens have his or her eyes examined for cataract formations. The testing for cataracts should be by a licensed ophthalmologist and should be performed at the beginning of employment and annually thereafter.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85

333-112-0035
Records

The licensee shall maintain records showing the results of leakage measurements on each microwave oven serviced. The records shall be maintained for inspection by the Authority and shall be so filed as to be readily available for review. The records shall contain at least the following information:

(1) The name of the individual who performed the service.

(2) The date the service was completed.

(3) The maximum leakage levels before and after servicing as applicable.

(4) The location of the maximum leakage levels.

Stat. Auth.: ORS 453.605 - 453.745
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91

333-112-0040
Operation of Microwave Ovens

(1) No person shall operate or direct the operation of a microwave oven that has been determined to leak microwave radiation in excess of the following limits:

(a) For ovens manufactured after October 1, 1971, leakage in excess of five milliwatts per square centimeter at any point five centimeters or more from the external surface of the oven;

(b) For ovens manufactured before October 1, 1971, leakage in excess of ten milliwatts per square centimeter at any point five centimeters or more from the external surface of the oven.

(2) Microwave ovens shall be considered to be in compliance with section (1) of this rule if the maximum power density of microwave radiation leakage measured in the test procedures specified in OAR 333-112-0020 does not exceed the microwave radiation leakage limits specified in section (1) of this rule measured through at least one stirrer cycle.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85

DIVISION 113

RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OPERATIONS AND SUB-SURFACE TRACER STUDIES

333-113-0001
Purpose and Scope

(1) The rules in this division establish radiation safety requirements for persons using sources of radiation for well logging operations including mineral logging, radioactive markers and subsurface

tracer studies. The requirements of this division are in addition to, and not in substitution for, the requirements of divisions 100, 102, 111 and 120 of these rules.

(2) The rules in this division apply to all licensees or registrants who use sources of radiation for well logging operations including mineral logging, radioactive markers or subsurface tracer studies.

(3) The requirements set out in this division do not apply to the issuance of a license authorizing the use of licensed material in tracer studies involving multiple wells, such as field flooding studies, or to the use of sealed sources auxiliary to well logging but not lowered into wells.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0005
Definitions

As used in this division, the following definitions apply:

(1) "Energy compensation source (ECS)" means a small sealed source, with an activity not exceeding 3.7 MBq (100 microcuries), used within a well logging tool, or other tool components, to provide a reference standard to maintain the tool's calibration when in use.

(2) "Field Station" means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary jobsites.

(3) "Fresh water aquifer," for the purpose of this part, means a geologic formation that is capable of yielding fresh water to a well or spring.

(4) "Injection Tool" means a device used for controlled subsurface injection of radioactive tracer material.

(5) "Irretrievable well logging source" means any sealed source containing licensed material that is pulled off or not connected to the wireline that suspends the source in the well and for which all reasonable effort at recovery has been expended.

(6) "Licensed material" means byproduct, source, or special nuclear material received, processed, used, or transferred under a license issued by the Authority under the rules in this chapter.

(7) "Logging assistant" means any individual who, under the personal supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by 333-113-0401.

(8) "Logging Supervisor" means the individual who uses licensed material or provides personal supervision of the use of licensed sources of radiation at the well site and who is responsible to the licensee for assuring compliance with the requirements of Authority rules and the conditions of the license.

(9) "Logging Tool" means a device used subsurface to perform well-logging.

(10) "Mineral Logging" means any logging performed for the purpose of mineral exploration other than oil or gas.

(11) "Personal Supervision" means guidance and instruction by a logging supervisor who is physically present at the jobsite and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance given as required.

(12) "Radioactive Marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation. For purposes of these rules, this term includes radioactive collar markers and radioactive iron nails.

(13) "Safety review" means a periodic review provided by the licensee for its employees on radiation safety aspects of well logging. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, accidents or errors that have been observed, and opportunities for employees to ask safety questions.

(14) "Sealed source" means any licensed material that is encased in a capsule designed to prevent leakage or escape of the licensed material

(15) "Source Holder" means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-logging operations.

(16) "Subsurface Tracer Study" means the release of unsealed license material or a substance tagged with licensed radioactive material for the purpose of tracing the movement or position of the tagged substance in the well-bore or adjacent formation.

(17) "Surface casing for protecting fresh water aquifers" means a pipe or tube used as a lining in a well to isolate fresh water aquifers from the well.

(18) "Temporary Jobsite" means a location where radioactive materials are present for the purpose of performing well logging operations or subsurface tracer studies.

(19) "Tritium neutron generator target source" means a tritium source used within a neutron generator tube to produce neutrons for use in well logging applications.

(20) "Uranium Sinker Bar" means a weight containing depleted uranium used to pull a logging tool down toward the bottom of a well.

(21) "Well" means a drilled hole in which well logging operations and subsurface tracer studies are performed. As used in this division, "well" includes drilled holes for the purpose of oil, gas, mineral, groundwater or geological exploration.

(22) "Well-Logging" means all operations involving the lowering and raising of measuring devices or tools which may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well or adjacent formations that are used in oil, gas, mineral, groundwater or geological exploration.

(23) "Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0007
Specific Licenses For Well Logging

(1) A person, as defined in 333-100-0005 must file an application for a specific license authorizing the use of radioactive materials for well logging in accordance with 333-102-0190.

(2) The Authority will approve an application for a specific license for the use of radioactive material in well logging if the applicant meets the following requirements:

(a) The applicant must satisfy the general requirements specified in 333-102-0200 for radioactive material and any special requirements contained in this division.

(b) The applicant must develop a program for training well logging supervisors and well logging assistants and submit to the Authority a description of this program which specifies the:

(A) Initial training;

(B) On-the-job training;

(C) Annual safety reviews provided by the licensee;

(D) Means the applicant will use to demonstrate the logging supervisor's knowledge and understanding of and ability to comply with the Authority's rules and licensing requirements and the applicant's operating and emergency procedures; and

(E) Means the applicant will use to demonstrate the logging assistant's knowledge and understanding of and ability to comply with the applicant's operating and emergency procedures.

(c) The applicant must submit to the Authority written operating and emergency procedures as described in 333-113-0205 or an outline or summary of the procedures that includes the important radiation safety aspects of the procedures.

(d) The applicant must establish and submit to the Authority its program for annual inspections of the job performance of each logging supervisor to ensure that the Authority's rules, license requirements, and the applicant's operating and emergency procedures are followed. Inspection records must be retained in accordance with 333-100-0057.

(e) The applicant must submit a description of its overall organizational structure as it applies to the radiation safety responsibilities

in well logging, including specified delegations of authority and responsibility.

(f) If an applicant wants to perform leak testing of sealed sources, the applicant must identify the manufacturers and the model numbers of the leak test kits to be used. If the applicant wants to analyze its own wipe samples, the applicant must establish procedures to be followed and submit a description of these procedures to the Authority. The description must include the:

(A) Instruments to be used;

(B) Methods of performing the analysis; and

(C) Pertinent experience of the person who will analyze the wipe samples.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0010
Agreement With Well Owner of Operator

(1) No licensee must perform well logging operations with a sealed source(s) unless, prior to commencement of the operation, the licensee has a written agreement with the well operator, well owner, drilling contractor or landowner. This written agreement must identify who will meet the following requirements:

(a) In the event that a well to be logged, using radioactive material, penetrates a potable aquifer or contains potable water, that well must be cased from top to bottom prior to the well-logging;

(b) In the event a sealed source is lodged downhole, a reasonable effort at recovery will be made;

(c) No person shall attempt to recover a sealed source in a manner which, in the licensee's opinion, could result in its rupture; and

(d) In the event a decision is made to abandon the sealed source down hole, the requirements of OAR 333-113-0501(3) must be met within 30 days.

NOTE: A written agreement between the licensee and the well owner or operator is not required if the licensee and the well owner, or operator, are part of the same corporate structure or otherwise similarly affiliated.

(2) The licensee must retain a copy of the written agreement after the completion of the well logging operation in accordance with 333-100-0057.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

Equipment Control

333-113-0101
Limits on Levels of Radiation

Sources of radiation must be used, stored and transported in such a manner that the requirements of division 120 of this chapter are met.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0105
Storage Precautions

(1) Each source of radiation, except accelerators, must be provided with a storage and/or transport container. The container must be provided with a lock, or tamper seal for calibration sources, to prevent unauthorized removal of, or exposure to, the source of radiation.

(2) Sources of radiation must be stored in a manner which will minimize danger from explosion and/or fire.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0110
Transport Precautions

(1) The licensee may not transport licensed material unless the material is packaged, labeled, marked, and accompanied with appropriate shipping papers in accordance with rules set out in 49 CFR Parts 171 to 178.

(2) Security precautions during storage and transportation.

(a) The licensee must store each source containing licensed material in a storage container or transportation package. The container or package must be locked and physically secured to prevent tampering or removal of licensed material from storage by unauthorized personnel. The licensee must store licensed material in a manner which will minimize danger from explosion or fire.

(b) The licensee must lock and physically secure the transport package containing licensed material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the licensed material from the vehicle.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0115
Radiation Survey Instruments

(1) The licensee or registrant must maintain sufficient calibrated and operable radiation survey instruments, capable of detecting beta and gamma radiation, at each field station and temporary jobsite to make physical radiation surveys as required by this division and by OAR 333-120-0200. Instrumentation must be capable of measuring 0.001 mSv (0.1 mrem) per hour through at least 0.5 mSv (50 mrem) per hour.

(2) Each radiation survey instrument must be calibrated:

(a) At intervals not to exceed six months and after each instrument servicing;

(b) For linear scale measurements, at least two points located approximately 1/3 and 2/3 of full-scale on each scale; for logarithmic scale instruments, at midrange of each decade and at two points of at least one decade; and for digital instruments, at appropriate points; and

(c) So that accuracy within 20 percent of the true radiation level can be demonstrated on each scale.

(3) Calibration records must be maintained in accordance with 333-100-0057.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0120
Leak Testing of Sealed Sources

(1) Testing and Record Keeping Requirements. Each licensee using sealed sources of radioactive material must have the sources tested for leakage at intervals not to exceed six months. Records of leak test results must be kept in units of microcuries (Bq) and maintained in accordance with 333-100-0057.

(2) Method of Testing. Tests for leakage must be performed only by persons specifically authorized to perform such tests by the Authority, the U.S. Nuclear Regulatory Agency, an Agreement State or a Licensing State. The test sample must be taken from the surface of the source, source holder or from the surface of the device in which the source is stored or mounted and on which one might expect contamination to accumulate. The test sample must be analyzed for radioactive contamination and the analysis must be capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample.

(3) Interval of Testing. Each sealed source of radioactive material must be tested at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made prior to the transfer, the sealed source must not be put into use until tested. If, for any reason, it is suspected that a sealed source may be leaking, it must be removed from service immediately and tested for leakage as soon as practical.

(4) Leaking or Contaminated Sources.

(a) If the test reveals the presence of 0.005 microcurie (185 Bq) or more of leakage or contamination, the licensee must immediately withdraw the source from use and have it decontaminated, repaired or disposed of in accordance with these rules.

(b) The licensee must check the equipment associated with the leaking source for radioactive contamination and, if contaminated, have it decontaminated or disposed of in accordance with these rules.

(c) A report describing the leaking source and equipment involved, the test results and the corrective action taken must be filed with the Authority within 30 days of discovery.

(5) Exemptions. The following sources are exempted from the periodic leak test requirements of sections (1) through (4) of this rule:

(a) Hydrogen-3 sources;

(b) Sources of radioactive material with a half-life of 30 days or less;

(c) Sealed sources of radioactive material in gaseous form;

(d) Sources of beta and/or gamma emitting radioactive material with an activity of 100 microcuries (3.7 MBq) or less;

(e) Sources of alpha emitting radioactive material with an activity of ten microcuries (0.370 MBq) or less;

(f) Each ECS that is not exempt from testing in accordance with section (5)(e) of this rule must be tested at intervals not to exceed three years. In the absence of a certificate from a transferor that a test has been made within the three years before the transfer, the ECS may not be used until tested; and

(g) Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it must be tested before use or transfer unless it has been tested for leakage within six months before the date of use or transfer.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0125
Physical Inventory

Each licensee or registrant must conduct a semiannual physical inventory to account for all sources of radiation. Records of inventories must be maintained in accordance with 333-100-0057 and must include the quantities and kinds of sources of radiation, the location where sources of radiation are assigned, the date of the inventory and the name of the individual conducting the inventory. Physical inventory records may be combined with leak test records.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0130
Utilization Records

Each licensee or registrant must be maintained in accordance with 333-100-0057 showing the following information for each source of radiation:

(1) Make, model number and a serial number or a description of each source of radiation used. In the case of unsealed licensed material used for subsurface tracer studies, the radionuclide and quantity of activity used in a particular well and the disposition of any unused tracer materials;

(2) The identity of the well-logging supervisor or field unit to whom assigned;

(3) Locations where used and dates of use; and

(4) In the case of tracer material and radioactive markers, the utilization record must indicate the radionuclide and activity used in a particular well.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0135
Design, Performance and Certification Criteria for Sealed Sources

(1) Each sealed source, except those containing radioactive material in gaseous form, used in well logging operations and manufactured after May 1, 1983 must be certified by the manufacturer, or other testing organization acceptable to the Authority, to meet the following minimum criteria:

(a) Be of doubly encapsulated construction;

(b) Contain radioactive material whose chemical and physical forms are as insoluble and nondispersible as practical; and

(c) Has been individually pressure tested to at least 24,600 pounds per square inch absolute (1.695 x 107 pascals) without failure.

(2) For sealed sources, except those containing radioactive material in gaseous form, acquired after May 1, 1984 in the absence of a certificate from a transferor certifying that an individual sealed source meets the requirements of section (1) of this rule, the sealed source must not be put into use until such determinations and testing have been performed.

(3) Each sealed source, except those containing radioactive material in gaseous form, used in well logging operations after May 1, 1985 must be certified by the manufacturer, or other testing organization acceptable to the Authority, as meeting the sealed source performance requirements for oil well-logging as contained in the **American National Standard N43.6**, "Classification of Sealed Radioactive Sources," (formerly N542, ANSI/NBS 126).

(4) After source disposal certification documents must be maintained in accordance with 333-100-0057. If the source is abandoned downhole, the certification documents must be maintained until the Authority authorizes disposition.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0140
Labeling

(1) Each source, source holder or logging tool containing radioactive material must bear a durable, legible and clearly visible marking or label, which has, as a minimum, the standard radiation caution symbol specified in 333-120-0400, without the conventional color requirement, and the following wording:

DANGER
RADIOACTIVE
or
CAUTION
RADIOACTIVE

This labeling must be on the smallest component transported as a separate piece of equipment.

(2) Each container used to store or transport radioactive materials must have permanently attached to it a durable, legible and clearly visible label that has, as a minimum, the standard radiation caution symbol and the following wording:

DANGER
RADIOACTIVE
or
CAUTION
RADIOACTIVE
NOTIFY CIVIL AUTHORITIES OR
(NAME OF COMPANY)

(3) The licensee may use a uranium sinker bar in well logging applications only if it is legibly impressed with the words:

"CAUTION — RADIOACTIVE — DEPLETED URANIUM" and
"NOTIFY CIVIL AUTHORITIES (or COMPANY NAME) IF FOUND."

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0145
Inspection and Maintenance

(1) Each licensee or registrant must conduct, at intervals not to exceed six months, a visual check of source holders, logging

tools, source handling tools, storage containers, transport containers and injection tools to ensure proper labeling and physical condition. Records of inspection and maintenance must be maintained in accordance with 333-100-0057.

(2) If any inspection conducted pursuant to section (1) of this rule reveals defects or damage to labeling or components, the device must be removed from service until repairs have been made.

(3) If a sealed source is stuck in the source holder, the licensee must not perform any operation, such as drilling, cutting or chiseling, on the source holder unless the licensee is specifically approved by the U.S. Nuclear Regulatory Agency, an Agreement State or a Licensing State to perform this operation.

(4) The repair, opening or modification of any sealed source must be performed only by persons specifically authorized to do so by the Authority, the U.S. Nuclear Regulatory Agency, an Agreement State or a Licensing State.

(5) Removal of a sealed source from a source holder or logging tool, and maintenance on sealed sources or holders in which sealed sources are contained may not be performed by the licensee unless a written procedure has been developed and approved either by the Authority, the Nuclear Regulatory Agency or by an Agreement State or a Licensing State.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0150
Use of a Sealed Source in a Well without a Surface Casing

The licensee may use a sealed source in a well without a surface casing for protecting fresh water aquifers only if the licensee follows a procedure for reducing the probability of the source becoming lodged in the well. The procedure must be approved by the Authority, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 4-2007, f. & cert. ef. 3-1-07

Requirements for Personnel Safety

333-113-0201
Training Requirements

(1) No licensee or registrant shall permit any individual to act as a logging supervisor as defined in this division until such individual has:

(a) Received, in a course recognized by the Authority, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, instruction in the subjects outlined in OAR 333-113-0203 and demonstrated an understanding thereof;

(b) Read and received instruction in the rules contained in this division and the applicable rules of divisions 100, 120 and 111 of these rules or their equivalent, conditions of appropriate license or certificate of registration, and the licensee's or registrant's operating and emergency procedures, and demonstrated an understanding thereof;

(c) Demonstrated competence to use sources of radiation, related handling tools and radiation survey instruments which will be used on the job by a field evaluation; and

(d) Has demonstrated understanding of the requirements in section (1)(a) and (1)(b) of this rule by successfully completing a written exam.

(2) No licensee or registrant shall permit any individual to assist in the handling of sources of radiation until such individual has:

(a) Read or received instruction in the licensee's or registrant's operating and emergency procedures and demonstrated an understanding thereof;

(b) Demonstrated competence to use, under the personal supervision of the logging supervisor, the sources of radiation, related handling tools and radiation survey instruments which will be used on the job; and

(c) The licensee must provide safety reviews for logging supervisors and logging assistants at least once during each calendar year.

(3) The licensee or registrant must maintain employees training records until inspection by the Authority following termination of the individual's employment.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0203
Subjects to be Included in Training Courses for Logging Supervisors

(1) Fundamentals of radiation safety:
(a) Characteristics of radiation;
(b) Units of radiation dose and quantity of radioactivity;
(c) Significance of radiation dose:
(A) Radiation protection standards;
(B) Biological effects of radiation dose.
(d) Levels of radiation from sources of radiation;
(e) Methods of minimizing radiation dose:
(A) Working time;
(B) Working distances;
(C) Shielding.
(f) Radiation safety practices including prevention of contamination and methods of decontamination.
(2) Radiation detection instrumentation to be used:
(a) Use of radiation survey instruments:
(A) Operation;
(B) Calibration;
(C) Limitations.
(b) Survey techniques;
(c) Use of personnel monitoring equipment.
(3) Equipment to be used:
(a) Handling equipment;
(b) Sources of radiation;
(c) Storage and control of equipment;
(d) Operation and control of equipment.
(4) The Requirements of pertinent federal and state regulations.
(5) The licensee's or registrant's written operating and emergency procedures.
(6) The licensee's or registrant's record keeping procedures.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0205
Operating and Emergency Procedures

The licensee's or registrant's operating and emergency procedures must include instructions in at least the following:

(1) Handling and use of sources of radiation to be employed so that:

(a) No individual is likely to be exposed to radiation doses in excess of the standards established in division 120 of these rules; and

(b) Use of sealed sources in wells without surface casing for protecting fresh water aquifers, if appropriate.

(2) Methods and occasions for conducting radiation and contamination surveys. (See 333-113-0401).

(3) Methods and occasions for locking and securing sources of radiation.

(4) Personnel monitoring and the use of personnel monitoring equipment.

(5) Transportation to temporary jobsites and field stations, including the packaging and placing of sources of radiation in vehicles, placarding of vehicles and securing sources of radiation during transportation to prevent accidental loss, tampering, or unauthorized removal;

(6) Minimizing exposure of individuals in the event of an accident. Including, but not limited to, unshielded sources and inhalation or ingestion of licensed tracer materials.

(7) Procedure for notifying proper personnel in the event of an accident.

(8) Maintenance of records.

(9) Use, inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers and injection tools.

(10) Procedures to be followed in the event a sealed source is lodged downhole.

(11) Procedures to be used for picking up, receiving and opening packages containing radioactive material.

(12) For the use of tracers, decontamination of the environment, equipment and personnel.

(13) Maintenance of records generated by logging personnel at temporary jobsites.

(14) Notifying proper persons in the event of an accident.

(15) Actions to be taken if a sealed source is ruptured, including actions to prevent the spread of contamination and minimize inhalation and ingestion of radioactive material and actions to obtain suitable radiation survey instruments as required by OAR 333-113-0115.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0210
Personnel Monitoring

(1) The licensee must not permit an individual to act as a logging supervisor or logging assistant unless that person wears, at all times during the handling of licensed radioactive materials, a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and other personnel dosimeters replaced at least quarterly. After replacement, each personnel dosimeter must be promptly processed.

(2) The licensee must provide bioassay services to individuals using licensed materials in subsurface tracer studies if required by the license.

(3) Personnel monitoring records must be maintained in accordance with 333-100-0057 and for inspection until the Authority authorizes disposition.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

Precautionary Procedures in Logging and Subsurface Tracer Studies

333-113-0301
Security

(1) A logging supervisor must be physically present at a temporary jobsite whenever licensed materials are being handled or are not stored and locked in a vehicle or storage place. The logging supervisor may leave the jobsite in order to obtain assistance if a source becomes lodged in a well.

(2) During well logging, except when radiation sources are below ground or in shipping or storage containers, the logging supervisor or other individual designated by the logging supervisor must maintain direct surveillance of the operation to prevent unauthorized entry into a restricted area, as defined in 333-100-0005.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0305
Handling Tools

The licensee must provide and require the use of tools that will assure remote handling of sealed sources other than low activity calibration sources.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0310
Subsurface Tracer Studies

(1) Protective gloves and other appropriate protective clothing and equipment must be used by all personnel handling radioactive tracer material. Precautions must be taken to avoid ingestion or inhalation of radioactive materials.

(2) No licensee shall cause the injection of radioactive material into potable aquifers without prior written authorization from the Authority.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0315
Particle Accelerators

No licensee or registrant shall permit above-ground testing of particle accelerators, designed for use in well-logging, which results in the production of radiation, except in areas or facilities so controlled or shielded that the requirements of OAR 333-120-0100 and 333-105-0030 as applicable, are met.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0325
Energy Compensation Source

The licensee may use an Energy Compensation Source (ECS) which is contained within a logging tool, or other tool components, only if the ECS contains quantities of licensed material not exceeding 3.7 MBq (100 microcuries).

(1) For well logging applications with a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of 333-113-0120, 333-113-0125 and 333-113-0130.

(2) For well logging applications without a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of 333-113-0010, 333-113-0120, 333-113-0125, 333-113-0130, 333-113-0150 and 333-113-0501.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0335
Tritium Neutron Generator Target Source

(1) Use of a tritium neutron generator target source, containing quantities not exceeding 1,110 GBq (30 curies) and in a well with a surface casing to protect fresh water aquifers, is subject to the requirements of this division except 333-113-0010, 333-113-0135 and 333-113-0501.

(2) Use of a tritium neutron generator target source, containing quantities exceeding 1,110 GBq (30 curies) or in a well without a surface casing to protect fresh water aquifers, is subject to the requirements of this division except 333-113-0135.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

Radiation Surveys and Records

333-113-0401
Radiation Surveys

(1) Radiation surveys must be made and recorded for each area where radioactive materials are used and stored.

(2) Radiation surveys must be made and recorded before transport for the radiation levels in all occupied positions and on the exterior of each vehicle used to transport radioactive material. Such surveys must include each source of radiation or combination of sources to be transported in the vehicle.

(3) If the sealed source assembly is removed from the logging tool before departing the jobsites, the logging tool detector must be energized, or a survey meter used, to assure that the logging tool is free of contamination.

(4) Radiation surveys must be made and recorded at the jobsite or well-head for each tracer operation, except those using hydrogen-3, carbon-14 and sulfur-35. These surveys must include measurements of radiation levels before and after the operation.

(5) If the licensee has reason to believe that, as a result of any operation involving a sealed source, the encapsulation of the sealed source could be damaged by the operation, the licensee must conduct a radiation survey, including a contamination survey, during and after the operation.

(6) The licensee must make a radiation survey at the temporary jobsite before and after each subsurface tracer study to confirm the absence of contamination.

(7) Records required pursuant to sections (1) through (6) of this rule must include the dates, the identification of individual(s) making the survey, the identification of survey instruments(s) used and an exact description of the location of the survey. Records of these surveys must be maintained in accordance with 333-100-0057.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0403
Radioactive Contamination Control

(1) If the licensee detects evidence that a sealed source has ruptured or licensed materials have caused contamination, the licensee must initiate immediately the emergency procedures required by 333-113-0205.

(2) If contamination results from the use of licensed material in well logging, the licensee must decontaminate all work areas, equipment, and unrestricted areas.

(3) During efforts to recover a sealed source lodged in the well, the licensee must continuously monitor, with an appropriate radiation detection instrument or a logging tool with a radiation detector, the circulating fluids from the well, if any, to check for contamination resulting from damage to the sealed source.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0405
Documents and Records Required at Field Stations

Each licensee or registrant must maintain, for inspection by the Authority, the following documents and records for the specific devices and sources used at the field station:

(1) Appropriate license, certificate of registration or equivalent document(s);

(2) Operating and emergency procedures;

(3) Applicable rules;

(4) Records of the latest survey instrument calibrations pursuant to OAR 333-113-0115;

(5) Records of the latest leak test results pursuant to OAR 333-113-0120;

(6) Records of quarterly inventories required pursuant to OAR 333-113-0125;

(7) Utilization records required pursuant to OAR 333-113-0130;

(8) Records of inspection and maintenance required pursuant to OAR 333-113-0145;

(9) Survey records required pursuant to OAR 333-113-0401; and

(10) Training records required pursuant to OAR 333-113-0201.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-113-0410
Documents and Records Required at Temporary Jobsites

Each licensee or registrant conducting operations at a temporary jobsite must have the following documents and records available at that site for inspection by the Authority:

(1) Operating and emergency procedures;

(2) Survey records required pursuant to OAR 333-113-0401 for the period of operation at the site;

(3) Evidence of current calibration for the radiation survey instruments in use at the site;

(4) When operating in the state under reciprocity, a copy of the appropriate license, certificate of registration or equivalent document(s);

(5) Shipping papers for the transportation of radioactive material;

(6) Copy of the license;

(7) Current leak test; and

(8) Validation certificate.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

Notification

333-113-0501
Notification of Incidents, Abandonment and Lost Sources

(1) Notification of incidents and sources lost in other than well logging operations must be made in accordance with appropriate provisions of division 120 of these rules.

(2) Whenever a sealed source or device containing radioactive material is lodged downhole the licensee must:

(a) Monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations;

(b) If the environment, any equipment, or personnel are contaminated with licensed material, they must be decontaminated before release from the site or release for unrestricted use; and

(c) Notify the Authority immediately by telephone and subsequently, within 30 days, by confirmatory letter if the licensee knows or has reason to believe that a sealed source has been ruptured. This letter must identify the well or other location, describe the magnitude and extent of the escape of radioactive material, assess the consequences of the rupture and explain efforts planned or being taken to mitigate these consequences.

(3) When it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee must:

(a) Notify the Authority by telephone of the circumstances that resulted in the inability to retrieve the source:

(A) Obtain Authority approval to implement abandonment procedures; or

(B) That the licensee implemented abandonment before receiving Authority approval because the licensee believed there was an immediate threat to public health and safety;

(b) Advise the well-operator of requirements specified in these rules regarding abandonment and an appropriate method of abandonment, that must include:

(A) The immobilization and sealing in place of the radioactive source with a cement plug;

(B) The setting of a whipstock or other deflection device unless the source is not accessible to any subsequent drilling operations; and

(C) The mounting of a permanent identification plaque at the surface of the well, containing the appropriate information required by section (4) of this rule.

(c) Notify the Authority by telephone, giving the circumstances of the loss and request approval of the proposed abandonment procedures; and

(d) File a written report with the Authority within 30 days of the abandonment. The report must contain the following information:

(A) Date of occurrence;

(B) A description of the well logging source involved, including the radionuclide and its quantity, and chemical and physical form;

(C) Surface location and identification of the well;

(D) Results of efforts to immobilize and seal the source in place;

(E) A brief description of the attempted recovery effort;

(F) Depth of the source;

(G) Depth of the top of the cement plug;

(H) Depth of the well;

(I) The immediate threat to public health and safety justification for implementing abandonment if prior Authority approval was not obtained in accordance with section (3)(a)(b) of this rule;

(J) Any other information, such as a warning statement, contained on the permanent identification plaque; and

(K) The names of state agencies receiving a copy of this report.

(4) Whenever a sealed source containing radioactive material is abandoned downhole, the licensee must provide a permanent plaque for posting the well or well-bore. This plaque must:

(a) Be constructed of long-lasting material, such as stainless steel or monel; and

(b) Contain the following information engraved on its face:

(A) The word CAUTION;

(B) The radiation symbol without the conventional color requirement;

(C) The date of abandonment;

(D) The name of the well-operator or well-owner;

(E) The well name and well identification number(s) or other designation;

(F) The sealed source(s) by radionuclide and activity;

(G) The source depth and the depth to the top of the plug;

(H) An appropriate warning, depending on the specific circumstances of each abandonment and approved by the Authority; and

(I) The size of the plaque should be convenient for use on active or inactive wells, e.g., a seven-inch square. Letter size of the word "CAUTION" should be approximately twice the letter size of the rest of the information, e.g., 1/2-inch and 1/4-inch letter size, respectively.

(5) The licensee must immediately notify the Authority by telephone and subsequently by confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable aquifer. Such notice must designate the well location and must describe the magnitude and extent of loss of radioactive material, assess the consequences of such loss and explain efforts planned or being taken to mitigate these consequences.

(6) The licensee may apply to the Authority for a variance to the requirements of this division for abandonment of an irretrievable well logging source. The request must include the reason these rules cannot be followed and the proposed acceptable alternative. The request must be signed by both the licensee and the well owner/operator.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

DIVISION 114

TRAINING FOR EMERGENCY RESPONSE TO RADIOACTIVE MATERIAL INCIDENTS

333-114-0001
General

The purpose of these rules is to insure that the response to a radioactive material accident be both swift and appropriate to minimize damage to any person, property, domestic animals, wildlife or the environment.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.755
Hist.: HD 10-1987, f. & ef. 7-28-87; HD 1-1991, f. & cert. ef. 1-8-91

333-114-0005
Definitions

For the purposes of ORS 469.611 and these rules:

(1) "Certified Training" means radiological safety training in which performance has been demonstrated through the satisfactory completion of an authorized exam.

(2) "Authorized Exam" means an exam, either written or oral; or a performance demonstration that has been authorized by the Authority as adequate to demonstrate the competency of a particular skill level. Whenever possible authorized exams will be developed consistent with the programs and policies with the Oregon Department of Energy, Oregon Department of Environmental Quality, State Fire Accreditation Board, and the Board on Police Standards and Training.

(3) "Skill Level" means:

(a) "Radiological Monitor (RM)" means person who has demonstrated competency through the satisfactory completion of an authorized (RM) exam and therefore is qualified to be a member of a radiological response team. An RM must be recertified every four years;

(b) "Regional Radiological Technical Assistant (RRTA)" means a person who has demonstrated competency through the satisfactory completion of an authorized RRTA exam. An RRTA is also qualified to instruct employees of emergency services agencies in the proper response to transportation accident involving radioactive materials. An RRTA must be recertified every two years;

(c) "Radiological Officer (RO)" means a person who has demonstrated competency through the satisfactory completion of an authorized RO exam and therefore is qualified to advise a community before during and after a nuclear attack and/or incident. A RO must be recertified every three years;

(d) "Radiological Monitor Instructor (RMI)" means a person who has demonstrated competency through the satisfactory completion of an authorized RMI exam and therefore is qualified to be an instructor of "Radiological Monitoring." An RMI must be recertified every three years.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.775
Hist.: HD 10-1987, f. & ef. 7-28-87; HD 1-1991, f. & cert. ef. 1-8-91

333-114-0010
Training

In order to receive certification in radiological safety training from the Oregon State Public Health Division a person must satisfactorily complete the authorized exam administered by an authorized Public Health Division representative. A county will receive certification of training after it has qualified two Regional Radiological Technical Assistants, and completed a radioactive/hazardous materials emergency response exercise as defined in these rules. An "emergency services agency," as defined in ORS 401.025, will receive certification of training after it has qualified one Radiological Monitor per duty shift.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.775
Hist.: HD 10-1987, f. & ef. 7-28-87; HD 1-1991, f. & cert. ef. 1-8-91

333-114-0015
Radioactive/Hazardous Materials Emergency Response Exercise

This is defined as a practice response to an accident involving radioactive or other hazardous materials. The exercise should involve all organizations that would normally be present in a real incident, including but not limited to: Firefighting, law enforcement, prehospital and hospital emergency medical care, highway maintenance and state technical support agencies.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.775
Hist.: HD 10-1987, f. & ef. 7-28-87; HD 1-1991, f. & cert. ef. 1-8-91

DIVISION 115

RADIATION SAFETY REQUIREMENTS FOR X-RAY AND HYBRID GAUGES

333-115-0001
Purpose and Scope

This division provides special requirements for X-ray and hybrid gauges. The requirements of this division are in addition to, and not substitutions for, applicable requirements in divisions 100, 101, 102, 111, and 120 of these rules.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 10-1987, f. & ef. 7-28-87; HD 1-1995, f. & cert. ef. 4-26-95

333-115-0005
Definitions

(1) "X-Ray Gauge" means an X-ray producing device designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density level or interface location.

(2) "Fail-Safe Characteristics" mean design features which cause beam port shutters to close or which otherwise prevent emergence of the primary beam upon failure of a safety or warning device.

(3) "Primary Beam" means ionizing radiation which passes through an aperture of the source housing by a direct path from the X-ray tube or a radioactive source located in the radiation source housing.

(4) "Hybrid Gauge" means a gauging device utilizing both X-ray and radioactive material sources.

(5) "Open-Beam Configuration" means a gauging system in which an individual could accidentally place some part of the body in primary beam path during normal operation.

Stat. Auth.: ORS 453.605 - 453.775
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 10-1987, f. & ef. 7-28-87; HD 1-1991, f. & cert. ef. 1-8-91

Equipment Requirements

333-115-0010
Safety Device

(1) Except where impractical, an interlocking device which prevents the entry of any portion of an individual's body into the primary beam, or causes the primary beam to be shut off upon entry into its path, shall be provided.

(2) In cases where the primary radiation beam is not intercepted by the detector device under all conditions of operation, protective measures shall be provided, such as auxiliary shielding, to avoid exposure to any individual from the transmitted primary radiation.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 10-1987, f. & ef. 7-28-87

333-115-0015
Warning Devices

A sign bearing the words, "**Warning — X-rays (or ionizing radiation) — Do not place hands in jaws of gauge**," or equivalent, shall be so located that it is visible to any person operating, aligning or adjusting a gauging device.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 10-1987, f. & ef. 7-28-87

333-115-0020
Ports

Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 10-1987, f. & ef. 7-28-87

333-115-0025
Labeling

All gauges shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

(1) **CAUTION — HIGH INTENSITY X-RAY BEAM**, or words having a similar intent on the X-ray source housing; and

(2) **CAUTION RADIATION — THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED**, or words having a similar intent, near any switch that energizes an X-ray tube if the radiation source is an X-ray tube; and

(3) **CAUTION — RADIOACTIVE MATERIAL**, on the source housing if the radiation source is a radionuclide.

Stat. Auth.: ORS 453.605 - 453.775
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 10-1987, f. & ef. 7-28-87; HD 1-1991, f. & cert. ef. 1-8-91

333-115-0030
Shutters

A visible indication of the status of the shutter shall be provided, e.g., red light indicating beam on, green light indicating beam off. This device shall be tested to ensure operations will not continue without a proper functioning warning device. On equipment installed after January 1, 1978, this device shall be of fail-safe design.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 10-1987, f. & ef. 7-28-87

333-115-0035
Warning Lights

(1) An easily visible light labeled with the words "**BEAM ON**," or words having a similar intent, shall be located:

(a) Near any switch that energizes an X-ray tube and shall be illuminated only when the tube is energized; or

(b) In the case of a radioactive source, near any switch that opens a housing shutter and which shall be illuminated only when the shutter is open.

(2) On equipment installed after January 1, 1978, warning lights shall have fail-safe characteristics.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 10-1987, f. & ef. 7-28-87

Area Requirements

333-115-0101
Radiation Levels

The local components of a gauge shall be so located and arranged and shall include sufficient shielding or access control that no radiation levels exists in any area surrounding the local component groups which could result in a dose to an individual present therein in excess of the dose limits given in OAR 333-120-0180. For systems using X-ray tubes, these levels shall be met at any specified tube rating.

Stat. Auth.: ORS 453.605 - 453.775
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 10-1987, f. & ef. 7-28-87; HD 1-1995, f. & cert. ef. 4-26-95

333-115-0105
Surveys

(1) Radiation surveys, as required by OAR 333-120-0200, of all X-ray and Hybrid gauges sufficient to show compliance with OAR 333-115-0101 shall be performed:

(a) Upon installation of the equipment;

(b) A review of all safety devices shall be performed at least quarterly to insure their proper operation (i.e., signs, labels, interlocks, etc.);

(c) Annual surveys and monitoring to insure that operations are conducted safely;

(d) Following any change in the initial arrangement, number or type of local components in the system;

(e) Following any maintenance requiring the disassembly or removal of a local component in the system;

(f) Any time a visual inspection of the local components in the system reveals an abnormal condition;

(g) Whenever personnel monitoring devices show a significant increase over the previous monitoring period or when the readings are approaching the radiation dose limits specified in OAR 333-120-0100.

(2) Records of all reviews and surveys shall be maintained for inspection by the Authority.

Stat. Auth.: ORS 453.605 - 453.775
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 10-1987, f. & ef. 7-28-87; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

333-115-0110
Posting

Each area or room containing any gauge shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words **CAUTION — X-RAY EQUIPMENT**, or words having similar intent.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 10-1987, f. & ef. 7-28-87

333-115-0115
Security

When not in operation, the equipment shall be secured in such a way as to be accessible to, or operable by, only authorized personnel.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 10-1987, f. & ef. 7-28-87

333-115-0120
Operating Requirements

Normal and Emergency operating procedures shall be written and available to all X-ray and Hybrid gauge equipment workers.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 10-1987, f. & ef. 7-28-87

Personnel Requirements

333-115-0201
Instructions

(1) No person shall be permitted to operate or maintain X-ray or Hybrid gauges unless such person has received instruction in and demonstrated competence with regard to:

(a) Identification of radiation hazards associated with the use of the equipment;

(b) Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

(c) Proper operating procedures for equipment;

(d) Symptoms of an acute localized exposure; and

(e) Proper procedures for reporting an active or suspected exposure.

(2) Each licensee or registrant shall maintain, for inspection by the Authority, records of training which demonstrate that the requirements of this rule have been met.

Stat. Auth.: ORS 453.605 - 453.775
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 10-1987, f. & ef. 7-28-87; HD 1-1991, f. & cert. ef. 1-8-91

333-115-0205
Personnel Monitoring

Finger or wrist dosimetric devices shall be provided to and shall be used by all personnel working with open beam gauging equipment.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 10-1987, f. & ef. 7-28-87

DIVISION 116

USE OF RADIONUCLIDES IN THE HEALING ARTS

333-116-0010
Purpose and Scope

This division contains the requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material in Oregon. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this division are in addition to, and not in substitution for, others in these rules. The requirements and provisions of these rules apply to applicants and licensees subject to this division unless specifically exempted.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0020
Definitions

As used in this division, the following definitions apply:

(1) "Address of use" means the building or buildings identified on the license as the location(s) where radioactive material may be received, used, or stored.

(2) "Area of use" means location(s) at the address of use set aside for the purpose of receiving, using or storing radioactive material.

(3) "Attestation" means required training, experience and appropriate board certification is validated using the Nuclear Regulatory Commission's form 313A.

(4) "Authorized Medical Physicist" means an individual who:

(a) Meets the requirements in OAR 333-116-0730, or 333-116-0905 and 333-116-0760; or

(b) Is identified as an authorized medical physicist or teletherapy physicist on:

(A) A specific medical use license issued by the Authority or an Agreement State or the US Nuclear Regulatory Commission;

(B) A medical use permit issued by a Commission master material licensee;

(C) A permit issued by a Commission or Agreement State broad scope medical use licensee; or

(D) A permit issued by a Commission master material license broad scope medical use permittee.

(5) "Authorized nuclear pharmacist" means a pharmacist who:

(a) Meets the requirements in OAR 333-116-0910 and 333-116-0915;

(b) Is identified as an authorized nuclear pharmacist on an Authority, Agreement State, or U.S. Nuclear Regulatory Commission license that authorizes the use of radioactive material in the practice of nuclear pharmacy;

(c) Is identified as an authorized nuclear pharmacist on a license issued by an Authority, Agreement State, or U.S. Nuclear Regulatory Commission specific licensee of broad scope that is authorized to permit the use of radioactive material in the practice of nuclear pharmacy; or

(d) Is approved as an authorized nuclear pharmacist by a nuclear pharmacy licensed (authorized) by the Authority, the U.S. Nuclear Regulatory Commission, or an Agreement State to approve authorized nuclear pharmacists.

(6) "Authorized user" means a physician, dentist or podiatrist who:

(a) Meets the requirements listed in OAR 333-116-0660, 333-116-0670, 333-116-0680, 333-116-0683, 333-116-0687, 333-116-0690, 333-116-0700, 333-116-0710, 333-116-0720, and 333-116-0740;

(b) Is identified as an authorized user on an Authority, Agreement State, Licensing State or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material; or

(c) Is identified as an authorized user on a permit issued by an Authority, Agreement State, or U.S. Nuclear Regulatory Commission licensee of broad scope that is authorized to permit the medical use of radioactive material.

(7) "Black Box" means the radiopharmaceutical production purification system used in a PET facility.

(8) "Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

(9) "Brachytherapy source" means an individual sealed source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose of radiation within a few centimeters, by surface, intracavitary, or interstitial application that is not designed to be disassembled by the user.

(10) "Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

(11) "Dental use" means the intentional external administration of the radiation from radioactive material to human beings in the practice of dentistry in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(12) "Dentist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

(13) "Diagnostic clinical procedures manual" means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

(14) "High dose-rate remote afterloader" means a device that remotely delivers a brachytherapy source, with a dose rate in excess of two gray (200 rad) per hour, to the point or surface where the dose is prescribed.

(15) "Human Research Subject" means a living person that an authorized user, conducting research, obtains data resulting from the intentional internal or external administration of radioactive material, or the radiation from radioactive material, to the individual. For the purpose of these rules, unless otherwise noted, the term patient applies to a human research subject.

(16) "Low dose-rate remote afterloader" means a device that remotely delivers a brachytherapy source, with a dose rate of less than two gray (200 rad) per hour, to the point or surface where the dose is prescribed.

(17) "Management" means the chief executive officer or that individual's designee.

(18) "Manual Brachytherapy", as used in this part, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed on, or in close proximity, to the treatment site or inserted directly into the tissue volume.

(19) "Medical Event" means an event where a patient or human research subject: (a) Receives a dose that differs from the prescribed dose by:

(A) The total dose delivered differs from the prescribed dose by 20 percent or more; or

(B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(C) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more; or

(D) A dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; or

(E) An administration of a wrong radiopharmaceutical drug containing radioactive material; or

(F) An administration of a radiopharmaceutical drug containing radioactive material by the wrong route of administration; or

(G) An administration of a dose or dosage to the wrong individual or human research subject; or

(H) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(I) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(b) An event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician shall be considered as a medical event.

(c) A leaking sealed source shall be considered as a medical event.

(20) "Medical institution" means an organization in which more than one medical discipline is practiced.

(21) "Medical use" means the intentional internal or external administration of radioactive material, or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

(22) "Ministerial change" means a change that is made, after ascertaining the applicable requirements, by persons in authority in conformance with the requirements and without making a discretionary judgment about whether those requirements should apply in the case at hand.

(23) "Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

(24) "Nuclear Pharmacist" means an authorized nuclear pharmacist, as defined in OAR 333-116-0020, who has received additional training, pursuant to OAR 333-116-0910 and 333-116-0915 in the management and handling of radiopharmaceutical drugs and is authorized by license to receive, use, transfer, and dispose of such radiopharmaceutical drugs.

(25) "Output" means the exposure rate, dose rate or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

(26) "Patient Intervention" means actions taken by a patient or human research subject, whether intentional or unintentional, interrupt or terminate the administration of radioactive materials or radiation.

(27) "PET" means Positron Emission Tomography.

(28) "PET Isotope Nuclear Pharmacy" means a licensed facility that compounds radiopharmaceuticals using positron emitting isotopes for use at licensed medical facilities.

(29) "PET cyclotron facility" means a facility that manufactures short-lived radioisotopes for use in compounding radiopharmaceuticals at a PET Isotope Nuclear Pharmacy.

(30) "PET Medical Facility" means a clinical nuclear medicine facility that utilizes positron-emitting isotopes for diagnostic imaging.

(31) "Pharmacist" means an individual licensed by a state or territory of the United States, The District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

(32) "Physician" means a medical doctor or doctor of osteopathy licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

(33) "Podiatric use" means the intentional external administration of the radiation from byproduct material to human beings in the practice of podiatry in accordance with a license issued by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(34) "Podiatrist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

(35) "Positron Emission Tomography (PET) facility" means a facility comprised of an accelerator that produces positron-emitting isotopes, a radiopharmacy that specializes in preparation of PET radiopharmaceuticals, and/or a clinic that uses PET isotopes for medical diagnostic purposes.

(36) "Preceptor" means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer. The preceptor must have previously met all of the applicable requirements and be so named on a radioactive materials license issued by the Authority, the Nuclear Regulatory Commission, an Agreement State or licensing state.

(37) "Prescribed dosage" means the specified activity or range of activity of a radiopharmaceutical or radioisotope as documented:

(a) In a written directive; or

(b) Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

(38) "Prescribed dose" means:

(a) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(b) For teletherapy, the total dose and dose per fraction as documented in the written directive;

(c) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(d) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

(39) "Pulsed dose-rate remote afterloader" means a special type of remote afterloading device that uses a single source capable of delivering dose rates in the "high dose rate" range, but is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

(40) "Radiation Safety Officer" means an individual who:

(a) Meets the requirements in OAR 333-116-0640, 333-116-0650, 333-116-0740 and 333-116-0760; or

(b) Is identified as a Radiation Safety Officer on:

(A) A specific medical use license issued by the Nuclear Regulatory Commission or Agreement State; or

(B) A medical use permit issued by a Nuclear Regulatory Commission master material licensee.

(41) "Recordable Event" (See Medical Event).

(42) "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

(43) "Stereotactic Radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a dose to a tissue volume.

(44) "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

(45) "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

(46) "Teletherapy physicist" means the individual identified as the qualified teletherapy physicist on an Authority license.

(47) "Therapeutic Dosage" means a dosage of unsealed byproduct material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

(48) "Therapeutic Dose" means a radiation dose delivered from a source containing byproduct material to a patient or human research subject for palliative or curative treatment.

(49) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(50) "Unit dosage" means a dosage intended for medical use in a single patient or human research subject that has been obtained from a manufacturer or preparer licensed by the Authority as a nuclear pharmacy.

(51) "Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.

(52) "Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in OAR 333-116-0125(1)(e), containing the following information:

(a) For any administration of quantities greater than 1.11 megabecquerels (30 uCi) of either sodium iodide I-125 or I-131: the dosage;

(b) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

(c) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;

(d) For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;

(e) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or

(f) For all other brachytherapy:

(A) Prior to implantation: the radioisotope, number of sources, and source strengths; and

(B) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 25-2016, f. 8-26-16, cert. ef. 9-1-16

333-116-0025
FDA, Other Federal, and State Requirements

Nothing in this part relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radiopharmaceutical drugs or devices.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-116-0027
Implementation

(1) A licensee must implement the provisions in division 333-116 no later June 15, 2006.

(2) When a requirement in division 333-116 differs from the requirement in an existing license condition, the more restrictive requirement must govern until there is a license amendment or license renewal.

(3) Any existing license condition, not affected by a requirement in division 333-116, remains in effect until the license is amended or renewed.

(4) If a license condition exempted a licensee from a provision of division 333-116 on June 15, 2006, it will continue to exempt a licensee from the corresponding provision in division 333-116.

(5) If a license condition cites provisions in division 333-116 that will be deleted on June 15, 2006, then the license condition remains in effect until the license is amended or renewed to modify or remove the condition.

(6) Licensees must continue to comply with any license condition that requires it to implement procedures required by OAR 333-116-0525, 333-116-0580, 333-116-0583, and 333-116-0587 until there is a license amendment or renewal that modifies the license condition.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0030
License Required

(1) No person shall manufacture, produce, acquire, receive, possess, use or transfer radioactive material for medical use except in accordance with a specific or general license issued pursuant to this division or as otherwise provided in this division.

(2) Unless prohibited by license condition, a specific license is not needed for an individual to:

(a) Receive, possess, use or transfer radioactive material in accordance with the rules in this division under the supervision of an authorized user as provided in OAR 333-116-0100; or

(b) Prepare unsealed byproduct material for medical use in accordance with the rules in this division under the supervision of an authorized nuclear pharmacist or authorized user as provided in OAR 333-116-0100.

(3) Notwithstanding the above requirements, any licensee licensed pursuant to this rule also is authorized to use radioactive material under the general license in OAR 333-102-0130 for the specified *in vitro* uses without filing the form as required by 333-102-0130(2); the licensee is subject to the other provisions of 333-102-0130.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0035
Application for License, Amendment, or Renewal

(1) An application must be signed by the management of the facility.

(2) An application for a license for medical use of radioactive material as described in OAR 333-116-0300, 333-116-0320, 333-116-0360, 333-116-0400, 333-116-0420 and 333-116-0480 and medical use of byproduct material as described in OAR 333-116-0485 must be made by filing a "Radioactive Materials License Application: Medical." A request for a license amendment or renewal may be submitted in letter format.

(3) Licensing of remote afterloaders as described in OAR 333-116-0480 requires a separate "Radioactive Materials License Application: The Medical License application must be completed and submitted to the Authority. A request for a license amendment or renewal may be submitted in letter format.

(4) An application for a license for medical use of radioactive material as described in OAR 333-116-0800, Licensing and Registration of Positron Emission Tomography (PET) Facilities, must be made by filing a "Radioactive Materials License Application: Medical."

(a) In addition to the information required in the "Radioactive Materials License Application: Medical," the application must also include information regarding any radiation safety aspects of the medical use of the radioactive material that is not addressed in this division, as well as any specific information necessary for:

(A) Radiation safety precautions and instructions;

(B) Training and experience of proposed users;

(C) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(D) Calibration, maintenance, and repair of equipment necessary for radiation safety.

(b) The applicant of licensee must also provide any other information requested by the Authority in its review of the application.

NOTE: An applicant that satisfies the requirements specified in OAR 333-102-0900 may apply for a Broad Scope A specific license.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-116-0040
License Amendments

A licensee must apply for and must receive a license amendment:

(1) Before receiving or using radioactive material for a method or type of medical use not permitted by the license issued under this division;

(2) Before permitting anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license except:

(a) For an authorized user; an individual who meets the requirements in OAR 333-116-0760, 333-116-0660, 333-116-0670, 333-116-0680, 333-116-0683, 333-116-0687, 333-116-0690, 333-116-0710 and 333-116-0720.

(b) For an authorized nuclear pharmacist; an individual who meets the requirements in OAR 333-116-0910 and 333-116-0760.

(c) For an authorized medical physicist; an individual who meets the requirements in OAR 333-116-0905 and 333-116-0760.

(d) An individual Identified as an authorized user, authorized nuclear pharmacist, or an authorized medical physicist on a Nuclear Regulatory Commission or Agreement State license that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy.

(3) Before changing the Radiation Safety Officer except as provided in OAR 333-116-0090;

(4) Before receiving radioactive material in excess of the amount authorized on the license;

(5) Before adding to or changing the areas of use or mailing address identified on the license; and

(6) Before revising procedures required by OAR 333-116-0495, 333-116-0580, 333-116-0583, and 333-116-0587 as applicable where such revision reduces radiation safety.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2013, f. & cert. ef. 1-29-13

333-116-0045
Provisions for Research Involving Human Subjects.

(1) A licensee may conduct research involving human research subjects only if it uses the byproduct materials specified in, and for the uses authorized by its license.

(2) If the research is conducted, funded, supported, or regulated by a federal agency that has implemented the Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research:

(a) Obtain review and approval of the research from an Institutional Review Board, as defined and described in the Federal Policy; and

(b) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject.

(3) If the research is not conducted, funded, supported, or regulated by another federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, submit a license amendment request to the Authority and receive approval by amendment. The amendment request must include a written commitment that the licensee must, before conducting research;

(a) Obtain review and approval of the research from an Institutional Review Board, as defined and described in the Federal Policy; and

(b) Obtain informed consent, as defined and described in the Federal Policy, from the human research subject.

(4) Nothing in this rule relieves licensees from complying with other requirements in this division.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 24-2014, f. & cert. ef. 8-15-14

333-116-0050
Notifications

(1) A licensee must provide to the Authority a copy of the board certification, the Nuclear Regulatory Commission or Agreement State license, or the permit issued by a licensee of Broad Scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, or an authorized nuclear pharmacist pursuant to OAR 333-116-0040(2)(a) through (d).

(2) A licensee must notify the Authority by letter no later than 30 days after:

(a) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

(b) The licensee's mailing address changes;

(c) The licensee's name changes, but the name does not constitute a transfer of control of the license as described in OAR 333-102-0305; or

(d) The licensee has added to or changed the areas where radioactive material is used in accordance with OAR 333-116-0200 and 333-116-0300.

(3) The licensee must mail the documents required in this division to the Authority for review.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2013, f. & cert. ef. 1-29-13

333-116-0055
Exemptions Regarding Type a Specific Licenses of Broad Scope

A licensee possessing a Type A specific license of broad scope for medical use is exempt from:

(1) The provisions of OAR 333-116-0040(2);

(2) The provisions of OAR 333-116-0040(5) regarding additions to or changes in areas of use only at the addresses specified in the license;

(3) The provisions of OAR 333-116-0050(1);

(4) The provisions of OAR 333-116-0050(2)(a) for an authorized user, or authorized nuclear pharmacist, and

(5) The provisions of OAR 333-116-0140(1).

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0057
License Issuance

(1) The Authority must issue a license for the medical use of radioactive material if:

(a) The applicant has filed a "Radioactive Materials License Application: Medical" in accordance with the instructions in OAR 333-116-0035;

(b) The applicant has paid any applicable fee as provided in division 103 of these rules;

(c) The Authority finds the applicant equipped and committed to observe the safety standards established by the Authority in these rules for the protection of the public health and safety; and

(d) The applicant meets the requirements of division 102 of these rules.

(2) The Authority must issue a license for mobile services if the applicant:

(a) Meets the requirements in section (1) of this rule; and

(b) Assures that individuals or human research subjects to whom radiopharmaceuticals or radiation from implants will be administered may be released following treatment in accordance with OAR 333-116-0460.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0059
Specific Exemptions

The Authority may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in this division as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0090
Authority and Responsibilities for the Radiation Protection Program

(1) In addition to the radiation protection program requirements of OAR 333-120-0020, a licensee's management must approve in writing:

(a) Requests for a license application, renewal, or amendment before submittal to the Authority;

(b) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

(c) Radiation protection program changes that do not require a license amendment and are permitted under OAR 333-116-0123.

(2) A licensee's management must appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, must ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

(3) For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer, under OAR 333-116-0650, 333-116-0740 and 333-116-0760, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in section (7) of this rule, if the licensee takes the actions required in

sections (2), (5), (7) and (8) of this rule and notifies the Authority in accordance with OAR 333-116-0050(2).

(4) A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with section (3) of this rule, if needed to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different types of uses of byproduct material permitted by the license.

(5) A licensee must establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

(6) A licensee must provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

(a) Identify radiation safety problems;

(b) Initiate, recommend, or provide corrective actions;

(c) Stop unsafe operations; and

(d) Verify implementation of corrective actions.

(7) Licensees that are authorized for two or more different types of uses of radioactive material under OAR chapter 333, division 116, must establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

(8) A licensee's Radiation Safety Committee must meet at intervals not to exceed six months. The licensee must maintain minutes of each meeting in accordance with OAR 333-100-0057.

(9) A licensee must retain a record of actions taken under sections (1), (2) and (5) of this rule in accordance with OAR 333-100-0057. These records must be retained for the life of the license.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2013, f. & cert. ef. 1-29-13

333-116-0100
Supervision

(1) A licensee who permits the receipt, possession, use or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by OAR 333-116-0030 must:

(a) In addition to the requirements in OAR 333-111-0010, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, the licensee's written quality management program, the Oregon Rules for the Control of Radiation and the license conditions appropriate to that individual's use of radioactive material; and

(b) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, regulations of division 333-116, and license conditions with respect to the medical use of radioactive material.

(2) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by OAR 333-116-0030(3) must:

(a) In addition to the requirements in OAR 333-111-0010, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's use of radioactive material; and

(b) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures established by the licensee and division 333-116, and license conditions.

(3) A licensee that permits supervised activities under sections (1) and (2) of this rule is responsible for the acts and omissions of the supervised individual.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0105
Written Directives

(1) A written directive must be prepared, dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 Megabecquerels (MBq) (30 microcuries (uCi)), or any therapeutic dosage of a radiopharmaceutical, or any therapeutic dose of radiation from radioactive material.

(2) The written directive must contain the patient or human research subject's name and the following:

(a) For any administration of quantities greater than 1.11 MBq (30 uCi) of sodium iodide I-131 or I-125; the dosage;

(b) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-131: the radiopharmaceutical dosage, and route of administration;

(c) For gamma stereotactic radiosurgery: target coordinates (including gamma angle), collimator size, plug pattern, total dose for the treatment, and the total treatment volume for each anatomically distinct treatment site;

(d) For teletherapy: the total dose, dose per fraction, number of fractions, treatment site, and overall treatment period;

(e) For remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(f) For all other brachytherapy:

(A) Prior to implantation: treatment site, the radionuclide, number of sources and source strengths or dose; and

(B) After implantation but prior to completion of the procedure: the radionuclide, treatment site, and total source strength and exposure time (or equivalently, the total dose).

(3) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(4) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

(5) The licensee must retain the written directive in accordance with OAR 333-100-0057.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-116-0107
Procedures for Administrations Requiring a Written Directive

(1) For any administration requiring a written directive, the licensee must develop, implement, and maintain written procedures to provide high confidence that:

(a) The patient's or human research subject's identity is verified before each administration; and

(b) Each administration is in accordance with the written directive.

(2) The procedures required by section (1) of this rule must, at a minimum, address the following items applicable to the licensee's use of radioactive material:

(a) Verifying the identity of the patient or human research subject;

(b) Verifying that the specific details of the administration are in accordance with the written directive and, if applicable, the treatment plan;

(c) Checking both manual and computer-generated dose calculations; and

(d) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices.

(3) The licensee must retain a copy of procedures in accordance with OAR 333-100-0057.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0110
Visiting Authorized User

(1) A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:

(a) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee;

(b) The licensee has a copy of the Authority license or a license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, that identifies the visiting authorized user by name as an authorized user for medical use; and

(c) Only those procedures for which the visiting authorized user is specifically authorized by the Authority license are performed by that individual.

(2) A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in section (1) of this rule.

(3) A licensee must retain copies of the records specified in this rule in accordance with OAR 333-100-0057.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0120
Mobile Nuclear Medicine Service Administrative Requirements

(1) The Authority will only license mobile nuclear medicine services in accordance with OAR 333-116-0300, 333-116-0320, and 333-116-0400 of this division and OAR 333-102-0130.

(2) Mobile nuclear medicine service licensees must:

(a) Obtain a letter signed by the management of each client for which services are rendered that authorizes use of licensed radioactive material at the client's address of use. This letter must clearly delineate the authority and responsibility of both the client and the mobile medical service. If the client is licensed, the letter must document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's address for use by the mobile medical service. The mobile nuclear medicine service licensee must retain the letter for three years after the last provision of service.

(b) Check instruments used to measure the activity of unsealed byproduct material for proper function before use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function must include a constancy check;

(c) Check survey instruments for proper operation with a dedicated check source before use at each client's address; and

(d) Survey all areas of use to ensure compliance with the requirements in division 333-120 before leaving a client's address.

(3) If a mobile nuclear medicine service provides services that the client also is authorized to provide, the client is responsible for assuring that services are conducted in accordance with the rules in this division while the mobile nuclear medicine service is under the client's direction.

(4) A mobile nuclear medicine service may not order radioactive material to be delivered directly from the manufacturer or the distributor to the client's address of use unless the client has a radioactive materials license. Radioactive material delivered to the client's address of use must be received and handled in conformance with the client's license.

(5) A mobile medical service licensee must, at a minimum, maintain the following documents onboard each mobile unit:

(a) Current operating and emergency procedures;

(b) Copy of the current license;

(c) Copies of the letter required by section (2) of this rule;

(d) Current calibration records for each survey instrument and diagnostic equipment or dose delivery device in use; and

(e) Survey records covering uses associated with the mobile unit during, at a minimum, the preceding 90 calendar days.

(6) A licensee must retain copies of the records specified in this rule in accordance with OAR 333-100-0057. The records required for subsections (2)(b), (2)(c) and (2)(d) of this rule must include the date of the survey or test, the results of the survey or test, the instrument used to make the survey or source used to perform the test, and the name of the individual who performed the survey or test.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0123
Radiation Safety Program Changes

(1) A licensee may revise its radiation protection program without Authority approval if:

(a) The revision does not require a license amendment under OAR 333-116-0040;

(b) The revision is in compliance with the regulations and the license;

(c) The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and, if applicable, the Radiation Safety Committee; and

(d) The affected individuals are instructed on the revised program before the changes are implemented.

(2) A licensee must retain a record of each change in accordance with OAR 333-100-0057. The record must include the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected authorized users and of management, or, in a medical institution, the Radiation Safety Committee's chairman and the management representative.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0125
Quality Management Program

(1) Each applicant or licensee under this division, as applicable, must establish and maintain a written quality management program to provide high confidence that radioactive material or radiation from radioactive material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following specific objectives:

(a) That, prior to administration, a written directive (see NOTE below) is prepared for:

(A) Any teletherapy radiation dose;

(B) Any gamma stereotactic radiosurgery radiation dose;

(C) Any brachytherapy radiation dose;

(D) Any administration of quantities greater than 1.11 megabecquerels (30 uCi) of either sodium iodide I-125 or I-131; or

(E) Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131;

(b) That, prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive;

(c) That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

(d) That each administration is in accordance with the written directive; and

(e) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

NOTE: If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision. Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

(2) The licensee shall:

(a) Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of:

(A) A representative sample of patient administrations,

(B) All recordable events, and

(C) All medical events to verify compliance with all aspects of the quality management program; these reviews shall be conducted at intervals no greater than 12 months;

(b) Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of subsection (2)(a) of this rule; and

(c) Retain records of each review, including the evaluations and findings of the review, in an auditable form for three years.

(3) The licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:

(a) Assembling the relevant facts including the cause;

(b) Identifying what, if any, corrective action is required to prevent recurrence; and

(c) Retaining a record, in an auditable form, for five years or until inspected by the Authority, of the relevant facts and what corrective action, if any, was taken.

(4) The licensee shall retain:

(a) Each written directive; and

(b) A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in subsection (1)(a) of this rule, in an auditable form, for five years, or until inspected by the Authority, after the date of administration.

(5) The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. The licensee shall furnish the modification to the Authority within 30 days after the modification has been made.

(6) Each applicant for a new license, as applicable, shall submit to the Authority in accordance with OAR 333-102-0190 a quality management program as part of the application for a license and implement the program upon issuance of the license by the Authority.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 25-2016, f. 8-26-16, cert. ef. 9-1-16

333-116-0140
Suppliers

A licensee may use for medical use only:

(1) Radioactive material manufactured, produced, labeled, prepared, compounded, packaged and distributed in accordance with a license issued pursuant to these rules or the equivalent rules of another Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission.

(2) Reagent kits, radiopharmaceuticals, and/or radiobiologics that have been manufactured, labeled, packaged and distributed in accordance with an approval issued by the U.S. Department of Health and Human Services, Food and Drug Administration.

(3) Radiopharmaceuticals compounded from a prescription in accordance with the regulations of the state Board of Pharmacy.

(4) Teletherapy and brachytherapy sources manufactured and distributed in accordance with a license issued pursuant to these regulations, or the equivalent regulations of another Agreement State, a Licensing State, or the Nuclear Regulatory Commission.

(5) Sealed sources or devices non-commercially transferred from a 10 CFR, Part 35 licensee or Agreement State medical licensee.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10

General Technical Requirements

333-116-0150
Quality Control of Imaging Equipment

(1) Each licensee must establish written quality control procedures for all diagnostic equipment used to obtain images from radionuclide studies. As a minimum the quality control procedures and frequencies must include quality control procedures recommended by equipment manufacturers or procedures which have been approved by the Authority. The licensee must conduct quality control procedures in accordance with written procedures.

(2) Copies of procedures and records generated from implementing these procedures must be maintained in accordance with OAR 333-100-0057.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0160
Possession, Use, Calibration and Check of Dose Calibrators

(1) A medical use licensee authorized to administer either radiopharmaceuticals or unsealed radioactive materials must possess a dose calibrator and use it to measure the amount of activity of radionuclides prior to administration to each patient or human research subject. The licensee must also develop, implement and maintain written procedures for proper calibration and operation of the dose calibrator.

(2) At a minimum, a licensee must:

(a) Check each dose calibrator for constancy and proper operation with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this rule, the check must be done on a frequently used setting with a sealed source of not less than 1.85 megabecquerels (50 uCi) of any photon-emitting radionuclide with a half-life greater than 90 days. The results of this test must be within +ten percent of the sources stated activity. Sources used for the daily constancy test must be determined by the manufacturer to be within +five percent of the stated activity and traceable to the National Institute of Standards and Technology or other standards recognized as being equivalent by the National Institute of Standards and Technology.

(b) Test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least two sealed sources containing different photon-emitting radionuclides 1.85 megabecquerels (50 uCi) each, at least one of

which has a principal photon energy between 100 keV and 500 keV. All sources used to satisfy the accuracy test must be determined by the manufacturer to be within +five percent of the stated activity and traceable to the National Institute of Standards and Technology or other standards recognized as being equivalent by the National Institute of Standards and Technology;

(c) Test each dose calibrator for linearity upon installation and at intervals not to exceed three months thereafter over the range of use between 1.1 megabecquerels (30 microcuries) and the highest dosage that will be administered; and

(d) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee must keep a record of this test for the duration of the use of the dose calibrator.

(3) A licensee must mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 1.1 megabecquerels (30 microcuries) and must repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

(4) A licensee must also perform checks and tests required by section (2) of this rule following adjustment or repair of the dose calibrator and prior to use.

(5) A licensee must retain a record of each check and test required by section (2) of this rule in accordance with OAR 333-100-0057. The records required by section (2) of this rule must include:

(a) For constancy, the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings and the initials of the individual who performed the check;

(b) For accuracy, the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings and the signature of the Radiation Safety Officer;

(c) For linearity, the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test and the signature of the Radiation Safety Officer; and

(d) For geometry dependence, the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test and the signature of the Radiation Safety Officer.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0165
Possession, Use Calibration, and Check of Instruments to Measure Dosages of Alpha- or Beta-emitting Radionuclides

(1) For other than unit dosages, a licensee must possess and use instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. A licensee must measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha- or beta-emitting radionuclides prior to administration to each patient or human research subject.

(2) A licensee must develop, implement, and maintain written procedures for use of the instrumentation. At a minimum, a licensee must:

(a) Perform tests before initial use, and following repair, on each instrument for accuracy, linearity, and geometry dependence, unless it is not appropriate for the use of the instrument; and make adjustments when necessary;

(b) Perform accuracy annually;

(c) Perform linearity tests annually over the range of medical use; and

(d) Check each instrument for constancy and proper operation at the beginning of each day of use.

(3) Accuracy tests must be performed with source(s) that are traceable to National Institute of Standards and Technology (NIST) or by a supplier who has compared the source to a source that was calibrated by NIST.

(4) A licensee must retain a record of each check and test required by this rule in accordance with OAR 333-100-0057.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0170
Calibration and Check of Survey Instrument

(1) A licensee must ensure that the survey instruments used to show compliance with OAR chapter 333, divisions 116 and 120 have been calibrated before first use, annually and following repair.

(2) To satisfy the requirements of section (1) of this rule the licensee must:

(a) Calibrate all required scale readings up to 10 millisieverts (1000 mrem) per hour with a radiation source;

(b) For each scale that must be calibrated, calibrate two readings separated by at least 50 percent of scale reading; and

(c) Conspicuously note on the instrument the date of calibration.

(3) To satisfy the requirements of section (2) of this rule, the licensee must:

(a) Consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 10 percent; and

(b) Consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent if a correction chart or graph is conspicuously attached to the instrument.

(4) A licensee must check each survey instrument for proper operation with the dedicated check source before each use. (5) The licensee must retain a record of each calibration required in section (1) of this rule in accordance with OAR 333-100-0057. The record must include:

(a) A description of the calibration procedure; and

(b) A description of the source used and the certified exposure rates from the source and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration and the date of calibration.

(6) To meet the requirements of sections (1), (2) and (3) of this rule, the licensee may obtain the services of individuals licensed by the Authority, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform calibrations of survey instruments. Records of calibrations which contain information required by section (5) of this rule must be maintained by the licensee calibration in accordance with OAR 333-100-0057.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10

333-116-0180
Determination of Dosages of Unsealed Radioactive Material for Medical Use

A licensee must:

(1) Assay, within 30 minutes before medical use, the activity of each radiopharmaceutical dosage that contains more than 370 kilobecquerels (10 uCi) of an alpha-, beta-, or photon-emitting radionuclide;

(2) For a dosage of an alpha- or beta-emitting radionuclide prepared by the licensee, this determination must be made by direct measurement or by a combination of measurements and calculations.

(3) A licensee must not use a dosage if the dosage differs from the prescribed dosage by more than 20 percent, unless authorized in writing by an authorized user.

(4) Retain a record of the assays required by this rule in accordance with OAR 333-100-0057. The record must contain the:

(a) Generic name, trade name or abbreviation of the radiopharmaceutical, its lot number and expiration dates and the radionuclide;

(b) Patient's name and identification number if one has been assigned;

(c) Prescribed dosage and activity of the dosage at the time of assay or a notation that the total activity is less than 370 kilobecquerels (10 uCi);

(d) Date and time of the assay;

(e) Date and time of administration; and

(f) Initials of the individual who performed the assay.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0190
Authorization for Calibration and Reference Source

Any person authorized by OAR 333-116-0030 for medical use of radioactive material may receive, possess and use the following radioactive material for check, calibration and reference use:

(1) Sealed sources manufactured and distributed by persons specifically licensed pursuant to OAR 333-102-0290 or equivalent provisions of the U.S. Nuclear Regulatory Commission (NRC) Agreement State or Licensing State and that do not exceed 1.11GBq (30 mCi) each;

(2) Any radioactive material listed in OAR 333-116-0300, 333-116-0320 or 333-116-0360 with a half-life of 100 days or less in individual amounts not to exceed 1.11GBq (30 mCi), except Y-90 sources not to exceed 2.8 GBq (75 mCi);

(3) Any radioactive material listed in OAR 333-116-0300, 333-116-0320 or 333-116-0360 with a half-life greater than 100 days in individual amounts not to exceed 7.4 MBq (200 uCi) each; and

(4) Technetium-99m in amounts as needed.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 24-2014, f. & cert. ef. 8-15-14; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-116-0200
Requirements for Possession of Sealed Sources and Brachytherapy Sources

(1) A licensee in possession of any sealed source or brachytherapy source must follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Authority, and must maintain the instructions for the duration of source use in a legible form convenient to users.

(2) A licensee in possession of a sealed source must assure that:

(a) The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

(b) The source is tested for leakage at intervals not to exceed six months or at intervals approved by the Authority, another Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission in the Sealed Source and Device Registry (SS&D).

(3) To satisfy the leak test requirements of this division, the licensee must assure that:

(a) Leak tests are capable of detecting the presence of 185 Bq (0.005 uCi) of radioactive material on the test sample, or in the case of radium, the escape of radon at the rate of 37 Bq (0.001 uCi) per 24 hours;

(b) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and

(c) For teletherapy units, test samples are taken when the source is in the "off" position.

(4) A licensee must retain leak test records in accordance with OAR 333-100-0057. The records must contain the model number and serial number if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (Bq), a description of the method used to measure each test sample, the date of the test and the signature of the Radiation Safety Officer.

(5) If the leak test reveals the presence of 185 Bq (0.005 uCi) or more of removable contamination, the licensee must:

(a) Immediately withdraw the sealed source from use and store it in accordance with the requirements of these rules; and

(b) File a report within five days of receiving the leakage test results with the Authority describing the equipment involved, the test results and the action taken.

(6) A licensee need not perform a leak test on the following sources:

(a) Sources containing only radioactive material with a half-life of less than 30 days;

(b) Sources containing only radioactive material as a gas;

(c) Sources containing 3.7 MBq (100 uCi) or less of beta or photon-emitting material or 370 kBq (10 uCi) or less of alpha-emitting material;

(d) Seeds of iridium-192 encased in nylon ribbon; and

(e) Sources stored and not being used. The licensee must, however, test each such source for leakage before any use or transfer unless it has been tested for leakage within six months before the date of use or transfer.

(7) A licensee in possession of a sealed source or brachytherapy source must conduct a semi-annual physical inventory of all such sources in its possession. The licensee must retain each inventory record in accordance with OAR 333-100-0057. The inventory records must contain the model number of each source and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of the inventory and the signature of the Radiation Safety Officer.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0220
Labeling of Vials and Syringes

Each syringe and vial that contains unsealed byproduct material must be labeled to identify the radiopharmaceutical drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded. The label must include the radiopharmaceutical name or abbreviation, the type of diagnostic study or therapy procedure to be performed and the patient's name.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-116-0250
Surveys for Contamination and Ambient Radiation Dose Rate

(1) A licensee must survey with an appropriate radiation detection survey instrument, at the end of each day of use, all areas where radiopharmaceuticals are routinely prepared for use or administered. Radiation surveys are not required in areas where patients or human research subjects are confined when they cannot be released under OAR 333-116-0260. Radiation surveys are

required when patients receive a therapeutic dose or brachytherapy implant and prior to release.

(2) A licensee must survey with an appropriate radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.

(3) A licensee must conduct the surveys required by section (1) and (2) of this rule so as to be able to measure dose rates as low as 1 uSv (0.1 mrem) per hour.

(4) A licensee must establish dose rate action levels for the surveys required by sections (1) and (2) of this rule and must require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

(5) A licensee must survey for removable contamination each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered and each week where radioactive materials are stored.

(6) A licensee must conduct the surveys required by section (5) of this rule so as to be able to detect contamination on each wipe sample of 33.3 Bq (2000 dpm).

(7) A licensee must establish removable contamination action levels for the surveys required by section (5) of this rule and must require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

(8) A licensee must retain a record of each survey required by this rule in accordance with OAR 333-100-0057. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in Sv mrem per hour or the removable contamination in each area expressed in Bq (dpm) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples and the initials of the individual who performed the survey.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-116-0255
Surveys Of Patients And Human Research Subjects Treated With A Remote Afterloader Unit

(1) Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

(2) A licensee shall retain a record of these surveys in accordance with OAR 333-100-0057.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0260
Release of Patients Containing Therapeutic Quantities of Byproduct material or Permanent Implants

(1) The licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed five millisieverts (0.5 rem).

Note: The current revision of NUREG-1556, Vol. 9, ``Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses'' describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

(2) The licensee must provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain radiation exposures to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed one millisievert (0.1 rem). If the dose to a breast-feeding infant or child could exceed one millisievert (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include:

(a) Guidance on the interruption or discontinuation of breast-feeding; and

(b) Information on the potential consequences, if any, of failure to follow the guidance.

(3) The licensee must maintain a record of the basis for authorizing the release of an individual, for a minimum of five years after the date of release in accordance with OAR 333-100-0057.

(4) The licensee must maintain a record, for a minimum of five years after the date of release, in accordance with OAR 333-100-0057, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding five millisieverts (0.5 rem).

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-116-0280
Storage of Volatiles and Gases

(1) A licensee must store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container.

(2) A licensee must store and use a multidose container in a properly functioning fume hood.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0290
Decay-In-Storage

(1) A licensee may hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash and is exempt from the requirements of OAR 333-120-0500 of these rules if the licensee:

(a) Holds radioactive material for decay a minimum of 10 half-lives;

(b) Monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument for the radiation being monitored, set on its most sensitive scale and with no interposed shielding;

(c) Removes or obliterates all radiation labels, except radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

(d) Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

(2) For radioactive material disposed in accordance with these rules the licensee must retain a record of each disposal until inspection by the Authority. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the model and serial number of the survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container and the name of the individual who performed the survey.

(3) Iodine-125 waste in microcurie amounts may be held for a minimum of five half-lives. Such waste must be surveyed with an appropriate instrument prior to disposal to confirm that waste is indistinguishable from background.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-116-0300
Use of Unsealed Radioactive Material for Uptake, Dilution or Excretion Studies for Which a Written Directive Is Not Required

(1) A licensee may use any unsealed radioactive material for a diagnostic use involving measurements of uptake, dilution or excretion that:

(a) The Food and Drug Administration (FDA) has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA); and

(b) Is obtained from a manufacturer or preparer licensed under OAR 333-102-0285 or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(c) Is prepared and compounded by an authorized nuclear pharmacist, a physician who is an authorized user, or an individual under the supervision of either as specified in OAR 333-116-0100, 333-116-0670 and 333-116-0670(3)(B); or

(d) Is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

(2) A licensee using a radiopharmaceutical specified in section (1) of this rule for a clinical procedure other than one specified in the product label or package insert instructions for use must comply with the product label or package insert instructions regarding physical form, route of administration and dosage range.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10

333-116-0310
Possession of Survey Instrument

A licensee authorized to use radioactive material for uptake, dilution and excretion studies must have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range one Sv (0.1 mrem) per hour to one mSv (100 mrem) per hour. The instrument must be operable and calibrated in accordance with OAR 333-116-0170.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

Imaging and Localization

333-116-0320
Use of Radiopharmaceuticals, Generators and Reagents Kits for Imaging and Localization Studies for Which a Written Directive Is Not Required

(1) A licensee may use any radioactive material in a diagnostic radiopharmaceutical, except aerosol or gaseous form, or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for:

(a) Which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA); or

(b) Which is prepared and compounded by an authorized nuclear pharmacist, a physician who is an authorized user, or an individual under the supervision of either as specified in OAR 333-116-0100, 333-116-0670 or 333-116-0680; or

(c) Obtained from a manufacturer or preparer licensed under divisions 333-102 and 333-116 or equivalent Nuclear Regulatory Commission or Agreement State requirements.

(2) A licensee using radiopharmaceuticals specified in section (1) of this rule for clinical procedures other than one specified in the product label or package insert instructions must comply with the product label or package insert regarding physical form and dosage range.

(3) A licensee must elute generators in compliance with OAR 333-116-0330 and prepare radiopharmaceuticals from kits in accordance with the manufacturer's instructions.

(4) Technetium-99m pentetate as an aerosol for lung function studies is not subject to the restrictions in section (1) of this rule. Provided the conditions of OAR 333-116-0340 are met, a licensee must use radioactive aerosols or gases only if specific application is made to and approved by the Authority.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-116-0330
Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentration

(1) A licensee must not administer to humans a radiopharmaceutical containing more than 0.15 kBq (0.15 uCi) of molybdenum-99 per MBq (mCi) of technetium-99m; or

(2) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).

(3) A licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators must measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with section (1) of this rule.

(4) A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with section (1) of this rule.

(5) A licensee who must measure molybdenum concentration or strontium-82 and strontium-85 must retain a record of each measurement in accordance with OAR 333-100-0057. The record must include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in MBq (mCi), the measured activity of the molybdenum expressed in kBq (uCi), the ratio of the measures expressed as kBq (uCi) of molybdenum per MBq (mCi) of technetium, the date of the test and the initials of the individual who performed the test.

(6) A licensee must report immediately to the Authority each occurrence of molybdenum-99 concentration exceeding the limits specified in section (1) of this rule.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-116-0340
Control of Aerosols and Gases

(1) A licensee who administers radioactive aerosols or gases must do so with a system that will keep airborne concentrations within the limits prescribed by OAR 333-120-0130 and 333-120-0180.

(2) The system must either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(3) A licensee must only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

(4) Before receiving, using or storing a radioactive gas, the licensee must calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in 10 CFR Part 20 Appendix B to 20.1001 to 20.2401. The calculation must be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

(5) A licensee must post the time calculated in accordance with section (4) of this rule at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

(6) A licensee must check the operation of collection systems before each use and measure the ventilation rates in areas of use at intervals not to exceed six months. Records of these checks and measurements must be maintained for five years or until inspected by the Authority.

(7) A copy of the calculations required in section (4) of this rule must be recorded and retained for the duration of the license.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0350
Possession of Survey Instruments

A licensee authorized to use radioactive material for imaging and localization studies must have in its possession a portable, radiation detection survey instrument capable of detecting dose rates over the range of one Sv (0.1 mrem) per hour to one mSv (100 mrem) per hour and a portable radiation measurement survey instrument capable of measuring dose rates over the range ten Sv (1 mrem) per hour to ten millisieverts (1000 mrem) per hour. The instruments must be operable and calibrated in accordance with OAR 333-116-0170.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0360
Use of Unsealed Radioactive Materials or Radiopharmaceuticals for Which a Written Directive is Required

A licensee may use for therapeutic administration any unsealed radioactive material or radiopharmaceutical prepared for medical use that:

(1) Has been granted acceptance or approval by the Food and Drug Administration; and

(2) Has been prepared by an authorized nuclear pharmacist, a physician who is an authorized user on a license from the Authority, other Agreement State, or the U.S. Nuclear Regulatory Commission and meets the specified requirements in OAR 333-116-0670 or 333-116-0680; or

(3) Has been manufactured and distributed under a license from the Authority, other Agreement State, or the U.S. Nuclear Regulatory Commission; or

(4) Obtained from and prepared by the Authority or Nuclear Regulatory Commission or Agreement State licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

(5) Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-116-0370
Safety Instruction

(1) A licensee must provide oral and written radiation safety instruction for all personnel caring for patients or human research subjects undergoing radiopharmaceutical therapy who cannot be released under OAR 333-116-0260. Refresher training must be provided at intervals not to exceed one year.

(2) To satisfy section (1) of this rule, the instruction must describe the licensee's procedures for:

(a) Patient or human research subject control;

(b) Visitor control; including

(A) Routine visitation to hospitalized individuals in accordance with OAR 333-120-0180(1)(a); and

(B) Visitation authorized in accordance with OAR 333-120-0180(3).

(c) Contamination control;

(d) Waste control; and

(e) Notification of the Radiation Safety Officer or authorized user in case of the patient's death or medical emergency.

(3) A licensee must maintain, in accordance with OAR 333-100-0057, a list of individuals receiving instruction required by section (1) of this rule, a description of the instruction, the date of instruction and the name of the individual who gave the instruction.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0380
Safety Precautions

(1) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with OAR 333-116-0260 or 333-116-0190, a licensee must:

(a) Provide a private room with a private sanitary facility;

(b) Post the door with a "Caution: Radioactive Material" sign and note on the door or on the patient's chart where and how long visitors may stay in the patient's room;

(c) Authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

(d) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of OAR 333-120-0180 of these rules and retain until inspection by the Authority a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in mrem per hour, the instrument used to make the survey and the initials of the individual who made the survey;

(e) Either monitor material and items removed from the room to determine that any contamination cannot be distinguished from the natural background radiation level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle materials and items as radioactive waste;

(f) Instruct the patient or human research subject and, where appropriate, the individual's family, orally and in writing concerning radiation safety precautions that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the individual;

(g) Survey the room and private sanitary facility for removable contamination with an appropriate radiation detection survey instrument before assigning another patient to the room. The room must not be reassigned until removable contamination is less than 33.3 Bq (2000 dpm) per 100 square centimeters; and

(h) Measure the thyroid burden of each individual who helped prepare or administer a liquid dosage of iodine-131 within three days after administering the dosage. A record of each thyroid burden measurement must be retained in accordance with OAR 333-120-0650 of these rules. Each record must contain the date of

measurement, the name of the individual whose thyroid burden was measured, the calculated thyroid burden, the effective dose equivalent, the name of the individual who made the measurements and the signature of the Radiation Safety Officer. Other procedures acceptable to the Authority may be used for individuals who only prepare, but do not administer, doses of stabilized I-131.

(2) A licensee must notify the Radiation Safety Officer or the authorized user immediately if the patient or human research subject dies or has a medical emergency.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0390
Possession of Survey Instruments

A licensee authorized to use radioactive material for radiopharmaceutical therapy must have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 1 uSv (0.1 mrem) per hour to 1 mSv (100 mRem) per hour and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 uSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The instruments must be operable and calibrated in accordance with OAR 333-116-0170.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-116-0400
Use of Sealed Sources for Diagnosis

A licensee must only use sealed sources for diagnostic medical use as approved in the Sealed Source and Device Registry.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0410
Availability of Survey Instrument

A licensee authorized to use radioactive material as a sealed source for diagnostic purposes must have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range one uSv (0.1 mrem) per hour to 100 mrem (one mSv) per hour and a portable radiation measurement survey instrument capable of measuring dose rates over the range ten uSv (1 mrem) per hour to ten mSv (1000 mrem) per hour. The instrument must be operable and calibrated in accordance with OAR 333-116-0170.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0420
Use of Sources for Manual Brachytherapy

A licensee must use only brachytherapy sources for therapeutic medical uses:

(1) As approved in the Sealed Source and Device Registry; or

(2) In research with an active Investigational Device Exemption (IDE) application accepted by the Food and Drug Administration and are manufactured, labeled, packaged and distributed under a specific license issued by the Nuclear Regulatory Commission or an Agreement State.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0425
Surveys After Source Implant and Removal

(1) Immediately after implanting sources in a patient or a human research subject, the licensee must make a survey to locate and account for all sources that have not been implanted.

(2) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee must make a survey of the room and the patient or the human research subject with an appropriate radiation detection survey instrument to confirm that all sources have been removed.

(3) A licensee must retain a record of the surveys required by sections (1) and (2) of this rule in accordance with OAR 333-100-0057.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0430
Safety Instructions

(1) The licensee must provide oral and written radiation safety instruction to all personnel caring for a patient receiving implant therapy. Refresher training must be provided at intervals not to exceed one year.

(2) To satisfy section (1) of this rule, the instruction must describe:

(a) Size and appearance of the brachytherapy sources;

(b) Safe handling and shielding instructions in case of a dislodged source;

(c) Procedures for patient control;

(d) Procedures for visitor control including both:

(A) Routine visitation to hospitalized individuals in accordance with OAR 333-120-0180(1)(a); and

(B) Visitation authorized in accordance with OAR 333-120-0180(3); and

(e) Procedures for notification of the Radiation Safety Officer or authorized user if the patient dies or has a medical emergency.

(3) A licensee must retain a record of individuals receiving instruction required by section (1) of this rule in accordance with OAR 333-100-0057. The record must contain a description of the instruction, the date of instruction and the name of the individual who gave the instruction.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0440
Safety Precaution

(1) A licensee must, for each patient or human research subject receiving implant therapy:

(a) Not place the patient or human research subject in the same room with a patient or human research subject who is not receiving radiation therapy;

(b) Post the patient's or human research subject's door with a "Caution: Radioactive Materials" sign and note on the door or in the patient's chart where and how long visitors may stay in the patient's room;

(c) Authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

(d) Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with OAR 333-120-0180 of these rules. Retain a record of each survey in accordance with OAR 333-100-0057. Each record must include the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in microsieverts (mrem) per hour, the instrument used to make the survey and the initials of the individual who made the survey; and

(e) Instruct the patient or human research subject and, where appropriate, the patient's or human research subject's family, orally and in writing concerning radiation safety precautions that will help to keep the radiation dose to household members and the public as low as reasonably achievable before releasing the patient if the patient was administered a permanent implant.

(2) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

(a) Dislodged from the patient; and

(b) Lodged within the patient following removal of the source applicators.

(3) A licensee must notify the Radiation Safety Officer or authorized user immediately if the patient or human research subject dies or has a medical emergency.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-116-0445
Calibration Measurements of Brachytherapy Sources

(1) Before the first medical use of a brachytherapy source on or after July 1, 2006, a licensee must have:

(a) Determined the source output or activity using a dosimetry system that meets the requirements of OAR 333-116-0560(1);

(b) Determined source positioning accuracy within applicators; and

(c) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of section (1) of this rule.

(2) Instead of a licensee making its own measurements as required in this rule, the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with section (1) of this rule.

(3) A licensee must mathematically correct the outputs or activities determined in section (1) of this rule for physical decay at intervals consistent with one percent physical decay.

(4) Only an authorized medical physicist must calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under section (1) of this rule.

(5) A licensee must retain a record of each calibration in accordance with OAR 333-100-0057. Each record must include:

(a) The date of the calibration;

(b) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(c) The source output or activity;

(d) The source positioning accuracy within the applicators; and

(e) The name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

(6) Records of decay of strontium-90 sources for ophthalmic treatments must maintain a record of the activity of a strontium-90 source for the life of the source. The record must include:

(a) The date and initial activity of the source; and

(b) For each decay calculation, the date and the source activity.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0447
Decay of Strontium-90 Sources for Ophthalmic Treatments

(1) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under OAR 333-116-0445.

(2) A licensee shall retain a record of the activity of each strontium-90 source in accordance with OAR 333-100-0057.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0450
Brachytherapy Sources Inventory

(1) A licensee must maintain accountability at all times for all brachytherapy sources in storage or use.

(2) As soon as possible after removing sources from a patient or human research subject, the licensee must return brachytherapy sources to a secure storage area.

(3) A licensee must retain the records required in sections (1) and (2) of this rule in accordance with OAR 333-100-0057.

(a) For temporary implants, the record must include:

(A) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

(B) The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

(b) For permanent implants, the record must include:

(A) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

(B) The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and

(C) The number and activity of sources permanently implanted in the patient or human research subject.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0460
Release of Patients Treated with Temporary Implant

(1) Immediately after removing the last temporary implant source from a patient or human research subject, the licensee must make a radiation survey of the patient or human research subject with an appropriate radiation detection survey instrument to confirm that all sources have been removed. The licensee must not release from confinement for medical care a patient or human research subject treated by temporary implant until all sources have been removed.

(2) A licensee must retain a record of patient surveys which demonstrate compliance with section (1) of this rule in accordance with OAR 333-100-0057. Each record must include the date of the survey, the name of the patient, the dose rate from the patient expressed as Sv (mrem) per hour and measured within one meter from the patient and the initials of the individual who made the survey.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0470
Possession of Survey Instruments

A licensee authorized to use radioactive material for implant therapy must have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 1 uSv (0.1 mrem) per hour to 1 mSv (100 mRem)per hour and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 uSv (1 mrem) per hour to 10

mSv (1000 mrem) per hour. The instruments must be operable and calibrated in accordance with OAR 333-116-0170.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-116-0475
Therapy Related Computer Systems

(1) The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays; and

(d) The accuracy of the software used to determine sealed source positions from radiographic images.

(2) Acceptance testing must be performed when new software is installed, for each software revision and when new computer hardware or treatment planning system hardware is installed or repaired.

(3) Records of acceptance testing must be retained in accordance with OAR 333-100-0057.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0480
Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit

A licensee must use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

(1) As approved in the Sealed Source and Device Registry; or

(2) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA and are manufactured, labeled, packaged and distributed under a specific license issued by the Nuclear Regulatory Commission or an Agreement State.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0485
Other Medical Uses of Byproduct Material or Radiation from Byproduct Material

A licensee shall use byproduct or a radiation source not specifically addressed in OAR 333-116-0300 through 333-116-0480 in accordance with the manufacturer's radiation safety and operating instructions.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 4-2010, f. & cert. ef. 2-16-10

333-116-0490
Installation, Maintenance, Adjustment and Repair

(1) Only a person specifically licensed by the Nuclear Regulatory Commission or an Agreement State must install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(2) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Nuclear Regulatory Commission or an Agreement State must install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

(3) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Nuclear Regulatory Commission or an Agreement State or an authorized medical physicist must install, replace, relocate, or remove a sealed source(s) contained in the unit.

(4) A licensee must retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with OAR 333-100-0057. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0495
Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

(1) A licensee must:

(a) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(b) Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(c) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

(d) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

(A) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(B) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(C) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(2) A copy of the procedures required by subsection (1)(d) of this rule must be physically located at the unit console.

(3) A licensee must post instructions at the unit console to inform the operator of:

(a) The location of the procedures required by subsection (1)(d) of this rule; and

(b) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(4) A licensee must provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties in:

(a) The procedures identified in subsection (1)(d) of this rule; and

(b) The operating procedures for the unit.

(5) A licensee must ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(6) A licensee must retain a record of individuals receiving instruction required by section (4) of this rule in accordance with OAR 333-100-0057.

(7) A licensee must retain a copy of the procedures required by subsections (1)(d) and (4)(b) of this rule until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0500
Amendment

In addition to the requirements specified in OAR 333-116-0040, a licensee must apply for and must receive a license amendment before:

(1) Making any change in the treatment room shielding;

(2) Making any change in the location of the teletherapy unit within the treatment room;

(3) Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

(4) Relocating the teletherapy unit; or

(5) Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0525
Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

(1) A licensee must control access to the treatment room by a door at each entrance.

(2) A licensee must equip each entrance to the treatment room with an electrical interlock system that will:

(a) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(b) Cause the source(s) to be shielded when an entrance door is opened; and

(c) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(3) A licensee must require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(4) Except for low-dose remote afterloader units, a licensee must construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(5) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee must only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(6) In addition to the requirements specified in sections (1) through (5) of this rule, a licensee must:

(a) For medium dose-rate and pulsed dose-rate remote afterloader units, require:

(A) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(B) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(b) For high dose-rate remote afterloader units, require:

(A) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(B) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(c) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(d) Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(7) A licensee must have applicable emergency response equipment available near each treatment room to respond to a source:

(a) Remaining in the unshielded position; or

(b) Lodged within the patient following completion of the treatment.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0530
Possession of Survey Instrument

A licensee authorized to use radioactive material in a teletherapy therapy unit must have in its possession either both a portable radiation detection survey instrument capable of detecting dose rates over the range one Sv (0.1 mrem) per hour to 100 mrem (one mSv) per hour and a portable radiation measurement survey instrument capable of measuring dose rates over the range ten Sv (1 mrem) per hour to ten mSv (1000 mrem) per hour. The instruments must be operable and calibrated in accordance with OAR 333-116-0170.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0540
Radiation Monitoring Device

(1) A licensee must have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

(2) Each radiation monitor must be capable of providing visible evidence of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels must be observable by an individual prior to entering the teletherapy room.

(3) Each radiation monitor must be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system or other type of uninterruptible power supply (UPS).

(4) Each radiation monitor must be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients.

(5) A licensee must maintain a record of the check required by section (4) of this rule until inspection by the Authority. The record must include the date of the check, notation that the monitor indicates when the source is exposed and the initials of the individual who performed the check.

(6) If a radiation monitor is inoperable, the licensee must require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter must be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee must keep a record as described in section (4) of this rule.

(7) If a radiation monitor is inoperable, the licensee must require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism. The instrument or dosimeter must be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee must keep a record as described in section (5) of this rule.

(8) A licensee must promptly repair or replace the radiation monitor if it is inoperable.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0550
Viewing System

A licensee must construct or equip each teletherapy room to permit continuous observation of the patient from the teletherapy unit console during irradiation.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0560
Dosimetry Equipment

(1) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee must have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(a) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(b) The system must have been calibrated within the previous four years; 18 to 30 months after that calibration, the system must have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the AAPM. The intercomparison meeting must be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM. The results of the intercomparison meeting must show that the calibration factor of the licensee's system had not changed by more than two percent. The licensee must not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee must use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(2) The licensee must have available for use a dosimetry system for spot-check output measurements, if applicable. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with section (1) of this rule. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in section (1) of this rule.

(3) The licensee must retain a record of each calibration, intercomparison and comparison for the duration of the license. For each calibration, intercomparison or comparison, the record must include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared or compared as required by sections (1) and (2) of this rule, the correction factors that were deduced, the names and credentials of the individuals who performed the calibration, intercomparison or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by AAPM.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0570
Full Calibration Measurement

(1) A licensee authorized to use a teletherapy unit for medical use must perform full calibration measurements on each teletherapy unit:

(a) Before the first medical use of the unit; and

(b) Before medical use under the following conditions:

(A) Whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(B) Following replacement of the radioactive source or following reinstallation of the teletherapy unit in a new location;

(C) Following any repair of the teletherapy unit that includes removal of the radioactive source or major repair of the components associated with the source exposure assembly; and

(c) At intervals not exceeding one year.

(2) To satisfy the requirement of section (1) of this rule, full calibration measurements must include determination of:

(a) The output within three percent for the range of field sizes and for the distance or range of distances used for medical use;

(b) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(c) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(d) Timer accuracy, constancy, and linearity;

(e) On-off error; and

(f) The accuracy of all distance measuring and localization devices in medical use.

(3) A licensee must use the dosimetry system described in OAR 333-116-0560(1) to measure the output for one set of exposure conditions. The remaining radiation measurements required in subsection (2)(a) of this rule may then be made using a dosimetry system that indicates relative dose rates.

(4) A licensee must make full calibration measurements required by section (1) of this rule in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee must correct mathematically the outputs determined in subsection (2)(a) of this rule for physical decay for intervals not exceeding one month for cobalt-60 and intervals not exceeding six months for cesium-137, or at intervals consistent with one percent decay for all other nuclides.

(6) Full calibration measurements required by section (1) of this rule and physical decay corrections required by section (5) of this rule must be performed by a teletherapy or medical physicist certified to perform such measurements and named on the licensee's license or authorized by a license issued by the Nuclear Regulatory Commission or an Agreement State to perform such services.

(7) A licensee must retain a record of each calibration in accordance with OAR 333-100-0057. The record must include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated on-off error, the estimated accuracy of each distance measuring or localization device and the signature of the teletherapy physicist.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0573
Full Calibration Measurements on Remote Afterloader Units

(1) A licensee authorized to use a remote afterloader unit for medical use must perform full calibration measurements on each unit:

(a) Before the first medical use of the unit;

(b) Before medical use under the following conditions:

(A) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(B) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(c) At intervals not exceeding three months for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

(d) At intervals not exceeding one year for low dose-rate remote afterloader units.

(2) To satisfy the requirement of section (1) of this rule, full calibration measurements must include, as applicable, determination of:

(a) The output within five percent;

(b) Source positioning accuracy to within one millimeter;

(c) Source retraction with backup battery upon power failure;

(d) Length of the source transfer tubes;

(e) Timer accuracy and linearity over the typical range of use;

(f) Length of the applicators; and

(g) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(3) A licensee must use the dosimetry system described in OAR 333-116-0560(1) to measure the output.

(4) A licensee must make full calibration measurements required by section (1) of this rule in accordance with published protocols accepted by nationally recognized bodies.

(5) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in section (2) of this rule, a licensee must perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.

(6) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with sections (1) through (5) of this rule.

(7) A licensee must mathematically correct the outputs determined in subsection (2)(a) of this rule for physical decay at intervals consistent with one percent physical decay.

(8) Full calibration measurements required by subsection (2)(a) of this rule and physical decay corrections required by subsection (2)(g) of this rule must be performed by the authorized medical physicist.

(9) A licensee must retain a record of each calibration in accordance with OAR 333-100-0057.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0577
Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use must perform full calibration measurements on each unit:

(a) Before the first medical use of the unit;

(b) Before medical use under the following conditions:

(A) Whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(B) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(C) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(c) At intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(2) To satisfy the requirement of subsection (1)(a) of this rule, full calibration measurements must include determination of:

(a) The output within +/-three percent;

(b) Relative helmet factors;

(c) Isocenter coincidence;

(d) Timer accuracy and linearity over the range of use;

(e) On-off error;

(f) Trunnion centricity;

(g) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(h) Helmet microswitches;

(i) Emergency timing circuits; and

(j) Stereotactic frames and localizing devices (trunnions).

(3) A licensee must use the dosimetry system described in OAR 333-116-0560(1) to measure the output for one set of exposure conditions. The remaining radiation measurements required in subsection (2)(a) of this rule may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee must make full calibration measurements required by section (1) of this rule must be performed in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee must mathematically correct the outputs determined in subsection (2)(a) of this rule at intervals not exceeding one month for cobalt-60 and at intervals consistent with one percent physical decay for all other radionuclides.

(6) Full calibration measurements required by section (1) of this rule and physical decay corrections required by section (5) of this rule must be performed by the authorized medical physicist.

(7) A licensee must retain a record of each calibration in accordance with OAR 333-100-0057.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0580
Periodic Spot-Checks for Teletherapy Units

(1) A licensee authorized to use teletherapy units for medical use must perform output spot-checks on each teletherapy unit at intervals not to exceed one month that include the determination of:

(a) Timer constancy, accuracy, and linearity over the range of use;

(b) On-off error;

(c) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(d) The accuracy of all distance measuring and localization devices used for medical use;

(e) The output for one typical set of operating conditions measured with the dosimetry system described in OAR 333-116-0560; and

(f) The difference between the measurement made in section (1) of this rule and the anticipated output, expressed as a percentage of the anticipated value obtained at last full calibration corrected mathematically for physical decay.

(2) A licensee must use the dosimetry system described in OAR 333-116-0560 to make the measurement required in section (1) of this rule.

(3) A licensee must perform measurements required by section (1) of this rule in accordance with procedures established by the teletherapy or medical physicist. That individual is not required to actually perform the output spot-check measurements.

(4) A licensee must have the teletherapy or medical physicist review the results of each output spot-check within 15 days of each measurement. The teletherapy or medical physicist must promptly

notify the licensee in writing of the results of each output spot-check. The licensee must keep a copy of each written notification in accordance with OAR 333-100-0057.

(5) A licensee authorized to use a teletherapy unit for medical use must perform safety spot-checks of each teletherapy facility at intervals not to exceed one month and after each source installation to assure proper operation of:

(a) Electrical interlocks at each teletherapy room entrance;

(b) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism;

(c) Beam condition indicator lights on the teletherapy unit, on the control console and in the facility;

(d) Viewing systems;

(e) Treatment room doors from inside and outside the treatment room; and

(f) Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off".

(6) A licensee must lock the control console in the "off" position if any door interlock malfunctions. No licensee must use the unit until the interlock system is repaired unless specifically authorized by the Authority.

(7) A licensee must promptly repair any system identified in section (5) of this rule that is not operating properly.

(8) A licensee must retain a record of each spot-check required by sections (1) and (5) of this rule in accordance with OAR 333-100-0057. The record must include, the date of the spot-check, the manufacturer's name, model number and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, the measured timer accuracy, the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated on-off error, the estimated accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors and the signature of the individual who performed the periodic spot-check.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0583
Periodic Spot-checks for Remote Afterloader Units

(1) A licensee authorized to use a remote afterloader unit for medical use must perform spot-checks of each remote afterloader facility and on each unit:

(a) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

(b) Before each patient treatment with a low dose-rate remote afterloader unit; and

(c) After each source installation.

(2) A licensee must perform the measurements required by section (1) of this rule in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(3) A licensee must have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist must notify the licensee as soon as possible in writing of the results of each spot-check.

(4) To satisfy the requirements of section (1) of this rule, spot-checks must, at a minimum, assure proper operation of:

(a) Electrical interlocks at each remote afterloader unit room entrance;

(b) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(c) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(d) Emergency response equipment;

(e) Radiation monitors used to indicate the source position;

(f) Timer accuracy;

(g) Clock (date and time) in the unit's computer; and

(h) Decayed source(s) activity in the unit's computer.

(5) If the results of the checks required in section (4) of this rule indicate the malfunction of any system, a licensee must lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(6) A licensee must retain a record of each check required by section (4) of this rule in accordance with OAR 333-100-0057. The record must include, as applicable:

(a) The date of the spot-check;

(b) The manufacturers name, model number for the remote afterloader and source;

(c) An assessment of timer accuracy;

(d) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

(e) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(7) A licensee must retain a copy of the procedures required by section (4) of this rule until the licensee no longer possesses the remote afterloader unit.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0585
Additional Technical Requirements for Mobile Remote Afterloader Units

(1) A licensee providing mobile remote afterloader service must:

(a) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

(b) Account for all sources before departure from a client's address of use.

(2) In addition to the periodic spot-checks required by OAR 333-116-0583, a licensee authorized to use mobile afterloaders for medical use must perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:

(a) Electrical interlocks on treatment area access points;

(b) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(c) Viewing and intercom systems;

(d) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

(e) Radiation monitors used to indicate room exposures;

(f) Source positioning (accuracy); and

(g) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(3) In addition to the requirements for checks in section (2) of this rule, a licensee must ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(4) If the results of the checks required in section (2) of this rule indicate the malfunction of any system, a licensee must lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(5) A licensee must retain a record of each check required by section (2) of this rule in accordance with OAR 333-100-0057. The record must include:

(a) The date of the check;

(b) The manufacturer's name, model number, and serial number of the remote afterloader unit;

(c) Notations accounting for all sources before the licensee departs from a facility;

(d) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and

(e) The signature of the individual who performed the check.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-116-0587

Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use must perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

(a) Monthly;

(b) Before the first use of the unit on a given day; and

(c) After each source installation.

(2) A licensee must:

(a) Perform the measurements required by section (1) of this rule in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(b) Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist must notify the licensee as soon as possible in writing of the results of each spot-check.

(3) To satisfy the requirements of subsection (1)(a) of this rule, spot-checks must, at a minimum:

(a) Assure proper operation of:

(A) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(B) Helmet microswitches;

(C) Emergency timing circuits; and

(D) Stereotactic frames and localizing devices (trunnions).

(b) Determine:

(A) The output for one typical set of operating conditions measured with the dosimetry system described in OAR 333-116-0560;

(B) The difference between the measurement made in paragraph (3)(b)(A) of this rule and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(C) Source output against computer calculation;

(D) Timer accuracy and linearity over the range of use;

(E) On-off error; and

(F) Trunnion centricity.

(4) To satisfy the requirements of subsections (1)(b) and (1)(c) of this rule, spot-checks must assure proper operation of:

(a) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(b) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(c) Viewing and intercom systems;

(d) Timer termination;

(e) Radiation monitors used to indicate room exposures; and

(f) Emergency off buttons.

(5) A licensee must arrange for the repair of any system identified in section (3) of this rule that is not operating properly as soon as possible.

(6) If the results of the checks required in section (4) of this rule indicate the malfunction of any system, a licensee must lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(7) A licensee must retain a record of each check required by sections (3) and (4) of this rule in accordance with OAR 333-100-0057. The record must include:

(a) The date of the spot-check;

(b) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(c) An assessment of timer linearity and accuracy;

(d) The calculated on-off error;

(e) A determination of trunnion centricity;

(f) The difference between the anticipated output and the measured output;

(g) An assessment of source output against computer calculations;

(h) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

(i) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(8) A licensee must retain a copy of the procedures required by section (2) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0590

Radiation Surveys Therapeutic Treatment Units

(1) In addition to the survey requirement in OAR 333-120-0200, a person licensed under this rule must make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

(2) The licensee must make the survey required by section (1) of this rule at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(3) A licensee must retain a record of the radiation surveys required by section (1) of this rule for the duration of use of the unit. The record must include:

(a) The date of the measurements;

(b) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

(c) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(d) The signature of the individual who performed the test.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0600
Safety Checks and Five-year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units

(1) A licensee must have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(2) This inspection and servicing may only be performed by persons specifically licensed to do so by the Nuclear Regulatory Commission or an Agreement State.

(3) If the results of the checks required in section (1) of this rule indicate the malfunction of any system, the licensee must lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace or check the malfunctioning system.

(4) A licensee must retain, in accordance with OAR 333-100-0057, a record of the facility checks following installation of a source. The record must include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors and the signature of the Radiation Safety Officer. In addition each record must contain:

(a) The inspector's radioactive materials license number;

(b) The date of inspection;

(c) The manufacturer's name and model number and serial number of both the treatment unit and source;

(d) A list of components inspected and serviced, and the type of service; and

(e) The signature of the inspector.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0605
Therapy-Related Computer Systems

The licensee must perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(1) The source-specific input parameters required by the dose calculation algorithm;

(2) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(3) The accuracy of isodose plots and graphic displays;

(4) The accuracy of the software used to determine sealed source positions from radiographic images; and

(5) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0610
Modification of Teletherapy Unit or Room Before Beginning a Treatment Program

(1) If the survey required by OAR 333-116-0590 indicates that any individual member of the public is likely to receive a dose in excess of the limits specified in 333-120-0180, before beginning the treatment program the licensee must:

(a) Either equip the unit with stops or add additional radiation shielding to ensure compliance with OAR 333-120-0180;

(b) Perform the survey required by OAR 333-116-0590 again; and

(c) Include in the report required by OAR 333-116-0620 the results of the initial survey, a description of the modification made to comply with subsection (1)(a) of this rule, and the results of the second survey.

(2) As an alternative to the requirements set out in subsection (1)(a) of this rule a licensee may request a license amendment under OAR 333-120-0180(3) that authorizes radiation levels in unrestricted areas greater than those permitted by 333-120-0180(1). A licensee may not begin the treatment program until the license amendment has been issued.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0620
Reports of Teletherapy Surveys, Checks, Tests and Measurements

A licensee must furnish a copy of the records required in OAR 333-116-0590, 333-116-0600, 333-116-0610 and the output from the teletherapy source expressed as rem (Sv) per hour at one meter from the source and determined during the full calibration required in OAR 333-116-0570 to the Authority within 30 days following completion of the action that initiated the record requirement.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0640
Radiation Safety Officer Training and Experience Requirements

Except as provided in OAR 333-116-0740, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in OAR 333-116-0090 to be an individual who:

(1) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in sections (4) and (5) of this rule. (The names of board certifications which have been recognized by the Commission or an Agreement State are posted on the NRC's webpage.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a)(A) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(B) Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and

(C) Pass an examination administered by diplomats of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(b)(A) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(B) Have two years of full-time practical training and supervised experience in medical physics:

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(ii) In clinical nuclear medicine facilities providing diagnostic and therapeutic services under the direction of physicians who meet the requirements for authorized users in OAR 333-116-0670, 333-116-0680 or 333-116-0740;

(C) Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(2) Has completed a structured educational program consisting of 200 hours of classroom and laboratory training as follows:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Radiation biology;

(e) Radiopharmaceutical chemistry;

(f) Radiation dosimetry; and

(g) One year of full time experience in radiation safety at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on an Authority, Agreement State, Licensing State or U.S. Nuclear Regulatory Commission license that authorizes similar type(s) of medical use of radioactive material involving the following:

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(C) Securing and controlling byproduct material;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(F) Using emergency procedures to control byproduct material; and

(G) Disposing of radioactive material; or

(3)(a) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State under OAR 333-116-0905(1) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in sections (4) and (5) of this rule; or

(b) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities; and

(4) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in section (5) and in paragraphs (1)(a)(A) and (1)(b)(B) or paragraphs (1)(b)(A) and (1)(b)(B) or section (2), or subsections (3)(a) or (3)(b) of this rule, and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and

(5) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2013, f. & cert. ef. 1-29-13; PH 25-2016, f. 8-26-16, cert. ef. 9-1-16

333-116-0650

Training for Experienced Radiation Safety Officer

An individual identified as a Radiation Safety Officer on an Agency, Agreement State, Licensing State or U.S. Nuclear Regulatory Commission license on July 1, 2006 who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of OAR 333-116-0640.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0660

Training for Uptake, Dilution or Excretion Studies

Except as provided in OAR 333-116-0740, the licensee shall require the authorized user of a radiopharmaceutical listed in 333-116-0300 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in section (4) of this rule (The names of board certifications recognized by the NRC or an Agreement State are posted on the NRC's website). To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Complete 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include paragraphs (3)(a)(A) through (3)(b)(F) of this rule; and

(b) Pass an examination administered by diplomats of the specialty board that assesses knowledge and competence in radiation safety, radionuclide handling and quality control; or

(2) Is an authorized user under OAR 333-116-0670, 333-116-0680, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(3) Has completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include:

(a) Classroom and laboratory training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0660, 333-116-0670, 333-116-0680 and 333-116-0740 or Nuclear Regulatory Commission or equivalent Agreement State requirements, involving:

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages of radiopharmaceutical drugs to patients or human research subjects; and

(4) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements, in OAR 333-116-0740, 333-116-0660, 333-116-0670, or 333-116-0680, or Nuclear Regulatory Commission or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in subsection (1)(a) or section (3) of this rule and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 333-116-0300.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 4-2013, f. & cert. ef. 1-29-13; PH 14-2013, f. 12-26-13, cert. ef. 1-1-14

333-116-0670
Training for Imaging and Localization Studies

Except as provided in OAR 333-116-0740, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under OAR 333-116-0320 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in section (4) of this rule. (The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's website). To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies as described in subsection (3)(a) through paragraph (2)(b)(G) of this rule; and

(b) Pass an examination administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling and quality control; or

(2) Is an authorized user under OAR 333-116-0680 and meets the requirements in OAR 333-116-0670(3)(b)(G) or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(3) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies.

(a) The training and experience must include at a minimum classroom and laboratory training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(b) Work experience, under the supervision of an authorized user, who meets the requirements in this rule or OAR 333-116-0670, 333-116-0680, 333-116-0740 and 333-116-0670(3)(b)(G) or equivalent Nuclear Regulatory Commission or Agreement State requirements, involving:

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(G) Eluting generator systems appropriate for preparation of radiopharmaceutical drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radiopharmaceutical drugs; and

(4) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this rule or OAR 333-116-0670(3)(b)(G), 333-116-0680, 333-116-0740 or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in subsection (1)(a) or section (3) of this rule and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under OAR 333-116-0300 and 333-116-0320.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 4-2013, f. & cert. ef. 1-29-13

333-116-0680
Training for Use of Unsealed Byproduct Material for Which a Written Directive is Required

Except as provided in OAR 333-116-0740, the licensee must require an authorized user of unsealed byproduct material for the uses authorized under 333-116-0360 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in paragraph (2)(b)(F) and subsection (2)(c) of this rule. (Specialty boards whose certification processes have been recognized by the NRC or an Agreement State shall be posted on the NRC's webpage). To be recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in subsection (2)(a) through paragraph (2)(b)(E). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required; or

(2) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include:

(a) Classroom and laboratory training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0740, and sections (1) and (2) of this rule, or NRC or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in section (2) of this rule, must have experience in administering dosages in the same dosage category or categories as given in OAR 333-116-0680(2)(b)(F) as the individual requesting authorized user status. The work experience must involve:

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey instruments;

(C) Calculating, measuring and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages of radiopharmaceutical drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

(i) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;

(ii) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;

NOTE: Experience with at least three cases in subparagraph (ii) also satisfies the requirement in subparagraph (i).

(iii) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; or

(iv) Parenteral administration of any other radionuclide; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in sections (1) and (2) and paragraph (2)(b)(F) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under OAR 333-116-0360. The written attestation must be signed by a preceptor authorized user who meets the requirements in 333-116-0740, 333-116-0680 or equivalent NRC or Agreement State requirements. The preceptor authorized user, who meets the requirements in section (2) of this rule, must have experience in administering dosages in the same dosage category or categories as given in 333-116-0680(2)(b)(F)(i), (ii), (iii), or (iv) as the individual requesting authorized user status.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 4-2013, f. & cert. ef. 1-29-13; PH 14-2013, f. 12-26-13, cert. ef. 1-1-14; PH 24-2014, f. & cert. ef. 8-15-14; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-116-0683

Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 millicuries)

Except as provided in OAR 333-116-0740, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive and the total treatment quantity is less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in section (3) of this rule and whose certification has been recognized by the NRC or an Agreement State and who meets the requirements in subsection (3)(c) of this rule. (The names of board certifications which have been recognized by the NRC or an Agreement State are posted on the NRC's webpage); or

(2) Is an authorized user under OAR 333-116-0680 for uses listed in 333-116-0680(2)(b)(F)(i) or (ii) or 333-116-0687, or equivalent Agreement State requirements; or

(3) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive.

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(b) Has work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0680, 333-116-0683, 333-116-0687, 333-116-0740 or equivalent NRC or Agreement State requirements. A supervising authorized user who meets the requirements in 333-116-0680(2) must have experience in administering dosages as specified in 333-116-0680(2)(b)(F)(i) or (ii). The work experience must involve:

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

(C) Calculating, measuring and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (3)(a) and (3)(b) of this rule and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under OAR 333-116-0360. The written attestation must be signed by a preceptor authorized user who meets the requirements in OAR 333-116-0740, 333-116-0680, 333-116-0683, 333-116-0687 or equivalent NRC or Agreement State requirements. A preceptor authorized user, who meets the requirement in OAR 333-116-0680(2), must also have experience in administering dosages as specified in OAR 333-116-0680(2)(b)(F)(i) or (ii).

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 4-2013, f. & cert. ef. 1-29-13; PH 14-2013, f. 12-26-13, cert. ef. 1-1-14; PH 24-2014, f. & cert. ef. 8-15-14

333-116-0687

Training for Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater than 1.22 Gigabecquerels (33 millicuries)

Except as provided in OAR 333-116-0740, the licensee must require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in subsection (3)(a) and (3)(b) of this rule and whose certification has been recognized by the NRC or an Agreement State, and who meets the requirements in subsection (3)(c) of this rule. (The names of board certifications which have been recognized by the NRC or an Agreement State are posted on the NRC's webpage); or

(2) Is an authorized user under OAR 333-116-0680 for uses listed in OAR 333-116-0680(2)(b)(F)(ii), or equivalent NRC or Agreement State requirements; or

(3) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive.

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(b) Has work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0680, 333-116-0687, 333-116-0740, or equivalent NRC or Agreement State requirements. A supervising authorized user, who meets the requirements in OAR 333-116-0680(2), must have experience in administering dosages as specified in OAR 333-116-0680(2)(b)(F)(ii). The work experience must involve:

(A) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

(C) Calculating, measuring and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (3)(a) and (3)(b) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under OAR 333-116-0360. The written attestation must be signed by a preceptor authorized user who meets the requirements in 333-116-0680, 333-116-0687, 333-116-0740, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in 333-116-0680(2), must have experience in administering dosages as specified in 333-116-0680(2)(b)(F)(ii).

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 4-2013, f. & cert. ef. 1-29-13; PH 14-2013, f. 12-26-13, cert. ef. 1-1-14; PH 24-2014, f. & cert. ef. 8-15-14

333-116-0690
Training for Therapeutic Use of Brachytherapy Source

Except as provided in OAR 333-116-0740, the licensee must require the authorized user using manual brachytherapy sources specified in OAR 333-116-0420 for therapy to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State, and who meets the requirements in subsection (2)(d) of this rule. (The names of board certifications which have been recognized by the NRC or an Agreement State are posted on the NRC's webpage.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomats of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance and clinical use of manual brachytherapy; or

(2) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

(a) 200 hours of classroom and laboratory training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(b) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this rule, OAR 333-116-0740 or equivalent NRC or Agreement State requirements at a medical institution, involving:

(A) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Checking survey meters for proper operation;

(C) Preparing, implanting and removing brachytherapy sources;

(D) Maintaining running inventories of material on hand;

(E) Using administrative controls to prevent a medical event involving the use of byproduct material; and

(F) Using emergency procedures to control byproduct material; and

(c) Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in OAR 333-116-0740, 333-116-0690, or equivalent NRC or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education, or the Royal College of Physicians and Surgeons of Canada, or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subsection (2)(b) of this rule; and

(d) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in OAR 333-116-0740, 333-116-0690, or equivalent NRC or Agreement State requirements, that the individual has satisfactorily completed the requirements in subsection (1)(a), or subsections (2)(a), (2)(b) and (2)(c) of this rule and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 333-116-0420.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 4-2013, f. & cert. ef. 1-29-13; PH 14-2013, f. 12-26-13, cert. ef. 1-1-14; PH 24-2014, f. & cert. ef. 8-15-14

333-116-0700
Training for Ophthalmic Use of Strontium-90

Except as provided in OAR 333-116-0740, the licensee must require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:

(1) Is an authorized user under OAR 333-116-0690 or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(2) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy.

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:

(A) Examination of each individual to be treated;

(B) Calculation of the dose to be administered;

(C) Administration of the dose;

(D) Follow up and review of each individual's case history; and

(E) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in OAR 333-116-0740, 333-116-0690, 333-116-0700, or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in section (2) of this rule and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 4-2013, f. & cert. ef. 1-29-13; PH 14-2013, f. 12-26-13, cert. ef. 1-1-14

333-116-0710
Training for Use of Sealed Sources for Diagnosis

Except as provided in OAR 333-116-0740 the licensee must require the authorized user using a sealed source in a device specified in OAR 333-116-0400 to be a physician, dentist or podiatrist who:

(1) Is certified in:

(a) Radiology, diagnostic radiology with special competence in nuclear radiology, radiation oncology or therapeutic radiology by the American Board of Radiology; or

(b) Nuclear medicine by the American Board of Nuclear Medicine; or

(c) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology.

(2) Has completed eight hours of instruction in basic radioisotope handling techniques specifically applicable to the use of the device. To satisfy the requirement for instruction, the training must include:

(a) Radiation physics, mathematics pertaining to the use and measurement of radioactivity and instrumentation;

(b) Radiation biology;

(c) Radiation protection and training in the use of the device for the purposes authorized by the license; and

(d) Training in the use of the device for the uses requested.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0715

Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written Directive

Except as provided in OAR 333-116-0740, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

(1) Is an authorized user under OAR 333-116-0680 for uses listed in 333-116-0680(2)(b)(F)(iii) or 333-116-0680(2)(b)(F)(iv) or equivalent Agreement State requirements; or

(2) Is an authorized user under OAR 333-116-0690 or 333-116-0720, or equivalent Agreement State or Nuclear Regulatory Commission requirements and who meets the requirements in section (4) of this rule; or

(3) Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State under OAR 333-116-0690 or 333-116-0720, and who meets the requirements in section (4) of this rule.

(4) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, or parenteral administration of any other radionuclide for which a written directive is required.

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(b) Has work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0680, 333-116-0715, 333-116-0740 or equivalent Nuclear Regulatory Commission or Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in 333-116-0680 must have experience in administering dosages as specified in 333-116-0680(2)(b)(F)(iii) or 333-116-0680(2)(b)(F)(iv). The work experience must involve:

(A) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and

(F) Administering dosages to patients or human research subjects, that include at least three cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and at least three cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in sections (2) or (3) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in OAR 333-116-0680, 333-116-0715, 333-116-0740 or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in 333-116-0680, must have experience in administering dosages as specified in 333-116-0680(2)(b)(F)(iii) or 333-116-0680(2)(b)(F)(iv).

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 4-2013, f. & cert. ef. 1-29-13; PH 14-2013, f. 12-26-13, cert. ef. 1-1-14

333-116-0720

Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Except as provided in OAR 333-116-0740, the licensee must require the authorized user of a sealed source specified in OAR 333-116-0480 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission (NRC) or an Agreement State and who meets the requirements in subsection (2)(c) and section (3) of this rule. (The names of board certifications which have been recognized by the Commission or an Agreement State are posted on the NRC's webpage.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(2) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit:

(a) Which includes the following:

(A) 200 hours of classroom and laboratory training in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

(B) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0720, 333-116-0740 or equivalent Nuclear Regulatory Commission or Agreement State requirements at a medical institution, involving:

(i) Reviewing full calibration measurements and periodic spot-checks;

(ii) Preparing treatment plans and calculating treatment doses and times;

(iii) Using administrative controls to prevent a medical event involving the use of byproduct material;

(iv) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(v) Checking and using survey meters; and

(vi) Selecting the proper dose and how it is to be administered; and

(b) Has completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in OAR 333-116-0720, 333-116-0740 or equivalent Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (2)(a)(B) of this rule; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (1)(a) or (2)(a) and (2)(b), and section (3) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in OAR 333-116-0720, 333-116-0740 or equivalent Nuclear Regulatory Commission or Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(3) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2013, f. & cert. ef. 1-29-13; PH 25-2016, f. 8-26-16, cert. ef. 9-1-16

333-116-0730
Training for Teletherapy or Brachytherapy Physicist

The licensee must require the teletherapy physicist to:

(1) Be certified by the American Board of Radiology in:

(a) Therapeutic radiological physics; or

(b) Roentgen ray and gamma ray physics; or

(c) X-ray and radium physics; or

(d) Radiological physics; or

(2) Be certified by the American Board of Medical Physics in radiation oncology physics; or

(3) Hold a master's or doctor's degree in physics, biophysics, radiological physics or health physics and have completed one year of full time training in therapeutic radiological physics and also one year of full time work experience under the supervision of a teletherapy or brachytherapy physicist at a medical institution. To meet this requirement, the individual must have performed the tasks listed in OAR 333-116-0200, 333-116-0570, 333-116-0580 and 333-116-0590 under the supervision of a teletherapy or brachytherapy physicist during the year of work experience.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0740
Training for Experienced Authorized User, Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Nuclear Pharmacist or Authorized Nuclear Pharmacist

(1) An individual identified as a Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist on a Nuclear Regulatory Commission or Agreement State license before July 1, 2006 need not comply with the training requirements of OAR 333-116-0640, 333-116-0905 or 333-116-0910.

(2) Practitioners of the healing arts identified as authorized users for the human use of radioactive material on an Authority, Nuclear Regulatory Commission or Agreement State or Licensing State license before July 1, 2006 who perform only those methods of use for which they were authorized on that date need not comply with the training requirements OAR 333-116-0640, 333-116-0905, or 333-116-0910. .

(3) Individuals who need not comply with training requirements as described in this rule may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2013, f. & cert. ef. 1-29-13

333-116-0750
Physician Training in a Three Month Program

A physician who, before July 1, 1984, began a three month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program is exempted from the requirements of OAR 333-116-0660 or 333-116-0670.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0760
Recentness of Training

The training and experience specified in OAR 333-116-0640 through 333-116-0730 and 333-116-0905 through 333-116-0915 must have been obtained within the seven years preceding the date of application or the individual must have had continuing education and experience since the required training and experience was completed.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

Specific Requirements for Positron Emission Tomography (PET) Facilities

333-116-0800
Licensing and Registration of Positron Emission Tomography (PET) Facilities

(1) Each component of a PET facility (accelerator, radiopharmacy, and clinic) must be separately licensed pursuant to OAR 333-101-0005, 333-102-0200, 333-103-0005 or 333-103-0010.

(2) The licensee or registrant must receive applicable Authority authorization at least 30 days prior to the production of any accelerator-produced radioactive material or any change in accelerator configuration, shielding, location, room shielding or configuration, nuclide production method, ventilation systems, rabbit or other delivery systems, operating or emergency procedures, radiation safety personnel, authorized users or operators, or other applicable provisions authorized pursuant to these rules.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0810
Supervision of PET Facilities

(1) Management must ensure that there is a qualified Radiation Safety Officer (RSO) who must oversee the radiation safety aspects of the PET facility and be responsible for radiation safety of the accelerator facility, pharmacy, and PET clinic.

(a) In the case of separate licenses for different components in a PET facility, there must be a cooperative consortium of management and radiation safety personnel that acts as directors for the facility.

(b) Management, whether singular or in consortium, must write a statement of authority and responsibility for all staff handling or controlling the production and use of PET isotopes.

(2) The RSO must be assisted by personnel specifically trained and designated for the area of concern, whether accelerator operation, pharmaceutical production, or PET clinic.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10

333-116-0820
Other Applicable Requirements

(1) The licensee must ensure that any radiopharmaceutical for which an Investigational New Drug (IND) status does not exist, or which must be used for research purposes in humans, is reviewed by an Institutional Review Board (IRB) or Human Subjects Review Board or Committee. The licensee must establish procedures, reviews, quality assurance, and emergency procedures for all procedures reviewed by the IRB. The IRB, the PET Radiation Safety Committee or subcommittee, and the PET or facility Radiation Safety Officer must review and approve any and all PET procedures, unless otherwise authorized in a radioactive materials license pursuant to OAR 333-102-0200.

(2) Transfers of radioisotopes must be in accordance with requirements in OAR 333-102-0330.

(3) PET facility radiation protection programs, occupational dose limits, radiation dose limits for the public, surveys and monitoring, restricted area control, storage of radioactive materials, internal exposure control, precautionary procedures, waste disposal, records, and reports must meet all applicable requirements of division 333-120.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0830
Accelerator Facility Requirements

((1) Accelerators must meet all requirements of division 333-109. Shielded-room accelerators must be equipped with interlocks and personnel control; self-shielded accelerators must be shielded such that personnel access is prevented during operation.

(2) Non-ionizing radiation must meet requirements of division 333-112.

(3) Target maintenance and repair, contamination control, and emergency actions must be conducted pursuant to division 333-120.

(4) There must be an Understanding of Transfer (UOT) when isotopes are transferred from one licensee or entity to another for processing, specifying at what point control is transferred to personnel handling radiochemical production or radiopharmacy operation.

(5) Radiation surveys must be made prior to any accelerator operation or isotope production with a radiation survey instrument calibrated in accordance with requirements in OAR 333-116-0390. Periodic surveys must be done throughout times of operation to ensure that radiation levels meet all applicable requirements in division 333-120 (Radiation Protection Standards).

(6) Ventilation controls must be implemented to ensure compliance with all applicable local, state, and federal requirements. Controls must include monitoring of stacks and computer modeling of air emissions to confirm compliance with standards.

(7) Real-time (integrating) monitors must be used to confirm requirements in OAR 333-120-0100, 333-120-0160, 333-120-0170, and 333-120-0180.

(8) Contamination wipes for radioactive material must be made pursuant to requirements in OAR 333-116-0250;

(9) Dosimetry must address both gamma and beta doses in all areas of the facility. Licensees and registrants must monitor extremities to ensure compliance with OAR 333-120-0100. Bioassays, as defined in 333-100-0005, are not required, but there must be evaluation of internal exposures, pursuant to 333-120-0130, based on calculated releases and monitoring.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0840
Safety Considerations and Quality Management for PET Facilities

(1) The licensee must establish and implement a Quality Management program pursuant to OAR 333-116-0125 for PET products, as well as other production and calibration products.

(2) PET instrumentation and other equipment unique to the PET process must meet all applicable radiation protection standards pursuant to division 120 of these rules.

(3) Area monitors must be visible and audible to accelerator operators. Monitors must be checked for proper operation daily.

(4) Wasted targets must be treated as radioactive waste and must be properly dismantled, shielded, stored, and disposed.

(5) Accelerator shielding design and safety must meet requirements of OAR 333-109-0025.

(6) Shielding around guide-bends, targets, hot-cells, purification manifolds, etc. must ensure that limits in OAR 333-120-0180 and 333-120-0190 have been met in all areas of beam and nuclide production.

(7) Security provisions for unauthorized access, janitorial services, maintenance, visitors, tours, and personnel-in-training must conform to requirements in OAR 333-120-0180, 333-120-0250 and 333-120-0260.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0850
Radiopharmacy and Radiochemical Production

(1) All preparations used in humans must meet the Oregon State Board of Pharmacy standards, as well as applicable federal Food and Drug Administration (FDA) requirements.

(a) All research products to be used in humans must be reviewed and approved by the licensee's or consortium Institutional Review Board (IRB).

(b) No research radiopharmaceutical must be used in a human being until its pyrogenicity and purity have been shown to meet applicable standards.

(2) Pharmacy or chemistry personnel must work directly under the supervision of a physician who meets the training criteria in OAR 333-116-0670.

(3) There must be no transfers between or among licensees unless there is a signed Memorandum or Understanding of Transfer. Such memorandum must preclude any transfers from one licensee entity to another if there is incomplete information, purity questions, or non-approval from the IRB.

(4) There must be a detailed description of the shielding and operation of the "black box" (hot cell).

(5) There must be operating and emergency, training, and survey procedures for ease of movement of the product within the pharmacy production area. Emergency procedures must address potential high dose rate emergencies such as stuck rabbit (transport container), pneumatic tube contamination, manifold leak or spill, hot cell emergency, or other incident.

(6) Equipment and procedures must include:

(a) Hood with continuous stack monitoring system and procedures to confirm air emission standards compliance;

(b) Remote handling equipment for very high dose rates (all handling must be done remotely);

(c) Dose calibration, system validation, and calibration standards, for all individual doses;

(d) Ba-133 must not be used as a calibration source;

(e) Dose calibrator linearity check using a positron emitter (beta shield must be evaluated to prevent interference with annihilation measurement);

(f) Product delivery system design, shielding, carrier, and emergency procedures;

(g) Leak tests (hermeticity) of delivery container;

(h) Labeling requirements, transportation manifests, and packaging for outside deliveries;

(i) Transportation requirements pursuant to division 333-118;

(j) Inventory control, "cradle to grave" tracking, and communication with PET clinic;

(k) Waste disposal procedures.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-116-0870
Rubidium-82 Generator

Rubidium-82 generators require quality assurance procedures for equipment, patient injection, waiting area, imaging, and post-imaging care. There also must be a procedure for spills, and a handling procedure for liquid quality assurance sources for early model PET cameras. Dose calibration procedures are the same as in OAR 333-116-0850(6).

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1995, f. & cert. ef. 4-26-95; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0880
Training and Experience for PET, PET/CT and SPECT/CT Personnel

(1) Pharmacy or chemistry personnel must have 40 extra hours above Nuclear Pharmacy requirements and 40 hours specific to PET. The 40 hours can be divided equally between didactic and practical applications.

(2) Authorized users who meet training requirements for human use in OAR 333-116-0670 must complete an additional 40 hours at an accepted PET training center.

(3) Technical personnel working under an authorized user must have basic radiation safety training, plus 40 additional hours specific to PET.

(4) Positron Emission-Computed Tomography (PET/CT) or Single Photon Emission-Computed Tomography (SPECT/CT) systems must be operated by technologists licensed by the Oregon Board of Medical Imaging who are:

(a) Any registered radiographer with the credential R.T. (R);

(b) Registered radiation therapist with the credential R.T. (T);

(c) Registered certified nuclear medicine technologist with the credentials R.T. (N); or

(d) Certified Nuclear Medicine Technologist (CNMT) by the Nuclear Medicine Technologist Certification Board (NMTCB).

(5) The individuals mentioned in section (4) of this rule must also have successfully completed appropriate additional education and training and demonstrated competency in the use and operation of PET/CT or SPECT/CT systems.

(6)(a) Appropriate additional training is considered training that covers the topic areas outlined in the PET/CT curriculum developed by the Multi-Organizational Curriculum Project Group sponsored by the American Society of Radiologic Technologists and the Society of Nuclear Medicine Technologists, or equivalent training approved by the Authority; and

(b) Includes the content specified in the PET/CT curriculum for the area(s) that the individual is not already trained or certified in; or

(c) Individuals meeting the requirements of section (4) of this rule and who have successfully completed training that the Authority has evaluated and judged to be substantially equivalent to that specified in subsection (6)(a) of this rule.

(7) An R.T. (N) or CNMT certified in Computed Tomography through the American Registry of Radiologic Technologists is considered to have met the training requirements in section (4) of this rule.

(8) Technologists operating PET/CT or SPECT/CT systems must do so under the direction of an authorized user licensed to perform imaging and localization studies in accordance with OAR 333-116-0320.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1995, f. & cert. ef. 4-26-95; PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2013, f. & cert. ef. 1-29-13

333-116-0905
Training for Authorized Medical Physicist

Except as provided in OAR 333-116-0740, the licensee shall require the authorized medical physicist to be an individual who:

(1) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in subsection (2)(b) and section (3) of this rule. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(b) Have two years of full-time practical training and supervised experience in medical physics:

(A) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(B) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in OAR 333-116-0740, 333-116-0690 or 333-116-0720; and

(c) Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(2) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization.

(a) This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services and must include:

(A) Performing sealed source leak tests and inventories;

(B) Performing decay corrections;

(C) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(D) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(b) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (1)(a) and (1)(b) of this rule, or subsection (2)(a) and section (3) of this rule, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in this rule, OAR 333-116-0740, 333-116-0905, or equivalent Agreement State requirements for an authorized medical

physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(3) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 4-2013, f. & cert. ef. 1-29-13; PH 25-2016, f. 8-26-16, cert. ef. 9-1-16

333-116-0910
Training for an Authorized Nuclear Pharmacist

Except as provided in OAR 333-116-0740, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(1) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in subsection (2)(b) of this rule. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(b) Hold a current, active license to practice pharmacy;

(c) Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

(d) Pass an examination in nuclear pharmacy administered by diplomats of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(2)(a) Has completed 700 hours in a structured educational program consisting of both:

(A) 200 hours of classroom and laboratory training in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(B) Supervised practical experience in a nuclear pharmacy involving:

(i) Shipping, receiving, and performing related radiation surveys;

(ii) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(iii) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(iv) Using administrative controls to avoid medical events in the administration of byproduct material; and

(v) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(b) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in subsections (1)(a), (1)(b), and (1)(c) or (2)(a) of this rule and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 25-2016, f. 8-26-16, cert. ef. 9-1-16

333-116-0915
Training for Experienced Nuclear Pharmacists

A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in OAR 333-116-0910(2)(a) before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement in 333-116-0910(2)(b) and recentness of training in 333-116-0760 to qualify as an authorized nuclear pharmacist.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-1000
Report and Notification of a Medical Event

(1) A licensee must report any medical event as defined in OAR 333-116-0020(19), except for an event that results from patient intervention..

(2) The licensee must notify by telephone the Authority no later than the next calendar day after discovery of the medical event.

(3) The licensee must submit a written report to the Authority within 15 days after discovery of the medical event.

(a) The written report must include:

(A) The licensee's name;

(B) The name of the prescribing physician;

(C) A brief description of the event;

(D) Why the event occurred;

(E) The effect, if any, on the individual(s) who received the administration;

(F) What actions, if any, have been taken or are planned to prevent recurrence; and

(G) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(b) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(4) The licensee must provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee must notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this rule, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee must inform the individual, or appropriate responsible relative or guardian that a written description of the event can be obtained from the licensee upon request. The licensee must provide such a written description if requested.

(5) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 25-2016, f. 8-26-16, cert. ef. 9-1-16

333-116-1015
Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child

(1) A licensee must report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(2) A licensee must report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual who:

(a) Is greater than 50 mSv (5 rem) total effective dose equivalent; or

(b) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(3) The licensee must notify the Authority by telephone no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in sections (1) or (2) of this rule.

(4) The licensee must submit a written report to the Authority within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in sections (1) or (2) of this rule.

(a) The written report must include:

(A) The licensee's name;

(B) The name of the prescribing physician;

(C) A brief description of the event;

(D) Why the event occurred;

(E) The effect, if any, on the embryo/fetus or the nursing child;

(F) What actions, if any, have been taken or are planned to prevent recurrence; and

(G) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

(b) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(5) The licensee must provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under sections (1) or (2) of this rule, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee must make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this rule, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee must inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee must provide such a written description if requested.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-1030
Report Of A Leaking Source

A licensee must file a report with the Authority within five days if a leak test required by OAR 333-116-0200 reveals the presence of 185 Bq (0.005 uCi) or more of removable contamination. The written report must include:

(1) The model number and serial number of the leaking source, if assigned;

(2) The radionuclide and its estimated activity;

(3) The results of the test;

(4) The date of the test; and

(5) The action taken.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

DIVISION 117

REGULATION AND LICENSING OF NATURALLY OCCURRING RADIOACTIVE MATERIALS (NORM)

333-117-0010
Purpose

This division establishes radiation protection standards for the possession, use, transfer and disposal of naturally occurring radioactive materials (NORM) not subject to regulation under the Atomic Energy Act of 1954, as amended.

Stat. Auth.: ORS 453.605 - 453.775
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

333-117-0020
Scope

(1) These rules apply to any person who engages in the extraction, mining, beneficiating, processing, use, transfer or disposal of NORM in such a manner as to technologically alter the natural sources of radiation or their potential exposure pathways to humans.

(2) The Rules in this division address the introduction of NORM into products in which neither the NORM nor the radiation emitted from the NORM is considered to be beneficial to the products. The manufacture and distribution of products containing NORM in which the NORM and/or its associated radiation(s) is considered to be a beneficial attribute are licensed under the provisions of division 102.

(3) This division also addresses waste management and disposal standards which apply to both inactive and active sites and facilities.

Stat. Auth.: ORS 453.605 - 453.745
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

333-117-0030
Definitions

As used in this division, the following definitions apply:

(1) "Beneficial Attribute" or "Beneficial to the Product" means that the radioactivity of the product is necessary to the use of the product.

(2) "Beneficiating" means the processing of materials for the purpose of altering the chemical or physical properties to improve the quality, purity or assay grade of a desired product.

(3) "General Environment" means the total terrestrial, atmospheric and aquatic environments outside sites within which any activity, operation or process authorized by a general or specific license issued under this Division is performed.

(4) "Naturally Occurring Radioactive Material (NORM)" means any nuclide which is radioactive in its natural physical state (i.e., not man-made), but does not include source or special nuclear material.

(5) "Working Level (WL)" means any combination of short-lived radon decay products in one liter of air that will result in the ultimate emission of alpha particles with a total energy of 130 billion electron volts. (2.1×10^{-8}J).

Stat. Auth.: ORS 453.605 - 453.745
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

333-117-0040
Exemptions

(1) Persons who receive, possess, use, process, transfer, distribute and dispose of NORM are exempt from the requirements of these Rules if: The materials contain or are contaminated at concentrations less than five picocuries per gram (185 Bq/kg) of radium, 0.05 percent by weight of uranium or thorium or 150 picocuries per gram (5.55 kBq/kg) of any other NORM radionuclide, provided that these concentrations are not exceeded at any time.

(2) Persons who receive products or materials containing NORM distributed in accordance with a specific license issued by the Agency pursuant to OAR 333-117-0220(2) or an equivalent license issued by another Licensing State are exempt from these rules.

(3) The manufacturing, distribution, use and disposal of the following products/materials are exempt from the requirements of these rules:

(a) Potassium and potassium compounds which have not been isotopically enriched in the radionuclide K-40; and

(b) Brazil nuts.

(4) The wholesale and retail distribution (including custom blending), possession and use of the following products/material are exempt from the requirements of these:

(a) Phosphate and potash fertilizer;

(b) Phosphogypsum for agricultural uses; and

(c) Materials used for building construction if such materials contain NORM which has not been technologically enhanced.

(5) The possession and use of natural gas and natural gas products as a fuel are exempt from the requirements of these rules. The distribution of natural gas and the manufacturing and distribution of natural gas products are exempt from the specific license requirements of this division but are subject to the general license requirements in OAR 333-117-0100 and 333-117-0130.

Stat. Auth.: ORS 453.605 - 453.745
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

333-117-0050
Effective Date

The provision and requirements of this division shall take effect January 1990 and shall apply to all facilities or sites owned or controlled by a person on that date. Products distributed and disposals made prior to that date are not subject to the provisions of this division.

Stat. Auth.: ORS 453.605 - 453.745
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

General License

333-117-0100
General License

(1) A general license is hereby issued to mine, extract, receive, possess, own, use, process and dispose of NORM not exempted in OAR 333-117-0040 without regard to quantity. This general license does not authorize the manufacturing or distribution of products containing NORM in concentrations greater than those specified in OAR 333-117-0040(1).

(2) Facilities and equipment contaminated with NORM in excess of the levels set forth in **Table 1** of this division shall not be released for unrestricted use. The decontamination or maintenance of such equipment and facilities shall only be performed by persons specifically licensed by the Agency or another Licensing State to conduct such work. Each general licensee shall establish written procedures for the evaluation (or screening) of equipment and components to ensure that the levels in **Table 1** of this division are not exceeded.

(3) No person shall transfer land for unrestricted use where the concentration of radium-226 or radium-228 in soil averaged over any 100 square meters exceeds the background level by more than:

(a) Five pCi/gm, averaged over the first 15 cm of soil below the surface; and

(b) Fifteen pCi/gm, averaged over 15 cm thick layers of soil more than 15 cm below the surface.

(4) Equipment contaminated with NORM in excess of the levels set forth in **Table 1** of this division may be released for maintenance and/or overhaul provided the recipient is specifically licensed to perform the activity on contaminated equipment. The decontamination or maintenance of equipment, facilities and land, as described in OAR 333-117-0200(2) shall only be performed by persons specifically licensed by the Agency or another Licensing State to conduct such work.

[ED. NOTE: Tables referenced are available from the agency.]
Stat. Auth.: ORS 453.605 - 453.745
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

333-117-0110
Protection of Workers During Operations

Each person subject to the general license in OAR 333-117-0100 shall conduct operations in compliance with the standards for radiation protection set out in division 111 and division 120, except for releases of radioactivity in effluents, which shall be governed by 333-117-0120 and disposal, which shall be governed by 333-117-0130.

Stat. Auth.: ORS 453.605 - 453.745
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

333-117-0120
Protection of the General Population from Releases of Radioactivity

Concentrations of radioactive material which may be released to the general environment in groundwater, surface water, air, soil, plants and animals shall not result in an annual dose above background exceeding an equivalent of 25 millirem (0.25 mSv) to the whole body or 75 millirem (0.75 mSv) to the critical organ of any member of the public. Doses due to radon-220, radon-222 and their respective decay products, are excluded from these limits. Effort shall be made to maintain releases of radioactivity in effluents to the general environment as low as is reasonably achievable.

Stat. Auth.: ORS 453.605 - 453.745
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

333-117-0130
Disposal and Transfer of Waste for Disposal

Each person subject to the general license in OAR 333-117-0100 shall manage and dispose of wastes containing NORM in accordance with the applicable requirements of the U.S. Environmental Protection Agency for disposal of such wastes or in a manner equivalent to the requirements for uranium and thorium byproduct materials in **40 CFR 192** or shall transfer wastes for disposal to a land disposal facility licensed by the U.S. Nuclear Regulatory Commission or an Agreement State or a Licensing State. Records of disposal including manifests, shall be maintained pursuant to the provisions of division 120. Transfers of waste containing NORM for disposal shall be made only to a person specifically licensed to receive such waste.

Stat. Auth.: ORS 453.605 - 453.745
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95

Specific License

333-117-0200
Specific License

(1) Unless otherwise exempted under the provisions of division 102 of the Rules, the manufacturing and distribution of any material or product containing NORM shall be specifically licensed pursuant to the requirements of this division or pursuant to equivalent regulations of another Licensing State.

(2) Persons conducting the following activities involving equipment and facilities contaminated with NORM in excess of the levels set forth in **Table 1** of this division shall be specifically licensed pursuant to the requirements of this division:

(a) Decontamination of equipment, facilities and land;

(b) Maintenance of equipment and facilities involving the exposure of individuals to radiation or radioactive materials; or

(c) Disposal of the resulting waste.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91

333-117-0210

Filing Application for Specific Licenses

(1) Applications for specific licenses shall be filed in a manner and on a form prescribed by the Agency.

(2) The Agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(3) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

(4) An application for a license may include a request for a license authorizing one or more activities.

(5) In an application, the applicant may incorporate by reference information contained in previous application, statements or reports filed with the Agency provided such references are clear and specific.

(6) Applications and documents submitted to the Agency may be made available for public inspection except that the Agency may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91

333-117-0220

Requirements for the Issuance of Specific Licenses

(1) A license application will be approved if the Agency determines that:

(a) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these rules in such a manner as to minimize danger to public health and safety or property;

(b) The applicant's proposed equipment, facilities and procedures are adequate to minimize danger to public health and safety or property;

(c) The issuance of the license will not be inimical to the health and safety of the public; and

(d) The applicant satisfies any applicable special requirement in this division.

(2) An application for a specific license to decontaminate or perform maintenance on equipment and facilities contaminated with NORM in excess of the levels set forth in **Table 1** of this division and to dispose of the resulting waste will be approved if:

(a) The applicant satisfies the general requirements specified in section (1) of this rule; and

(b) The applicant has adequately addressed the following items in the application:

(A) Procedures and equipment for protection of workers;

(B) An evaluation of the radiation levels and concentrations of contamination expected during normal operations;

(C) Operating and emergency procedures, including procedures for waste reduction and quality assurance of items released for unrestricted use; and

(D) Method of disposing of the radioactive material removed from contaminated equipment and facilities.

(3) An application for a specific license to manufacture and/or initially transfer products or materials containing NORM to persons exempted from these rules pursuant to OAR 333-117-0040(2) will be approved if:

(a) The applicant satisfies the general requirements specified in section (1) of this rule;

(b) The NORM is not contained in any food, beverage, cosmetic, drug or other commodity designed for ingestion or inhalation by or application to, a human being; and

(c) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking and conditions of handling, storage, use and disposal of the NORM material or product to demonstrate that the material or product will meet the safety criteria set forth in OAR 333-117-0230. The information shall include:

(A) A description of the material or product and its intended use or uses;

(B) The type, quantity and concentration of NORM in each material or product;

(C) The chemical and physical form of the NORM in the material or product and changes in chemical and physical form that may occur during the useful life of the material or product;

(D) An analysis of the solubility in water and body fluids of the NORM in the material or product;

(E) The details of manufacture and design of the material or product relating to containment and shielding of the NORM and other safety features under normal and severe conditions of handling, storage, use, reuse and disposal of the material or product;

(F) The degree of access of human beings to the material or product during normal handling, use and disposal;

(G) The total quantity of NORM expected to be distributed annually in the material or product;

(H) The expected useful life of the material or product;

(I) The proposed method of labeling or marking each unit of the material or product with identification of the manufacturer and/or initial transferor of the product and the radionuclide(s) and quantity of NORM in the material or product;

(J) Procedures for prototype testing of the material or product to demonstrate the effectiveness of the containment, shielding and other safety features under both normal and severe conditions of handling, storage, use, reuse and disposal;

(K) Results of the prototype testing of the material or product, including any change in the form of the NORM contained in it, the extent to which the NORM may be released to the environment, any change in radiation levels and any other changes in safety features;

(L) The estimated external radiation doses and dose commitments relevant to the safety criteria in OAR 333-117-0230 and the basis for such estimates;

(M) A determination that the probabilities with respect to doses referred to in OAR 333-117-0230 meet the criteria;

(N) Quality control procedures to be followed in the production of production lots of material or product and the quality control standards the material or product will be required to meet; and

(O) Any additional information, including experimental studies and tests, required by the Agency to facilitate a determination of the safety of the material or product.

(4) Notwithstanding the provisions of OAR 333-117-0230(2) the Agency may deny an application for a specific license if the end uses of the product are frivolous or cannot be reasonably foreseen.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91

333-117-0230

Safety Criteria

An applicant for a license under OAR 333-117-0220(3) shall demonstrate that the product is designed and will be manufactured so that:

(1) In normal use and disposal it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material, excluding radon and radon decay products, in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or

radioactive material from the material or product, will exceed the doses in **Column I** of **Table 2**.

(2) In normal handling and storage of the quantities of the material or product likely to accumulate in one location during marketing, distribution, installation and servicing of the material or product it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material, excluding radon, in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the material or product, will exceed the doses in **Column II** of **Table 2**.

(3) In normal use, disposal, handling and storage, it is unlikely that the radon released from the material or product will result in an average radon concentration in air of more than 0.4 picocurie per liter (14.8 Bq/m3).

(4) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding or other safety features of the material or product from wear and abuse likely to occur in normal handling and use of the material or product during its useful life.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 453.605 - 453.745

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91

333-117-0240

Issuance of Specific Licenses

(1) Upon a determination that an application meets the requirements of the Act and rules of the Agency, the Agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(2) The Agency may incorporate in any license at the time of issuance or thereafter by amendment, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to this division as it deems appropriate or necessary in order to:

(a) Minimize danger to public health and safety or property;

(b) Require such reports and the keeping of such records and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(c) Prevent loss or theft of material subject to this division.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91

333-117-0250

Conditions of Licenses Issued Under OAR 333-117-0220

(1) General Terms and Conditions:

(a) Each license issued pursuant to this division shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations and orders of the Authority;

(b) No license issued or granted under this division and no right to possess or utilize radioactive material granted by any license issued pursuant to this division shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Authority shall, after securing full information find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing;

(c) Each person licensed by the Authority pursuant to this division shall confine use and possession of the material licensed to the locations and purposes authorized in the license;

(d) Each person licensed by the Authority pursuant to this division is subject to the general license provisions of OAR 333-117-0110, 333-117-0120 and 333-117-0130;

(e) Each licensee shall notify the Authority, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the **United States Code (11 U.S.C.)** by or against:

(A) A licensee;

(B) An entity (as that term is defined in **11 U.S.C. 101 (14)**) controlling a licensee or listing the license of licensee as property of the estate; or

(C) An affiliate (as that term is defined in **11 U.S.C. 101 (2)**) of the licensee.

(f) The notification indicated in subsection(1)(e) of this rule must:

(A) Indicate the bankruptcy court in which the petition for bankruptcy was filed; and

(B) The date of the filing of the petition.

(2) Quality Control, Labeling and Reports of Transfer. Each person licensed under OAR 333-117-0220(2) shall:

(a) Carry out adequate control procedures in the manufacture of the material or product to assure that each production lot meets the quality control standards approved by the Authority;

(b) Label or mark each unit so that the manufacturer, processor, producer or initial transferor of the material or product and the NORM in the material or product can be identified; and

(c) Maintain records identifying, by name and address, each person to whom NORM is transferred for use under OAR 333-117-0040(2) or the equivalent regulations of another Licensing State and stating the kinds, quantities and uses of NORM transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Authority. Each report shall cover the year ending December 31, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to OAR 333-117-0220(2) during the reporting period, the report shall so indicate.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91

333-117-0260

Expiration and Termination of Licenses

(1) Except as provided in OAR 333-117-0270(2) and subsection (4)(c) of this rule, each specific license shall expire at the end of the specified day in the month and year stated therein.

(2) Each licensee shall notify the Authority immediately, in writing, and request termination of the license when the licensee decides to terminate all activities involving materials authorized under the license. This notification and request for termination of the license must include the reports and information specified in paragraph (4)(a)(D) of this rule. The licensee is subject to the provisions of sections (4) and (5) of this rule, as applicable.

(3) No less than 30 days before the expiration date specified in a specific license, the licensee shall either:

(a) Submit an application for license renewal under OAR 333-117-0270; or

(b) Notify the Authority in writing, under section (2) of this rule, if the licensee decides to discontinue all activities involving NORM.

(4) If a licensee does not submit an application for license renewal under OAR 333-117-0270, the licensee shall on or before the expiration date specified in the license:

(a) Terminate use of NORM;

(b) Remove radioactive contamination to the extent practicable;

(c) Properly dispose of NORM;

(d) Submit a record of disposal of radioactive material and radiation survey(s) to confirm the absence of NORM or to establish the levels of residual radioactive contamination, unless the licensee demonstrates the absence of residual radioactive contamination in some other manner. The licensee shall, as appropriate;

(e) Report levels of radiation in units of microrad per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces and report levels of radioactivity in units of disintegrations per minute (or microcuries) per 100 square centimeters removable and fixed on surfaces, microcuries per milliliter in water and picocuries per gram in contaminated solids such as soils or concrete; and

(f) Specify the instruments(s) used and certify that each instrument is properly calibrated and tested.

(5) If no radioactivity attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive contamination was found. If the Authority determines that the information submitted under subsection (4)(b) of this rule and paragraph (4)(a)(D) of this rule is adequate and surveys confirm the findings, the Authority will notify the licensee in writing that the license is terminated.

(6) If detectable levels of residual radioactivity attributable to activities conducted under the license are found, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual NORM until the Authority notifies the licensee in writing that the license is terminated. During this time, the licensee is subject to the provisions of section (5) of this rule and OAR 333-103-0010. In addition to the information submitted under paragraph (4)(a)(D) of this rule, the licensee shall submit a plan, if appropriate, for decontaminating the location(s) and disposing of the residual NORM.

(7) Each licensee who possesses residual radioactive material under subsection (4)(c) of this rule shall:

(a) Be limited to actions involving NORM related to preparing the location(s) for release for unrestricted use; and

(b) Continue to control entry to restricted areas until the location(s) are suitable for release for unrestricted use and the Authority notifies the licensee in writing that the license is terminated.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

333-117-0270
Renewal of Licenses

(1) Applications for renewal of specific licenses shall be filed in accordance with OAR 333-117-0210.

(2) In any case in which a licensee, not less than 30 days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the Authority.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

333-117-0280
Amendment of Licenses at Request of Licensee

Applications for amendment of a license shall be filed in accordance with OAR 333-117-0210 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

333-117-0290
Authority Action on Applications to Renew and Amend

In considering an application by a licensee to renew or amend the license, the Authority will apply the criteria set forth in OAR 333-117-0220.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

333-117-0300
Modification and Revocation of Licenses

(1) The terms and conditions of all licenses shall be subject to amendment, revision or modification or the license may be suspended or revoked by reason of amendments to the Act or by reason of rules, regulations and orders issued by the Authority.

(2) Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act or because of conditions revealed by such application or statement of fact or any report, record or inspection or other means which would warrant the Authority to refuse to grant a license on an original application or for violation of, or failure to observe any of the terms and conditions of the Act or of the license or of any rule, regulation or order of the Authority.

(3) Except in cases of willfulness or those in which the public health, interest or safety requires, otherwise, no license shall be modified, suspended or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

Reciprocity

333-117-0370
Reciprocal Recognition of Licenses

Subject to these Rules any person who holds a specific license from a Licensing State and issued by the authority having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in any calendar year provided that:

(1) The licensing document does not limit the activity authorized by such document to specified installations or locations.

(2) The out-of-state licensee notifies the Authority in writing at least three days prior to engaging in such activity. Such notification shall indicate the location, period and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Authority, obtain permission to proceed sooner. The Authority may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaged in activities under the general license provided in section (1) of this rule.

(3) The out-of-state licensee complies with all applicable rules of the Authority and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the Authority.

(4) The out-of-state licensee supplies such other information as the Authority may request.

(5) The out-of-state licensee shall not transfer or dispose of NORM possessed or used under the general license provided in section (1) of this rule except by transfer to a person:

(a) Specifically licensed by the Authority or by another Licensing State to receive such material; or

(b) Exempt from the requirements for a license for such material under OAR 333-117-0040.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91

DIVISION 118

TRANSPORTATION OF RADIOACTIVE MATERIAL

333-118-0010
Purpose and Scope

The rules in this division apply to any licensee authorized by specific or general license to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified in the license, or transports that material on public highways. No provision of this part authorizes possession of licensed material.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-118-0020
Definitions

As used in this division, the following definitions apply:

(1) "A1" means the maximum activity of special form radioactive material permitted in a Type A package. This value is either listed in Appendix A to10 CFR Part 71, Table A-1, or may be derived in accordance with the procedures prescribed in Appendix A to10 CFR Part 71.

(2) "A2" means the maximum activity of radioactive material, other than special form material, LSA, and SCO material, permitted in a Type A package. This value is either listed in Appendix A to10 CFR Part 71, Table A-1, or may be derived in accordance with the procedures prescribed in Appendix A to10 CFR Part 71.

(3) "Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

(4) "Closed transport vehicle" means a transport vehicle equipped with a securely attached exterior enclosure that during normal transportation restricts the access of unauthorized persons to the cargo space containing the radioactive material. The enclosure may be either temporary or permanent but shall limit access from top, sides, and ends. In the case of packaged materials, it may be of the "see-through" type.

(5) "Consignment" means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

(6) "Conveyance" means for transport by public highway or rail any transport vehicle or large freight container; or for transport by water any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; or for transport by aircraft.

(7) "Criticality Safety Index (CSI)" means the dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages containing fissile material during transportation. Determination of criticality safety index is described in 10 CFR 71.22, 71.23, and 71.59.

(8) "Deuterium" means for the purposes of 10 CFR Parts 71.15 and 71.22, deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000.

(9) "Exclusive use" means the sole use of a conveyance by a single consignor and for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier must ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the consignor.

NOTE: The term "exclusive use" is used interchangeably with the terms "sole use" or "full load" in other regulations, such as Title 49 of the Code of Federal Regulations.

(10) "Fissile material" means the radionuclides plutonium-239, plutonium-241, uranium-233, and uranium-235, or any combination of these radionuclides. Fissile material means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium, and natural uranium or depleted uranium that has been irradiated in thermal reactors only, are not included in this definition. Certain exclusions from fissile material controls are provided in 10 CFR 71.15.

NOTE: Authority jurisdiction is limited to special nuclear material in quantities not sufficient to form a critical mass as defined in division 100 of this chapter.

(11) "Fissile material package" means a fissile material packaging together with its fissile material contents.

(12) "Graphite" means for the purposes of 10 CFR 71.15 and 71.22 and graphite with a boron equivalent content less than five parts per million and density greater than 1.5 grams per cubic centimeter.

(13) "Indian tribe" means an Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a.

(14) "Licensed material" means radioactive or special nuclear material received, possessed, used, or transferred under a general or specific license issued by the Authority.

NOTE: The definition of licensed material in this division is used in the same way as in 49 CFR 173.403.

(15) "Low specific activity (LSA) material" means radioactive material with limited specific activity that is nonfissile or is exceptedunder 10 CFR 71.15, and that satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material must be in one of three groups:

(a) LSA-I:

(A) Ores containing only naturally occurring radionuclides, such as uranium and thorium, that are not intended to be processed for the use of these radionuclides;

(B) Solid unirradiated natural uranium, depleted uranium, natural thorium, or their solid or liquid compounds or mixtures;

(C) Radioactive material, other than fissile material, for which the A2 value is unlimited; or

(D) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with 10 CFR 71, Appendix A.

(b) LSA-II:

(A) Water with tritium concentration up to 0.8 TBq/liter (20.0 Ci/liter); or

(B) Material in which the radioactive material is distributed throughout, and the average specific activity does not exceed 10-4 A2/g for solids and gases, and 10-5 A2/g for liquids.

(c) LSA-III. Solids (consolidated wastes, activated materials) in which:

(A) The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, and ceramic);

(B) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for seven days, shall not exceed 1E-1 A2; and

(C) The estimated average specific activity of the solid does not exceed 2E-3 A2 per gram.

(16) "Low toxicity alpha emitters" means natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than 10 days.

(17) "Natural thorium" means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

(18) "Normal form radioactive material" means radioactive material that has not been demonstrated to qualify as "special form radioactive material."

(19) "Package" means the packaging together with its radioactive contents as presented for transport.

(a) Fissile material package or Type AF package, Type BF package, Type B(U)F package, or Type B(M)F package means a fissile material packaging together with its fissile material contents.

(b) Type A package means a Type A packaging together with its radioactive contents. A Type A package is defined and must comply with the DOT regulations in 49 CFR part 173.

(c) Type B package means a Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kPa (100 lbs/in2)

gauge or a pressure relief device that may allow the release of radioactive material to the environment under the tests specified in 10 CFR 71.73 (hypothetical accident conditions), in which case it shall receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in 49 CFR Part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in 10 CFR 71.19.

(20) "Packaging" means the assembly of components necessary to ensure compliance with the packaging requirements of 10 CFR Part 71.4. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

(21) "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189 and Parts 390-397.

(22) "Regulations of the U.S. Nuclear Regulatory Commission" means the regulations in 10 CFR 71.

(23) "Special form radioactive material" means radioactive material that satisfies the following conditions:

(a) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(b) The piece or capsule has at least one dimension not less than five millimeters (0.2 inch.); and

(c) It satisfies the requirements of 10 CFR Part 71.75. A special form encapsulation designed in accordance with the requirements of 10 CFR Part 71.4 in effect on June 30, 1983 (see 10 CFR Part 71, revised as of January 1, 1983), and constructed before July 1, 1985 and a special form encapsulation designed in accordance with the requirements of 10 CFR Part 71.4 in effect on March 31, 1996 (see 10 CFR Part 71, revised as of January 1, 1983), and constructed before April 1, 1998, may continue to be used. Any other special form encapsulation must meet the specifications of this definition.

(24) "Specific activity" of a radionuclide means the radioactivity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

(25) "State" means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(26) "Surface contaminated object (SCO)" means a solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO must be in one of two groups with surface activity not exceeding the following limits:

(a) SCO-I: a solid object on which:

(A) The non-fixed contamination on the accessible surface averaged over 300 cm2 (or the area of the surface if less than 300 cm2) does not exceed 4 Bq/cm2 (10-4 microcurie/cm2) for beta, gamma and low toxicity alpha emitters, or 0.4 Bq/cm2 (10-5 microcurie/cm2) for all other alpha emitters;

(B) The fixed contamination on the accessible surface averaged over 300 cm2 (or the area of the surface if less than 300 cm2) does not exceed 4x104 Bq/cm2 (1.0 microcurie/cm2) for beta, gamma and low toxicity alpha emitters, or 4x103 Bq/cm2 (0.1 microcurie/cm2) for all other alpha emitters; and

(C) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm2 (or the area of the surface if less than 300 cm2) does not exceed 4x104 Bq/cm2 (1 microcurie/cm2) for beta, gamma and low toxicity alpha emitters, or 4x103 Bq/cm2 (0.1 microcurie/cm2) for all other alpha emitters.

(b) SCO-II: a solid object on which the limits for SCO-I are exceeded and on which:

(A) The nonfixed contamination on the accessible surface averaged over 300 cm2 (or the area of the surface if less than 300 cm2) does not exceed 400 Bq/cm2 (10-2 microcurie/cm2) for beta and gamma and low toxicity alpha emitters or 40 Bq/cm2 (10-3 microcurie/cm2) for all other alpha emitters;

(B) The fixed contamination on the accessible surface averaged over 300 cm2 (or the area of the surface if less than 300 cm2) does not exceed 8 x 105 Bq/cm2 (20 microcuries/cm2) for beta and gamma and low toxicity alpha emitters, or 8 x 104 Bq/cm2 (2 microcuries/cm2) for all other alpha emitters; and

(C) The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm2 (or the area of the surface if less than 300 cm2) does not exceed 8 x 105 Bq/cm2 (20 microcuries/cm2) for beta and gamma and low toxicity alpha emitters, or 8 x 104 Bq/cm2 (2 microcuries/cm2) for all other alpha emitters.

(27) "Transport index (TI)" means the dimensionless number, (rounded up to the next tenth) placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at one meter (3.3 ft) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at one meter (3.3 ft)).

(28) "Tribal official" means the highest ranking individual that represents Tribal leadership, such as the Chief, President, or Tribal Council leadership.

(29) "Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A1 for special form radioactive material or A2 for normal form radioactive material, where A1 and A2 are given in 10 CFR Part 71 Appendix A or may be determined by procedures described in 10 CFR Part 71 Appendix A.

(30) "Type A package" means a packaging that, together with its radioactive contents limited to A1 or A2 as appropriate, meets the requirements of 49 CFR 173.410 and 173.412 and is designed to retain the integrity of containment and shielding under normal conditions of transport as demonstrated by the tests set forth in 173.465 or 173.466, as appropriate.

(31) "Type B package" means a Type B packaging together with its radioactive contents.

NOTE: A Type B package design is designated as B(U) or B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, refer to 49 CFR Part 173. A Type B package approved prior to September 6, 1983, was designated only as Type B. Limitations on its use are specified in OAR 333-118-0035.

(32) "Type B packaging" means a packaging designed to retain the integrity of containment and shielding when subjected to the normal conditions of transport and hypothetical accident test conditions set forth in 10 CFR Part 71.

(33) "Type B quantity" means a quantity of radioactive material greater than Type A quantity.

NOTE: 10 CFR Part 71 Appendix A referred to or incorporated by reference in this rule is attached to this division or available from the Authority.

(34) "Unirradiated uranium" means uranium containing not more than 2E+3 Bq of plutonium per gram of uranium-235, not more than 9E+6 Bq of fission products per gram of uranium-235, and not more than 5E-3 g of uranium-236 per gram of uranium-235.

(35) "Uranium — natural, depleted, enriched":

(a) "Natural uranium" means uranium isotopes with the naturally occurring distribution of uranium, isotopes (which is approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238).

(b) "Depleted uranium" means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

(c) "Enriched uranium" means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

[ED. NOTE: Tables and Appendices referenced are available from the agency.]

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 24-2014, f. & cert. ef. 8-15-14

General Regulatory Provisions

333-118-0030
Requirement for License

No person shall transport radioactive material or deliver radioactive material to a carrier for transport except as authorized in a general or specific license issued by the Authority or as exempted in OAR 333-118-0040.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 4-2007, f. & cert. ef. 3-1-07

333-118-0040
Exemptions

(1) Common and contract carriers, freight forwarders, warehouse workers, and the U.S. Postal Service are exempt from the regulations in this division and divisions 102, 105, 113, 116, 121 and 125, and the requirements for a license to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto. Common and contract carriers who are not subject to the requirements of the U.S. Department of Transportation or U.S. Postal Service are subject to OAR 333-118-0030 and other applicable requirements of these rules.

(2) Any licensee is exempt from the requirements of this division to the extent that the licensee delivers to a carrier for transport a package containing radioactive material having a specific activity not greater than (0.002 microcurie per gram 70 Becquerels per gram (Bq/g).

(3) Any physician licensed under division 116 or by an Agreement State or the Nuclear Regulatory Commission to dispense radiopharmaceuticals in the practice of medicine, is exempt from OAR 333-118-0050 with respect to transporting licensed material for use in the practice of medicine.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2013, f. 12-26-13, cert. ef. 1-1-14; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-118-0050
Transportation of Licensed Material

(1) Each licensee who transports licensed material outside the site of usage, as specified in the Authority license, or where transport is on public highways, or who delivers licensed material to a carrier for transport shall:

(a) Comply with the applicable requirements, appropriate to the mode of transport, of the regulations of the U.S. Department of Transportation in 49 CFR Parts 107, 171-180, and 390-397, appropriate to the mode of transportation. The licensee shall particularly note the regulations of U.S. Department of Transportation in the following areas:

(A) Packaging — 49 CFR Part 173: Subparts A, B and I.

(B) Marking and labeling — 49 CFR Part 172: Subpart D, 172.400 through 172.407, and 172.436 through 172.441 of Subpart E.

(C) Placarding — 49 CFR Part 172: Subpart F, especially 172.500 through 172.519, and 172.556, and Appendices B and C.

(D) Accident reporting — 49 CFR Part 171: 171.15 and 171.16.

(E) Shipping papers and emergency information — 49 CFR Part 172: Subparts C and G.

(F) Hazardous material employee training — 49 CFR Part 172: Subpart H.

(G) Security plans — 49 CFR Part 172: Subpart I

(H) Hazardous material shipper/carrier registration — 49 CFR Part 107: Subpart G.

(b) The licensee also shall comply with applicable U.S. Department of Transportation regulations pertaining to the following modes of transportation:

(A) Rail — 49 CFR Part 174: Subparts A through D and K.

(B) Air — 49 CFR Part 175.

(C) Vessel — 49 CFR Part 176: Subparts A through F and M.

(D) Public highway — 49 CFR Part 177 and Parts 390 through 397.

(c) Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee.

(2) If, for any reason, the regulations of the U.S. Department of Transportation are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of 49 CFR Parts 170 through 189 appropriate to the mode of transport and to the same extent as if the shipment were subject to the regulations.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10

333-118-0051
Deliberate Misconduct

(1) This rule applies to any:

(a) Licensee;

(b) Certificate holder;

(c) Quality assurance program approval holder;

(d) Applicant for a license, certificate, or quality assurance program approval;

(e) Contractor (including a supplier or consultant) or subcontractor, to any person identified in subsection (1)(d) of this section; or

(f) Employees of any person identified in subsections (1)(a) through (e) of this rule.

(2) A person identified in subsections (1)(a) through (f) of this rule who knowingly provides to an entity any components, materials, or other goods or services that relate to a licensee's, certificate holder's, quality assurance program approval holder's, or applicant's activities subject to this rule may not:

(a) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate holder, quality assurance program approval holder, or any applicant to be in violation of any rule, regulation, or order; or any term, condition or limitation of any license, certificate, or approval issued by the Authority; or

(b) Submit to the Authority, a licensee, a certificate holder, quality assurance program approval holder, an applicant for a license, certificate or quality assurance program approval, or a licensee's, applicant's, certificate holder's, or quality assurance program approval holder's contractor or subcontractor, information that the person knows to be incomplete or inaccurate.

(3) A person who violates section (2) of this rule may be subject to enforcement action by the Authority.

(4) For the purposes of section (2) of this rule, deliberate misconduct means an intentional act or omission that the person knows:

(a) Would cause a licensee, certificate holder, quality assurance program approval holder, or applicant for a license, certificate, or quality assurance program approval to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license or certificate issued by the Authority; or

(b) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate holder, quality assurance program approval holder, applicant, or the contractor or subcontractor of any of them.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 4-2010, f. & cert. ef. 2-16-10

333-118-0052
Exemption for Low Level Materials

A licensee is exempt from all the requirements of division 118 with respect to shipment or carriage of the following low-level materials:

(1) Natural material and ores containing naturally occurring radionuclides that are not intended to be processed for use of these radionuclides, provided the activity concentration of the material does not exceed 10 times the values specified in 10 CFR Parts 71, Appendix A, Table A-2.

(2) Materials for which the activity concentration is not greater than the activity concentration values specified in 10 CFR Parts 71, Appendix A, Table A-2, or for which the consignment activity is not greater than the limit for an exempt consignment found in 10 CFR Parts 71, Appendix A, Table A-2.

[ED. NOTE: Tables referenced are available from the agency.]
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 4-2010, f. & cert. ef. 2-16-10

333-118-0053
Exemption from Classification as Fissile Material

Fissile material meeting the requirements of at least one section of this rule are exempt from classification as fissile material and from the fissile material package standards of 10 CFR Parts 71.55 and 71.59, but are subject to all other requirements of this rule, except as noted.

(1) Individual package containing two grams or less fissile material.

(2) Individual or bulk packaging containing 15 grams or less of fissile material provided the package has at least 200 grams of solid nonfissile material for every gram of fissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass for solid nonfissile material.

(3) Low concentrations of solid fissile material commingled with solid nonfissile material, provided that:

(a) There is at least 2000 grams of solid nonfissile material for every gram of fissile material; and

(b) There is no more than 180 grams of fissile material distributed within 360 kg of contiguous nonfissile material.

(4) Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass of solid nonfissile material.

(5) Uranium enriched in uranium-235 to a maximum of one percent by weight, and with total plutonium and uranium-233 content of up to one percent of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than five percent of the uranium mass.

(6) Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of two percent by mass, with a total plutonium and uranium-233 content not exceeding 0.002 percent of the mass of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of two. The material must be contained in at least a DOT Type A package.

(7) Packages containing, individually, a total plutonium mass of not more than 1000 grams, of which not more than 20 percent by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 4-2010, f. & cert. ef. 2-16-10

General Licenses

333-118-0060
General Licenses for Carriers

(1) A general license is hereby issued to any common or contract carrier not exempt under OAR 333-118-0040 to receive, possess, transport, and store radioactive material in the regular course of their carriage for others or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation, insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.

NOTE: Notification of an incident shall be filed with, or made to, the Authority as prescribed in 49 CFR, regardless of and in addition to the notification made to the U.S. Department of Transportation or other agencies.

(2) A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation, insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.

(3) Persons who transport radioactive material pursuant to the general licenses in sections (1) or (2) of this rule are exempt from the requirements of divisions 111 and 120 of these rules to the extent that they transport radioactive material.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

333-118-0070
General License: Nuclear Regulatory Commission-Approved Packages

(1) A general license is hereby issued to any licensee of the Authority to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, Certificate of Compliance (CoC), or other approval has been issued by the U.S. Nuclear Regulatory Commission.

(2) This general license applies only to a licensee who:

(a) Has a quality assurance program approved by the Nuclear Regulatory Commission as satisfying the provisions of 10 CFR Part 71, Subpart H and applicable requirements in OAR 333-118-0200;

(b) Has a copy of the specific license, certificate of compliance, or other approval by the Nuclear Regulatory Commission of the package and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;

(c) Complies with the terms and conditions of the license, certificate, or other approval by the Nuclear Regulatory Commission, as applicable, and the applicable requirements of division 118; and

(d) Prior to the licensee's first use of the package, has registered with the U.S. Nuclear Regulatory Commission outlined in 10 CFR Part 71.17.

(3) The general license in section (1) of this rule applies only when the package approval authorizes use of the package under this general license.

(4) For previously approved Type B packages which are not designated as either B(U) or B(M) in the Certificate of Compliance, this general license is subject to additional restrictions in OAR 333-118-0080. For a Type B or fissile material package, the design of which was approved by Nuclear Regulatory Commission before April 1, 1996, the general license is subject to additional restrictions of OAR 333-118-0080.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10

333-118-0080
General License: Previously Approved Packages

(1) A Type B package previously approved by the U.S. Nuclear Regulatory Commission, but not designated as B(U) or B(M) in the Certificate of Compliance, may be used under the general license of OAR 333-118-0070 with the following additional limitations:

(a) Fabrication of the packaging was satisfactorily completed before August 31, 1986, as demonstrated by application of its model number in accordance with U.S. Nuclear Regulatory Commission regulations at 10 CFR 71.85(c); and

(b) The package may not be used for a shipment to a location outside the United States except when approved under special arrangement in accordance with 49 CFR 173.471. A package used for a shipment to a location outside the United States is subject to multilateral approval, as defined in U.S. Department of Transportation regulations at 49 CFR 173.403; and

(c) A serial number that uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging.

(2) A Type B(U) package, a Type B(M) package, a low specific activity (LSA) material package or a fissile material package, previously approved by the Nuclear Regulatory Commission but without the designation "-85" in the identification number of the Nuclear Regulatory Commission certificate of compliance, may be used under the general license of OAR 333-118-0070 with the following additional conditions:

(a) Fabrication of the package is satisfactorily completed by April 1, 1999, as demonstrated by application of its model number in accordance with Nuclear Regulatory Commission regulations at 10 CFR 71.85(c);

(b) A package used for a shipment to a location outside the United States is subject to multilateral approval except approved under special arrangement in accordance with U.S. Department of Transportation regulations at 49 CFR 173.403; and

(c) A serial number that uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-118-0090
General License: U.S. Department of Transportation Specification Container

(1) A general license is issued to any licensee of the Authority to transport, or to deliver to a carrier for transport, licensed material in a specification container containing a fissile material or a Type B quantity of radioactive material as specified in 49 CFR Parts 173 and 178.

(2) This general license applies only to a licensee who has a quality assurance program required by OAR 333-118-0200 and approved by the Authority.

(a) Has a copy of the specification;

(b) Complies with the terms and conditions of the specification and the applicable requirements of division 118; and

(c) Has a quality assurance program required by OAR 333-118-0200.

(3) The general license in this rule is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States except by multilateral approval as defined in 49 CFR 173.403.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

333-118-0100
General License: Use of Foreign Approved Package

(1) A general license is issued to any licensee of the Authority to transport, or to deliver to a carrier for transport, licensed material in a package the design of which has been approved in a foreign national competent authority certificate which has been revalidated by the U.S. Department of Transportation as meeting the applicable requirements of 49 CFR 171.12.

(2) This general license applies only to international shipments.

(3) This general license applies only to a licensee who:

(a) Has a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;

(b) Complies with the terms and conditions of the certificate and revalidation and with the applicable requirements of this division.

(c) Has a quality assurance program approved by the Nuclear Regulatory Commission.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

333-118-0110
General License: Fissile Material

A general license is issued to any licensee of the Authority to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with 10 CFR Part 71.22.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-

1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10

333-118-0120
General License: Plutonium Beryllium Special Form Material

A general license is issued to any licensee of the Authority to transport fissile material in the form of plutonium-beryllium (Pu-Be) special form sealed sources, or to deliver Pu-Be sealed sources to a carrier for transport, if the material is shipped in accordance with 10 CFR Part 71.23.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10

333-118-0125
External Radiation Standards for All Packages

Each package of radioactive materials offered for transportation must be designed and prepared for shipment so that under conditions normally incident to transportation the radiation level does not exceed 2 mSv/h (200 mrem/h) at any point on the external surface of the package, and the transport index does not exceed 10. A package that exceeds the radiation level must be transported by exclusive use shipment only, and the radiation levels for such shipment must be in accordance with 10 CFR Part 71.47.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 4-2010, f. & cert. ef. 2-16-10

Operating Controls and Procedures

333-118-0130
Fissile Material: Assumptions as to Unknown Properties of Fissile Material

When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties had credible values that would cause the maximum neutron multiplication.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

333-118-0140
Preliminary Determinations

Prior to the first use of any packaging for the shipment of radioactive material:

(1) The licensee shall show that there are no cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce the effectiveness of the packaging;

(2) Where the maximum normal operating pressure will exceed 35 kilopascals (five pounds per square inch (psi)) gauge, the licensee shall test the containment system at an internal pressure at least 50 percent higher than the maximum normal operating pressure to show that the system will maintain its structural integrity at that pressure;

(3) The licensee shall determine that the packaging meets 10 CFR Part 71.85(b); and

(4) The licensee shall conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number as assigned by the U.S. Nuclear Regulatory Commission.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10

333-118-0150
Routine Determinations

Prior to each shipment of licensed material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this division and of the license. The licensee shall determine that:

(1) The package is proper for the contents to be shipped.

(2) The package is in unimpaired physical condition except superficial defects such as marks or dents.

(3) Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects.

(4) Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid.

(5) Any pressure relief device is operable and set in accordance with written procedures.

(6) The package has been loaded and closed in accordance with written procedures.

(7) Any structural part of the package which could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements specified in 10 CFR 71.45.

(8) For fissile material, any moderator or neutron absorber, if required, is present and in proper condition.

(9) The level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable and within the limits specified in Department of Transportation regulations outlined in 49 CFR Part 173.443.

(a) External radiation levels around the package and around the vehicle, if applicable, cannot exceed the limits specified in 10 CFR Part 71.47 at anytime during transportation; and

(b) Accessible package surface temperatures cannot exceed the limits specified in 10 CFR Part 71.43(g) at any time during transportation.

(10) External radiation levels around the package and around the vehicle, if applicable, cannot exceed the limit specified in 10 CFR Part 71.45 at any time during transport.

(11) Accessible package surfaces temperatures cannot exceed the limits specified in 10 CFR Part 71.43.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 4-2013, f. & cert. ef. 1-29-13

333-118-0160
Air Transport of Plutonium

(1) Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this division or included indirectly by citation of the U.S. Department of Transportation regulations 49 CFR Chapter I, as may be applicable, the licensee shall assure that plutonium in any form is not transported by air, or delivered to a carrier for air transport, unless:

(a) The plutonium is contained in a medical device designed for individual human application;

(b) The plutonium is contained in a material in which the specific activity is less than or equal to the activity concentration values for plutonium specified in 10 CFR Part 71, Appendix A, Table A-2 and in which the radioactivity is essentially uniformly distributed;

(c) The plutonium is shipped in a single package containing no more than an A2 quantity of plutonium in any isotope or form and is shipped in accordance with OAR 333-118-0050 and 10 CFR Part 71.5; or

(d) The plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the Certificate of Compliance for that package issued by the Nuclear Regulatory Commission Part.

(2) Nothing in OAR 333-118-0160(1)(a) is to be interpreted as removing or diminishing the requirements in 10 CFR Part 73.24.

(3) For a shipment of plutonium by air, which is subject to OAR 333-118-0160(1)(d), the licensee shall, through special arrangement with the carrier, require compliance with 49 CFR 175.704, U.S. Department of Transportation regulations applicable to the air transport of plutonium.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10

333-118-0162
Opening Instructions

Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with 10 CFR 20.1906(e).

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 4-2010, f. & cert. ef. 2-16-10

333-118-0170
Shipment Records

Each licensee shall maintain for a period of three years after shipment, or until inspected by the Authority, a record of each shipment of licensed material not exempt under OAR 333-118-0040, showing, where applicable:

(1) Identification of the packaging by model and serial number;

(2) Verification that the packaging, as shipped, had no significant defects;

(3) Volume and identification of coolant;

(4) Type and quantity of licensed material in each package, and the total quantity of each shipment;

(5) Date of the shipment;

(6) Name and address of the transferee;

(7) Address to which the shipment was made; and

(8) Results of the determinations required by OAR 333-118-0150.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

333-118-0180
Reports

The licensee shall report to the Authority within 30 days:

(1) Any instance in which there is significant reduction in the effectiveness of any approved Type B or fissile packaging during use; and

(2) Details of any defects with safety significance in the Type B or fissile packaging after first use, with the means employed to repair the defects and prevent their recurrence or

(3) Instances in which the conditions of approval in the certificate of compliance were not observed in making a shipment.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

333-118-0190
Advance Notification of Transport of Nuclear Waste

Nuclear waste transports shall be transported as specified in 10 CFR Part 71.97.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10; PH 24-2014, f. & cert. ef. 8-15-14; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

Quality Assurance

333-118-0200
Quality Assurance Requirements

(1) Each licensee shall establish and maintain a Quality Assurance program specified by the Nuclear Regulatory Commission, 10 CFR, Subpart H, Parts 71.101 through 71.137.

(2) Licensees shall provide the Authority their Quality Assurance program or plans for review and approval by the Authority.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10

333-118-0800
Referenced Materials

(1) This division of OAR chapter 333 incorporates by reference material originally published elsewhere. Certified copies of the complete text of incorporated materials referenced are available for public inspection during regular business hours at the Radiation Protection Services Office. Copies of referenced material will be provided at cost upon request. Information regarding how the incorporated material may be obtained or examined is available from Radioactive Materials Program, Radiation Protection Services, 800 NE Oregon Street, Portland, Oregon 97232.

(2) Material referenced in this division does not include amendments to or revised editions of the material published later than the effective date of the relevant section.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

DIVISION 119

REGISTRATION OF TANNING FACILITIES

333-119-0001
Purpose and Scope

(1) The purpose of this division is to regulate tanning facilities to minimize the risks associated with tanning by artificial Ultraviolet light. These risks include, but may not be limited to:

(a) Sunburn;
(b) Premature aging of the skin;
(c) Skin cancer;
(d) Retinal damage;
(e) Formation of cataracts;
(f) Suppression of the immune system;
(g) Damage to the vascular system; and
(h) Improper sanitation of tanning devices.

(2) The requirements of this division apply to any tanning facility that operates any tanning devices. Physicians' phototherapy devices are exempted, see OAR 333-119-0130(2).

(3) In addition to the requirements of this division, all registrants are subject to the applicable provisions of other parts of these rules.

Stat. Auth.: ORS 431.925 - 431.955
Stats. Implemented: ORS 431.925 - 431.955
Hist.: HD 15-1991, f. & cert. ef. 10-1-91; PH 14-2008, f. & cert. ef. 9-15-08

333-119-0010
Definitions

(1) "Authority" means the Oregon Health Authority.

(2) "Customer" means any member of the public who is provided access to a tanning device in exchange for a fee or other compensation, or any individual who, in exchange for a fee or other compensation, is afforded use of a tanning device as a condition or benefit of membership or access.

(3) "Employee" means any individual, including a minor whether lawfully or unlawfully employed, who engages to furnish services for remuneration, financial or otherwise, subject to the

direction and control of an employer and includes any individual who is required to have workers' compensation coverage.

(4) "EPA" means the U.S. Environmental Protection Agency.

(5) "FDA" means the U.S. Food and Drug Administration.

(6) "Fitzpatrick Skin Type Scale" means a numerical classification diagram used as a way to classify the response of different types of skin to ultraviolet (UV) light.

(7) "Formal Training" means a course of instruction reviewed and approved by the Authority and which is conducted or presented under formal classroom conditions or online by a qualified expert possessing adequate knowledge and experience to offer a curriculum, associated training, and certification testing pertaining to and associated with the correct use of tanning equipment. Operator training shall cover ultraviolet radiation and effects on the skin, photosensitivity, FDA and State of Oregon regulations, eye protection, and equipment maintenance.

(8) "Handrails" means a suitable physical aid that will help to maintain proper exposure distance.

(9) "Identification" means:

(a) A government-issued photo identification that displays the individual's date of birth; or

(b) A government or non-government issued photo identification when submitted with a completed Oregon Underage Tanning Medical Recommendation form.

(10) "Individual" means any human being.

(11) "Minor" means any individual under the age of 18 years old.

(12) "Operator" means the person who is an employee (defined by the Oregon Occupational Safety and Health Division, OAR 437-003-0011(2)) or contractor of the tanning facility who has received a certificate from an approved formal training course and who is responsible for any of the following:

(a) Determining customer's skin type;

(b) Determining the suitability for use of a tanning device;

(c) Providing information regarding the dangers of ultraviolet radiation exposure including photoallergic reactions and photosensitizing agents;

(d) Assuring that all required forms are understood and properly signed by the customer;

(e) Maintaining required exposure records;

(f) Recognizing and reporting injuries or alleged injuries to the registrant;

(g) Determining the customer's exposure schedule;

(h) Setting timers which control the duration of exposure;

(i) Instructing the customer in the proper use of protective eyewear;

(j) Verifying and documenting age of clients; and

(k) Sanitizing tanning devices.

(13) "Other Compensation" means the payment or exchange of goods, services or anything of value for use of the tanning device or devices.

(14) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent or agency of these entities.

(15) "Phototherapy Device" means equipment that emits ultraviolet radiation used by a health care professional in the treatment of disease or illness.

(16) "Program" means the Radiation Protection Services section of the Public Health Division.

(17) "Protective Eyewear" means suitable eyewear that protects the eye from ultraviolet radiation and allows adequate vision.

(18) "Public Places" means the area where members of the public may assemble and are not directly affected by tanning operations.

(19) "Recommendation" means a written directive using a form provided by the Authority and signed by a licensed physician.

(20) "Registrant" means a tanning facility registered with the Authority as required by provisions of this division.

(21) "Registration" means registration with the Authority in accordance with provisions of this division.

(22) "Remote" means a timer that is placed away from the tanning device so it can only be programmed by the tanning operator.

(23) "Safe Level" means not more than 50 colonies of microorganisms per four square inches of equipment surface.

(24) "Sanitize" means the effective bactericidal treatment of surfaces of equipment and devices by an EPA or FDA registered product that provides a sufficient concentration of chemicals, and enough time to reduce the bacterial count, including pathogens, to a safe level.

(25) Skin Types:

(a) "Type 1" means skin burns easily and severely (painful burn); tans little or none and peels.

(b) "Type 2" means skin burns easily and severely (painful burn); tans minimally or lightly and also peels.

(c) "Type 3" means skin burns moderately and tans about average.

(d) "Type 4" means skin burns minimally, tans easily and above average with each exposure; exhibits immediate pigment darkening reaction.

(e) "Type 5" means skin rarely burns, tans easily and substantial; always exhibits immediate pigment darkening reaction

(26) "Storage" means when a tanning device is not actively being used, as evidenced by the removal of all tanning lamps and lack of connection to a power supply.

(27) "Tanning Device" means any equipment used for tanning of the skin, that emits electromagnetic radiation with wavelengths in the air between 200 and 400 nanometers including, but not limited to, a sunlamp, Ultraviolet Lamp, tanning booth, facial unit, UVA wand, or tanning bed. "Tanning device" also means any accompanying equipment, including, but not limited to, protective eyewear, timers, ballasts, starters, lamps, reflectors, cooling fans, acrylics, comfort pillows and handrails.

(28) "Tanning Facility" means any location, place, area, structure, or business that provides persons access to any tanning device.

(29) "Timer" means an electronic device designed specifically to terminate tanning sessions at a preset time interval.

(30) "Ultraviolet Radiation" means radiation that has a wavelength between two hundred nanometers and four hundred nanometers.

Stat. Auth.: ORS 431.925 - 431.955
Stats. Implemented: ORS 431.925 - 431.955
Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 20-2010, f. & cert. ef. 9-1-10; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 14-2013, f. 12-26-13, cert. ef. 1-1-14; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-119-0020
Registration

(1) Prior to the operation of any tanning device used by the public for a fee or other compensation, the owner or operator shall file an application with the Authority and pay applicable fee(s) in the amount and in the manner specified in OAR 333-103-0025 to register each tanning device.

(2) If the owner or operator owns or operates more than one such tanning facility, the owner or operator shall file a separate application for each such facility owned or operated.

(3) Registration application shall be made on forms furnished by the Authority.

(4) A validation certificate or acknowledgement of validation will be issued by the Authority.

(5) The certificate issued by the Authority shall be effective for one year beginning January 1 through December 31.

(6) The certificate shall be displayed in a conspicuous open public area of the tanning facility.

(7) The Authority will provide an identification number that will be affixed by an Authority inspector to each tanning device during the initial or follow-up facility inspection:

(a) Identification numbers shall not be removed without written permission of the Authority; and

(b) Identification numbers shall not be defaced.

(8) The registrant shall notify the Authority in writing before making any change that would render the information contained in the application for registration or the validation of registration no longer accurate.

(9) No registration may be transferred from one person to another person, from one tanning facility to another tanning facility, or from one tanning device to another tanning device.

(10) Failure to properly register a tanning device is subject to the imposition of a civil penalty per ORS 431.950 and ORS 431.262.

(11) The Authority may require tanning facility registrants to complete and update application forms and information concerning tanning devices.

Stat. Auth.: ORS 431.925 - 431.955
Stats. Implemented: ORS 431.925 - 431.955
Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 20-2010, f. & cert. ef. 9-1-10; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

General Requirements

333-119-0030
Administrative Responsibilities

(1) The registrant shall be responsible for directing the operation of the tanning facility that has been registered with the Authority. That individual or individual's agent shall assure that the provisions of these rules are met in the operation of tanning devices.

(2) A tanning device which does not meet the provisions of these rules shall not be operated and may be tagged "Out of Service for Non-compliance with OAR 333-119 Requirements" by Authority inspectors. Devices tagged as non-compliant shall not be operated until written authorization is received by the registrant from the Authority.

(3) The registrant shall assure that the tanning facility will comply with all applicable federal laws and regulations.

(4) In addition to the requirements of this division, all registrants are subject to the applicable requirements of divisions 100, 103 and 111 of this chapter.

(5) The Authority Inspection Findings report shall be conspicuously posted in public view until all items of non-compliance have been corrected and a written Authority release from this requirement is received by the registrant.

(6) The registrant shall post in a conspicuous place the Authority "Notice To The Public".

(7) The registrant shall ensure that the "Warning", "Notice to the Public" and "Persons Under Age 18" signs are not covered or obscured, and are easily seen by clients at either the main reception area of the establishment or in each tanning device room.

(8) The registrant shall notify the Authority of any injury for which medical attention was sought or obtained from the use of a registered tanning device within one working day after learning of the occurrence, and provide the Authority any information about the incident the Authority deems necessary.

Stat. Auth.: ORS 431.925 - 431.955
Stats. Implemented: ORS 431.930 & 431.935
Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 14-2008, f. & cert. ef. 9-15-08; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-119-0040
Construction and Operation of Tanning Facilities

Unless otherwise ordered or approved by the Authority, each tanning facility shall be constructed, operated and maintained to meet the following minimum requirements:

(1) All tanning facilities shall be equipped with convenient toilet facilities and dressing rooms. Such toilet facilities shall include a toilet and hand washing sinks. Such toilet and dressing rooms shall be properly maintained, as well as meet all state and local codes.

(2) Rooms or other enclosures containing tanning devices shall be maintained below 100 degrees Fahrenheit (38 degrees Centigrade) during operation.

(3) Tanning facilities shall be constructed, operated and maintained in accordance with applicable city, county and state codes.

(4) Clean sanitary towels shall be provided to all patrons using tanning facilities.

(5) A hamper or receptacle must be provided for all soiled towels and linen.

(6) No pets or animals are permitted in tanning facilities other than service animals.

Stat. Auth.: ORS 431.925 - 431.955
Stats. Implemented: ORS 431.930
Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2013, f. & cert. ef. 1-29-13; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-119-0041
Cleaning and Sanitation

(1) All areas of the tanning facility, including tanning devices, equipment and apparatus, shall be maintained in a clean and sanitary manner by the facility operator.

(2) The tanning device(s) and protective eyewear shall be sanitized after each client use, by the facility operator.

(3) A clean paper or cloth towel shall be used each time the tanning device is sanitized.

(4) An operator cannot require the consumer to sanitize the tanning equipment or protective eyewear and shall not post any signs requesting such sanitation be performed by the consumer.

(5) The sanitizer must contain a concentration of Quaternary Ammonium between 400ppm-800ppm.

(6) A test kit that accurately measures the concentration of the sanitizing solution in parts per million (ppm) shall be used to measure the strength of the sanitizing solution when the concentrate and water dilution is initially prepared and tested weekly thereafter to ensure sufficient strength remains within the sanitizing solution.

Stat. Auth.: ORS 431.925 - 431.955
Stats. Implemented: ORS 431.930
Hist.: PH 4-2013, f. & cert. ef. 1-29-13; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

Specific Requirements

333-119-0050
Warning Statement

(1) At each customer's initial visit to a tanning facility, and at least annually thereafter, the customer shall be provided a written statement to review and sign, which warns the customer that:

(a) Not wearing appropriate protective eyewear may cause damage to the eyes; and

(b) Overexposure to the tanning process may cause burns; and

(c) Repeated exposure to the tanning process may cause skin cancer or premature aging of the skin or both; and

(d) Abnormal skin sensitivity or burning may result from the tanning process if the customer is also consuming or using certain foods, cosmetics or medications (such as tranquilizers, antibiotics, diuretics, blood pressure medication or birth control pills); and

(e) Any person taking a prescription or over-the-counter drug should consult a physician before using a tanning device; and

(f) The frequency and duration of tanning sessions must not exceed tanning device manufacturer recommendations; and

(g) Frequent users should be regularly screened for skin cancer by a physician.

(2) An Authority approved tanning client card may be used to satisfy the requirement of section (1) of this rule.

(3) The warning language in the written statement must be in 14 point or larger font.

Stat. Auth.: ORS 431.925 - 431.955
Stats. Implemented: ORS 431.925 - 431.955
Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 14-2008, f. & cert. ef. 9-15-08; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-119-0060
Warning Sign

(1) The registrant shall conspicuously post the warning sign described in section (2) of this rule within one meter (39.37 inches) of each tanning device and in such a manner that the sign is clearly visible, not obstructed by any barrier, equipment or other object, and can be easily viewed by the customer before operating the tanning device.

(2) The warning sign in section (1) of this rule shall meet the following requirements:

(a) The sign shall be printed on paper or similar material no smaller than 8.5 inches by 11 inches. Signs are available for printing on the Authority's website.

(b) The major sign heading shall be labeled "DANGER" and the section entitled "FAILURE" shall be a minimum of Times New Roman, bold with a minimum font size of 40.

(c) The body text shall be a minimum of Times New Roman with a minimum font size of 20.

DANGER — ULTRAVIOLET RADIATION
Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and/or skin cancer.
Frequent users should be regularly screened for skin cancer.
FAILURE TO USE PROTECTIVE EYEWEAR MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES.
Medications or cosmetics may increase your sensitivity to the Ultraviolet radiation. Consult a physician before using sunlamp or tanning device if you are using medications or have a history of skin problems or believe yourself to be especially sensitive to sunlight.
If you do not tan in the sun, you are unlikely to tan from the use of this product.
Tanning session frequency and time shall not exceed the device manufacturer's recommendations.

Stat. Auth.: ORS 431.925 - 431.955
Stats. Implemented: ORS 431.925 - 431.955
Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 14-2008, f. & cert. ef. 9-15-08; PH 20-2010, f. & cert. ef. 9-1-10; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-119-0070
Protective Eyewear

(1) The registrant shall make available protective eyewear for use during tanning sessions.

(2) The protective eyewear in section (1) of this rule shall meet the requirements of 21 Code of Federal Regulations (CFR) Part 1040, Section 1040.20(c)(4).

(3) Tanning facility operators shall ensure, before each tanning session, that clients have approved protective eyewear.

Stat. Auth.: ORS 431.925 - 431.955
Stats. Implemented: ORS 431.925 - 431.955
Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 14-2008, f. & cert. ef. 9-15-08; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-119-0080
Training of Personnel

(1) The registrant shall ensure that tanning devices are operated only while an adequately trained operator is present at the tanning facility.

(2) All operators of registered tanning devices must successfully complete an Authority approved tanning training course prior to commencement of tanning operations.

(3) Approved training will include, at a minimum, content covering the rules of this division, skin typing, recognition of overexposure, as well as any other topic determined by the Authority to be critical to client protection.

Stat. Auth.: ORS 431.925 - 431.955
Stats. Implemented: ORS 431.930
Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 20-2010, f. & cert. ef. 9-1-10; PH 4-2013, f. & cert. ef. 1-29-13; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-119-0090
Protection of Consumers

The registrant and operators are responsible for protecting the customers from overexposure to Ultraviolet Light by ensuring that:

(1) Only one customer may occupy the tanning room. In the case of a customer using a tanning device who may need the aid or assistance from another person, that individual must also be provided with and wear protective eyewear.

(2) No customer under the age of 18 years shall be allowed to use a tanning device without a completed Oregon Underage Tanning Medical Recommendation form completed by a licensed physician and identification. The recommendation:

(a) Must identify the physician and client and describe the recommended tanning session frequency(s) and duration(s);

(b) Must identify dates for starting and ending of the tanning sessions; and

(c) Cannot exceed the exposure scheduled per OAR 333-119-0100(14)(b).

(3) A sign shall be posted in conspicuous view at or near the reception area with the following text in a minimum of at least 36 point type:

"PERSONS UNDER AGE 18 ARE NOT ALLOWED TO USE A TANNING DEVICE WITHOUT A WRITTEN RECOMMENDATION FROM A LICENSED PHYSICIAN"

(4) Each person using a tanning device shall be instructed by the operator on the maximum exposure time and proper exposure distance, as recommended by the manufacturer of the device. The operator shall also instruct the customer as to the location and proper operation of the tanning device's emergency shut off switch.

(5) Infants and minors are not permitted to be in the tanning device room during exposure by parents or guardians.

(6) Tanning operators shall limit exposure time to the device manufacturer's recommendations. The maximum exposure time recommended by the manufacturer of the device shall not be exceeded in any 24-hour period.

(7) A copy of the manufacturer's recommended exposure schedule shall be maintained at the remote timer controls for each device.

(8) At the time of their initial visit, all clients shall have their skin type determined according to the Fitzpatrick Skin Type Scale, and their skin type recorded in the client record.

(9) Tanning operators shall maintain a list of the common photosensitizing agents as provided by the Public Health Division, FDA, or other appropriate authorities, available for review by customers.

(10) Tanning facilities are prohibited from controlling the use of tanning devices solely with token timer systems or a mechanical timer system.

Stat. Auth.: ORS 431.925 - 431.955
Stats. Implemented: ORS 431.930
Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 14-2013, f. 12-26-13, cert. ef. 1-1-14; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-119-0100
Equipment

(1) The registrant shall use only tanning devices manufactured in accordance with the specifications set forth in 21 CFR Part 1040, Section 1040.20, "Sunlamp Products and Ultraviolet Lamps Intended for Use in Sunlamp Products."

(2) Each tanning device shall be labeled in accordance with 21 CFR Part 1040.

(3) Adequate means shall be provided to enable a customer to summon assistance from the exposure position.

(4) All persons hired for servicing and repair of tanning devices shall be State of Oregon licensed electricians.

(5) State of Oregon electrical codes must be observed during service and repair actions.

(6) Replacement lamps shall be certified by the manufacturer as equivalent to the original lamp type as specified by the manufacturer, or certified as an equivalent lamp per 21 CFR 1040.20.

(7) If equivalent lamps are used instead of the Original Equipment Manufacturer (OEM) required lamps, a copy of the equivalency certification, provided by the lamp supplier, shall be maintained for review by the Authority during inspections.

(8) Lamps removed from a tanning device shall be disposed of in a safe and proper manner to prevent unauthorized and unsafe use as lighting devices. Used tanning lamps are prohibited from being resold for any purpose.

(9) If the ultraviolet tanning device is not in an individual cubicle, then a suitable screen, curtain, or other shield shall be provided, maintained, and used to prevent unnecessary exposure to ultraviolet radiation of persons not using the device.

(10) Each tanning device shall have a timer that complies with the requirements of 21 CFR Part 1040, Section 1040.20 (c)(2).

(11) The maximum timer interval shall not exceed the manufacturer's maximum recommended exposure time, or 20 minutes, whichever is less.

(12) A tanning facility shall use the following exposure schedule for tanning devices originally designed with a 30 minute maximum exposure time that have been reduced to a 20 minute maximum exposure time. A copy of this exposure schedule must be affixed to the tanning device, and a copy maintained at the timer controls.

(a) Skin type 1:

(A) Week 1: 1–3 minutes;

(B) Week 2: 4–6 minutes;

(C) Week 3: 7–10 minutes;

(D) Week 4: 11–15 minutes.

(b) Skin type 2 and 3:

(A) Week 1: 4 minutes;

(B) Week 2: 8 minutes;

(C) Week 3: 12 minutes;

(D) Week 4: 16 minutes;

(E) Weekly maintenance: 20 minutes.

(c) Skin Type 4 and 5:

(A) Week 1: 4 minutes;

(B) Week 2: 12 minutes;

(C) Week 3: 16 minutes;

(D) Week 4: 20 minutes;

(E) Weekly maintenance: 20 minutes.

(13) Tanning device timers shall be controlled by a trained operator. A remote timer control system shall be used for this purpose.

(14) Each tanning device shall be equipped with a functional emergency shut-off mechanism to allow manual termination of the UV exposure by the customer, as required by 21 CFR 1040.20(c)(3).

(15) Each timer must be functional and accurate to within ± 10 percent.

(16) The registrant shall ensure that the timer is checked annually for accuracy and the results recorded.

(17) The registrant shall ensure that the emergency shut-off is tested annually for proper function and results recorded.

(18) All tanning devices shall be maintained to the minimum requirements of the manufacturer.

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.655, 431.930 & 431.945

Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-119-0110
Records and Reports

(1) The registrant shall maintain a record of each customer's total number of tanning visits, dates and durations of tanning exposures.

(2) The registrants shall maintain a record of each customer's signature and acknowledgement that they understand the potential risks involved with exposure to ultraviolet radiation and overexposure, and that they have reviewed a photosensitizing drug list.

(3) The registrant shall maintain and have available when requested by the Authority, all completed Oregon Underage Tanning Medical Recommendation forms with copies of the identification used for each minor allowed to use a tanning device.

(4) Upon their initial visit, all tanning clients must present acceptable identification as proof of age. The type of identification, identification number, client's name, and date of birth shall be recorded by the registrant in the client's record. When requested by the Authority, records shall be available for review.

(5) The registrant shall maintain a record of operator training as required in OAR 333-119-0080(3).

(6) The registrant shall maintain a copy of the owner's manual for each tanning device.

(7) Records shall be maintained showing the method of disposal of all tanning devices and lamps.

(8) All required records shall be maintained in a location and format as to be readily available for review during inspections conducted by the Authority.

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.925 - 431.955

Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 14-2008, f. & cert. ef. 9-15-08; PH 14-2013, f. 12-26-13, cert. ef. 1-1-14; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-119-0120
Advertising

(1) Registrants shall not claim or distribute promotional materials that claim using a tanning device is safe, free from risk or that using the device will result in medical or health benefits. Only cosmetic claims can be promoted.

(2) No person, in any advertisement, shall refer to the fact that such person, or such person's facility is registered with the Authority pursuant to the provisions of this division, and no person shall state or imply that any activity under such registration has been approved by the Authority.

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.930

Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 14-2008, f. & cert. ef. 9-15-08; PH 20-2010, f. & cert. ef. 9-1-10; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-119-0130
Exemptions

(1) The Authority may, upon application therefore or upon its own initiative, grant such exemptions or exceptions from the requirements of the rules in this section as it determines are authorized by law and will not result in undue hazard to public health and safety.

(2) A phototherapy device used by or under the direct supervision of a physician licensed under ORS Chapter 677 is exempt from the requirements of this division.

(3) Any individual is exempt from the provisions of this division to the extent that such individual owns a tanning device exclusively for personal use.

(4) Tanning devices, while in transit or storage, are exempt from the registration provisions of this division.

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.925 - 431.955

Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 14-2008, f. & cert. ef. 9-15-08; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-119-0140
Denial, Revocation, Termination of Registration

(1) The Authority may deny, suspend or revoke registration issued pursuant to this division:

(a) For any written false statement in the application for registration or in any statement of fact as required by provisions of this division; or

(b) Because of conditions revealed by the application or any report, record, inspection or other means which would warrant the Authority to refuse to grant a registration; or

(c) For operation of the tanning facility in a manner that causes or threatens to cause hazard to the public health or safety; or

(d) For failure to allow authorized representatives of the Authority to enter the tanning facility at reasonable times for the purpose of determining compliance with the provisions of this division, or an order of the Authority; or

(e) For violation of, or failure to observe any of the terms and conditions of the rules in this division, or an order of the Authority; or

(f) For failure to properly dispose of used tanning lamps and thus allowing possible use in an unauthorized or hazardous manner.

(2) Except in cases of willfulness or cases in which the public health, interest or safety requires otherwise, prior to the institution of proceedings for suspension or revocation of a registration, the Authority shall:

(a) Call to the attention of the registrant, in writing, the facts or conduct which may warrant such actions; and

(b) Provide reasonable opportunity for the registrant to demonstrate or achieve compliance with all lawful requirements.

(3) Any person aggrieved by a decision by the Authority to deny a registration or to suspend or revoke a registration after issuance may request a hearing.

(4) The Authority may terminate a registration upon receipt of a written request for termination from the registrant.

(5) The Authority may, by rule, regulation, or order, impose upon any registrant such requirements in addition to those established in this regulation as it deems appropriate or necessary to minimize danger to public health and safety or property.

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.935 - 431.950

Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 14-2008, f. & cert. ef. 9-15-08

333-119-0200
Vendor Responsibilities

(1) Any person who sells, leases, transfers, or lends tanning devices in this state shall notify the Authority of the following within 30 days after each sale or installation:

(a) Name and address of persons who have received these devices;

(b) The manufacturer model and serial numbers of each device; and

(c) The date of transfer.

(2) No person shall make, sell, lease, transfer, lend or install tanning devices or the supplies used in connection with such devices unless such supplies and equipment when placed in operation and use, will meet the requirements of these rules.

(3) State of Oregon identification numbers shall not be removed, altered or defaced by any vendor doing business in this state, without written permission of the Authority.

(4) Vendors of tanning devices, replacement lamps, sanitizers, protective eyewear, UV light measurement devices, calibration of measurement equipment, remote timer systems, computer control systems, repair or cleaning services, parts supplies, or operator training are required to apply for a license for sales, services and servicing as specified in OAR 333-101-0020. Vendor license application forms will be furnished by the Authority. Vendors are prohibited from providing tanning equipment installation, servicing and/or services prior to the Authority issuing a licensing certificate to the vendor.

(5) Vendors providing operator training services are required to apply for a license for services as specified in OAR 333-101-0020. The Authority will furnish license application forms. Prior to offering training services, vendors shall submit to the Authority the following:

(a) A list of qualified on-site training personnel including a curriculum vitae or resume outlining training experiences;

(b) A copy of all training materials to be used; and

(c) A copy of examinations to be used.

(6) Upon approval, a letter will be sent to the training service vendor giving permission to offer tanning operator training within the State of Oregon.

(7) The Authority shall be notified prior to training material revisions. The Authority shall review and approve all changes made to the training materials.

(8) Vendors shall maintain records of course completion and test results for a period of at least three years from the date of the operator training course. A copy of the list of persons successfully completing operator training shall be furnished to the Authority and include the following:

(a) Name of persons trained;

(b) Individual test scores; and

(c) Associated tanning facility, name and address.

(9) The Authority shall be provided access to audit any operator training courses offered within the State of Oregon without charge.

Stat. Auth.: ORS 431.925 - 431.955
Stats. Implemented: ORS 431.925 - 431.955
Hist.: HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94; PH 14-2008, f. & cert. ef. 9-15-08; PH 20-2010, f. & cert. ef. 9-1-10

DIVISION 120

STANDARDS FOR PROTECTION AGAINST RADIATION

General Provisions

333-120-0000
Purpose

(1) This division establishes standards for protection against ionizing radiation resulting from activities conducted under licenses and registrations issued by the Authority. These rules are issued

under ORS 453.605 to 453.807, and the State of Oregon's agreement with the U.S. Nuclear Regulatory Commission.

(2) It is the purpose of the rules in this division to control the receipt, possession, use, transfer, and disposal of licensed radioactive material and sources of radiation by any licensee or registrant in such a manner that the total dose to an individual (including doses resulting from licensed and unlicensed radioactive material and from radiation sources other than background radiation) does not exceed the standards for protection against radiation prescribed in this division. However, nothing in this division shall be construed as limiting actions that may be necessary to protect health and safety.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 4-2007, f. & cert. ef. 3-1-07

333-120-0010
Scope

The rules in this division apply to persons licensed or registered by the Authority to receive, possess, use, transfer, or dispose of licensed radioactive material or registered devices. The limits in this division do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs.

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Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 4-2007, f. & cert. ef. 3-1-07

333-120-0015
Definitions

(1) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

(2) "Activity" is the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the becquerel (Bq) and the Curie (Ci). The becquerel is equal to one disintegration per second (dps) and the Curie is equal to 3.7x1010 dps.

(3) "Accelerator produced radioactive material" means any material made radioactive by a particle accelerator.

(4) "Adult" means an individual 18 or more years of age.

(5) "Airborne radioactive material" means radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

(6) "Airborne radioactivity area" means a room, enclosure, or area in which the airborne radioactive materials, composed wholly or partly of licensed material, exist in concentrations:

(a) In excess of the derived air concentrations (DACs) specified in 10 CFR 20 Appendix B; or

(b) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours present in a week, and intake of 0.6 percent of the annual limit of intake (ALI) or 12 DAC hours.

(7) "Air-purifying respirator" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

(8) "ALARA" (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this division as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to the use of licensed materials in the public interest.

(9) "Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given on page 1 of Tables 1, 2, and 3, Appendix B to 10 CFR Part 20.

(10) "Assigned protection factor (APF)" means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

(11) "Atmosphere supplying respirator" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

(12) "Background radiation" means radiation from cosmic sources; naturally occurring radioactive material, including radon (except as a decay product of source or special nuclear material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include radiation from radioactive or special nuclear materials regulated by the Authority.

(13) "Bioassay" (radiobioassay) means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body.

(14) "Byproduct material" means:

(a) Any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or using special nuclear material.

(b) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute ''byproduct material'' within this definition.

(c) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity. Any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity.

(d) Any discrete source of naturally occurring radioactive material, other than source materials, that:

(A) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency determines a threat to the public health and safety or the common defense, is similar to the threat posed by a discrete source of radium-226 material to the public health and safety or the common defense and security; and

(B) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical or research activity.

(15) "Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days; for Class W, Weeks, from 10 to 100 days; and for Class Y, Years, of greater than 100 days. For purposes of these regulations, "lung class" and "inhalation class" are equivalent terms.

(16) "Collective dose" is the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

(17) "Committed dose equivalent" (HT,50) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

(18) "Committed effective dose equivalent" (HE,50) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues (HE,50) = The Sum of WTHT,50.

(19) "Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

(20) "Consortium" means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radiopharmaceutical drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a federal facility or a medical facility.

(21) Constraint (dose constraint) means a value above which specified licensee actions are required.

(22) "Critical Group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

(23) "Declared pregnant woman" means a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

(24) "Decommission" means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:

(a) Release of the property for unrestricted use and termination of the license; or

(b) Release of the property under restricted conditions and termination of the license.

(25) "Deep-dose equivalent" (Hd), which applies to external whole-body exposure, is the dose equivalent at a tissue depth of one cm (1000 mg/cm2).

(26) "Demand respirator" means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

(27) "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these regulations, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of 10 CFR 20 Appendix B.

(28) "Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

(29) "Discrete Source" means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical or research activities.

(30) "Disposable respirator" means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

(31) "Distinguishable from background" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

(32) "Dose or radiation dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent, as defined in this rule.

(33) "Dose equivalent" (HT) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

(34) "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

(35) "Effective Dose Equivalent" (HE) is the sum of the products of the dose equivalent to the organ or tissue (HT) and the weighting factor (WT) applicable to each of the body organs or tissues that are irradiated (HE = The Sum of WTHT).

(36) "Embryo/fetus" means the developing human organism from conception until the time of birth.

(37) "Entrance or access point" means any location through which an individual could gain access to radiation areas or to radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

(38) "Exposure" means being exposed to ionizing radiation or to radioactive material.

(39) "External dose" means that portion of the dose equivalent received from radiation sources outside the body.

(40) "Extremity" means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

(41) "Eye dose equivalent" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm 2). (See "lens dose equivalent").

(42) "Filtering facepiece (dust mask)" means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

(43) "Fit factor" means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

(44) "Fit test" means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

(45) "Generally applicable environmental radiation standards" means standards issued by the Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

(46) "Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

(47) "High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of one mSv (0.1 rem) in one hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

(48) "Hood" means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

(49) "Individual" means any human being.

(50) "Individual monitoring" means:

(a) The assessment of dose equivalent by the use of devices designed to be worn by an individual;

(b) The assessment of committed effective dose equivalent by bioassay (see Bioassay) or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e. DAC-hours; or

(c) The assessment of dose equivalent by the use of survey data.

(51) "Individual monitoring devices" (individual monitoring equipment) means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.

(52) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

(53) "Lens dose equivalent (LDE)" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm 2).

(54) "Loose fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

(55) "Member of the public" means any individual except when that individual is receiving an occupational dose.

(56) "Minor" means an individual less than 18 years of age.

(57) "Monitoring (radiation monitoring, radiation protection monitoring)" means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

(58) "Nationally Tracked Source" means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of radioactive material listed in 10 CFR Part 20, Appendix E. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded in a solid form and that is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel rod, or fuel pellet.

(a) Category 1 nationally traced sources are those containing radioactive material at a quantity equal to or greater than Category 1 threshold.

(b) Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

(59) "Negative pressure respirator (tight fitting)" means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

(60) "Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these regulations, "deterministic effect" is an equivalent term.

(61) "Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material for medical purposes and released under OAR 333-116-0260, from voluntary participation in medical research programs, or as a member of the public.

(62) "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 mega-electron volt. For purposes of this definition, "accelerator" is an equivalent term.

(63) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

(64) "Positive pressure respirator" means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

(65) "Powered air purifying respirator" (PAPR) means an air purifying respirator that uses a blower to force the ambient air through air purifying elements to the inlet covering.

(66) "Pressure demand respirator" means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

(67) "Public dose" means the dose received by a member of the public from exposure to radiation or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material for medical purposes and released under OAR 333-116-0260, or from voluntary participation in medical research programs.

(68) "Qualitative fit test (QLFT)" means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

(69) "Quantitative fit test (QNFT)" means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

(70) "Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

(71) "Radiation" (ionizing radiation) means alpha particles, beta particles, gamma rays, X-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. Radiation, as used in this part, does not include non-ionizing radiation, such as radio- or microwaves, or visible, infrared, or ultraviolet light.

(72) "Radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

(73) "Reference man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health employees to standardize results of experiments and to relate biological insult to a common base. A description of the reference man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."

(74) "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site.

(75) "Restricted area" means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

(76) "Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

(77) "Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

(78) "Self-contained breathing apparatus" (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

(79) "Shallow-dose equivalent" (HS), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm2) averaged over an area of one square centimeter.

(80) "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

(81) "Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these regulations, "probabilistic effect" is an equivalent term.

(82) "Supplied-air respirator" (SAR) or airline respirator means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

(83) "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

(84) "Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

(85) "Total Effective Dose Equivalent" (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

(86) "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee.

(87) "User seal check" means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

(88) "Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of five gray (500 rad) in one hour at one meter from a source of radiation or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.

(89) "Waste" means those low-level radioactive wastes containing source, special nuclear or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel or byproduct material as defined in subsections (14)(b), (14)(c), and (14)(d) of this rule.

(90) "Weighting factor" (WT) for an organ or tissue means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of WT are:

Organ Dose Weighting Factors

Organ or Tissue	WT
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30 (see (a) below)
Whole Body	1.00 (see (b) below)

(a) 0.30 results from 0.06 for each of five "remainder" organs, excluding the skin and the lens of the eye that receives the highest doses.

(b) For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, WT = 1.0, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

(91) "Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

(92) "Working level" (WL) is any combination of short-lived radon daughters (for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212) in one liter of air that will result in the ultimate emission of 1.3x105 MeV of potential alpha particle energy.

(93) "Working level month" (WLM) means an exposure to one working level for 170 hours (2,000 working hours per year/12 months per year equals approximately 170 hours per month).

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333-120-0017
Implementation

(1) Any existing license or registration condition that is more restrictive than OAR 333-120 remains in force until there is an amendment or renewal of the license or registration.

(2) If a license or registration condition exempts a licensee or registrant from a provision of OAR 333-120 in effect on or before July 1, 2006, it also exempts the licensee or registrant from the corresponding provision of OAR 333-120.

(3) If a license or registration condition cites provisions of OAR 333-120 in effect prior to July 1, 2006, which do not correspond to any provisions of OAR 333-120, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

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Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-120-0020
Radiation Protection Programs

(1) Each licensee or registrant must develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed or registered activities and sufficient to ensure compliance with the provisions of this division. (See OAR 333-120-0610 for record keeping requirements relating to these programs.)

(2) Each licensee or registrant must use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

(3) Each licensee or registrant must periodically (at least annually) review the radiation protection program content and implementation.

(4) To implement the ALARA requirements of section (2) of this rule, and notwithstanding the requirements in OAR 333-120-0180, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, must be established by licensees such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of ten mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee must report the excess as provided in OAR 333-120-0720 and promptly take appropriate corrective action to ensure against recurrence.

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Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

Radiation Dose Limits

333-120-0100
Occupational Dose Limits For Adults

(1) Each licensee or registrant must control the occupational dose to individual adults, except for planned special exposures under OAR 333-120-0150, to the following dose limits:

(a) An annual limit, which is the more limiting of:

(A) The total effective dose equivalent being equal to 0.05 Sv (5 rem); or

(B) The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 Sv (50 rem).

(b) The annual limits to the lens of the eye, to the skin, and to the extremities that are:

(A) A lens dose equivalent of 0.15 Sv (15 rem); and

(B) A shallow-dose equivalent of 0.50 Sv (50 rem) to the skin of the whole body or to the skin of any extremity.

(2) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, must be subtracted from the limits for planned special exposures, as defined in OAR 333-100-0005, that the individual may receive during the current year OAR 333-120-0150(5)(a) and during the individual's lifetime OAR 333-120-0150(5)(b).

NOTE: A licensee or registrant may permit a radiation worker to receive more than 0.05 Sv (5 rem) per year TEDE or 0.5 Sv (50 rem) to the skin, extremities, or organ, or 0.15 Sv (15 rem) to the lens of the eye during a planned special exposure (PSE) only if: (a) there are no other alternatives available or practical; (b) the PSE is authorized in writing before it occurs; (c) the individuals who will be exposed are told the reason for the PSE, the dose they are expected to receive, the risks from that dose and the conditions under which they will be working (e.g. radiation or contamination levels), and how to keep their doses ALARA; (d) the licensee or registrant determines the worker's prior doses (lifetime history); (e) the total dose expected from the PSE plus any previous doses over the annual limit do not exceed the standard annual dose limits, or five times the standard limits in the worker's lifetime; (f) the licensee or registrant maintains the appropriate records and files the appropriate reports; and (g) after the PSE, the licensee or registrant records the dose received and notifies the worker in writing of the dose received within 30 days after the PSE. The dose received from the PSE does not affect the worker's ability to receive the standard annual doses but is included in the worker's lifetime history and added to any future PSEs.

(3) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the Authority. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous ten square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable:

(a) The deep-dose equivalent, lens dose equivalent and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable; or

(b) When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified in OAR 333-120-0210(1)(e) the effective dose equivalent for external radiation must be determined as follows:

(A) When only one individual monitoring device is used and it is located at the neck outside the protective apron, the reported deep dose equivalent must be the effective dose equivalent for external radiation; or

(B) When only one individual monitoring device is used and it is located at the neck outside the protective apron, and the reported dose exceeds 25 percent of the limit specified in section (1) of this rule the reported deep dose equivalent value multiplied by 0.3 must be the effective dose equivalent for external radiation; or

(C) When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation must be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

(4) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in 10 CFR Part 20 Table 1 of Appendix B to 20.1001 to 20.2401 and may be used to determine the individual's dose (OAR 333-120-0650) and to demonstrate compliance with the occupational dose limits.

(5) In addition to the annual dose limits, the licensee must limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity (see 10 CFR Part 20 footnote 3 of Appendix B to 20.1001 to 20.2401).

(6) When monitoring is required by OAR 333-120-0210 each licensee or registrant must reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person (OAR 333-120-0630(5)).

(7) The licensee must reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person.

[ED. NOTE: Appendices referenced are available from the agency.]

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-120-0110
Compliance with Requirements for Summation of External and Internal Doses

(1) If the licensee is required to monitor under OAR 333-120-0210(1) and (2), the licensee must demonstrate compliance with the dose limits by summing external and internal doses. If the licensee is required to monitor only under OAR 333-120-0210(1) or only under 333-120-0210(2), then summation is not required to demonstrate compliance with the dose limits. The licensee may demonstrate compliance with the requirements for summation of external and internal doses by meeting one of the conditions specified in section (2) of this rule and the conditions in sections (3) and (4) of this rule.

NOTE: The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

(2) Intake by Inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep-dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

(a) The sum of the fractions of the inhalation ALI for each radionuclide; or

(b) The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000; or

(c) The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit.

NOTE: An organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, WT, and the committed dose equivalent, HT,50, per unit intake is greater than ten percent of the maximum weighted value of HT50 (i.e. WTHT50) per unit intake for any organ or tissue.

(3) Intake by Oral Ingestion. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than ten percent of the applicable oral ALI, the licensee

must account for this intake and include it in demonstrating compliance with the limits.

(4) Intake Through Wounds or Absorption Through Skin. The licensee must evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be further evaluated.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-120-0120
Determination of External Dose from Airborne Radioactive Material

Licensees must, when determining the dose from airborne radioactive material, include the contribution to the deep-dose equivalent, lens dose equivalent, and shallow-dose equivalent from external exposure to the radioactive cloud (10 CFR, Part 20, Appendix B, Footnotes 1 and 2 to 20.1001 to 20.2401).

NOTE: Airborne radioactivity measurements and DAC values should not be used as the primary means to assess the deep-dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep-dose equivalent to an individual should be based upon measurements using instruments or individual monitoring devices.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-120-0130
Determination of Internal Exposure

(1) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee must, when required under OAR 333-120-0210, take suitable and timely measurements of:

(a) Concentrations of radioactive materials in air in work areas; or

(b) Quantities of radionuclides in the body; or

(c) Quantities of radionuclides excreted from the body; or

(d) Combinations of these measurements.

(2) Unless respiratory protective equipment is used, as provided in OAR 333-120-0320 or the assessment of intake is based in bioassays, the licensee must assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

(3) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior or the material in an individual is known, the licensee may:

(a) Use that information to calculate the committed effective dose equivalent, and, if used, the licensee must document that information in the individual's record; and

(b) Upon prior approval of the Authority, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material (e.g. aerosol size distribution or density); and

(c) Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of given radionuclide (see 10 CFR Part 20 Appendix B to 20.1001 to 20.2401) to the committed effective dose equivalent.

(4) If the licensee chooses to assess intakes of Class Y material using the measurements given in sections (1), (2) or (3) of this rule, the licensee may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by OAR 333-120-0710 or 333-120-0720, in order to permit the licensee to make additional measurements basic to the assessments.

(5) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours must be either:

(a) The sum of the ratios of the concentration to the appropriate DAC value (e.g. D, W, Y) from 10 CFR Part 20 Appendix B to 20.1001 to 20.2401 for each radionuclide in the mixture; or

(b) The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

(6) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture must be the most restrictive DAC of any radionuclide in the mixture.

(7) When a mixture of radionuclides in air exists, licensees may disregard certain radionuclides in the mixture if:

(a) The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in OAR 333-120-0100 and in complying with the monitoring requirements in 333-120-0210(2); and

(b) The concentration of any radionuclide disregarded is less than 10 percent of its DAC; and

(c) The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

(8) When determining the committed effective dose equivalent, the following information may be considered:

(a) In order to calculate the committed effective dose equivalent, the licensee may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 0.05 Sv (5 rem) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

(b) When the ALI (and the associated DAC) is determined by the nonstochastic organ dose limit of 0.50 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) (the stochastic ALI) is listed in parentheses in 10 CFR Part 20 Table 1 of Appendix B to 20.1001 to 20.2401. In this case, the licensee may, as a simplifying assumption, use the stochastic ALIs to determine committed effective dose equivalent. However, if the licensee uses the stochastic ALIs, the licensee also must demonstrate that the limit in OAR 333-120-0100(1)(a)(B) is met.

[ED. NOTE: Appendices referenced are available from the agency.]
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-120-0150
Planned Special Exposures

A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in OAR 333-120-0100 provided that each of the following conditions is satisfied:

(1) The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the higher exposure are unavailable or impractical.

(2) The licensee or registrant (and employer if the employer is not the licensee or registrant) specifically authorizes the planned special exposure, in writing, before the exposure occurs.

(3) Before a planned special exposure, the licensee or registrant ensures that the individuals involved are:

(a) Informed of the purpose of the planned operation;

(b) Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

(c) Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

(4) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses, as required by OAR 333-120-0630(2), during the lifetime of the individual for each individual involved.

(5) Subject to OAR 333-120-0100(2), the licensee or registrant does not authorize a planned special exposure that would cause an

individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

(a) The numerical values of any of the dose limits in OAR 333-120-0100(1) in any year; and

(b) Five times the annual dose limits in OAR 333-120-0100(1) during the individual's lifetime.

(6) The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with OAR 333-120-0640 and submits a written report in accordance with OAR 333-120-0730.

(7) The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures is not to be considered in controlling future occupational dose of the individual under OAR 333-120-0100(1) but is to be included in evaluations required by 333-120-0100(4) and (5).

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 4-2007, f. & cert. ef. 3-1-07

333-120-0160
Occupational Dose Limits for Minors

The annual occupational dose limits for minors are 10 percent of the annual dose limits specified for adult workers in OAR 333-120-0100.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-120-0170
Dose to an Embryo/Fetus

(1) The licensee or registrant must ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman does not exceed five mSv (0.5 rem). Records must be kept in accordance with OAR 333-120-0650.

NOTE: A woman is not a declared pregnant woman unless she says so in writing without being coerced. Unless a woman, who also is a radiation worker, has declared her pregnancy as required, she is to be treated as any other radiation worker. Pursuant to Title VII of the Civil Rights Act of 1964, as amended, no employer may restrict a fertile female's job because of concern for the health of the fetus that a woman might conceive. The court held that sex-specific fetal-protection policies are forbidden. Additionally, a female worker legally can declare pregnancy if she does not yet have documented medical proof. The document, "Instruction Concerning Prenatal Radiation Exposure," discusses declared pregnancy. It is available from Public Health Division, Radiation Protection Services Suite 640, 800 N.E. Oregon St., Portland, OR 97232, phone (971) 673-0490.

(2) The licensee or registrant must make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in section (1) of this rule.

(3) The dose equivalent to an embryo/fetus must be taken as the sum of:

(a) The deep-dose equivalent to the declared pregnant woman; and

(b) The dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman, If the dose equivalent to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, by the time the woman declares the pregnancy to the licensee, the licensee shall be deemed to be in compliance with subsection (3)(a) of this rule if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

(4) If the dose equivalent to the embryo/fetus is found to have exceeded five mSv (0.5 rem), or is within 0.5 mSv (0.05 rem), by the time the woman declares the pregnancy to the licensee or registrant, the licensee or registrant shall be deemed to be in compliance with section (1) of this rule if the additional dose to the embryo/fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

NOTE: If a pregnant radiation worker declares in writing to the licensee that she is pregnant, the dose limit to the embryo/fetus is five mSv (0.5 rem) during the entire pregnancy. The dose that is controlled is the dose to the embryo/fetus, not the dose to the woman, although for external penetrating radiation, the two are virtually synonymous.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-120-0180
Dose Limits for Individual Members of the Public

(1) Each licensee or registrant must conduct operations so that:

(a) The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed one mSv (0.1 rem) in a year, exclusive of the dose contributions from background, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with OAR 333-116-0260, from voluntary participation in medical research programs, and the licensee's disposal of radioactive material into sanitary sewerage in accordance with OAR 333-120-0520; and

(b) The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with OAR 333-116-0260, does not exceed 0.02 mSv (0.002 rem) in any one hour.

(2) If the licensee or registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

(3) Notwithstanding subsection (1)(a) of this rule, a licensee may permit visitors to an individual who cannot be released, under OAR 333-116-0260, to receive a radiation dose greater than 0.1 rem (1 mSv) if:

(a) The radiation dose received does not exceed 0.5 rem (5 mSv); and

(b) The authorized user, as defined in OAR 333-116-0020, has determined prior to the visit that it is appropriate.

(4) A licensee, registrant or applicant may apply for prior Authority authorization to operate up to an annual dose limit for an individual member of the public of five mSv (0.5 rem). The licensee, registrant or applicant must include the following information in this application:

(a) Demonstration of the need for and the expected duration of operations in excess of the limit in section (1) of this rule; and

(b) The licensee's or registrant's program to assess and control dose within the five mSv (0.5 rem) annual limit; and

(c) The procedures to be followed to maintain the dose as low as is reasonably achievable.

(5) In addition to the requirements of this division, a licensee or registrant subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR Part 190 must comply with those standards.

(6) The Authority may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-120-0190
Compliance with Dose Limits for Individual Members of the Public

(1) The licensee or registrant must make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unre-

stricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in OAR 333-120-0180.

(2) A licensee or registrant must show compliance with the annual dose limit in OAR 333-120-0180 by:

(a) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or

(b) Demonstrating that:

(A) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in 10 CFR Part 20 Table 2 of **Appendix B** to 20.1001 to 20.2401; and

(B) If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in a year.

(3) Upon approval from the Authority, the licensee or registrant may adjust the effluent concentration values in 10 CFR Part 20 Table 2 of **Appendix B** to 20.1001 to 20.2401 for members of the public, to take into account the actual physical and chemical characteristics of the effluents (e.g aerosol size distribution, solubility, density, radioactive decay equilibrium, chemical form).

[ED. NOTE: Appendices referenced are available from the agency.]

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

Surveys and Monitoring

333-120-0200
General

(1) Each licensee or registrant must make or cause to be made, surveys that:

(a) Are necessary for the licensee or registrant to comply with the rules in this division; and

(b) Are reasonable under the circumstances to evaluate:

(A) The magnitude and extent of radiation levels; and

(B) The concentrations or quantities of radioactive material; and

(C) The potential radiological hazards that could be present.

(2) Notwithstanding OAR 333-120-0620, records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning. Records must be retained in accordance with 10 CFR parts 30.35(g), 40.36(f), and 70.25

(3) The licensee or registrant must ensure that instruments and equipment used for quantitative radiation measurements (such as dose rate and effluent monitoring) are calibrated at intervals not to exceed 12 months for the radiation measured, except when a more frequent interval is specified in another applicable division or a license condition.

(4) All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees or registrants to comply with OAR 333-120-0100, with other applicable provisions of this division or with conditions specified in a license must be processed and evaluated by a dosimetry processor:

(a) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(b) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

(5) The licensee or registrant must ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-120-0210
Conditions Requiring Individual Monitoring of External and Internal Occupational Dose

Each licensee or registrant must monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this division. As a minimum:

(1) Each licensee or registrant must monitor occupational exposure to radiation and must supply and require the use of individual monitoring devices by:

(a) Adults likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the limits in OAR 333-120-0100(1);

(b) Minors likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of any of the applicable limits in OAR 333-120-0160 or 333-120-0170;

(c) Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of one mSv (0.1 rem);

(d) Individuals entering a high or very high radiation area; and

(e) Individuals working with medical fluoroscopic equipment.

(A) An individual monitoring device used for the dose to an embryo/fetus of a declared pregnant woman, pursuant to OAR 333-120-0170(1), must be located under the protective apron at the waist.

(B) An individual monitoring device used for lens dose equivalent must be located at the neck, or an unshielded location closer to the lens, outside the protective apron.

(C) When only one individual monitoring device is used to determine the effective dose equivalent for external radiation pursuant to OAR 333-120-0100(3)(b) it must be located at the neck outside the protective apron. When a second individual monitoring device is used, for the same purpose, it must be located under the protective apron at the waist. The second individual monitoring device is required for a declared pregnant woman.

(2) Each licensee or registrant must monitor (OAR 333-120-0130) the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(a) Adults likely to receive, in one year, an intake in excess of 10 percent of the applicable ALI(s) in 10 CFR Part 20 Table 1, Columns 1 and 2, of Appendix B to 20.1001 to 20.2401; and

(b) Minors likely to receive, in one year, from radiation sources external to the body, a deep dose equivalent in excess of one mSv (0.1 rem), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv).

(c) Declared pregnant women likely to receive, during the entire pregnancy, from radiation sources external to the body, a committed effective dose equivalent in excess of 0.1 rem (1 mSv).

[ED. NOTE: Appendices referenced are available from the agency.]

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-120-0215
Location of Individual Monitoring Devices

Each licensee or registrant must ensure that individuals who are required to monitor occupational doses in accordance with OAR 333-120-0210(1) wear individual monitoring devices as follows:

(1) An individual monitoring device used for monitoring the dose to the whole body must be worn at the unshielded location of the whole body likely to receive the highest exposure. When a pro-

tective apron is worn, the location of the individual monitoring device is typically at the neck (collar);

(2) An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman, pursuant to OAR 333-120-0170(1), must be located at the waist under any protective apron being worn by the woman;

(3) An individual monitoring device used for monitoring the lens dose equivalent, to demonstrate compliance with OAR 333-120-0100(1)(b)(A), must be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye;

(4) An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with OAR 333-120-0100(1)(b)(B), must be worn on the extremity likely to receive the highest exposure. Each individual monitoring device must be oriented to measure the highest dose to the extremity being monitored.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

Control of Exposure from External Sources in Restricted Areas

333-120-0220
Control of Access to High Radiation Areas

(1) The licensee or registrant must ensure that each entrance or access point to a high radiation area has one or more of the following features:

(a) A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep-dose equivalent of one mSv (0.1 rem) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates;

(b) A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

(c) Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

(2) In place of the controls required by section (1) of this rule for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(3) A licensee or registrant may apply to the Authority for approval of alternative methods for controlling access to high radiation areas.

(4) The licensee or registrant must establish the controls required by sections (1) and (3) of this rule in a way that does not prevent individuals from leaving a high radiation area.

(5) Control is not required for each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation (49 CFR) provided that:

(a) The packages do not remain in the area longer than three days; and

(b) The dose rate at one meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.

(6) Control of entrance or access to rooms or other areas in hospitals is not required solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who will take the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the limits established in this division and to operate within the ALARA provisions of the licensee's or registrant's radiation protection program.

(7) The licensee or registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in this rule if the licensee or registrant has met all the specific requirements for access and control specified in other applicable divisions of chapter 333, such as, 333-105 for industrial radiography, 333-106 for x-rays in the healing arts, and 333-109 for particle accelerators.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-120-0230
Control of Access to Very High Radiation Areas

(1) In addition to the requirements in OAR 333-120-0220, the licensee or registrant must institute additional measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at five gray (500 rad) or more in one hour at one meter from a radiation source or any surface through which the radiation penetrates.

(2) The licensee or registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in OAR 333-120-0220 if the licensee or registrant has met all the specific requirements for access and control specified in OAR chapter 333, division 105 (industrial radiography), division 106 (X-rays in the healing arts), division 109 (particle accelerators), and division 123 (therapeutic radiation machines).

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-120-0240
Control of Access to Very High Radiation Areas — Irradiators

This rule applies to licensees or registrants with sources of radiation in non-self-shielded irradiators. It does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.

(1) Each area in which there may exist radiation levels in excess of five gray (500 rad) in one hour at one meter from a sealed radioactive source that is used to irradiate materials must meet the following requirements.

(a) Each entrance or access point must be equipped with entry control devices which:

(A) Function automatically to prevent any individual from inadvertently entering the area when very high radiation levels exist; and

(B) Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the sealed source, to be reduced below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of one mSv (0.1 rem) in one hour; and

(C) Prevent operation of the source if the source would produce radiation levels in the area that could result in a deep-dose equivalent to an individual in excess of one mSv (0.1 rem) in one hour.

NOTE: This rule applies to radiation from accelerators, and byproduct, source, NARM, or special nuclear radioactive materials that are used in sealed sources in non-self-shielded irradiators. This rule does not apply to radioactive or X-ray sources that are used in teletherapy or medical accelerators, in radiography, or in completely self-shielded irradiators in which the source is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual. This rule also does not apply to sources from which the radiation is incidental to

some other use.

(b) Additional control devices must be provided so that, upon failure of the entry control devices to function as required by subsection (1)(a) of this rule:

(A) The radiation level within the area, from the sealed source, or radiation source is reduced below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of one mSv (0.1 rem) in one hour; and

(B) Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.

(c) The licensee or registrant must provide control devices so that, upon failure or removal of physical radiation barriers other than the radiation source's shield or shielded storage container:

(A) The radiation level from the radiation source is reduced below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of one mSv (0.1 rem) in one hour; and

(B) Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee/registrant or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

(d) When the shield for the stored source is a liquid, the licensee or registrant must provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

(e) Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of subsections (1)(c) and (d) of this rule.

(f) Each area must be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source can be put into operation and in sufficient time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source from being put into operation.

(g) Each area must be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the radiation source.

(h) Each area must be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source, the radiation level from the source in the area is below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of one mSv (0.1 rem) in one hour.

(i) The entry control devices required in subsection (1)(a) of this rule must have been tested for proper functioning. Records of required testing must be maintained in accordance with OAR 333-120-0680.

(A) Testing must be conducted prior to initial operation with the source of radiation on any day (unless operations were continued uninterrupted from the previous day); and

(B) Testing must be conducted prior to resumption of operation of the source of radiation after any unintended interruption; and

(C) The licensee or registrant must submit and adhere to a schedule for periodic tests of the entry control and warning systems.

(j) The licensee or registrant may not conduct operations, other than those necessary to place the source in safe condition or to affect repairs on controls, unless control devices are functioning properly.

(k) Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, must be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for processed materials must be equipped to detect and signal the presence of any loose radiation sources that are carried toward such an exit and to automatically prevent loose radiation sources from being carried out of the area.

(2) Persons holding licenses or registrations or applicants for licenses or registrations for radiation sources that are within the purview of section (1) of this rule and that will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of section (1) of this rule, such as those for the automatic control of radiation levels, may apply to the Authority for approval of the use of alternative safety measures. Any alternative safety measures must provide a degree of personnel protection at least equivalent to those specified in section (1) of this rule. At least one of the alternative measures must include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such radiation sources are used.

(3) The entry control devices required by sections (1) and (2) of this rule must be established in such a way that no individual will be prevented from leaving the area.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

Storage and Control of Licensed Material

333-120-0250

Security of Stored Material

(1) The licensee must secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

(2) The registrant must secure registered radiation machines from unauthorized removal.

(3) The registrant must use devices or administrative procedures to prevent unauthorized use of registered radiation machines.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-120-0260
Control of Material Not in Storage

The licensee must control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas

333-120-0300
Use of Process or Other Engineering Controls

The licensee must use, to the extent practicable, process or other engineering controls (e.g., containment or ventilation) to control the concentrations of radioactive material in air.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-120-0310
Use of Other Controls

(1) When it is not practicable to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee must, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

(a) Control of access;

(b) Limitations of exposure times;

(c) Use of respiratory protection equipment; or

(d) Other controls.

(2) If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-120-0320
Use of Individual Respiratory Protection Equipment

(1) If the licensee uses respiratory protection equipment to limit intakes pursuant to OAR 333-120-0310:

(a) The licensee must use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health/Mine Safety and Health Administration (NIOSH/MSHA).

(b) The licensee may use equipment that has not been tested or certified by NIOSH/MSHA, has not had certification extended by NIOSH/MSHA, or for which there is no schedule for testing or certification, the licensee must submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

(c) The licensee must implement and maintain a respiratory protection program that includes:

(A) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures; and

(B) Surveys and bioassays, as appropriate, to evaluate actual intakes; and

(C) Testing of respirators for operability immediately prior to each use; and

(D) Written procedures regarding:

(i) Monitoring, including air sampling and bioassays;

(ii) Supervision and training of respirator users;

(iii) Fit testing;

(iv) Respirator selection;

(v) Breathing air quality;

(vi) Inventory and control;

(vii) Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;

(viii) Recordkeeping; and

(ix) Limitations on periods of respirator use and relief from respirator use; and

(E) Determination by a physician prior to initial fitting and use of respirators, and at least every 12 months thereafter, that the individual user is physically able to use the respiratory protection equipment.

(F) Fit testing, with fit factor > 10 times the APF for negative pressure devices, and a fit factor > 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed one year. Fit testing must be performed with the facepiece operating in the negative pressure mode.

(d) The licensee must issue a written policy statement on respirator usage covering:

(A) The use of process or other engineering controls, instead of respirators; and

(B) The routine, nonroutine, and emergency use of respirators; and

(C) The periods of respirator use and relief from respirator use.

(e) The licensee must advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

(f) The licensee must use equipment within limitations for type and mode of use and must provide proper visual, communication, low temperature work environments, the concurrent use of safety or radiological protection equipment and other special capabilities (such as adequate skin protection) when needed. The licensee must ensure equipment is used in such a way as not to interfere with the proper operation of the respirator.

(2) In estimating exposure of individuals to airborne radioactive materials, the licensee or registrant may make allowance for respiratory protection equipment used to limit intakes pursuant to OAR 333-120-0310, provided that the following conditions, in addition to those in section (1) of this rule, are satisfied:

(a) The licensee selects respiratory protection equipment that provides a protection factor (10 CFR Part 20 Appendix A to 20.1001 to 20.2401) greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in 10 CFR Part 20 Table 1, Column 3 of Appendix B to 20.1001 to 20.2401. If the selection of a respiratory protection device with a protection factor greater than the peak concentration is inconsistent with the goal specified in OAR 333-120-0310 of keeping the total effective dose equivalent ALARA, the licensee or registrant may select respiratory protection equipment with a lower protection factor only if such a selection would result in keeping the total effective dose equivalent ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than estimated, the corrected value must be used; if the exposure is later found to be less than estimated, the corrected value may be used; and

(b) The licensee must obtain authorization from the Authority before assigning respiratory protection factors in excess of those specified in 10 CFR Part 20 Appendix A to 20.1001 to 20.2401. The Authority may authorize a licensee to use higher protection factors on receipt of an application that:

(A) Describes the situation for which a need exists for higher protection factors; and

(B) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

(3) The licensee must use as emergency devices only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by NIOSH/MSHA.

(4) The licensee must notify the Authority, in writing, at least 30 days before the date that respiratory protection equipment is first used under the provisions of either sections (1) or (2) of this rule.

(5) Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons must observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

(6) Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997. Grade D quality air criteria include:

(a) Oxygen content (v/v) of 19.5-23.5%;

(b) Hydrocarbon (condensed) content of five milligrams per cubic meter of air or less;

(c) Carbon monoxide (CO) content of 10 ppm or less;

(d) Carbon dioxide content of 1,000 ppm or less; and

(e) Lack of noticeable odor.

(7) The licensee must ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

(8) In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; DEQ 14-2008, f. & cert. ef. 9-15-08

333-120-0330
Further Restrictions on the Use of Respiratory Protection Equipment

The Authority may impose restrictions in addition to those in OAR 333-120-0310 and 333-120-0320, and **10 CFR**, **Part 20**, **Appendix A** to 20.1001 to 20.2401 to:

(1) Ensure that the respiratory protection program of the licensee is adequate to limit exposures of individuals to airborne radioactive materials; and

(2) Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 4-2007, f. & cert. ef. 3-1-07

333-120-0340
Application for Use of Higher Assigned Protection Factors

The licensee shall obtain authorization from the Authority before using assigned protection factors in excess of those specified in 10 CFR Part 20, Appendix A. The Authority may authorize a licensee to use higher assigned protection factors on receipt of an application that:

(1) Describes the situation for which a need exists for higher protection factors; and

(2) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

Stat. Auth: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 14-2008, f. & cert. ef. 9-15-08

Precautionary Procedures

333-120-0400
Caution Signs

(1) Standard radiation symbol: Unless otherwise authorized by the Authority, the symbol prescribed by this division must use the colors magenta, purple, or black on yellow background. The symbol prescribed by this division is the three-bladed design: [Symbol not included. See ED. NOTE.]

(a) Cross-hatched area is to be magenta, or purple, or black; and

(b) The background is to be yellow.

(2) Exception To Color Requirements For Standard Radiation Symbol. Notwithstanding the requirements of section (1) of this rule, licensees and registrants are authorized to label sources, source holders, or device components containing sources of licensed materials that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

(3) Additional Information On Signs and Labels. In addition to the contents of signs and labels prescribed in this division, the licensee may provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

[ED NOTE: Symbol referenced is available from the agency.]
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-120-0410
Posting Requirements

(1) Posting of radiation areas: The licensee or registrant must post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "Caution, Radiation Area."

(2) Posting of high radiation areas: The licensee or registrant must post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "Caution, High Radiation Area" or "Danger, High Radiation Area."

(3) Posting of very high radiation areas: The licensee or registrant must post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "Grave Danger, Very High Radiation Area."

(4) Posting of airborne radioactivity areas: The licensee must post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "Caution, Airborne Radioactivity Area" or "Danger, Airborne Radioactivity Area."

(5) Posting of areas or rooms in which licensed material is used or stored: The licensee must post each area or room in which there is used or stored an amount of licensed material exceeding ten times the quantity of such material specified in 10 CFR, Part 20, Appendix C to 20.1001 to 20.2401 with a conspicuous sign or signs bearing the radiation symbol and the words "Caution, Radioactive Material(s)" or "Danger, Radioactive Material(s)."

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635

333-120-0420
Exceptions to Posting Requirements

(1) A licensee is not required to post caution signs in areas or rooms containing radioactive materials for periods of less than eight hours, if all of the following conditions are met:

(a) The materials are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to radiation or radioactive materials in excess of the limits established in this division; and

(b) The area or room is subject to the licensee's control.

(2) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to OAR 333-120-0410 provided that:

(a) A patient being treated with a permanent implant or therapeutic radiopharmaceutical could be released from confinement pursuant to OAR 333-116-0260 and 333-116-0265 of this chapter; and

(b) There are personnel in attendance who will take the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the limits established in this division and to operate within the ALARA provisions of the licensee's radiation protection program.

(3) A caution sign is not required to be posted in a room or area containing a sealed source, provided the radiation level at 30 centimeters from the surface of the source container or housing does not exceed 0.05 mSv (0.005 rem) per hour.

Stats. Implemented: ORS 453.605 - 453.807

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-120-0430
Labeling Containers

(1) The licensee must ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

(2) Each licensee must, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

Hist.: HD 15-1994, f. & cert. ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94; PH

(3) Each registrant must ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-120-0440
Exemptions to Labeling Requirements

A licensee is not required to label:

(1) Containers holding licensed material in quantities less than the quantities listed in 10 CFR, Part 20, Appendix C to 20.1001 to 20.2401; or

(2) Containers holding licensed material in concentrations less than those specified in 10 CFR, Part 20, Table 3 of Appendix B to 20.1001 to 20.2401; or

(3) Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this division; or

(4) Containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation (49 CFR); or

12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

NOTE: Labeling of packages containing radioactive materials is required

by the U.S. Department of Transportation (DOT) if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by DOT regulations 49 CFR 173.403(m) and (w) and 173.421-173.424.

(5) Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record (examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells). The record must be retained as long as the containers are in use for the purpose indicated on the records; or

(6) Installed manufacturing or process equipment, such as reactor components, piping, and tanks.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 4-2007, f. & cert. ef. 3-1-07

333-120-0450
Procedures for Receiving and Opening Packages

(1) Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in 49 CFR 173.435 Table of A1 and A2 Values for Radionuclides, must make arrangements to receive:

(a) The package when the carrier offers it for delivery; or

(b) Notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

(2) Each licensee must:

(a) Monitor the external surfaces of a labeled package for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as defined in OAR 333-118-0020;

(b) Monitor the external surfaces of a labeled package for radiation levels; and

NOTE: Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations, 49 CFR 172.403 and 172.436-440.

(c) Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

(3) The licensee must perform the monitoring required by section (2) of this rule as soon as practicable after receipt of the package, but not later than three hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than three hours from the beginning of the next working day if it is received after working hours.

(4) The licensee must immediately notify the final delivery carrier and the Authority, by telephone when:

(a) Removable radioactive surface contamination exceeds the limits of OAR 333-118-0150 **Table 3**;

(b) External radiation levels exceed the limits of OAR 333-118-0150(11).

(5) Each licensee must:

(a) Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

(b) Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

(6) Licensees transferring special form sources in licensee-owned or licensee-operated vehicles to and from a work site are exempt from the contamination monitoring requirements of section (2) of this rule, but are not exempt from the survey requirement in section (2) of this rule for measuring radiation levels, which is required to ensure that the source is still properly lodged in its shield.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-120-0460
Testing for Leakage or Contamination of Sealed Sources

(1) The licensee in possession of any sealed source must assure that:

(a) Each sealed source, except as specified in section (2) of this rule is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee has a certificate from the transferor indicating that the sealed source was tested within six months before transfer to the licensee; and

(b) Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed six months or at alternative intervals approved by the Authority, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission; and

(c) Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three months or at alternative intervals approved by the Authority, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission; and

(d) For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee must assure that the sealed source is tested for leakage or contamination before further use; and

(e) Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium-226, must be capable of detecting the presence of 185 Bq (0.005 uCi) of radioactive material on a test sample. Test samples must be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position; and

(f) The test for leakage for brachytherapy sources manufactured to contain radium-226 must be capable of detecting an absolute leakage rate of 37 Bq (0.001 uCi) of radon-222 in a 24 hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume and time; and

(g) Tests for contamination from radium-226 daughters must be taken on the interior surface of brachytherapy source storage containers and must be capable of detecting the presence of 185 Bq (0.005 uCi) of a radium daughter which has a half-life greater than four days.

(2) A licensee need not perform test for leakage or contamination on the following sealed sources:

(a) Sealed sources containing only radioactive material with a half-life of less than 30 days; or

(b) Sealed sources containing only radioactive material as a gas; or

(c) Sealed sources containing 3.7 MBq (100 uCi) or less of beta or photon-emitting material or 370 kBq (10 uCi) or less of alpha-emitting material; or

(d) Sealed sources containing only hydrogen-3; or

(e) Seeds of iridium-192 encased in nylon ribbon; or

(f) Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used, and identified as in storage. The licensee must, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within six months before the date of use or transfer.

(3) Tests for leakage or contamination from sealed sources must be performed by persons specifically authorized by the Authority, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such services.

(4) Test results must be kept in units of becquerel or microcurie and maintained for inspection by the Authority.

(5) The following must be considered evidence that a sealed source is leaking:

(a) The presence of 185 Bq (0.005 uCi) or more of removable contamination on any test sample; or

(b) Leakage of 37 Bq (0.001 uCi) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium-226; or

(c) The presence of removable contamination resulting from the decay of 185 Bq (0.005 uCi) or more of radium-226.

(6) The licensee must immediately withdraw a leaking sealed source from use and must take action to prevent the spread of contamination. The leaking sealed source must be repaired or disposed of in accordance with this division.

(7) Reports of test results for leaking or contaminated sealed sources must be made pursuant to OAR 333-120-0720(1)(e).

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

Waste Disposal

333-120-0500
General Requirements

(1) A licensee must dispose of licensed radioactive material only:

(a) By transfer to an authorized recipient as provided in OAR 333-102-0330; or

(b) By decay in storage; or

(c) By release in effluents within the limits in OAR 333-120-0520; or

(d) As authorized under OAR 333-120-0520, 333-120-0530, 333-120-0540 and 333-120-0545.

(2) A person must be specifically licensed to receive waste containing licensed material from other persons for:

(a) Treatment prior to disposal; or

(b) Treatment or disposal by incineration; or

(c) Decay in storage; or

(d) Disposal at a land disposal facility licensed under 10 CFR, Part 61 (U.S. Nuclear Regulatory Commission) or equivalent Agreement State regulations; or

(e) Storage until transferred to a storage or disposal facility authorized to receive the waste.

(3) As authorized under the provisions of Oregon Revised Statutes.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 20-2010, f. & cert. ef. 9-1-10

333-120-0510
Method for Obtaining Approval of Proposed Disposal Procedures

A licensee or applicant for a license may apply to the Authority for approval of proposed procedures, not otherwise authorized in the rules of this division, to dispose of licensed material generated in the licensee's activities. Each application must include:

(1) A description of the waste containing licensed material to be disposed of, including the physical and chemical properties important to risk evaluation, and the proposed manner and conditions of waste disposal; and

(2) An analysis and evaluation of pertinent information on the nature of the environment; and

(3) The nature and location of other potentially affected licensed and unlicensed facilities; and

(4) Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in this division.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-120-0520
Disposal by Release into Sanitary Sewerage

(1) A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

(a) The material is readily soluble (or is readily dispersible biological material) in water; and

(b) The quantity of licensed or other radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in 10 CFR Part 20 Table 3 of Appendix B to 20.1001 to 20.2401; and

(c) If more than one radionuclide is released, the following conditions also must be satisfied:

(A) The licensee must determine the fraction of the limit in 10 CFR Part 20 Table 3 of Appendix B to 20.1001 to 20.2401 represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in 10 CFR Part 20 Table 3 of Appendix B to 20.1001 to 20.2401; and

(B) The sum of the fractions for each radionuclide required by paragraph (1)(c)(A) of this rule does not exceed unity; and

(d) The total quantity of licensed and other radioactive material that the licensee releases into the sanitary sewerage system in a year does not exceed 185 GBq (5 Curies) of hydrogen-3, 37 GBq (1 Curie) of carbon-14, and 37 GBq (1 Curie) of all other radioactive materials combined.

(2) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material is not subject to the limitations contained in section (1) of this rule.

[ED. NOTE: Appendices referenced are available from the agency.]
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-120-0530
Treatment of Disposal by Incineration

A licensee may treat or dispose of licensed material by incineration only in the amounts and forms specified in OAR 333-120-0540 or as specifically approved by the Authority pursuant to OAR 333-120-0510.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 4-2007, f. & cert. ef. 3-1-07

333-120-0540
Disposal of Specific Wastes

(1) A licensee may dispose of the following licensed material as if it were not radioactive:

(a) 1.85 kBq (0.05 uCi), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

(b) 1.85 kBq (0.05 uCi), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

(2) A licensee may not dispose of tissue under subsection (1)(b) of this rule in a manner that would permit its use either as food for humans or as animal feed.

(3) The licensee must maintain records in accordance with OAR 333-120-0670.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-120-0545
Disposal of Certain Byproduct Material

(1) Licensed material as defined in subsections (c) and (d) of the definition of byproduct material outlined in OAR 333-120-0015(14) may be disposed of in accordance with 10 CFR Part 61

even though it is not defined as low-level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility or transferred for ultimate disposal at a facility licensed under 10 CFR Part 61 of this chapter must meet the requirements of OAR 333-120-0550.

(2) A licensee may dispose of byproduct material as defined in sections (c) and (d) of the definition of byproduct material outlined in OAR 333-120-0015(14) at a disposal facility authorized in accordance with any federal or state solid or hazardous waste laws including the Solid Waste Disposal Act as authorized under the Energy Policy Act of 2005.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 20-2010, f. & cert. ef. 9-1-10

333-120-0550
Transfer for Disposal and Manifests

(1) The requirements of this rule and 10 CFR Part 20 Appendix G to 20.1001 to 20.2401 are designed to control transfers of low-level radioactive waste intended for disposal at a land disposal facility (as defined in 10 CFR Part 61), establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes.

(2) Each shipment of radioactive waste intended for disposal at a licensed land disposal facility must be accompanied by a shipment manifest as specified in 10 CFR Part 20 section I of Appendix G to 20.1001 to 20.2401.

(3) Each shipment manifest must include a certification by the waste generator as specified in 10 CFR Part 20 section II of Appendix G to 20.1001 to 20.2401.

(4) Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, must comply with the requirements specified in 10 CFR Part 20 section III of Appendix G to 20.1001 to 20.2401.

(5) Any licensee shipping byproduct material defined in subsections (c) and (d) of the definition of byproduct material outlined in OAR 333-120-0015(14) intended for ultimate disposal at a land disposal facility licensed under 10 CFR Part 61 must document the information required on the Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with 10 CFR Part 20, Appendix G

[ED. NOTE: Appendices referenced are available from the agency.]
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 20-2010, f. & cert. ef. 9-1-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-120-0560
Compliance with Environmental and Health Protection Regulations

Nothing in chapter 333 divisions 100 through 123 relieves the licensee or registrant from complying with other applicable Federal, State, and local regulations or rules governing any other toxic or hazardous properties of materials that may be disposed of under division 333-120.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

Records

333-120-0600
General Provisions

(1) Each licensee must use the SI units becquerel, gray, sievert and coulomb per kilogram, or the special units curie, rad, rem, including multiples and subdivisions, and must clearly indicate the units of all quantities on records required by this division.

(2) The licensee must make a clear distinction among the quantities entered on the records required by this division (e.g. total effective dose equivalent, shallow-dose equivalent, lens dose equivalent, deep-dose equivalent, committed effective dose equivalent).

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-120-0610
Records of Radiation Protection Programs

(1) Each licensee must maintain records of the radiation protection program, including:

(a) The provisions of the program; and

(b) Audits and other reviews of program content and implementation.

(2) The licensee must retain the records required by subsection (1)(a) of this rule until the Authority terminates each pertinent license or registration requiring the record. The licensee must retain the records required by subsection (1)(b) of this rule for five years or until inspected by the Authority.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-120-0620
Records of Surveys and Leak Tests

(1) Each licensee or registrant must maintain records showing the results of surveys, sealed source leak tests, and calibrations required by OAR 333-120-0200, 333-120-0450(2) and 333-120-0460. The licensee or registrant must retain these records in accordance with OAR 333-100-0057.

(2) The licensee or registrant must retain each of the following records until the Authority terminates each pertinent license or registration requiring the record:

(a) Records of the results of surveys to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents. This includes records of survey results to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents required under the standards for protection against radiation in effect prior to January 1, 1994; and

(b) Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment for internal dose. This includes records documenting the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose required under the standards for protection against radiation in effect prior to January 1, 1994; and

(c) Records showing the results of air sampling, surveys, and bioassays required pursuant to OAR 333-120-0320(1)(c)(A) and (B). This includes records documenting the results of air sampling, surveys, and bioassays required under the standards for protection against radiation in effect prior to January 1, 1994; and

(d) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment. This includes records documenting the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment required under the standards for protection against radiation in effect prior to January 1, 1994.

(3) Records of Tests for Leakage or Contamination of Sealed Sources. Records of tests for leakage or contamination of sealed sources required by OAR 333-120-0460, must be kept in units of becquerels or microcuries and maintained for inspection by the Authority in accordance with 333-100-0057.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-120-0630
Determination of Prior Occupational Dose

(1) For each individual likely to receive, in a year, an occupational dose requiring monitoring pursuant to OAR 333-120-0210, the licensee or registrant must:

(a) Determine the occupational radiation dose received during the current year; and

(b) Attempt to obtain the records of lifetime cumulative occupational radiation dose.

(2) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant must determine:

(a) The internal and external doses from all previous planned special exposures; and

(b) All doses in excess of the limits (including doses received during accidents and emergencies) received during the lifetime of the individual.

(3) In complying with the requirements of section (1) or (2) of this rule, a licensee or registrant may:

(a) Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual may have received during the current year; or

(b) Accept, as the record of lifetime cumulative radiation dose, an up-to-date NRC Form 4, or equivalent, signed by the individual and counter-signed by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee or registrant); and

(c) Obtain reports of the individual's dose equivalent(s) from the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee or registrant) by telephone, telegram, electronic media, or letter. The licensee or registrant must request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(4) The licensee or registrant must record the exposure history, as required by section (1) of this rule, on NRC Form 4, or other clear and legible record, of all the information required on NRC Form 4. The form or record must show each period in which the individual received occupational exposure to radiation or radioactive material and must be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant must use the dose shown in the report in preparing NRC Form 4. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant must place a notation on NRC Form 4 indicating the periods of time for which data are not available.

(5) If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant must assume:

(a) In establishing administrative controls under OAR 333-120-0100(6) for the current year, that the allowable dose limit for the individual is reduced by 1.25 rem (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

(b) That the individual is not available for planned special exposures.

(6) The licensee or registrant must retain the records on NRC Form 4 or equivalent until the Authority terminates each pertinent license or registration requiring this record. The licensee or registrant must retain records used in preparing NRC Form 4 in accordance with OAR 333-100-0057.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2013, f. & cert. ef. 1-29-13

333-120-0640
Records of Planned Special Exposures

(1) For each use of the provisions of OAR 333-120-0150 for planned special exposures, the licensee must maintain records that describe:

(a) The exceptional circumstances requiring the use of a planned special exposure; and

(b) The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and

(c) What actions were necessary; and

(d) Why the actions were necessary; and

(e) How doses were maintained ALARA; and

(f) What individual and collective doses were expected to result, and the doses actually received in the planned special exposure.

(2) The licensee must retain the records until the Authority terminates each pertinent license or registration requiring these records.

(3) Upon termination of the license or registration, the licensee or registrant must permanently store records on Authority Form Y or equivalent, or must make provision with the Authority for transfer to the Agency.

[ED. NOTE: Forms referenced are available from the agency.]
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-120-0650
Records of Individual Monitoring Results

(1) Recordkeeping Requirement. Each licensee must maintain records of doses received by all individuals for whom monitoring was required pursuant to OAR 333-120-0210 and records of doses received during planned special exposures, accidents, and emergency conditions. These records must include, when applicable:

(a) The deep-dose equivalent to the whole body, lens dose equivalent, shallow-dose equivalent to the skin, and shallow-dose equivalent to the extremities; and

(b) The estimated intake or body burden of radionuclides (OAR 333-120-0110); and

(c) The committed effective dose equivalent assigned to the intake or body burden of radionuclides; and

(d) The specific information used to calculate the committed effective dose equivalent pursuant to OAR 333-120-0130(3); and

(e) The total effective dose equivalent when required by OAR 333-120-0110; and

(f) The total of the deep-dose equivalent and the committed dose to the organ receiving the highest total dose.

NOTE: Assessments of dose equivalent and records made using units in effect before the licensee's adoption of this division need not be changed.

(2) Recordkeeping Frequency: The licensee must make entries of the records specified in section (1) of this rule at least annually.

(3) Recordkeeping Format. The licensee must maintain the records specified in section (1) of this rule using NRC form 5 or equivalent, in accordance with the instructions for NRC's Form 5, or in clear and legible records containing all the information required by NRC's Form 5.

(4) Privacy Protection. The records required under this rule are protected from public disclosure because of their personal privacy nature. These records are protected and if transferred to the Authority, are protected under ORS Chapter 192.

(5) The licensee must maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman, as defined in OAR 333-100-0005. The declaration of pregnancy must also be kept on file, but may be maintained separately from the dose records.

(6) The licensee must retain each required form or record until the Authority authorizes disposition.

NOTE: The following information is required on Form 5, Occupational Exposure Record for a Monitoring Period: Name; identification number and type (Social Security Number (SSN), Passport Number (PPN), Canadian Social Insurance Number (CSI), Work Permit Number (WPN), INDEX Identification Number (IND), or Other (OTH)); sex; date of birth; monitoring period; licensee name; license or registration number; is dose is official record or estimate; if dose is routine or planned special exposure; intake, list radionuclide, class, mode, total intake (Ci); external dose(s), DDE (Deep Dose Equivalent in rems), LDE (Lens Dose Equivalent in rems), SDE(WB) (Shallow Dose Equivalent Whole Body in rems), SED(ME) (Shallow Dose Equivalent Maximum Extremity in rems), CEDE (Committed Effective Dose Equivalent in rems), CDE (Committed Dose Equivalent in rems), TEDE (Total Effective Dose Equivalent in rems) and TODE Total Organ Dose Equivalent in rems).

[ED. NOTE: Forms referenced are available from the agency.]

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 15-1994, f. & cert. ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-120-0660
Records of Dose to Individual Members of the Public

(1) Each licensee must maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public (OAR 333-120-0180).

(2) The licensee must retain the records required by section (1) of this rule until the Authority terminates each pertinent licensee requiring the record.

NOTE: The following information is required on Form 5, Occupational Exposure Record for a Monitoring Period: Name; identification number and type of number, such as SSN; sex; date of birth; monitoring period; licensee name; license or registration number; if dose is official record or estimate; if dose is routine or planned special exposure; intakes, list radionuclide, class, mode, and total intake (Ci); external dose(s), DDE, LDE, SDE (WB), SDE(ME), CEDE, CDE, TEDE and TODE; signature of monitored individual and date signed; certifying organization and signature.

[ED. NOTE: Forms referenced are available from the agency.]

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 15-1994, f. & cert. ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-120-0670
Records of Waste Disposal

(1) Each licensee shall maintain records of the disposal of licensed materials made under OAR 333-120-0510, 333-120-0520, 333-120-0530, 333-120-0540, 10 CFR Part 61, and disposal by burial in soil, including burials authorized before January 28, 1981.

(2) The licensee shall maintain the records required by section (1) of this rule until the Authority terminates each pertinent license requiring the record. Requirements for disposition of these records, prior to license termination are located in OAR 333-100-0055, 333-102-0355 and 10 CFR Part 72.80 for licensed activities.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-120-0680
Records of Testing Entry Control Devices for Very High Radiation Areas

(1) Each licensee must maintain records of tests made under OAR 333-120-0240(1)(i) on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

(2) The licensee must retain the records required by section (1) of this rule in accordance with OAR 333-100-0057.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 15-1994, f. & cert. ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-120-0690
Form of Records

Each record required by this division must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 15-1994, f. & cert. ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

Reports

333-120-0700
Reports of Theft or Loss of Licensed Material

(1) Telephone reports: Each licensee or registrant must report by telephone to the Authority as follows:

(a) Immediately after its occurrence becomes known to the licensee or registrant, any lost, stolen, or missing licensed or registered device, or licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in 10 CFR Part 20 Appendix C to 20.1001 to 20.2401, under such circumstances that it appears to the licensee or registrant that an exposure could result to persons in unrestricted areas; or

(b) Within 30 days after the occurrence of any lost, stolen, or missing licensed or registered device, or licensed radioactive material, becomes known to the licensee or registrant, all licensed or registered material in a quantity greater than ten times the quantity specified in 10 CFR Part 20 Appendix C to 20.1001 to 20.2401 that is still missing at this time.

(2) Written Reports: Each licensee or registrant required to make a report under section (1) of this rule must make a written report to the Authority, within 30 days after making the telephone report, setting forth the following information:

(a) A description of the device or licensed material involved, including kind, quantity, and chemical and physical form; and

(b) A description of the circumstances under which the loss or theft occurred; and

(c) A statement of disposition, or probable disposition, of the device or licensed material involved; and

(d) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

(e) Actions that have been taken, or will be taken, to recover the material; and

(f) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of a device or licensed material; and

(g) Subsequent to filing the written report, the licensee must also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

(3) The licensee must prepare any report filed with the Authority pursuant to this rule so that names of individuals who may have received exposure to radiation are stated in a separate and detachable part of the report.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-120-0710
Notification of Incidents

(1) Immediate notification: Notwithstanding any other requirements for notification, each licensee, or registrant, must immediately report any event involving a device or licensed radioactive material possessed by the licensee, or registrant, which may have caused or threatens to cause any of the following conditions:

(a) An individual to receive:

(A) A total effective dose equivalent of 0.25 Sv (25 rem) or more; or

(B) A lens dose equivalent of 0.75 Sv (75 rem) or more; or

(C) A shallow-dose equivalent to the skin or extremities of 2.5 gray (250 rad) or more; or

(b) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational annual limit on intake (the provisions of this rule do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures).

(2) Twenty-four hour notification: Each licensee or registrant must, within 24 hours of discovery of the event, report any event involving loss of control of a device or licensed material possessed by the licensee that may have caused, or threatens to cause, any of the following conditions:

(a) An individual to receive in a period of 24 hours:

(A) A total effective dose equivalent exceeding 0.05 Sv (5 rems); or

(B) A lens dose equivalent exceeding 0.15 Sv (15 rems); or

(C) A shallow-dose equivalent to the skin or extremities exceeding 0.5 Sv (50 rems); or

(b) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational annual limit on intake (the provisions of this rule do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures).

(3) The licensee must prepare any report filed with the Authority pursuant to this rule so that names of individuals who have received exposure to radiation or radioactive material are stated in a separate and detachable part of the report.

(4) Reports made by licensees, or registrants, in response to the requirements of subsections (1)(a) and (b) of this rule must be made by telephone and either by telegram, electronic mail, or facsimile to the Authority.

(5) The provisions of this rule do not include doses that result from planned special exposures, that are within the limits for planned special exposures, and that are reported under OAR 333-120-0730.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 24-2014, f. & cert. ef. 8-15-14; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-120-0720
Reports of Exposures, Radiation Levels, Leak Tests, and Concentrations of Radioactive Material Exceeding the Limits

(1) Reportable events: In addition to the notification required by OAR 333-120-0710, each licensee must submit a written report within 30 days after learning of any of the following occurrences:

(a) Any incident for which notification is required by OAR 333-120-0710; or

(b) Doses in excess of any of the following:

(A) The occupational dose limits for adults in OAR 333-120-0100; or

(B) The occupational dose limits for a minor in OAR 333-120-0160; or

(C) The limits for an embryo/fetus of a declared pregnant woman (as defined in OAR 333-100-0005) in 333-120-0170; or

(D) The limits for an individual member of the public in OAR 333-120-0180; or

(E) Any applicable limit in the license; or

(F) The ALARA constraints for air emissions established under 333-120-0020(4); or

(c) Levels of radiation or concentrations of radioactive material in:

(A) A restricted area in excess of any applicable limit in the license; or

(B) An unrestricted area in excess of ten times any applicable limit set forth in this division or in the license (whether or not involving exposure of any individual in excess of the limits in OAR 333-120-0180); or

(d) For licensee subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR Part 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

(e) Leaking or contaminated sealed sources in excess of limits in OAR 333-120-0460, must be reported within five days to the Authority describing the equipment involved, the test results and the corrective action taken.

(f) Erroneous overexposure dosimetry reports that resulted from non-personnel exposures;

(2) Contents of reports: Each report required by section (1) of this rule must describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(a) Estimates of each individual's dose; and

(b) The levels of radiation and concentrations of radioactive material involved; and

(c) The cause of the elevated exposures, dose rates, or concentrations; and

(d) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, generally applicable environmental standards, and associated license conditions; and

(e) For each individual exposed: the name, Social Security account number, and date of birth. The report must be prepared so that this information is stated in a separate and detachable part of the report.

NOTE: With respect to the limit for the embryo/fetus (OAR 333-120-0170) the identifiers should be those of the declared pregnant woman, as defined in OAR 333-100-0005.

(3) All licensees who make reports under section (1) this rule must submit the report in writing to the Authority.

(4) The Authority must prohibit the removal or expungement of any permanent dosimetry report submitted to the licensee or registrant. Evaluated erroneous personnel dose record changes to licensee or registrant records must be recorded only on Form 5 and retained by the licensee or registrant.

[ED. NOTE: Forms referenced are available from the agency.]
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-120-0730
Reports of Planned Special Exposures and Individual Monitoring

(1) The licensee must submit a written report to the Authority within 30 days following any planned special exposure conducted in accordance with OAR 333-120-0150 informing the Authority that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by OAR 333-120-0640.

(2) The following licensees must have available for inspection by the Authority a written report documenting results of individual monitoring carried out by the licensee for each individual for whom monitoring was required pursuant to OAR 333-120-0210 during that year.

(a) Licensees authorized to possess or use radioactive material for purposes of radiography pursuant to division 102 and 105 of these rules; or

(b) Licensees who receive radioactive waste from other persons for disposal pursuant to 10 CFR Part 61; or

(c) Licensees who possess or use at any time, for processing or manufacturing for distribution pursuant to division 102 or 116 of these rules, radioactive material in quantities exceeding any one of the following quantities:

Quantity of Radionuclide in Curies:

(A) Cesium-137 — 1;

(B) Cobalt-60 — 1;

(C) Gold-198 — 100;

(D) Iodine-131 — 1;

(E) Iridium-192 — 10;

(F) Krypton-85 — 1,000;

(G) Promethium-147 — 10;

(H) Technetium-99m — 1,000.

The Authority may require as a license condition, or by rule, regulation, or order pursuant to OAR 333-100-0030, reports from licensees who are licensed to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

NOTE: The licensee may include additional data for individuals for whom monitoring was provided but not required. The licensee shall use NRC's Form 5 or electronic media containing all the information required by NRC's Form 5.

[ED. NOTE: Forms referenced are available from the agency.]

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 15-1994, f. & cert. ef. 5-6-94; HD 24-1994, f. & cert. ef. 9-6-94; HD 1-1995, f. & cert. ef. 4-26-95; Administrative Reformatting 12-8-97; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 4-2013, f. & cert. ef. 1-29-13

333-120-0740
Reports to Individuals Exceeding Dose Limits

When a licensee or registrant is required, pursuant to the provisions of OAR 333-120-0720 or 333-120-0730, to report to the Authority any exposure of an identified occupationally exposed individual or an identified member of the public to radiation or radioactive material, the licensee or registrant must also provide the individual a report on his or her exposure data included in the report submitted to the Authority. This report must be transmitted at a time no later than the transmittal to the Authority.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

DIVISION 121

LICENSING AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

333-121-0001
Purpose and Scope

(1) This division contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive material in irradiators used to irradiate objects or materials using gamma radiation. This division also contains radiation safety requirements for operating irradiators. The requirements of this division are in addition to other requirements of these regulations. In particular, the provisions of divisions 100, 102, 120, and 111 of chapter 333 apply to applications and licenses subject to this division. Nothing in this division relieves the licensee from complying with other applicable federal, state and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

(2) The regulations in this division apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this division.

(3) The regulations in this division do not apply to self-contained dry-source-storage irradiators in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel; medical radiology or teletherapy; radiography for the irradiation of materials for nondestructive testing purposes; gauging; or open-field, agricultural, irradiations.

Stat. Auth.: ORS 453.675

Stats. Implemented: ORS 453.675

Hist.: PH 5-2005, f. & cert. ef. 4-11-05; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-121-0010
Definitions

(1) "Annually" means at intervals not to exceed one year.

(2) "Commencement of construction" means taking any action defined as "construction" or any other activity at the site of a facility subject to the regulations in this division that has a reasonable nexus to radiological health and safety.

(3) "Construction" means the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to the regulations in this division that are related to radiological safety or security. The term "construction" does not include:

(a) Changes for temporary use of the land for public recreational purposes;

(b) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

(c) Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

(d) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this division;

(e) Excavation;

(f) Erection of support buildings (such as construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

(g) Building of service facilities (such as paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);

(h) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or

(i) Taking any other action that has no reasonable nexus to radiological health and safety.

(4) "Doubly encapsulated sealed source" means a sealed source in which the radioactive material is sealed within an inner capsule and that capsule is sealed within an outer capsule.

(5) "Irradiator" means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays (500 rads) per hour exist at 1 meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

(6) "Irradiator operator" means an individual who has successfully completed the training and testing described in OAR 333-121-0300 and is authorized by the terms of the license to operate the irradiator without a supervisor present.

(7) "Irradiator operator supervisor" means an individual who meets the requirements for an irradiator operator and who physically oversees operation of the irradiator by an individual who is currently receiving training and testing described in OAR 333-121-0300.

(8) "Panoramic dry-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially

accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

(9) "Panoramic irradiator" means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

(10) "Panoramic wet-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

(11) "Pool irradiator" means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

(12) "Product conveyor system" means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

(13) "Radiation room" means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

(14) "Sealed source" means any radioactive material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the byproduct material.

(15) "Seismic area" means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10 percent, as designated by the US Geological Survey.

(16) "Underwater irradiator" means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

Stat. Auth.: ORS 453.675
Stats. Implemented: ORS 453.675
Hist.: PH 5-2005, f. & cert. ef. 4-11-05; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-121-0020
Application for a Specific License

(1) Applications for specific licenses shall be filed on a form prescribed by the Authority and satisfy the general requirements specified in OAR 333-102-0200.

(2) The Authority may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Authority to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(3) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

(4) An application for a license may include a request for a license authorizing one or more activities.

(5) In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Authority provided such references are clear and specific.

(6) Applications and documents submitted to the Authority may be made available for public inspection except that the Authority may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-121-0030
Specific Licenses for Irradiators

The Authority will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section.

(1) The applicant must satisfy the general requirements specified in division 102 of these regulations and the requirements contained in this division.

(2) The application must describe the training provided to irradiator operators including:

(a) Classroom training;

(b) On-the-job or simulator training;

(c) Safety reviews;

(d) Means employed by the applicant to test each operator's understanding of the Authority's regulations and licensing requirements and the irradiator operating, safety, and emergency procedures; and

(e) Minimum training and experience of personnel who may provide training.

(3) The application must include an outline of the written operating and emergency procedures listed in OAR 333-121-0310 that describes the radiation safety aspects of the procedures.

(4) The application must describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have radiation safety responsibilities or authorities. In particular, the application must specify who, within the management structure, has the authority to stop unsafe operations. The application must also describe the training and experience required for the position of radiation safety officer.

(5) The application must include a description of the access control systems required by OAR 333-121-0110 the radiation monitors required by 333-121-0140 the method of detecting leaking sources required by 333-121-0340 including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

(6) If the applicant intends to perform leak testing, the applicant must establish procedures for performing leak testing of dry-source-storage sealed sources and submit a description of these procedures to the Authority. The description must include the:

(a) Methods of collecting the leak test samples;

(b) Qualifications of the individual who collects the samples;

(c) Instruments to be used; and

(d) Methods of analyzing the samples.

(7) If licensee personnel are to load or unload sources, the applicant must describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading must be done by a person specifically authorized by the Authority, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State to load or unload irradiator sources.

(8) The applicant must describe the inspection and maintenance checks, including the frequency of the checks required by OAR 333-121-0350.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06

333-121-0040
Start of Construction

The applicant may not begin construction of a new irradiator prior to the submission to the Authority of both an application for a license for the irradiator and any fee required by the applicable state requirement or statute. As used in this division, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: engineering and design work, purchase of a site, site surveys or soil testing, site preparation, site excavation, construction of warehouse or auxiliary structures, and other similar tasks. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of the appropriate state statute, rules, regulations, and orders issued under the appropriate state statute.

Stat. Auth.: ORS 453.675
Stats. Implemented: ORS 453.675
Hist.: PH 5-2005, f. & cert. ef. 4-11-05

333-121-0050
Applications for Exemptions

Any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials

or objects may include proposed alternatives for the requirements of this division. The Authority will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

Stat. Auth.: ORS 453.675
Stats. Implemented: ORS 453.675
Hist.: PH 5-2005, f. & cert. ef. 4-11-05

333-121-0060
Request for Written Statements

Each license is issued with the condition that the licensee will, at any time before expiration of the license, upon the Authority's request, submit a written statement to enable the Authority to determine whether the license should be modified, suspended, or revoked.

Stat. Auth.: ORS 453.675
Stats. Implemented: ORS 453.675
Hist.: PH 5-2005, f. & cert. ef. 4-11-05

333-121-0100
Performance Criteria for Sealed Sources

(1) Requirements for sealed sources installed after September 1, 2002:

(a) Must have been evaluated in accordance with 10 CFR 32.210 or the equivalent state regulation;

(b) Must be doubly encapsulated;

(c) Must use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;

(d) Must be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and

(e) In prototype testing of the sealed source, must have been leak tested and found leak-free after each of the tests described in OAR 333-121-0100(2) through 333-121-0100(7) of this rule.

(2) Temperature. The test source must be held at -40°C for 20 minutes, 600°C for one hour, and then be subjected to thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds.

(3) Pressure. The test source must be twice subjected for at least five minutes to an absolute external pressure of 2 million newtons per square meter.

(4) Impact. A 2 kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of 1 meter onto the test source.

(5) Vibration. The test source must be subjected three times for ten minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of five times the acceleration of gravity. In addition, each test source must be vibrated for 30 minutes at each resonant frequency found.

(6) Puncture. A 50 gram weight and pin, 0.3 centimeter pin diameter, must be dropped from a height of 1 meter onto the test source.

(7) Bend. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of 2000 newtons at its center equidistant from two support cylinders, the distance between which is ten times the minimum cross-sectional dimension of the source.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06

333-121-0110
Access Control

(1) Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to the shielded position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources. The control panel lock must be designed so that the key cannot be removed unless the sources have been returned to the shielded position. The doors and barriers must not prevent any individual in the radiation room from leaving.

(2) In addition, each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm must also alert at least one other individual who is on-site of the entry. That individual must be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

(3) A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels must activate the alarm described in OAR 333-121-0110(2) of this rule. The monitor may be located in the entrance, normally referred to as the maze, but not in the direct radiation beam.

(4) Before the sources move from their shielded position in a panoramic irradiator, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.

(5) Each radiation room at a panoramic irradiator must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.

(6) Each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

(7) Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must have a sign bearing the radiation symbol and the words, "Caution (or danger) radioactive material." Panoramic irradiators must also have a sign stating "Grave danger, very high radiation area," but the sign may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

(8) If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. The requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

(9) Underwater irradiators must have a personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended. Only operators or facility management must have access to keys that operate the personnel access barrier. There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual who is not necessarily on-site but who is prepared to respond or summon assistance.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06

333-121-0120
Shielding

(1) The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.02

millisievert (2 mrem) per hour at any location 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 centimeters. Any area where the radiation dose rate exceeds 0.02 millisievert (2 mrem) per hour must be locked, roped off, or posted.

(2) The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 0.02 millisievert (2 mrem) per hour when the sources are in the fully shielded position.

(3) The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 0.02 millisievert (2 mrem) per hour and at 5 centimeters from the shield may not exceed 0.2 millisievert (20 mrem) per hour.

Stat. Auth.: ORS 453.675
Stats. Implemented: ORS 453.675
Hist.: PH 5-2005, f. & cert. ef. 4-11-05

333-121-0130
Fire Protection

(1) The radiation room at a panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting a person who is prepared to summon assistance promptly. The sources must automatically become fully shielded if a fire is detected.

(2) The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

Stat. Auth.: ORS 453.675
Stats. Implemented: ORS 453.675
Hist.: PH 5-2005, f. & cert. ef. 4-11-05

333-121-0140
Radiation Monitors

(1) Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this paragraph.

(2) Underwater irradiators that are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

Stat. Auth.: ORS 453.675
Stats. Implemented: ORS 453.675
Hist.: PH 5-2005, f. & cert. ef. 4-11-05

333-121-0150
Control of Source Movement

(1) The mechanism that moves the sources of a panoramic irradiator must require a key to actuate. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key.

(2) The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.

(3) The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position.

(4) Each control for a panoramic irradiator must be clearly marked as to its function.

Stat. Auth.: ORS 453.675
Stats. Implemented: ORS 453.675
Hist.: PH 5-2005, f. & cert. ef. 4-11-05

333-121-0160
Irradiator Pools

(1) For licenses initially issued after April 11, 2005, irradiator pools must either:

(a) Have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool; or

(b) Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee must have a method to safely store the sources during repairs of the pool.

(2) For licenses initially issued after April 11, 2005, irradiator pools must have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons must have siphon breakers to prevent the siphoning of pool water.

(3) A means must be provided to replenish water losses from the pool.

(4) A visible indicator must be provided in a clearly observable location to indicate if the pool water level is below the normal low water level or above the normal high water level.

(5) Irradiator pools must be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with a clarity so that the sources can be seen clearly.

(6) A physical barrier, such as a railing or cover, must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.

(7) If long-handled tools or poles are used in irradiator pools, the radiation dose rate to the operator at the handling areas of the tools may not exceed 0.02 millisievert (2 mrem) per hour.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06

333-121-0170
Source Rack Protection

If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a carrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

Stat. Auth.: ORS 453.675
Stats. Implemented: ORS 453.675
Hist.: PH 5-2005, f. & cert. ef. 4-11-05

333-121-0180
Power Failures

(1) If electrical power at a panoramic irradiator is lost for longer than ten seconds, the sources must automatically return to the shielded position.

(2) The lock on the door of the radiation room of a panoramic irradiator must remain locked in the event of a power failure.

(3) During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

Stat. Auth.: ORS 453.675
Stats. Implemented: ORS 453.675
Hist.: PH 5-2005, f. & cert. ef. 4-11-05

333-121-0190
Design Requirements

Irradiators whose construction begins after September 1, 2002, must meet the design requirements of this rule.

(1) Shielding. For panoramic irradiators, the licensee must design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding

requirements of OAR 333-121-0120. If the irradiator will use more than 2 x 1017 becquerels (5 million Ci) of activity, the licensee must evaluate the effects of heating of the shielding walls by the irradiator sources.

(2) Foundations. For panoramic irradiators, the licensee must design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.

(3) Pool integrity. For pool irradiators, the licensee must design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of OAR 333-121-0160(2) and that metal components are metallurgically compatible with other components in the pool.

(4) Water handling system. For pool irradiators, the licensee must verify that the design of the water purification system is adequate to meet the requirements of OAR 333-121-0160(5). The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

(5) Radiation monitors. For all irradiators, the licensee must evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by OAR 333-121-0140(1). The licensee must verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under OAR 333-121-0340(2), the licensee must verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

(6) Source rack. For pool irradiators, the licensee must verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee must determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables, or alternate means of support, will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee must review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

(7) Access control. For panoramic irradiators, the licensee must verify from the design and logic diagram that the access control system will meet the requirements of OAR 333-121-0110.

(8) Fire protection. For panoramic irradiators, the licensee must verify that the number, locations, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. The licensee must verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

(9) Source return. For panoramic irradiators, the licensee must verify that the source rack will automatically return to the fully shielded position if power is lost for more than ten seconds.

(10) Seismic. For panoramic irradiators to be built in seismic areas, the licensee must design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as the American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes, if current.

(11) Wiring. For panoramic irradiators, the licensee must verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06

333-121-0200
Construction Monitoring and Acceptance Testing

The requirements of this section must be met for irradiators whose construction begins after September 1, 2002. The requirements must be met prior to loading sources.

(1) Shielding. For panoramic irradiators, the licensee must monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

(2) Foundations. For panoramic irradiators, the licensee must monitor the construction of the foundations to verify that their construction meets design specifications.

(3) Pool integrity. For pool irradiators, the licensee must verify that the pool meets design specifications and must test the integrity of the pool. The licensee must verify that outlets and pipes meet the requirements of OAR 333-121-0160(2).

(4) Water handling system. For pool irradiators, the licensee must verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

(5) Radiation monitors. For all irradiators, the licensee must verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by OAR 333-121-0140(1). For pool irradiators, the licensee must verify the proper operation of the radiation monitors and the related alarm if used to meet 333-121-0340(2). For underwater irradiators, the licensee must verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by 333-121-0140(2).

(6) Source rack. For panoramic irradiators, the licensee must test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee must observe and test the operation of the conveyor system to assure that the requirements in OAR 333-121-0170 are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves that rack from moving product carriers.

(7) Access control. For panoramic irradiators, the licensee must test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

(8) Fire protection. For panoramic irradiators, the licensee must test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee must test the operability of the fire extinguishing system.

(9) Source return. For panoramic irradiators, the licensee must demonstrate that the source racks can be returned to their fully shielded positions without power.

(10) Computer systems. For panoramic irradiators that use a computer system to control the access control system, the licensee must verify that the access control system will operate properly if power is lost and must verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when the system is required to be operable.

(11) Wiring. For panoramic irradiators, the licensee must verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06

333-121-0300
Training

(1) Before an individual is permitted to act as an irradiator operator without a supervisor present, the individual must be instructed in:

(a) The fundamentals of radiation protection applied to irradiators. This must include the differences between external radiation and radioactive contamination, units of radiation dose, dose limits,

why large radiation doses must be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator;

(b) The requirements of division 111 and division 121 of these regulations that are relevant to the irradiator;

(c) The operation of the irradiator;

(d) Those operating and emergency procedures listed in OAR 333-121-0310 that the individual is responsible for performing; and

(e) Case histories of accidents or problems involving irradiators.

(2) Before an individual is permitted to act as an irradiator operator without a supervisor present, the individual must pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

(3) Before an individual is permitted to act as an irradiator operator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual must also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.

(4) The licensee must conduct safety reviews for irradiator operators at least annually. The licensee must give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following:

(a) Changes in operating and emergency procedures since the last review, if any;

(b) Changes in regulations and license conditions since the last review, if any;

(c) Reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;

(d) Relevant results of inspections of operator safety performance;

(e) Relevant results of the facility's inspection and maintenance checks; and

(f) A drill to practice an emergency or abnormal event procedure.

(5) The licensee must evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating, safety, and emergency procedures are followed. The licensee must discuss the results of the evaluation with the operator and must instruct the operator on how to correct any mistakes or deficiencies observed.

(6) Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, must be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in OAR 333-121-0310 that they are expected to perform or comply with, and their proper response to alarms required in this division. Tests may be oral.

(7) Individuals who must be prepared to respond to alarms required by OAR 333-121-0110(2), 333-121-0130(1), 333-121-0140(1) and 333-121-0340(2) must be trained and tested on how to respond. Each individual must be retested at least annually. Tests may be oral.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06

333-121-0310
Operating and Emergency Procedures

(1) The licensee must have and follow written operating procedures for:

(a) Operation of the irradiator, including entering and leaving the radiation room;

(b) Use of personnel dosimeters;

(c) Surveying the shielding of panoramic irradiators;

(d) Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;

(e) Leak testing of sources;

(f) Inspection and maintenance checks required by OAR 333-121-0350;

(g) Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and

(h) Inspection of movable shielding required by OAR 333-121-0110(8), if applicable.

(2) The licensee must have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for:

(a) Sources stuck in the unshielded position;

(b) Personnel overexposures;

(c) A radiation alarm from the product exit portal monitor or pool monitor;

(d) Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;

(e) A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;

(f) A prolonged loss of electrical power;

(g) A fire alarm or explosion in the radiation room;

(h) An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area;

(i) Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and

(j) The jamming of automatic conveyor systems.

(3) The licensee may revise operating and emergency procedures without Authority approval only if all of the following conditions are met:

(a) The revisions do not reduce the safety of the facility;

(b) The revisions are consistent with the outline or summary of procedures submitted with the license application;

(c) The revisions have been reviewed and approved by the radiation safety officer; and

(d) The users or operators are instructed and tested on the revised procedures before they are put into use.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06

333-121-0320
Personnel Monitoring

(1) Irradiator operators must wear a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter processor must be accredited by the National Voluntary Laboratory Accreditation Program for high energy photons in the normal and accident dose ranges, see 333-120-0200(3). Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be processed at least monthly, and other personnel dosimeters must be processed at least quarterly.

(2) Other individuals who enter the radiation room of a panoramic irradiator must wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of the paragraph, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within ±20% of the true radiation dose.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06

333-121-0330
Radiation Surveys

(1) A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators

must be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed three years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.

(2) If the radiation levels specified in OAR 333-121-0120 are exceeded, the facility must be modified to comply with the requirements in OAR 333-121-0120.

(3) Portable radiation survey meters must be calibrated at least annually to an accuracy of ±20% for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.

(4) Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in 10 CFR 20, Table II, Column 2 or Table III of Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sanitary Sewerage."

(5) Before releasing resins for unrestricted use, they must be monitored before release in an area with a background level less than 0.5 microsievert (0.05 mrem) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used must be capable of detecting radiation levels of 0.5 microsievert (0.05 mrem) per hour.

Stat. Auth.: ORS 453.675
Stats. Implemented: ORS 453.675
Hist.: PH 5-2005, f. & cert. ef. 4-11-05

333-121-0340
Detection of Leaking Sources

(1) Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed six months using a leak test kit or method approved by the Authority, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State. In the absence of a certificate from a transferor that a test has been made within the six months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 200 becquerels (0.005 uCi) of radioactive material and must be performed by a person approved by the Authority, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform the test.

(2) For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that leak test has been done within the six months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clear up contamination in the pool if specifically provided for in written emergency procedures.

(3) If a leaking source is detected, the licensee must arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by an Authority, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State licensee that is authorized to perform these functions. The licensee must promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee must arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee must arrange to have them decontaminated or disposed of by an Authority, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State licensee that is authorized to perform these functions. If a pool is contaminated, the licensee must arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table 2, Column 2, Appendix B of 10 CFR 20. See 333-120-0700 for reporting requirements.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06

333-121-0350
Inspection and Maintenance

(1) The licensee must perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

(a) Operability of each aspect of the access control system required by OAR 333-121-0110.

(b) Functioning of the source position indicator required by OAR 333-121-0150(2).

(c) Operability of the radiation monitor for radioactive contamination in pool water required by OAR 333-121-0340(2) using a radiation check source, if applicable.

(d) Operability of the over-pool radiation monitor at underwater irradiators as required by OAR 333-121-0140(2).

(e) Operability of the product exit monitor required by OAR 333-121-0140(1).

(f) Operability of the emergency source return control required by OAR 333-121-0150(3).

(g) Visual inspection of leak-tightness of systems through which pool water circulates.

(h) Operability of the heat and smoke detectors and extinguisher system required by OAR 333-121-0130, without turning extinguishers on.

(i) Operability of the means of pool water replenishment required by OAR 333-121-0160(3).

(j) Operability of the indicators of high and low pool water levels required by OAR 333-121-0160(4).

(k) Operability of the intrusion alarm required by OAR 333-121-0110(9) if applicable.

(l) Functioning and wear of the system, mechanisms, and cables used to raise and lower sources.

(m) Condition of the barrier to prevent products from hitting the sources or source mechanism as required by OAR 333-121-0170.

(n) Amount of water added to the pool to determine if the pool is leaking.

(o) Electrical wiring on required safety systems for radiation damage.

(p) Pool water conductivity measurements and analysis as required by OAR 333-121-0360(2).

(2) Malfunctions and defects found during inspection and maintenance checks must be repaired within time frames specified in the license or license application.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06

333-121-0360
Pool Water Purity

(1) Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee must take prompt actions to lower the pool water conductivity and must take corrective actions to prevent future recurrences.

(2) The licensee must measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06

333-121-0370
Attendance During Operation

(1) Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, must be present on site:

(a) Whenever the irradiator is operated using an automatic product conveyor system; and

(b) Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

(2) At a panoramic irradiator at which static irradiations with no movement of the product are occurring, a person who has received the training on how to respond to alarms described in OAR 333-121-0300(7) must be on site.

(3) At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training described in OAR 333-121-0300(6) and 333-121-0300(7). Static irradiations may be performed without a person present at the facility.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06

333-121-0380
Entering and Leaving the Radiation Room

(1) Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator must use a survey meter to determine that the source has returned to its fully shielded position. The operator must check the functioning of the survey meter with a radiation check source prior to entry.

(2) Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator must:

(a) Visually inspect the entire radiation room to verify that no one else is in it; and

(b) Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

(3) During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by OAR 333-121-0140(2) is operating with backup power.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06

333-121-0390
Irradiation of Explosive or Flammable Materials

(1) Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the Authority. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.

(2) Irradiation of more than small quantities of flammable material with a flash point below 140˚F is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the Authority. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

Stat. Auth.: ORS 453.675
Stats. Implemented: ORS 453.675
Hist.: PH 5-2005, f. & cert. ef. 4-11-05

333-121-0500
Records and Retention Periods

The licensee must maintain the following records at the irradiator for the periods specified.

(1) A copy of the license, the license conditions, documents incorporated into the license by reference, and amendments thereto until superseded by new documents or until the Authority terminates the license for documents not superseded.

(2) Records of each individual's training, tests, and safety reviews provided to meet the requirements of OAR 333-121-0300(1), 333-121-0300(2), 333-121-0300(3), 333-121-0300(4), 333-121-0300(6), and 333-121-0300(7) until three years after the individual terminates work.

(3) Records of the annual evaluations of the safety performance of irradiator operators required by 333-121-0300(5) for three years after the evaluation.

(4) A copy of the current operating and emergency procedures required by OAR 333-121-0310 until superseded or the Authority terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by 333-121-0310(3)(c) retained for three years from the date of the change.

(5) Film badge and other personnel dosimeters results required by OAR 333-121-0320 until the Authority terminates the license.

(6) Records of radiation surveys required by OAR 333-121-0330 for three years from the date of the survey.

(7) Records of radiation survey meter calibrations required by OAR 333-121-0330 and pool water conductivity meter calibrations required by 333-121-0360(2) until three years from the date of calibration.

(8) Records of the results of leak tests required by OAR 333-121-0340(1) and the results of contamination checks required by 333-121-0340(2) for three years from the date of each test.

(9) Records of inspection and maintenance checks required by OAR 333-121-0350 for three years.

(10) Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for three years after repairs are completed.

(11) Records of the receipt, transfer and disposal, of all licensed sealed sources as required by 333-102-0330 of these rules.

(12) Records on the design checks required by OAR 333-121-0190 and the construction control checks as required by 333-121-0200 until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.

(13) Records related to decommissioning of the irradiator as required by 333-102-0200(6).

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06

333-121-0510
Reports

(1) In addition to the reporting requirements in other parts of these regulations, the licensee must report the following events if not reported under other parts of these regulations:

(a) Source stuck in an unshielded position.

(b) Any fire or explosion in a radiation room.

(c) Damage to the source racks.

(d) Failure of the cable or drive mechanism used to move the source racks.

(e) Inoperability of the access control system.

(f) Detection of radiation source by the product exit monitor.

(g) Detection of radioactive contamination attributable to licensed radioactive material.

(h) Structural damage to the pool liner or walls.

(i) Water loss or leakage from the source storage pool, greater than the irradiator pool design parameters submitted by the licensee or applicant.

(j) Pool water conductivity exceeding 100 microsiemens per centimeter.

(2) The report must include a telephone report within 24 hours as described in 333-120-0710(2), and a written report within 30 days as described in 333-120-0720.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06

DIVISION 122

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL X-RAY MACHINE OPERATIONS

333-122-0001
Purpose

This division prescribes requirements for the industrial use of x-ray machines and radiation safety requirements for persons using industrial x-ray equipment.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0003
Scope

The provisions and requirements of this division are in addition to the general requirements of divisions 100, 101, 111 and 120.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0005
Definitions

As used in this division, the following definitions apply:

(1) "Annual refresher safety training" means a review conducted or provided by the registrant for its employees on radiation safety aspects of industrial X-ray. The review must include, as a minimum, a review of radiation safety aspects of industrial X-ray, any results of internal audits, Authority inspections, new procedures or equipment, new or revised regulations, and accidents or errors that have been observed. The review must also provide opportunities for employees to ask safety questions.

(2) "ANSI" means the American National Standards Institute.

(3) "Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet so shielded that every location on the exterior meets the dose limits for individual members of the public as specified in OAR 333-120-0180.

(4) "Cabinet X-ray system" means an X-ray system with the X-ray tube installed in an enclosure, hereinafter termed a cabinet that is independent of existing architectural structures except the floor. The cabinet X-ray system is intended to contain at least that portion of a material being irradiated, provide radiation attenuation and exclude personnel from its interior during generation of radiation. This definition includes X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad and bus terminals and in similar facilities, and all X-ray systems designed primarily for the inspection of letters, periodicals and packages in mailrooms. An X-ray tube used within a shielded part of a building, or X-ray equipment that may temporarily or occasionally incorporate portable shielding, is not considered a cabinet X-ray system.

(5) "Certifiable cabinet X-ray system" means an existing uncertified X-ray system that has been modified to meet the certification requirements specified in 21 CFR 1020.40.

(6) "Certified cabinet X-ray system" means an X-ray system that has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

(7) "Hands-on experience" means experience in all of those areas considered to be directly involved in the X-ray process, and includes taking radiographs, calibration of survey instruments, operational and performance testing of survey instruments and devices, film development, posting of radiation areas, set-up of X-ray equipment, and radiation surveys, as applicable. Trainees undergoing the "hands-on experience" must do so under the direct supervision of a qualified industrial X-ray machine operator.

(8) "Industrial X-ray" means a nondestructive examination of the structure of materials using an X-ray machine to make radiographic images.

(9) "Industrial X-ray instructor" means any industrial X-ray operator who has been authorized by the Authority to provide on-the-job training to industrial X-ray trainees in accordance with OAR 333-122-0200.

(10) "Industrial X-ray trainee" means any individual who, under the direct supervision of an industrial X-ray instructor, uses industrial X-ray machines, related handling tools or radiation survey instruments during the course of his instruction.

(11) "Industrial X-ray operations" means all activities performed with an industrial X-ray machine. Activities include using, setting up equipment, and any activity inside restricted area boundaries.

(12) "Industrial X-ray personnel" means any X-ray operator, X-ray instructor or X-ray trainee.

(13) "Permanent X-ray installation" means an enclosed shielded room, cell, or vault in which industrial X-ray is performed.

(14) "Personal supervision" means supervision in which the X-ray operator is physically present at the site where X-ray machines and associated equipment are being used, watching the performance of the X-ray operator's assistant and in such proximity that immediate assistance can be given if required.

(15) "Practical examination" means a demonstration through application of the safety rules and principles in industrial X-ray including use of all procedures and equipment to be used by industrial X-ray personnel.

(16) "Radiation safety officer for industrial X-ray" means an individual with the responsibility for the overall radiation safety program on behalf of the registrant and who meets the requirements of OAR 333-122-0175.

(17) "Shielded room X-ray using X-ray machines" means an enclosed room or vault in which industrial X-ray is performed the interior of which is not occupied during X-ray operations. The room must be so shielded that every location on the exterior meets conditions for an unrestricted area as specified in OAR 333-120-0180, and the only access is through openings that are interlocked so that the X-ray machine will not operate unless all openings are securely closed.

(18) "X-ray Operator" means any individual who handles, adjusts technique factors, activates the exposure switch or button on an industrial X-ray machine and is qualified under OAR 333-122-0200.

(19) "X-ray operator's assistant" means any individual who, under the direct supervision of an industrial X-ray operator, uses radiographic X-ray machines, related handling tools or radiation survey instruments in industrial X-ray.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

333-122-0050
Exemptions

(1) Uses of certified and certifiable cabinet x-ray systems and x-ray systems designed primarily for the inspection of baggage, etc. are exempt from the requirements of this division except for the following:

(a) For certified and certifiable cabinet x-ray systems, including those designed to allow admittance of individuals:

(A) No registrant must permit any individual to operate a cabinet x-ray system until the individual has received a copy of and instruction in the operating procedures for the unit. Records that demonstrate compliance with this subparagraph must be maintained for Agency inspection until disposal is authorized by the Authority.

(B) Tests for proper operation of interlocks must be conducted and recorded:

(i) Every six months for those systems that are designed to allow the admittance of individuals; or

(ii) Annually for those systems that are not designed to allow the admittance of individuals.

(C) Records of these tests must be maintained for Authority inspection until disposal is authorized by the Authority.

(D) The registrant must perform an evaluation of the radiation dose limits to determine compliance with 333-120-0180, 333-120-0190 and 21 CFR 1020.40, Cabinet X-Ray Systems (39 Federal Register 12986, April 10, 1974), at intervals not to exceed one year. Records of these evaluations must be maintained for Authority inspection for two years after the evaluation.

(b) Certified cabinet x-ray systems must be maintained in compliance with 21 CFR 1020.40, Cabinet X-Ray Systems (39) Federal Register 12986, April 10, 1974), and no modification must be made to the system unless prior Authority approval has been granted.

(2) Industrial uses of hand-held light intensified imaging devices are exempt from the requirements of this division if the dose rate 18 inches from any area surrounding the source of radiation does not exceed two millirem per hour. Devices that exceed this limit must meet the applicable requirements of this division and the licensing or registration requirements of division 333-101.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0075
Registration Requirements for Industrial Radiographic X-Ray Machine Operations

The Authority will approve an application for a registration for use of radiation machines if the applicant meets the following requirements:

(1) The applicant satisfies the general requirements specified in 333-101-0005 for radiation machine facilities, and any special requirements contained in this division;

(2) The applicant submits an adequate program for training x-ray equipment operators that meets the requirements of 333-122-0200(6) of these rules;

(3) The applicant provides documentation indicating that all industrial x-ray operators have completed the training and hands-on experience required in 333-122-0200(1) of these rules. The training must include all of the subjects in 333-122-0200(6) of these rules;

(4) The applicant provides documentation verifying x-ray equipment operators are currently certified in industrial x-ray by a certifying entity;

(5) The applicant submits written operating and emergency procedures as described in 333-122-0225 of these rules;

(6) The applicant submits a description of a program for inspections of the job performance of each x-ray operator and x-ray operator's assistant at intervals not to exceed six months as described in 333-122-0200(4)(a) of these rules;

(7) The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial x-ray, including specified delegation of authority and responsibility;

(8) The applicant submits the qualifications of the individual(s) designated as the radiation safety officer as described in 333-122-0175 of these rules;

(9) If the applicant intends to perform calibrations of survey instruments they must describe methods to be used and the experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in 333-122-0100 of these rules;

(10) The applicant identifies and describes the location(s) of all permanent x-ray installations;

(11) The applicant identifies the location(s) where all records required by this and other divisions of chapter 333 will be maintained; and

(12) A registration will be issued if 333-122-0075(1) through (11) of these rules are met.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0100
Radiation Survey Instruments

(1) The registrant must keep sufficient calibrated and operable radiation survey instruments at each location where industrial x-ray machines are present to make the radiation surveys required by this division and by division 120. Instrumentation required by this rule must be capable of measuring a range from 0.02 milliseiverts (2 mrem) per hour through 0.01 sievert (1 rem) per hour.

(2) The registrant must have each radiation survey instrument required under section (1) of this rule calibrated:

(a) At energies appropriate for use; and

(b) At intervals not to exceed one year or after instrument servicing, except for battery changes; and

(c) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; and for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 milliseiverts (2 and 1000 mrem) per hour; and

(d) So that an accuracy within plus or minus 20 percent of the true radiation dose rate can be demonstrated at each point checked.

(3) The registrant must maintain records of the results of the instrument calibrations in accordance with 333-122-0375 of these rules.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0125
Inspection and Maintenance of Industrial X-ray Machines, Associated Equipment, and Survey Instruments

(1) The registrant must perform visual and operability checks on survey meters, radiation machines and associated equipment before each day's use, or work shift, to ensure that the equipment is in good working condition

(2) Survey instrument operability must be performed using check sources or other appropriate means.

(3) If equipment problems are found, the equipment must be removed from service until repaired.

(4) Each registrant must have written procedures for and perform inspection and routine maintenance of industrial x-ray machines, associated equipment, and survey instruments at intervals not to exceed three months or before the first use thereafter to ensure the proper functioning of components important to safety. If equipment problems are found, the equipment must be removed from service until repaired.

(5) Records of equipment problems and of any maintenance performed under this rule must be made in accordance with 333-122-0425.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0150
Permanent Radiographic Installations

(1) Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation must have either:

(a) An entrance control of the type described in OAR 333-120-0220 that causes the radiation level upon entry into the area to be reduced; and or

(b) Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal must be actuated by radiation whenever the machine is energized. The audible signal must be actuated when an attempt is made to enter the installation while the machine is energized.

(2) The alarm system must be tested for proper operation with an x-ray machine each day before the installation is used for industrial x-ray operations. The test must include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry as designated in 333-122-0125(1)(a) of these rules must be tested monthly. If an entrance control device or an alarm is operating improperly, it must be immediately labeled as defective and repaired within seven calendar days. The x-ray machine may continue to be used during this seven-day period, provided the registrant implements the continuous surveillance requirements of 333-122-0300 of these rules and uses an alarming rate-meter. Test records for entrance controls and audible and visual alarms must be maintained in accordance with 333-122-0450 of these rules.

(3) Industrial x-ray machines must be physically secured to prevent tampering by unauthorized personnel.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0175
Radiation Safety Officer

The radiation safety officer of an industrial x-ray facility must ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the registrant's program.

(1) Minimum qualifications, training, and experience for radiation safety officers for industrial x-ray. A radiation safety officer must complete:

(a) The training and testing requirements of 333-122-0200(1) of these rules;

(b) 160 hours of hands-on experience as a qualified x-ray operator in industrial x-ray operations; and

(c) A minimum of eight hours of formal training in the establishment and maintenance of a radiation protection program.

(2) The Authority will consider alternative qualifications, training and experience for individuals who want to be a radiation safety officer in the industrial x-ray setting. However, the training and experience must be related to the field of ionizing radiation, and the establishment and maintenance of a radiation safety program.

(3) The specific duties and authorities of the radiation safety officer must include:

(a) Establishing and overseeing all operating, emergency, and ALARA procedures as required by division 333-120 and reviewing them regularly to ensure that they conform to Authority rules and to the registration conditions;

(b) Overseeing and approving the training program for industrial x-ray personnel to ensure that appropriate and effective radiation protection practices are taught;

(c) Ensuring that required radiation surveys are performed and documented in accordance with the rules, including any corrective measures when levels of radiation exceed established limits;

(d) Ensuring that personnel monitoring devices are calibrated, if applicable, and used properly and that records are kept of the monitoring results and that timely notifications are made as required by division 333-120; and

(e) Ensuring that operations are conducted safely and for implementing corrective actions including terminating operations.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0200
Training

(1) The registrant may not permit any individual to act as an industrial x-ray machine operator until the individual has received at least 40 hours of training in the subjects outlined in (6) of this rule, in addition to on the job training consisting of hands-on experience under the supervision of a qualified industrial x-ray machine operator. The on the job training must include a minimum of one month (160 hours) of active participation in the performance of industrial x-ray utilizing x-ray machines.

(2) The registrant may not permit any individual to act as an industrial x-ray machine operator until the individual:

(a) Has received copies of and instruction in the requirements described in the rules contained in this division, and applicable sections of divisions 333-120 and 333-111, in the registration under which the individual will perform industrial radiation machine operation, registrant's operating and emergency procedures;

(b) Has demonstrated an understanding of items in (2)(a) of this rule by successful completion of a written or oral examination;

(c) Has received training in the use of the registrant's radiation machines, associated equipment, and in the use of radiation survey instruments; and

(d) Has demonstrated understanding of the use of the equipment described in (2)(c) of this rule by successful completion of a practical examination.

(3) The registrant must provide annual refresher safety training, as defined in 333-122-0005 of these rules, for each radiation machine operator at intervals not to exceed 12 months.

(4) Except as provided in this rule, the radiation safety officer or designee must conduct an inspection program of the job performance of each industrial x-ray machine operator to ensure that the Authority's rules, registration requirements, and operating and emergency procedures are followed. The inspection program must:

(a) Include observation of the performance of each x-ray machine operator during an actual industrial radiographic x-ray machine operation, at intervals not to exceed six months.

(b) Provide that, if an industrial x-ray machine operator has not participated in an industrial x-ray machine operation for more than six months since the last inspection, the individual must demonstrate knowledge of the training requirements of this rule by a practical examination before these individuals can next participate in a radiation machine operation.

(c) The Authority may consider an alternate individual to conduct the inspection program and observation of the x-ray operator as required in (4)(a) and (b) of this rule, in those situations where the radiation machine operator is also the radiation safety officer.

(d) In those operations where a single individual serves as both x-ray operator and radiation safety officer, and performs all industrial x-ray machine operations, an inspection program is not required.

(5) The registrant must maintain training records including:

(a) Written, oral and practical examinations;

(b) Refresher safety training; and

(c) Inspections of job performance in accordance with 333-122-0475 of these rules.

(6) The training required in (1) of this rule must include the following subjects:

(a) Fundamentals of radiation safety including:

(A) Characteristics of x-radiation;

(B) Units of radiation dose;

(C) Hazards of exposure to radiation; and

(D) Methods of controlling radiation dose (time, distance, and shielding); and

(b) Radiation detection instruments including:

(A) Use, operation, calibration, and limitations of radiation survey instruments;

(B) Survey techniques; and

(C) Use of personnel monitoring equipment; and

(c) Equipment to be used including:

(A) Operation and control of radiation machines; and

(B) Inspection and maintenance of equipment; and

(d) The requirements of pertinent state and federal rules.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0225
Operating and Emergency Procedures

(1) Operating and emergency procedures must include, as a minimum, instructions in the following:

(a) Appropriate use of radiation machines so that no person is likely to be exposed to radiation doses in excess of the limits established in division 120 of these rules;

(b) Methods and occasions for conducting radiation surveys;

(c) Methods for posting and controlling access to radiation areas;

(d) Personnel monitoring and the use of personnel monitoring equipment;

(e) The inspection, maintenance, and operability checks of radiation machines, survey instruments;

(f) Steps that must be taken immediately by x-ray personnel in the event a pocket dosimeter is found to be off-scale;

(g) The procedure(s) for identifying and reporting defects and noncompliance, as required by 333-122-0425 of these rules;

(h) The procedure for notifying proper persons in the event of an accident or incident; and

(i) Maintenance of records.

(2) The registrant must maintain copies of current operating and emergency procedures in accordance with 333-122-0500 and 333-122-0575 of these rules.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0250
Personnel Monitoring

(1) The registrant may not permit any individual to act as a x-ray operator unless, at all times during radiographic operations, each x-ray operator wears, on the trunk of the body, a combination of direct reading dosimeter, and either a film badge or a TLD or other National Voluntary Laboratory Accreditation Program (NVLAP) approved technologies. X-ray operators who only operate cabinet x-ray machines are exempt from the requirement to wear a direct reading dosimeter.

(a) Pocket dosimeters must have a range from zero to 2 milliseiverts (200 mrem) and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

(b) Each film badge and TLD must be assigned to and worn by only one individual.

(c) Film badges and TLD's must be exchanged at periods not to exceed quarterly.

(d) After replacement, each film badge or TLD must be returned to the supplier for processing within 14 calendar days of the end of the monitoring period, or as soon as practicable. In circumstances that make it impossible to return each film badge or TLD in 14 calendar days, such circumstances must be documented and available for review by the Authority.

(2) Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with 333-122-0525 of these rules.

(3) Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed 12 months for correct response to radiation, and records must be maintained in accordance with 333-122-0525 of these rules. Acceptable dosimeters must read within plus or minus 20 percent of the true radiation exposure.

(4) If an individual's pocket dosimeter is found to be off-scale, or the electronic personal dosimeter reads greater than 2 milliseiverts (200 mrem), the individual's film badge or TLD must be sent for processing within 24 hours. In addition, the individual may not resume work associated with the use of sources of radiation until a determination of the individual's radiation exposure has been made. This determination must be made by the radiation safety officer or the radiation safety officer's designee. The results of this determination must be included in the records maintained in accordance with 333-122-0525 of these rules.

(5) If a film badge or TLD is lost or damaged, the worker must cease work immediately until a replacement film badge or TLD is provided and the exposure is calculated for the period from issuance to loss or damage of the film badge or TLD. The results of the calculated exposure and the period for which the film badge or TLD was lost or damaged must be included in the records maintained in accordance with 333-122-0525 of these rules.

(6) Reports received from the film badge or TLD processor must be retained in accordance with 333-122-0525 of these rules.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0275
Radiation Surveys

The licensee or registrant must conduct all surveys with a calibrated and operable radiation survey instrument that meets the requirements of 333-122-0100 of these rules.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0300
Surveillance

During each radiographic operation, the radiographer must ensure continuous direct visual surveillance of the operation to protect against unauthorized entry into a radiation area or a high radiation area, as defined in division 333-100, except at permanent radiographic installations where all entryways are locked and the requirements of 333-122-0150 of these rules are met.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0325
Posting

All areas in which industrial x-ray machines are operated must be conspicuously posted as required by 333-120-0410.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0350
Recordkeeping Requirements for Industrial X-Ray

Each registrant must maintain a copy of its registration, documents incorporated by reference, until the Authority terminates the registration.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0375
Records of Radiation Survey Instruments

Each registrant must maintain records of the calibrations of its radiation survey instruments that are required under 333-122-100 of these rules and retain each record for three years after it is made.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0400
Utilization Logs

(1) Each registrant must maintain utilization logs showing for each radiation machine the following information:

(a) A description, including the make, model, and serial number of the radiation machine;

(b) The identity and signature of the radiation machine operator; and

(c) For permanent radiographic installations, the dates each radiation machine is energized.

(2) The registrant must retain the utilization logs for three years.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0425
Records of Inspection and Maintenance of Radiation Machines, Associated Equipment, and Survey Instruments

(1) Each registrant must maintain records, specified in 333-122-0125 of these rules, of equipment problems found in daily

checks and quarterly inspections of radiation machines, associated equipment, and survey instruments; and retain each record for three years after it is made.

(2) The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was performed.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0450
Records of Alarm System and Entrance Control Checks at Permanent Radiographic Installations

Each registrant must maintain records of alarm system and entrance control device tests required by 333-122-0150 of these rules and retain each record for three years after it is made.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0475
Records of Training and Certification

Each registrant must maintain the following records for three years after the individual terminates employment:

(1) Records of training of each x-ray machine operator. The record must include copies of written tests, dates of oral and practical examinations, the names of individuals conducting and receiving the oral and practical examinations, and a list of items tested and the results of the oral and practical examinations; and

(2) Records of annual refresher safety training and semi-annual inspections of job performance for each x-ray machine operator. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any non-compliance observed by the radiation safety officer or designee.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0500
Copies of Operating and Emergency Procedures

Each registrant must maintain a copy of current operating and emergency procedures until the Authority terminates the registration.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0525
Records of Personnel Monitoring

Each registrant must maintain the following exposure records specified in 333-122-0250 of these rules:

(1) Direct reading dosimeter readings and yearly operability checks required by 333-122-0250(2) and 0250(3) of these rules for three years after the record is made;

(2) Reports received from the film badge or TLD processor until the Authority terminates the license or registration; and

(3) Records of estimates of exposures because of off-scale personal direct reading dosimeters, or lost or damaged film badges or TLD's, until the Authority terminates the license or registration.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0550
Form of Records

Each record required by this division must be legible throughout the specified retention period. The record may be the original, a reproduced copy, or a microform if the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee or registrant must maintain adequate safeguards against tampering with and loss of records.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0575
Location of Documents and Records

Each registrant must also maintain current copies of the following documents and records sufficient to demonstrate compliance at each facility:

(1) A current radiation machine registration certificate;

(2) A copy of divisions 100, 101, 111 and 120 of this chapter;

(3) Records of equipment problems identified in daily checks of equipment as required by 333-122-0125 of these rules;

(4) Records of alarm system and entrance control checks required by 333-122-0450 of these rules, if applicable;

(5) Records of dosimeter readings as required by 333-122-0525 of these rules;

(6) Operating and emergency procedures as required by 333-122-0225 of these rules;

(7) Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by 333-122-0100 of these rules;

(8) Evidence of the latest operability checks of dosimeters as required by 333-122-0525 of these rules; and

(9) Survey records as required by 333-122-0275 of these rules for the period of operation at the site.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

333-122-0600
Notifications

(1) In addition to the reporting requirements specified in 10 CFR 30.50 and in division 120 of these rules, each registrant must provide a written report to the Authority within 30 days of the occurrence of any of the following incidents involving x-ray equipment:

(a) Failure of any component, which is critical to safe operation of the x-ray machine, to properly perform its intended function; and/or

(b) An indicator on an x-ray machine fails to show that radiation is being produced, an exposure switch fails to terminate production of radiation when turned to the off position, or a safety interlock fails to terminate x-ray production.

(2) The registrant must include the following information in each report submitted under this rule and in each report of overexposure submitted under this division which involves failure of safety components of x-ray machines:

(a) Description of the equipment problem;

(b) Cause of each incident, if known;

(c) Name of the manufacturer and model number of equipment involved in the incident;

(d) Place, date, and time of the incident;

(e) Actions taken to establish normal operations;

(f) Corrective actions taken or planned to prevent recurrence; and

(g) Names and qualifications of personnel involved in the incident.

Stat. Auth.: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06

DIVISION 123

THERAPEUTIC RADIATION MACHINES

333-123-0001
Purpose and Scope

This Division establishes requirements for registrants of therapeutic radiation machines. Nothing in this Division relieves the registrant from complying with other applicable federal, state and local regulations.

Stat. Auth: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 23-2006, f. & cert. ef. 10-19-06

333-123-0005
Definitions

(1) "Absorbed dose (D)" means the mean energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of DE by DM, where DE is the mean energy imparted by ionizing radiation to matter of mass DM. The SI unit of absorbed dose is joule/kg and the special name of the unit of absorbed dose is the gray (Gy). The previously used special unit of absorbed dose (rad) is being replaced by the gray.

(2) "Absorbed dose rate" means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

(3) "Accessible surface" means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

(4) "Added filtration" means any filtration which is in addition to the inherent filtration that is in the primary beam.

(5) "Air kerma (K)" means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of DE/DM, where DE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass DM. The SI unit of air kerma is joule/kg.

(6) "Barrier" has the same meaning as "protective barrier".

(7) "Beam axis" means the axis of rotation of the beam-limiting device.

(8) "Beam-limiting device" means a field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

(9) "Beam monitoring system" means the system designed and installed in the radiation head to detect and appropriately measure the radiation present in the useful radiation beam.

(10) "Beam scattering foil" means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

(11) "Bent beam linear accelerator" means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

(12) "Changeable filters" means any filter, exclusive of inherent filtration, that can be removed from the useful beam through any electronic, mechanical, or physical process.

(13) "Contact therapy system" means a therapeutic radiation machine with a short target to skin distance (TSD), usually less than 5 cm.

(14) "Conventional Simulator" means any X-ray system designed to reproduce the geometric conditions of the radiation therapy equipment.

(15) "CT Simulator" means a computed tomography (CT) unit used in conjunction with relevant software which recreates the treatment machine, and that allows import, manipulation, display and storage of images from CT and other imaging modalities.

(16) "Detector" has the same meaning as "radiation detector".

(17) "Dose monitor unit (DMU)" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

(18) "Electronic brachytherapy" means a method of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation dosage.

(19) "Electronic brachytherapy device" means the system used to produce and deliver therapeutic radiation including the X-ray tube, the control mechanism, the cooling system, and the power source.

(20) "Electronic brachytherapy source" means the X-ray tube component used in an electronic brachytherapy device.

(21) "External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a specified distance from the body.

(22) "Field-flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.

(23) "Filter" means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to OAR 333-123-0025(2) and (3).

(24) "Gantry" means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

(25) "Gray (Gy)" means the SI unit of absorbed dose, kerma, and specific energy imparted equal to 1 joule/kg. The previous unit of absorbed dose (rad) is being replaced by the gray. (1 Gy = 100 rad; 1 cGy = 1 rad).

(26) "Half-value layer (HVL)" means the thickness of a specified material which attenuates incident ionizing radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-half of the value measured without the material at the same point.

(27) "Intensity Modulated Radiation Therapy (IMRT)" means radiation therapy that uses non-uniform radiation beam intensities, which have been determined by various computer-based optimization techniques.

(28) "Interlock" means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

(29) "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

(30) "Irradiation" means the exposure of a living tissue or matter to ionizing radiation.

(31) "Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry, collimator and couch move through the full range of motions.

(32) "Kilovolt (kV) (kilo electron volt (keV))" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum.

Note: Current convention is to use kV for photons and keV for electrons.

(33) "Lead equivalent" means the thickness of the material in question affording the same attenuation, under specified conditions, as lead.

(34) "Leakage radiation" means radiation emanating from the radiation therapy system except for the useful beam.

(35) "Light field" means the area illuminated by light, simulating the radiation field.

(36) "mA" means milliamperes.

(37) "Medical Treatment Event" means an event that meets the criteria in 333-123-0020(1).

(38) "Megavolt (MV) (mega electron volt (MeV))" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum.

Note: Current convention is to use MV for photons and MeV for electrons.

(39) "Monitor unit (MU)" has the same meaning as "dose monitor unit".

(40) "Moving beam radiation therapy" means radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes, but is not limited to arc, conformal, intensity modulation and rotational therapy.

(41) "Nominal treatment distance" means:

(a) For electron irradiation, the distance from the scattering foil, virtual source, or exit port of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

(b) For X-ray irradiation, the distance from the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance must be that specified by the manufacturer.

(42) "Patient" means an individual subjected to machine produced external beam radiation for the purposes of medical therapy.

(43) "Peak tube potential" means the maximum value of the potential difference across the X-ray tube during an exposure.

(44) "Periodic quality assurance check" means a procedure, which is performed at regular intervals to ensure that previously determined machine characteristics continue to be valid.

(45) "Phantom" means an object responding in essentially the same manner as tissue, with respect to absorption or scattering of the incident ionizing radiation in question.

(46) "Practical range of electrons" corresponds to classical electron range where the only remaining contribution to dose is from Bremsstrahlung X-rays.

(47) "Prescribed dose" means the total dose and dose per fraction as documented in the physician's written directive. The prescribed dose is an estimation from measured data from a specified therapeutic machine using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique.

(48) "Primary dose monitoring system" means a system which can monitor the useful beam during irradiation and which can terminate irradiation when a pre-selected number of dose monitor units have been delivered.

(49) "Primary protective barrier" has the meaning given that term in section (50) of this rule, "protective barrier".

(50) "Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

(a) Primary protective barrier means the material, excluding filters, placed in the useful beam.

(b) Secondary protective barrier means the material, which attenuates stray radiation.

(51) "Qualified Expert" means an individual qualified in accordance with OAR 333-100-0005.

(52) "Qualified Medical Physicist" means an individual qualified in accordance with OAR 333-123-0015(2)(b).

(53) "Qualified Radiation Therapy Physician" means an individual qualified in accordance with OAR 333-123-0015(1).

(54) "Radiation detector" means a device, which, in the presence of radiation provides, by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

(55) "Radiation field" has the same meaning as "useful beam".

(56) "Radiation head" means the structure from which the useful beam emerges.

(57) "Redundant beam monitoring system" means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

(58) "Scattered primary radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

(59) "Scattered radiation" means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation.

(60) "Secondary dose monitoring system" means a system, which will terminate irradiation in the event of failure of the primary dose monitoring system.

(61) "Secondary protective barrier" has the meaning given that term in section (50) of this rule, "protective barrier".

(62) "Service Engineer" means an individual who is qualified to service the radiation therapy equipment per manufacturer's standards.

(63) "Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

(64) "Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

(65) "Sievert (Sv)" means the SI unit of dose equivalence. The unit of dose equivalence is the joule/kg. The previous unit of dose equivalence (rem) is being replaced by the Sievert. [1 Sv=100 rem].

(66) "Simulator (radiation therapy simulation system)" means any X-ray system intended for localizing the tissue volume to be exposed during radiation therapy and establishing the position and size of the therapeutic irradiation field. See Conventional Simulator and Virtual Simulator.

(67) "Source" means the focal point or material from which the radiation emanates.

(68) "Source-skin distance (SSD)" has the same meaning as "target-skin distance".

(69) "Stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

(70) "Stray radiation" means the sum of leakage and scattered radiation.

(71) "Target" means that part of an X-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

(72) "Target-skin distance (TSD)" means the distance measured along the beam axis from the center of the front surface of the X-ray target or electron virtual source to the surface of the irradiated object or patient.

(73) "Tenth-value layer (TVL)" means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate, or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

(74) "Termination of irradiation" means the stopping of irradiation in a fashion, which cannot permit continuance of irradiation without the resetting of operating conditions at the control panel.

(75) "Therapeutic radiation machine" is a complex system designed and used for external beam radiation therapy. This system includes some or all of the following: equipment producing ionizing radiation (including, but not limited to X-rays, electrons, protons and neutrons), beam shaping devices, computer control unit, verify and record system, electronic portal imaging, treatment planning computer and other ancillary systems.

(76) "Tube" means an X-ray tube, unless otherwise specified.

(77) "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and filament transformers and other appropriate elements when such are contained within the tube housing.

(78) "Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the therapeutic radiation machine to produce radiation.

(79) "Virtual source" means a point from which radiation appears to originate.

(80) "Wedge filter" means a filter which effects continuous change in transmission over all or a part of the useful beam.

(81) "Written directive" means an order, written or electronic, for the administration of radiation to a specific patient as specified in OAR 333-123-0045(2).

(82) "X-ray tube" means any electron tube, which is designed to be used primarily for the production of X-rays.

Stat. Auth: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 23-2006, f. & cert. ef. 10-19-06; PH 4-2013, f. & cert. ef. 1-29-13

333-123-0010
General Requirements, Operating Procedures, Surveys, Dosimetry, and Instrument Calibration for Facilities Using Therapeutic Radiation Machines

(1) Administrative Controls. The registrant is responsible for directing the operation of the therapeutic radiation machines that they have registered with the Authority. The registrant or the registrant's agent must ensure that the requirements of this Division are met in the operation of the therapeutic radiation machine(s) and:

(a) A therapeutic radiation machine that does not meet the requirements of these rules must not be used for irradiation of patients; and

(b) The use of therapeutic radiation machines shall be by, or under the supervision of, a licensed practitioner of the healing arts who meets the training/experience criteria established by 333-123-0015(1).

(2) Operating Procedures. A copy of the current operating and emergency procedures must be available at each therapeutic radiation authority or clinic and at the therapeutic radiation machine control console; and

(a) Any alterations or changes to existing procedures and new radiation therapy treatment protocols must be approved by the Chief Medical Physicist and the Senior Radiation Therapy Physician or designee; and

(b) The date of the approval and the appropriate signatures must be placed on the first page of each radiation therapy procedure; and

(c) The registrant must retain a copy of all versions of the procedures for 5 years; and

(d) If the Qualified Medical Physicist is not a full-time employee of the registrant, the operating procedures must specify how to contact the Physicist. The procedures must list specific actions to be initiated until the Physicist assumes personal control.

(e) The therapeutic radiation machine must not be used for irradiation of patients unless the requirements of sections (1) and (2) have been met.

(f) Individuals must not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing or electronically by a qualified radiation therapy physician.

(g) This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing arts purposes.

(h) Therapeutic radiation machines, when not in operation, must be secured to prevent unauthorized use.

(i) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices must be used.

(j) No individual other than the patient must be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room must be protected by a barrier sufficient to meet the requirements of 333-120-0100.

(k) When adjustable beam limiting devices are used, the position and shape of the radiation field must be indicated by a light field.

(l) Written safety procedures and rules must be developed by a Qualified Medical Physicist and must be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator must be able to demonstrate familiarity with these rules.

(m) All individuals associated with the operation of a therapeutic radiation machine must be instructed in and must comply with the provisions of the registrant's quality assurance program. In addition to the requirements of 333-123-0015, these individuals are also subject to the requirements of divisions 111 and 120.

(3) Calibration Of Radiation Survey Instruments. Radiation Survey Instrument(s) for Photon and Electron Beam Therapy Systems 1 MV and Above. Each facility location authorized to use a therapeutic radiation machine in accordance with these rules must possess appropriately calibrated portable radiation monitoring equipment. As a minimum, such equipment must include a portable radiation survey instrument capable of measuring dose rates over the range 10 μSv/hr (1 mrem/hr) to 10 mSv/hr (1000 mrem/hr) with an energy response appropriate to the system being surveyed.

(a) The registrant must ensure that the survey instruments, which are used to show compliance with this Division, have been calibrated before first use, at intervals not to exceed 12 months, and following repair; and

(b) To satisfy the requirements of this rule, the registrant must:

(A) Calibrate all required scale readings up to 10 mSv (1000 mrem) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST); and

(B) The calibration must include at least 2 points on each scale tested. These points should be at approximately 1/3 and 2/3 of full-scale.

(c) To satisfy the requirements of section (3)(b)(B) of this rule, the registrant must:

(A) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent; and

(B) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent if a correction factor or graph is conspicuously attached to the instrument.

(d) The registrant must retain a record of each calibration required in section (3)(a) of this rule for 3 years. The record must include:

(A) A description of the instrument and the calibration procedure; and

(B) A description of the radiation source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

(e) The registrant may obtain the services of individuals licensed by the Authority, the US Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations must contain information required by section (3)(d) of this rule and be maintained by the registrant.

(4) Radiation Protection Surveys. The registrant must ensure that radiation protection surveys are performed at new facilities, and existing facilities not previously surveyed. Surveys must be conducted with an operable radiation survey instrument calibrated in accordance with of section (3) of this rule. In new facilities, a radiation protection survey must be completed prior to the first clinical use of a therapeutic radiation machine following installation.

(a) For machines capable of photon output at 10MV or above, registrants must perform or arrange to have performed a radiation survey to monitor neutron dose rates. The radiation survey instrument(s) used must be capable of measuring neutron dose rates over the range of 10 μSv/hr (1 mrem/hr) to 10 mSv/hr (1000 mrem/hr). The radiation survey instrument(s) used to measure must be operable and calibrated in accordance with section (3) of this rule. Neutron monitoring must be done prior to first patient treatment; and

(b) The survey must be performed with the therapeutic radiation machine in a BEAM-ON condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation; and

(c) The radiation protection survey must be performed by, or under the direction of, a Qualified Medical Physicist or a Qualified Expert as defined in 333-100-0005.

(d) The Qualified Medical Physicist or Qualified Expert must verify that:

(A) Radiation levels in restricted areas are not likely to cause personnel to receive exposures in excess of the limits specified in 333-120-0100(1); and

(B) Radiation levels in unrestricted areas do not exceed the limits specified in 333-120-0180 and 333-120-0190.

(e) In addition, a radiation protection survey must also be performed:

(A) Prior to any subsequent medical use; and

(B) After making any change in the treatment room shielding; and

(C) After making any change in the location of the therapeutic radiation machine within the treatment room; and

(D) After relocating the therapeutic radiation machine; or

(E) Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

(f) The radiation protection survey record must indicate all instances where the facility, in the opinion of the Qualified Medical Physicist or a Qualified Expert, is in violation of applicable regulations. The survey record must also include the:

(A) Date of the measurements; and

(B) Reason the survey is required; and

(C) Manufacturer's name, model number and serial number of the therapeutic radiation machine; and

(D) Manufacturer and model of the instrument(s) used to measure radiation levels and date last calibrated; and

(E) A floor plan of the areas surrounding the treatment room that were surveyed; and

(F) Measured dose rate at several points in each area expressed in mSv/hr or mrems/hr; and

(G) Calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area; and

(H) Signature of the individual responsible for conducting the survey.

(g) If the results of the radiation protection survey indicate any radiation levels in excess of the respective limit specified in 333-120-0180, the registrant must lock the control in the "OFF" position and not use the unit. The control must remain locked:

(A) Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

(B) Until the registrant has received a specific exemption from the Authority.

(h) If the radiation protection survey, indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 333-120-0180(1) and (2), before beginning the treatment program the registrant must:

(A) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 333-120-0180(1) and (2); and

(B) Perform the survey required by these rules again; and

(C) Include in the report required by section (4)(f) of this rule the results of the initial survey, a description of the modification made to comply with section (4)(g)(A) of this rule, and the results of the second survey; or

(D) Request and receive a registration amendment under 333-120-0180(3) that authorizes radiation levels in unrestricted areas greater than those permitted by 333-120-0180(1) and (2).

(5) Dosimetry Equipment. The registrant must have a calibrated dosimetry system available for use. The calibration must be traceable to the appropriate national standard. The calibration must have been performed within the previous 24 months and after any servicing that may have affected system calibration and:

(a) The dosimetry system must have been calibrated at an energy appropriate for the radiation being measured.

(b) The registrant must have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with section (5)(a) of this rule. This comparison must have been performed within the previous 12 months and after each servicing that may have affected system calibration. The quality assurance system may be the same system used to meet the requirement in section (5)(a) of this rule.

(c) The registrant must maintain a record of each dosimetry system calibration, intercomparison, and comparison, for the duration of the license and/or registration. For each calibration, intercomparison, or comparison, the record must include:

(A) The date;

(B) The model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by sections (5)(a) and (b) of this rule;

(C) The correction factors that were determined;

(D) The names of the individuals who performed the calibration, intercomparison, or comparison; and

(E) Evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a Qualified Medical Physicist.

(6) Reports Of External Beam Radiation Therapy Surveys And Measurements. The registrant for any therapeutic radiation machine subject to 333-123-0025 must furnish a copy of the records required in section (5)(c) of this rule to the Authority within 30 days following completion of the action that initiated the record requirement.

(7) Records Retention. All records required in this Division must be retained until disposal is authorized by the Authority unless another retention period is specifically authorized in the rule in this Division.

(a) All required records must be retained in an active file from at least the time of generation until the next Authority inspection.

(b) Any required record generated before the last Authority inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until such time as the Authority authorizes final disposal.

(c) The registrant must maintain the following information in a separate file or package for each therapeutic radiation machine, for inspection by the Authority:

(A) Report of acceptance testing; and

(B) Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by 333-123-0040, as well as the name(s) and business addresses of person(s) who performed such activities; and

(C) Records of maintenance and/or modifications performed on the therapeutic radiation machine after January 30, 2007, as well as the name(s) of person(s) who performed such services; and

(D) Signature of the Qualified Medical Physicist or service engineer authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

Stat. Auth: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 23-2006, f. & cert. ef. 10-19-06

333-123-0015
Training and Qualification Requirements for Individuals in the External Beam Radiation Therapy Area

(1) Radiation Therapy Physician. The registrant for any therapeutic radiation machine subject to 333-123-0030 must require that the Radiation Therapy Physician be:

(a) Licensed by an appropriate Oregon medical licensing board; and

(b) Certified in:

(A) Radiology, Therapeutic Radiology or Radiation Oncology by the American Board of Radiology; or

(B) Radiation Oncology by the American Osteopathic Board of Radiology; or

(C) Radiology, with specialization in Radiotherapy, as a British Fellow of the Faculty of Radiology or Fellow of the Royal College of Radiology; or

(D) Therapeutic Radiology by the Canadian Royal College of Physicians and Surgeons; or

(c) Actively pursuing board certification in therapeutic radiology, and completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy

unit, 500 hours of supervised work experience, and a minimum of 3 years full-time supervised clinical experience.

(A) To satisfy the requirement for instruction, the classroom and laboratory training must include:

(i) Radiation physics and instrumentation; and

(ii) Radiation protection; and

(iii) Mathematics pertaining to the use and measurement of ionization radiation; and

(iv) Radiation biology.

(B) To satisfy the requirement for supervised work experience, training must be under the supervision of a Radiation Therapy Physician qualified pursuant to sections (1)(a) or (b) of this rule and must include:

(i) Review of the full calibration measurements and periodic quality assurance checks; and

(ii) Evaluation of prepared treatment plans and calculation of treatment times and patient treatment settings; and

(iii) Using administrative controls to prevent medical treatment events; and

(iv) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and

(v) Checking and using radiation survey meters.

(C) To satisfy the requirement for a period of supervised clinical experience, training must include 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional 2 years of clinical experience in therapeutic radiology under the supervision of a Qualified Radiation Therapy Physician. The supervised clinical experience must include:

(i) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications; and

(ii) Selecting proper dose and how it is to be administered; and

(iii) Calculating the external beam radiation therapy doses and collaborating with the Qualified Radiation Therapy Physician in the review of patients' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients' reaction to radiation; and

(iv) Post-administration follow-up and review of case histories.

(d) To demonstrate compliance with sections (1)(a) through (c) of this rule, the individual must obtain written documentation that he or she has satisfactorily completed these requirements and have achieved a level of competency sufficient to function independently as a qualified radiation therapy physician. The documentation must be from the entities or individual(s) specified in this rule.

(e) Notwithstanding the requirements of sections (1)(a) and (b) of this rule, the registrant for any therapeutic radiation machine subject to 333-123-0025 may also submit the training of the prospective Radiation Therapy Physician for Authority review on a case-by-case basis.

(f) A physician must not act as a Radiation Therapy Physician for any therapeutic radiation machine until said physician's training has been reviewed and approved by the appropriate state licensing body.

(g) A registrant may permit any physician to act as a visiting Radiation Therapy Physician under the term of the registrant's Certificate of Registration for up to 60 days per calendar year under the following conditions:

(A) The visiting Radiation Therapy Physician has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee (where applicable); and

(B) The visiting Radiation Therapy Physician meets the requirements established in section (1) of this rule; and

(C) The registrant maintains copies of all records specified in section (1)(i) of this rule for 5 years from the date of the last visit.

(2) Medical Physicist Qualifications. The registrant for any therapeutic radiation machine subject to 333-123-0025 must require that the Medical Physicist(s), who are providing consultative services to them be licensed with the Authority, under the provisions of 333-101-0020, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units (The licensing requirement is only applicable to those physicists who provide medical physics consultation to facilities other than those of the registrant of which they are an employee).

(a) All Medical Physicists practicing in therapeutic radiological physics must be certified in Therapeutic Radiological Physics or Radiation Oncology by the:

(A) American Board of Radiology; or

(B) American Board of Medical Physics; or

(C) Canadian College of Physicists in Medicine.

(b) To demonstrate compliance, the individual must obtain written documentation that he or she is Board certified. The documentation must be from the credentialing body.

(c) Medical Physicists who, prior to January 1, 2007, have been actively working in the area of therapeutic radiation in the state of Oregon or licensed with the Authority to provide therapeutic radiation medical physics services in Oregon, are exempt from the certification requirement in section (2)(b) of this rule.

(d) Medical Physicists who, on or after January 1, 2007, wish to work in the area of therapeutic radiation or to be licensed with the Authority to provide therapeutic radiation services, must meet the certification requirements in section (2)(b) of this rule.

(e) Medical Physicists who do not meet the requirements of section (2)(b) of this rule must work under the supervision of a Qualified Medical Physicist.

(3) Therapeutic Radiation Machine Operator's Qualifications. Individuals who will be operating a therapeutic radiation machine for medical use must be registered with the American Registry of Radiologic Technologists (ARRT) as a radiation therapist with the credential RT(T)(ARRT). Individuals who do not meet this criterion must submit evidence that they have satisfactorily completed a radiation therapy technologist training program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology.

(a) Individuals who have been operating a therapeutic radiation machine prior to January 1, 2007 shall be exempt from the requirement in section (3) of this rule.

(b) The names and training records of all personnel currently operating a therapeutic radiation machine must be kept on file at the facility. Training records of former operators must be retained for a period of at least 2 years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

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333-123-0020
Reports and Notifications of Unplanned Medical Treatment

(1) A registrant must report any medical treatment event that causes an error in the treatment of a patient. Medical treatment events occur when the administration of an external beam radiation therapy dose:

(a) Administration results or will result in unintended permanent functional organ damage or physiological injury as determined by a Qualified Radiation Therapy Physician; or

(b) Involves the wrong patient, wrong treatment modality, or wrong treatment site; or

(c) Consists of 3 or fewer treatment fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose; or

(d) If the calculated weekly administered dose differs from the weekly prescribed dose by more than 30 percent; or

(e) If the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

(2) The registrant must notify the Authority by telephone no later than the next calendar day after the discovery of a medical treatment event.

(3) The registrant must submit a written report to the Authority within 15 days after the discovery of a medical treatment event. The written report must include:

(a) The registrant's name; and

(b) The name of the prescribing physician; and

(c) A brief description of the event; and

(d) Why the event occurred; and

(e) The effect, if any, on the patient(s) who received the administration; and

(f) Actions, if any, that have been taken, or are planned, to prevent recurrence; and

(g) Certification that the registrant notified the patient or the patient's legally authorized representative(s), and if not, why not; and

(h) The report may not contain the individual's name or any other information that could lead to the identification of the individual.

(4) The registrant shall notify the referring physician and also notify, the patient who is the subject of the medical treatment event, or their lawfully authorized representative no later than 24 hours after its discovery unless:

(a) The referring physician personally informs the registrant that he or she will inform the affected patient; or

(b) Based on his or her medical judgment the affected patient will not be informed because it would be harmful to the patient.

(5) The registrant is not required to notify the affected patient without first consulting the referring physician.

(6) If the referring physician or the affected patient cannot be reached within 24 hours, the notification will be as soon as possible.

(7) The registrant may not delay any appropriate medical care for the affected patient, including any necessary remedial care taken because of the medical treatment event.

(8) If a verbal notification is made, the registrant must inform the affected patient, or the patient's lawfully authorized representative(s), that a written description of the event can be obtained from the registrant upon request. The registrant must provide such a written description if requested.

(9) Aside from the notification requirement, nothing in this rule affects any rights or duties of registrants and physicians in relation to each other, to the patient affected by the medical treatment event, or to the patient's lawfully authorized representative(s).

(10) A copy of the record required must be provided to the referring physician if other than the registrant within 15 days after discovery of the medical treatment event.

(11) Records Of Medical Treatment Event. A registrant must retain a record of a medical treatment event, for 3 years. The record must be handled in accordance with the Health Insurance Portability and Accountability Act (HIPAA).

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333-123-0025
Requirements for Therapeutic Radiation Machines

(1) Grenz Ray. When the x-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate must not exceed the value specified at the distance specified for that classification of therapeutic radiation machine.

(2) For therapeutic radiation systems which operate at 5kV to 50 kV or are used for Grenz Ray application:

(a) The leakage air kerma rate measured at any position 5 cm from the tube housing assembly must not exceed 1 mGy (100 mRad) in any 1 hour.

(b) A timer with a display must be provided at the treatment control panel. The timer must have a pre-set time selector and an elapsed time or time remaining indicator. The timer must:

(A) Activate with an indication of BEAM-ON and retain it's reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, the timer must be reset; and

(B) Terminate irradiation when a pre-selected time has elapsed; and

(C) Permit accurate pre-setting and determination of exposure times as short as 1 second: and

(D) Must not permit an exposure if set at zero; and

(E) Be accurate to within 1 percent of the selected value or 1 second, whichever is greater.

(c) The control panel, in addition to the displays required by other provisions in these rules, must have:

(A) An indication of whether x-rays are being produced; and

(B) A means for indicating x-ray tube potential and current; and

(C) A means for terminating an exposure at any time; and

(D) A locking device which will prevent unauthorized use of the therapeutic radiation machine; or

(d) There must be a means of determining the central axis target-to-skin distance (TSD) within 1 cm and of reproducing this measurement to within 2 mm thereafter.

(3) Therapeutic Radiation Machines Operating At >50 Kv And <1 Mev. The leakage air kerma rate measured at a distance of 1 m from the target in any direction may not exceed 1 cGy (1 rad) in any 1 hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of 5 cm from the surface of the tube housing assembly must not exceed 30 cGy (30 rad) per hour.

(a) For each therapeutic radiation machine, the registrant must determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in this rule for the specified operating conditions. Records on leakage radiation measurements must be maintained at the installation for inspection by the Authority.

(b) Permanent Beam Limiting Devices. Permanent diaphragms or cones used for limiting the useful beam must provide at least the same degree of attenuation as required for the tube housing assembly.

(c) Adjustable or Removable Beam Limiting Devices. Adjustable or removable beam limiting devices, diaphragms, cones or blocks must not transmit more than 5 percent of the useful beam for the most penetrating beam used.

(d) When adjustable beam limiting devices are used, the position and shape of the radiation field must be indicated by a light field.

(e) Filter System. The filter system must be so designed that:

(A) Filters cannot be accidentally displaced at any possible tube orientation; and

(B) For equipment installed after January 30, 2007, an interlock system prevents irradiation if the proper filter is not in place; and

(C) The air kerma rate escaping from the filter slot does not exceed 1 cGy (1 rad) per hour at 1 m under any operating conditions; and

(D) Each filter is be labeled to indicate the material it is constructed of and its thickness.

(f) Tube Immobilization. The x-ray tube must be so mounted that it cannot accidentally turn or slide with respect to the housing aperture and the tube housing assembly must be capable of being immobilized for stationary portal treatments.

(g) Source Marking. The tube housing assembly must be so marked that it is possible to determine the location of the source to within 5 mm, and such marking must be readily accessible for use during calibration procedures.

(h) Timer. A suitable irradiation control device must be provided to terminate the irradiation after a pre-set time interval.

(i) A timer with a display must be provided at the treatment control panel and the timer must:

(A) Have a pre-set time selector and an elapsed time or time remaining indicator; and

(B) Be a cumulative timer that activates with an indication of BEAM-ON and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it must be necessary to reset the elapsed time indicator; and

(C) Terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation; and

(D) Permit accurate pre-setting and determination of exposure times as short as 1 second; and

(E) Not permit an exposure if set at zero; and

(F) Not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

(G) Timer must be accurate to within 1 percent of the selected value or 1 second, whichever is greater.

(j) Control Panel Functions. The control panel, in addition to the displays required by other provisions in this rule, must have:

(A) An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible; and

(B) An indication of whether x-rays are being produced; and

(C) A means for indicating x-ray tube potential and current; and

(D) The means for terminating an exposure at any time; and

(E) A locking device which will prevent unauthorized use of the therapeutic radiation machine; and

(F) For therapeutic radiation machines manufactured after January 30, 2007, a positive display of specific filter(s) in the beam.

(k) Multiple Tubes. When a control panel may energize more than one x-ray tube:

(A) It must be possible to activate only one x-ray tube at any time; and

(B) There must be an indication at the control panel identifying which x-ray tube is activated; and

(C) There must be an indication at the tube housing assembly when that tube is energized.

(l) Target-To-Skin Distance (TSD). There must be a means of determining the central axis TSD to within 1 cm and of reproducing this measurement to within 2 mm thereafter.

(m) Shutters. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within 5 seconds (sec) after the x-ray ON switch is energized, the beam must be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter must be controlled by the operator from the control panel. An indication of shutter position must appear at the control panel.

(4) Photon And Electron Beam Therapeutic Radiation Machines 1 Mv And Above.

(a) Leakage Radiation Outside The Maximum Useful Beam In Photon And Electron Modes. The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius 2 meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e., patient plane), must not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements must be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane; and

(b) Except for the area defined in section (3)(a) of this rule, the absorbed dose due to leakage radiation (excluding neutrons) at 1 m from the electron path between the electron source and the target or electron window, must not exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements must be averaged over an area not exceeding 100 square centimeters; and

(c) For equipment manufactured after January 30, 2007, the neutron absorbed dose outside the useful beam must be in compliance with International Electrotechnical Commission (IEC) Document 60601-2-1 dated June 30, 1998; and

(d) For each therapeutic radiation machine, the registrant must determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in sections (3)(a) through (c) of this rule for the specified operating conditions. Records on leakage radiation measurements must be maintained at the installation for inspection by the Authority.

(e) Leakage Radiation Through Beam Limiting Devices. The attenuation of leakage radiation through a beam-limiting device must meet the following requirements:

(A) Photon Radiation. All adjustable or interchangeable beam limiting devices must attenuate the useful beam such that at the nominal treatment distance and the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) must not exceed 2 percent (or the amount specified by the manufacturer), of the maximum absorbed dose on the central axis of the useful beam measured in a 100 square centimeters radiation field, or maximum available field size if less than 100 square centimeters; and

(B) Electron Radiation. All adjustable or interchangeable electron applicators must attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance must not exceed: and

(C) A maximum of 2 percent and average of 0.5 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit must apply beyond a line 7 cm outside the periphery of the useful beam; and

(D) A maximum of 10 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit must apply beyond a line 2 cm outside the periphery of the useful beam.

(f) Measurement Of Leakage Radiation. Measurement of leakage radiation shall be done after installation and before clinical usage and must include:

(A) Photon Radiation. Measurements of leakage radiation through the beam limiting devices must be made with the beam limiting devices closed and any residual aperture blocked by at least 2 tenth value layers of suitable absorbing material. In the case of overlapping beam-limiting devices, the leakage radiation through each set must be measured independently at the depth of maximum dose. Measurements must be made using a radiation detector of area not exceeding 10 square centimeters; and

(B) Electron Radiation. Measurements of leakage radiation through the electron applicators must be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding 1 square centimeters suitably protected against radiation, which has been scattered from material beyond the radiation detector. Measurements must be made using 1 cm of tissue/water equivalent material for build up.

(g) Filters/Wedges. Each wedge filter that is removable from the system must be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle must appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor must be re-measured; and

(A) For equipment manufactured after January 30, 2007 which utilizes wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils; and

(B) Irradiation must not be possible until a selection of a filter or a positive selection to use no filter has been made at the treatment control panel, either manually or automatically; and

(C) An interlock system must be provided to prevent irradiation if the wedge, flattening filter or scattering foil selected is not in the correct position; and

(D) A display must be provided at the treatment control panel showing the wedge or beam modifying filter(s) in use; and

(E) An interlock must be provided to prevent irradiation if any filter and/or beam scattering foil selection operation does not agree with the energy/mode selected by the operator at the control panel.

(h) Stray Radiation in the Useful Beam. For equipment manufactured after January 30, 2007, the registrant must determine during acceptance testing, or obtain from the manufacturer, stray x-ray radiation, and absorbed dose at the surface and neutron data. This data must be sufficient to ensure compliance with International Electrotechnical Commission (IEC) Document 60601-2-1 dated June 30, 1998.

(i) Beam Monitors. All therapeutic radiation machines subject to these rules must be provided with redundant beam monitoring systems. The sensors for these systems must be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

(j) Equipment manufactured after January 30, 2007 must be provided with at least 2 independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

(k) Equipment manufactured on or before January 30, 2007 must be provided with at least 1 radiation detector. This detector must be incorporated into a useful beam monitoring system; and

(l) The detector and the system into which that detector is incorporated must meet the following requirements:

(A) Each detector must form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated; and

(B) Each beam monitoring system must be capable of independently monitoring, interrupting, and terminating irradiation; and

(m) For equipment manufactured after January 30, 2007, the design of the beam monitoring systems must ensure that the:

(A) Malfunctioning of one beam monitoring system must not affect the correct functioning of the other system(s); and

(B) Failure of either system must terminate irradiation or prevent the initiation of radiation.

(n) Each beam monitoring system must have a legible display at the treatment control panel. For equipment manufactured after January 30, 2007, each display must:

(A) Maintain a display of the patient treatment parameters until intentionally reset;

(B) Have only one scale and no electrical or mechanical scale multiplying factors;

(C) Utilize a design such that increasing dose is displayed by increasing numbers; and

(D) In the event of power failure the beam monitoring information required in section (3)(k) of this rule must be displayed at the control panel, and at the time of failure, must be retrievable in at least one system for a 20 minute period of time.

(o) Beam Symmetry. A bent-beam linear accelerator with beam flattening filter(s) subject to this rule must be provided with auxiliary device(s) to monitor beam symmetry;

(A) The integrating dose meters referenced in section (3)(k) of this rule must be able to detect field asymmetry greater than 10 percent; and

(B) The integrating dose meters referenced in section (3)(k) of this rule must be configured to terminate irradiation if the specifications in section (3)(o)(A) of this rule cannot be maintained.

(p) Selection And Display Of Dose Monitor Units. Irradiation must not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel; and

(A) The pre-selected number of dose monitor units must be displayed at the treatment control panel until reset manually for the next irradiation; and

(B) After termination of irradiation, it must be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

(C) For equipment manufactured after January 30, 2007, after termination of irradiation, it must be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.

(q) Air Kerma Rate/Absorbed Dose Rate. For equipment manufactured after January 30, 2007, a system must be provided from which readings the air kerma rate or absorbed dose rate at a reference point can be calculated. [The radiation detectors specified in section (3)(k) of this rule may form part of this system]. In addition:

(A) The dose monitor unit rate must be displayed at the treatment control panel; and

(B) If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device must be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which irradiation is terminated at must be maintained in a record by the registrant.

(r) If the equipment can deliver, under any fault condition(s), an air kerma rate or absorbed dose rate at the nominal treatment distance of more than 10 times the maximum value specified by the manufacturer:

(A) A device must be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value; and

(B) Terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 4 Gy (400 rad); and

(C) For each therapeutic radiation machine, the registrant must determine, or obtain from the manufacturer, the maximum value(s) specified in section (3)(p) of this rule for the specified operating conditions. Records of these maximum value(s) must be maintained at the facility for 5 years or until inspected by the Authority.

(s) Termination or Interruption of Irradiation by the Beam Monitoring System or Systems During Stationary Beam Radiation Therapy. Each primary system must terminate irradiation when the pre-selected number of dose monitor units has been detected by the system; and

(A) If the original design of the equipment included a secondary dose monitoring system, that system must be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

(B) For equipment manufactured after January 30, 2007, an indicator on the control panel must show which monitoring system has terminated irradiation; and

(C) It must be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's protected position at the treatment control panel; and

(D) Interruption Of Radiation. If a therapeutic radiation machine has an interrupt mode, it must be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it must be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption, irradiation and equipment movements must be automatically terminated.

(t) Timer. A suitable irradiation control device must be provided to terminate the irradiation after a pre-set time interval; and

(A) The timer must be provided with a display at the treatment control panel. The timer must have a pre-set time selector and an elapsed time indicator; and

(B) The timer must be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it must be necessary to reset the elapsed time indicator; and

(C) The timer must terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

(u) Selection Of Radiation Type. Equipment capable of both x-ray therapy and electron therapy must meet the following additional requirements:

(A) Irradiation must not be possible until a selection of radiation type (x-rays or electrons) has been made at the treatment control panel and the patient's chart has been checked to verify that the selected radiation type is the one specified in the chart; and

(B) The radiation type selected must be displayed at the treatment control panel before and during irradiation.

(v) Interlocks must be provided to:

(A) Ensure that the equipment can principally emit only the radiation type that has been selected; and

(B) Prevent irradiation with x-rays, except to obtain an image, when electron applicators are fitted; and

(C) Prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and

(D) Prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(w) Selection Of Energy. Equipment capable of generating radiation beams of different energies must meet the following requirements:

(A) Irradiation must not be possible until a selection of the appropriate energy has been made at the treatment control panel and the patient's chart has been checked to verify that the selected energy is that which is specified in the patient's chart; and

(B) The nominal energy value selected must be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it must be necessary to reset the nominal energy value selected before subsequent treatment can be initiated; and

(C) Irradiation must not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location and the patient's chart has been checked to verify that the flattening filter or scattering foil is that which is specified in the chart; and

(D) For equipment manufactured after January 30, 2007, the selection of energy must comply with International Electrotechnical Commission (IEC) Document 60601-2-1 dated June 30, 1998.

(x) Selection of Stationary Beam Radiation Therapy or Moving Beam Radiation Therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy must meet the following requirements:

(A) Irradiation must not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel and the patient's chart has been checked to verify that the selection of stationary or moving beam radiation is that which is specified in the patient's chart; and

(B) The mode of operation must be displayed at the treatment control panel and interlocks must be provided to:

(C) Ensure that the equipment can operate only in the mode that has been selected; and

(D) Prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel.

(y) Moving beam radiation therapy must be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after January 30, 2007:

(A) An interlock system must be provided to terminate irradiation if the number of dose monitor units delivered in any 10° of rotation or 1 cm of linear motion differs by more than 20 percent from the selected value; and

(B) Where incident radiation beam angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered must differ by less than 5 percent from the dose monitor unit value selected; and

(C) An interlock must be provided to prevent motion of more than 5° or 1 cm beyond the selected limits during moving beam radiation therapy; and

(D) An interlock must be provided to require that a selection of direction be made at the treatment control panel in all units, which are capable of both clockwise, and counter-clockwise moving beam radiation therapy; and

(E) Moving beam radiation therapy must be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement; and

(F) Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation must be as required by section (3)(y)(A) of this rule; and

(G) An interlock system must be provided to terminate irradiation if movement; and

(H) Interruption occurs during stationary beam radiation therapy; or

(I) Treatment does not start or stop during moving beam radiation therapy unless such stoppage is a pre-planned function.

Stat. Auth: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 23-2006, f. & cert. ef. 10-19-06

333-123-0030
Facility Design Requirements for Therapeutic Radiation Machines

(1) Grenz Ray. In addition to shielding adequate to meet the requirements of division 120, treatment rooms must be provided with warning lights, in a readily observable position (preferably at eye level) out side of all access doors to the Grenz Ray room. The warning lights must indicate when the useful beam is "ON" or when the room is being used for Grenz Ray purposes.

(a) Except as provided in 333-106-0025, no individual other than the patient and operator must be in the treatment room during Grenz Ray radiation therapy treatment provided the operator is protected by a barrier sufficient to meet the requirements of division 120.

(b) A method must be provided to secure the room where the Grenz Ray radiation machine is located, against unauthorized entry.

(2) Therapeutic Radiation Machines 50 Kv To < 1 Mev. In addition to shielding adequate to meet requirements of division 120, the treatment room must meet the following design requirements:

(a) Provision must be made for continuous two-way aural communication between the patient and the operator at the control panel; and

(b) There must be continuous observation of the patient during irradiation. The viewing system must be configured such that the operator can observe the patient from the control panel.

(c) Treatment rooms that contain a therapeutic radiation machine capable of operating above 150 kV must meet the following additional requirements:

(A) All protective barriers must be fixed except for entrance doors or beam interceptors; and

(B) The control panel must be located outside the treatment room or in a totally enclosed booth. If within the treatment room, the booth must have a ceiling to provide total enclosure. The booth walls must meet the requirements of a protective barrier as specified in division 120; and

(C) Interlocks must be provided such that all entrance doors, including doors to any interior booths, will be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, the machine must be incapable of resuming operation with manual reinitiation at the control panel, and the machine must remain inoperable until the door is closed; and

(D) When any door, referred to in section (30)(2)(c)(C) of this rule, is opened while the x-ray tube is activated, the air kerma rate at a distance of 1 meter from the source must be reduced to less than 1 mGy (100 mRad) per hour.

(3) Facility Design Requirements for Therapeutic Radiation Machines Operating > 1 Mv. Each therapeutic radiation machine subject to 333-123-0025 must be provided with such primary

and/or secondary barriers as are necessary to ensure compliance with division 120; and

(a) Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy must be submitted for Authority approval before actual installation of the therapeutic radiation machine.

(b) In addition to shielding adequate to meet requirements of division 120, the following design requirements are made.

(c) Protective Barriers. All protective barriers must be fixed, except for access doors to the treatment room or movable beam interceptors.

(d) Control Panel. In addition to other requirements specified in this Division, the control panel must also:

(A) Be located outside the treatment room; and

(B) Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible; and

(C) Provide an indication of whether radiation is being produced; and

(D) Include an access control (locking) device that will prevent unauthorized use of the therapeutic radiation machine.

(e) Viewing Systems. Windows, mirrors, closed-circuit television or an equivalent viewing system must be provided to permit continuous observation of the patient following positioning and during irradiation and must be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine must not be used for patient irradiation unless at least one viewing system is operational.

(f) Aural Communications. Provision must be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine must not be used for irradiation of patients unless continuous two-way aural communication is possible.

(g) Room Entrances. Treatment room entrances must be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF".

(h) Entrance Interlocks. Interlocks must be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it must not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel;

(i) Beam Interceptor Interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with division 120, locks must be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s);

(j) Emergency Cutoff Switches. At least 1 emergency power cutoff switch must be located in the radiation therapy room and must terminate all equipment electrical power including radiation and mechanical motion. All emergency power cutoff switches must include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch;

(k) Safety Interlocks. All safety interlocks must be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine.

Stat. Auth: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 23-2006, f. & cert. ef. 10-19-06

333-123-0035
Calibration, Acceptance Testing and Commissioning of Therapeutic Radiation Machines

(1) Full calibration, acceptance testing and commissioning of a therapeutic radiation machine subject to 333-123-0025 of this rule must be performed by, or under the direct supervision of a Qualified Medical Physicist.

(2) Acceptance testing and commissioning shall be performed in accordance with industry standards of practice and the manufacturer's contractual specifications. Acceptance testing and commissioning shall be conducted before the first medical use following installation or re-installation of the therapeutic radiation machine.

(3) Full calibration must include all applicable parameters in accordance with industry standards of practice, carried out to determine that all parameters of the radiation therapy machine are within acceptable limits:

(a) Before the first medical use after installation or reinstallation; and

(b) Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multi-energy and/or multi-mode capabilities must only require measurements for those modes and/or energies that are not within their acceptable range; and

(c) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes and/or energies, measurements must be performed on the effected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with periodic quality assurance check procedures against the criteria in 333-123-0040; and

(d) At intervals not exceeding 1 year, although it shall not be necessary to complete all elements of a full calibration at the same time, all applicable parameters (for all energies) shall be completed at intervals not exceeding 12 calendar months.

(4) The registrant must maintain a record of each full calibration for the duration of the registration. The record must include:

(a) The date of the calibration;

(b) The manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the x-ray tube;

(c) The model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and

(d) The signature of the Qualified Medical Physicist responsible for performing the calibration.

(5) The calibration record must be maintained in an auditable form for the duration of the registration. The record must include:

(a) The date of the calibration;

(b) The manufacturer's name, model number and serial number for the therapeutic radiation machine;

(c) The model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and

(d) The signature of the Qualified Medical Physicist responsible for performing the calibration.

Stat. Auth: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 23-2006, f. & cert. ef. 10-19-06

333-123-0040
Quality Assurance And Safety Checks

(1) Periodic quality assurance checks must be performed on all therapeutic radiation machines subject to 333-123-0025 at intervals in accordance with industry standards of practice; and

(a) Quality assurance checks must include determination of central axis radiation output and a representative sampling of periodic quality assurance checks in accordance with the written procedures established by the Qualified Medical Physicist.

(b) Quality assurance checks required in this rule must be conducted using a dosimetry system that has been intercompared within the previous 12 months with the dosimetry system described in 333-123-0010(5) of this rule.

(c) The quality assurance procedures established by the Qualified Medical Physicist must:

(A) Specify the frequency at which tests or measurements are to be conducted; and

(B) Specify equipment required for the test; and

(C) Include the name of personnel conducting the test; and

(D) Include the acceptable tolerance for each parameter measured in the quality assurance check and the response triggered by test results that exceed tolerance levels.

(d) The registrant must have the Qualified Medical Physicist review and sign the results of each radiation output quality assurance check within 1 month of the date that the check was performed. The results of each periodic radiation output check must be reviewed according to the following procedures:

(A) The Radiation Therapy Physician and Qualified Medical Physicist must be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine must not be used clinically until the Qualified Medical Physicist has determined that all parameters are within their acceptable tolerances; and

(B) Notwithstanding the other requirements of this rule, the registrant must ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by section (1) of this rule have been performed within the 30 day period immediately prior to said administration.

(2) Safety Checks. Therapeutic radiation machines subject to 333-123-0025 of this rule must have applicable safety quality assurance check in accordance with industry standards of practice and performed at intervals not to exceed 1 week to ensure proper functioning and operation of:

(a) Electrical interlocks at each external beam radiation therapy room entrance; and

(b) The "BEAM-ON" and termination switches; and

(c) Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room; and

(d) Viewing and auditory systems; and

(e) If applicable, electrically operated treatment room doors from inside and outside the treatment room; and

(f) At least one emergency power cutoff switch. If more than one emergency cutoff switch is installed and not all switches are tested at once, each switch must be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the weekly treatment schedule in order to minimize possible stability problems with the therapeutic radiation machine or interruption of patient treatment schedules.

(3) The registrant must promptly repair any system identified in this rule that is not operating properly.

(4) The registrant must maintain a record of each quality assurance check required by section (1) of this rule for 3 years. The record must include:

(a) The date of the quality assurance check;

(b) The manufacturer's name, model number, and serial number of the therapeutic radiation machine control panel;

(c) The record must also include the manufacturer's name, model number and serial number and calibration date for the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and

(d) The signature of the individual who performed the periodic quality assurance check.

(5) Quality assurance for a conventional or virtual simulator must include acceptance testing and periodic verification of system performance in accordance with industry standards of practice for a conventional simulator or computed tomography simulators.

Stat. Auth: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 23-2006, f. & cert. ef. 10-19-06

333-123-0045
Quality Assurance Program

(1) Each registrant or applicant subject to 333-123-0025 must develop, implement, and maintain a quality assurance program to assure that radiation will be administered as directed by the Qualified Radiation Therapy Physician and in a manner that is safe for the patient, the general public, and radiation therapy staff.

(2) The program must include:

(a) Written or Electronic Directives:

(A) A written or electronic directive must be dated and signed by an radiation therapy physician before the administration of radiation; and

(B) If because of the patient's condition, a delay in the order to provide a written or electronic revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision; and

(C) The written directive must contain the patient's full name and patient identification number, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions; and

(D) A written revision to an existing written directive may be made if the revision is dated and signed by a radiation therapy physician before the administration of the external beam dose, or the next fractional dose; and

(E) The registrant must retain copies of written directives for 3 years; and

(F) Any unintended deviation from the written directive must be identified, evaluated and appropriate corrective action taken to prevent recurrence.

(b) The Quality Assurance program must include a process for ensuring that:

(A) Prior to the administration of each course of radiation treatments, the patient's identity is verified by more than one method as the individual named in the written or electronic directive; and

(B) Each administration is in accordance with the written or electronic directive; and

(C) External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written or electronic directive; and

(D) Manual or computer generated dose calculations and dose distribution plots are in accordance with the written or electronic directive; and

(E) Monitor units used, are verified and that set-up parameters and machine settings are correctly transferred to the control systems of radiation therapy machines; and

(F) At a minimum, prior to the administration of the first radiation treatment, a Port film or Portal image must be taken to check that the radiation field is properly aligned to the intended treatment area. The Port film or Portal image must be viewed and evaluated and the beam alignment approved by the Radiation Therapy Physician before radiation therapy commences. Thereafter, a weekly Port film or Portal image must be reviewed and signed by a Radiation Therapy Physician.

Stat. Auth: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 23-2006, f. & cert. ef. 10-19-06

333-123-0050
Qualified Medical Physicist Support in Facilities Having Therapeutic Radiation Machines with Energies of 1 Mv and Above

(1) The Qualified Medical Physicist is responsible for:

(a) Full calibration(s) required by 333-123-0035(3) and radiation protection surveys required by 333-123-0010(4); and

(b) Supervision and review of dosimetry; and

(c) Beam data acquisition and transfer for computerized dosimetry, and supervision of its use; and

(d) Quality assurance, including quality assurance check review required by 333-123-0040(2)(c); and

(e) Consultation with the authorized user in treatment planning, as needed; and

(f) Performing in a timely manner, calculations/assessments, regarding treatment errors, and report to the responsible user.

(2) Acceptance Testing, Commissioning and Full Calibration Measurements.

(a) Acceptance testing, commissioning and full calibration of a therapeutic radiation machine subject to this rule must be per-

formed by, or under the direct supervision of, a Qualified Medical Physicist.

(b) Acceptance testing must be performed in accordance with the manufacturer's contractual specifications. Commissioning must be performed according to the Medical Physicist's procedures before the first medical use following installation or after reinstallation of the therapeutic radiation machine.

Stat. Auth: ORS 453.605 – 453.807
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 23-2006, f. & cert. ef. 10-19-06

333-123-0055
Electronic Brachytherapy

(1) Electronic brachytherapy devices shall be exempt from the requirements in OAR 333-123-0025.

(a) An electronic brachytherapy device that does not meet the requirements of this rule shall not be used for irradiation of patients; and

(b) An electronic brachytherapy device shall only be utilized for human use applications specifically approved by the U.S. Food and Drug Administration (FDA) unless participating in a research study approved by the Authority.

(2) Each facility location authorized to use an electronic brachytherapy device shall possess calibrated portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument(s) shall be operable and calibrated in accordance with OAR 333-123-0010 for the applicable electronic brachytherapy source energy.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 4-2013, f. & cert. ef. 1-29-13

333-123-0060
Facility Design Requirements for Electronic Brachytherapy Devices

(1) In addition to shielding adequate to meet the requirements of division 120 of this chapter, a treatment room where an electronic brachytherapy device is used shall:

(a) Prevent simultaneous operation of more than one therapeutic radiation machine in a treatment room if applicable;

(b) Have a door at any entrance; and

(c) Permit communication with and visual observation of the patient from the treatment control panel during the irradiation from an electronic brachytherapy device.

(2) For electronic brachytherapy devices capable of operating at or below 50 kV, radiation shielding for the staff in the treatment room shall be available, either as a portable shield or as localized shielded material around the treatment site.

(3) For electronic brachytherapy devices capable of operating at greater than 150 kV:

(a) The control panel shall be located outside the treatment room; and

(b) Electrical interlocks shall be provided for all doors providing entrance into the treatment room that can:

(A) Prevent the operator from initiating the treatment cycle if a door remains open;

(B) Cause the source to be shielded when an entrance door is opened; and

(C) Prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off control is reset at the console.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 4-2013, f. & cert. ef. 1-29-13

333-123-0065
Electrical Safety for Electronic Brachytherapy Devices

(1) A high voltage transformer shall:

(a) Be electrically isolated to prevent electrical and magnetic interference with the surrounding environment and ancillary equipment;

(b) Be isolated from personnel (e.g., operator) and the environment by a protective housing that can only be accessed through a cover requiring a tool for access or with electrical interlocks to prevent operation while open; and

(c) Have appropriate safety labels warning personnel of potential electrical shock and heat related injuries.

(2) Brachytherapy manufactured equipment shall be in compliance with the most current revision of the following International Electrotechnical Commission (IEC) documents:

(a) IEC 60601-1:1998+A1+A2:1995;
(b) IEC 60601-1-2:2001;
(c) IEC 60601-2-8:1999; and
(d) IEC 60601-2-17:2004.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 4-2013, f. & cert. ef. 1-29-13

333-123-0070
Control Panel Functions

A control panel must be designed to provide:

(1) An indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible;

(2) An indication of whether X-rays are being produced;

(3) A means for displaying electronic brachytherapy source accelerating voltage(kV), beam current(μA), pre-set value of radiation dose(cGy) and real time display of dose delivered;

(4) The means for terminating an exposure at any time; and

(5) An access locking control device that can prevent unauthorized use of the electronic brachytherapy device.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 4-2013, f. & cert. ef. 1-29-13

333-123-0075
Timer

An irradiation control device timer shall be provided to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor.

(1) A timer shall be provided at the treatment control panel. The timer shall indicate planned setting and the time elapsed or remaining;

(2) A timer shall not permit an exposure if set at zero;

(3) A timer shall be a cumulative device that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

(4) A timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system has not previously terminated irradiation;

(5) A timer shall permit setting of exposure times as short as 0.1 second;

(6) A timer shall be accurate to within one percent of the selected value or 0.1 second, whichever is greater; and

(7) A redundant treatment monitoring system (backup timer) shall be present at the treatment console to use as the treatment stop criterion in case the primary treatment control device timer malfunctions.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 4-2013, f. & cert. ef. 1-29-13

333-123-0080
Medical Physicist

A Qualified Medical Physicist who meets the requirements of OAR 333-123-0015 is required in facilities having electronic brachytherapy devices. A Medical Physicist is responsible for:

(1) Evaluation of the output from the electronic brachytherapy source;

(2) Generation of the necessary dosimetric information;

(3) Supervision and review of treatment calculations prior to initial treatment of any treatment site;

(4) Establishing the periodic and day-of-use quality assurance checks and reviewing the data from those checks as required in sections (1) through (6) of this rule and OAR 333-123-0100;

(5) Consultation with a Radiation Therapy Physician in treatment planning as needed; and

(6) Performing calculations and assessments regarding patient treatments that may constitute a misadministration.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 4-2013, f. & cert. ef. 1-29-13

333-123-0085
Operating Procedures

(1) Only individuals approved by a Radiation Therapy Physician, Radiation Safety Officer, or Qualified Medical Physicist shall be present in the treatment room during treatment.

(2) Electronic brachytherapy devices shall not be made available for medical use unless the requirements of OAR 333-123-0010(4), 333-123-0090 and 333-123-0095 have been met.

(3) The electronic brachytherapy device shall be inoperable, either by hardware or password, when unattended by qualified staff or service personnel.

(4) During operation, the electronic brachytherapy device operator shall monitor the position of all persons in the treatment room, and all persons entering the treatment room, to prevent entering persons from unshielded exposure from the treatment beam.

(5) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

(6) Written procedures shall be developed, implemented, and maintained for responding to an abnormal situation. These procedures shall include:

(a) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions; and

(b) The names and telephone numbers of the Radiation Therapy Physician, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally.

(7) A copy of the current operating and emergency procedures shall be physically located at the electronic brachytherapy device control console. For control consoles that are integral to the electronic brachytherapy device, the required procedures shall be kept where the operator is located during electronic brachytherapy device operation.

(8) Instructions shall be posted at the electronic brachytherapy device control console to inform the operator of the names and telephone numbers of the authorized users, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally.

(9) A Radiation Therapy Physician shall be notified as soon as possible if the patient receiving brachytherapy treatment has a medical emergency, suffers injury or dies. A Radiation Safety Officer or designee shall be notified as soon as possible if there is any radiation related injury to the patient. A Radiation Safety Officer or a Qualified Medical Physicist shall inform the manufacturer and the Authority of the event.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 4-2013, f. & cert. ef. 1-29-13

333-123-0090
Safety Precautions for Electronic Brachytherapy Devices

(1) A Qualified Medical Physicist shall determine which persons in the treatment room require monitoring when the beam is energized.

(2) A Radiation Therapy Physician and a Qualified Medical Physicist shall be physically present during the initiation of all patient treatments involving the electronic brachytherapy device.

(3) A Qualified Medical Physicist and either an authorized user or a Radiation Therapy Physician or electronic brachytherapy device operator, under the supervision of an authorized user, who has been trained in the operation and emergency response for the electronic brachytherapy device, shall be physically present during continuation of all patient treatments involving the electronic brachytherapy device.

(4) When shielding is required by OAR 333-123-0060, the electronic brachytherapy device operator shall use a survey meter to verify proper placement of the shielding immediately upon initiation of treatment. Alternatively, a Qualified Medical Physicist shall designate shield locations sufficient to meet the requirements of division 120 of this chapter for any individual, other than the patient, in the treatment room.

(5) All personnel in the treatment room are required to remain behind shielding during treatment. A Qualified Medical Physicist shall approve any deviation from this requirement and shall designate alternative radiation safety protocols, compatible with patient safety, to provide an equivalent degree of protection.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: PH 4-2013, f. & cert. ef. 1-29-13

333-123-0095
Electronic Brachytherapy Source Calibration Measurements

(1) Calibration of the electronic brachytherapy source output for an electronic brachytherapy device shall be performed by, or under the direct supervision of a Qualified Medical Physicist.

(2) Calibration of the electronic brachytherapy source output shall be made for each electronic brachytherapy source annually, or after any repair affecting the X-ray beam generation, or when indicated by the electronic brachytherapy source quality assurance checks.

(3) Calibration of the electronic brachytherapy source output shall utilize a calibration procedure in accordance with OAR 333-123-0010(5). The dosimetry system shall have been calibrated at the applicable electronic brachytherapy source energy.

(4) Calibration of the electronic brachytherapy source output shall include, as applicable, determination of:

(a) The output within two percent of the expected value, if applicable, or determination of the output if there is no expected value;

(b) Timer accuracy and linearity over the typical range of use;

(c) Proper operation of back-up exposure control devices;

(d) Evaluation that relative dose distribution around the source is within the limit recommended by the manufacturer or recommendations from a recognized national professional association in electronic brachytherapy (when available); and

(e) Source positioning accuracy to within 1 mm within the applicator.

(5) Calibration of the X-ray source output shall be in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of a calibration protocol published by a national professional association, the manufacturer's calibration protocol shall be followed.

(6) The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include:

(a) The date of the calibration;

(b) The manufacturer's name, model number and serial number for the electronic brachytherapy device and a unique identifier for its electronic brachytherapy source;

(c) The model numbers and serial numbers of the instrument(s) used to calibrate the electronic brachytherapy device; and

(d) The name and signature of the Qualified Medical Physicist responsible for performing the calibration.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 4-2013, f. & cert. ef. 1-29-13

333-123-0100
Periodic and Day-of-Use Quality Assurance Checks for Electronic Brachytherapy Devices

(1) Quality assurance checks shall be performed by the medical physicists on each electronic brachytherapy device subject to this rule.

(a) At the beginning of each day of use; and

(b) After each X-ray tube installation.

(2) The registrant shall perform periodic quality assurance checks required by this rule in accordance with procedures established by a Qualified Medical Physicist.

(3) To satisfy the requirements of this rule, radiation output quality assurance checks shall include at a minimum:

(a) Verification that output of the electronic brachytherapy source falls within three percent of expected values, as appropriate for the device, as determined by:

(A) Output as a function of time; or

(B) Output as a function of setting on a monitor chamber.

(b) Verification of the consistency of the dose distribution to the output within two to three percent of the expected value, if applicable, or determination of the output if there is no expected value of that found during calibration required by OAR 333-123-0095.

(c) Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within 1 mm.

(4) The registrant shall use a dosimetry system that has been intercompared within the previous 12 months with the dosimetry system described in OAR 333-123-0010(5) to make the quality assurance checks required in this rule.

(5) The registrant shall review the results of each radiation output quality assurance check according to the following procedures:

(a) A Radiation Therapy Physician and a Qualified Medical Physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The electronic brachytherapy device shall not be made available for subsequent medical use until the Qualified Medical Physicist has determined that all parameters are within their acceptable tolerances.

(b) If all radiation output quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either a Radiation Therapy Physician or Qualified Medical Physicist within two days.

(c) A Qualified Medical Physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed 30 days.

(6) To satisfy the requirements of this rule, safety device quality assurance checks shall, at a minimum, assure:

(a) Proper operation of radiation exposure indicator lights on the electronic brachytherapy device and on the control console;

(b) Proper operation of viewing and intercom systems in each electronic brachytherapy facility, if applicable;

(c) Proper operation of radiation monitors, if applicable;

(d) The integrity of all cables, catheters or parts of the device that carry high voltages; and

(e) Connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.

(7) If the results of the safety device quality assurance checks required in this rule indicate the malfunction of any system, a registrant shall secure the control console in the OFF position and not use the electronic brachytherapy device except as may be necessary to repair, replace, or check the malfunctioning system.

(8) A registrant shall maintain a record of each quality assurance check required by sections (3) and (7) of this rule in an auditable form for three years.

(a) The record shall include:

(A) The date of the quality assurance check;

(B) The manufacturer's name, model number and serial number for the electronic brachytherapy device;

(C) The name and signature of the individual who performed the periodic quality assurance check; and

(D) The name and signature of the Qualified Medical Physicist who reviewed the quality assurance check.

(b) For radiation output quality assurance checks required by this rule, the record shall also include the unique identifier for the electronic brachytherapy source and the manufacturer's name, model number and serial number for the instrument(s) used to measure the radiation output of the electronic brachytherapy device.

Stat. Auth: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 4-2013, f. & cert. ef. 1-29-13

333-123-0105
Therapy Related Computer Systems

(1) A registrant shall perform acceptance testing on the treatment planning system of electronic brachytherapy-related computer systems in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of an acceptance testing protocol published by a national professional association, the manufacturer's acceptance testing protocol shall be followed.

(a) Acceptance testing shall be performed by, or under the direct supervision of a Qualified Medical Physicist. At a minimum, the acceptance testing shall include, as applicable, verification of:

(A) The source-specific input parameters required by the dose calculation algorithm;

(B) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(C) The accuracy of isodose plots and graphic displays;

(D) The accuracy of the software used to determine radiation source positions from radiographic images, if applicable; and

(E) If the treatment-planning system is different from the treatment-delivery system, the accuracy of electronic transfers of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

(2) The position indicators in the applicator shall be compared to the actual position of the source or planned swell positions, as appropriate, at the time of commissioning.

(3) Prior to each patient treatment regimen, the parameters for the treatment shall be evaluated and approved by a Radiation Therapy Physician and a Qualified Medical Physicist for correctness through means independent of that used for determination of the parameters.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 4-2013, f. & cert. ef. 1-29-13

333-123-0110
Training

(1) A registrant shall provide instruction, initially and at least annually, to all individuals who operate the electronic brachytherapy device, as appropriate to the individual's assigned duties, in the operating procedures identified in OAR 333-123-0085. If the interval between patients exceeds one year, retraining of the individuals shall be provided.

(2) In addition to the requirements of OAR 333-123-0015(1) for Radiation Therapy Physicians and OAR 333-123-0015(2) for Qualified Medical Physicists, these individuals shall also receive device specific instruction initially from the manufacturer, and annually from either the manufacturer or other qualified trainer. The training shall be of a duration recommended by a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of any training protocol recommended by a national professional association, the manufacturer's training protocol shall be followed. The training shall include, but not be limited to:

(a) Device-specific radiation safety requirements;

(b) Device operations;

(c) Clinical use for the types of use approved by the FDA;

(d) Emergency procedures, including an emergency drill; and

(e) The registrant's Quality Assurance Program.

(3) A registrant shall retain a record of individuals receiving instruction required by this rule for three years. The record shall include:

(a) A list of the topics covered;

(b) The date of the instruction;

(c) The name(s) of the attendee(s); and

(d) The name(s) of the individual(s) who provided the instruction.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 4-2013, f. & cert. ef. 1-29-13

333-123-0115
Mobile Electronic Brachytherapy Service

A registrant providing mobile electronic brachtherapy service shall, at a minimum:

(1) Check all survey instruments before medical use at each address of use or on each day of use, whichever is more restrictive;

(2) Account for the electronic brachytherapy source in the electronic brachytherapy device before departure from the client's address; and

(3) Perform, at each location on each day of use, all of the required quality assurance checks specified in OAR 333-123-0100 to assure proper operation of the device.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 4-2013, f. & cert. ef. 1-29-13

DIVISION 124

CIVIL PENALTIES

333-124-0001
Purpose and Scope

The rules in this division establish civil penalties for failure to comply with the statutory and administrative rule requirements in divisions 100 through 123.

Stat. Auth.: ORS 431.262, 431.950 & 453.771
Stats. Implemented: ORS 431.262, 431.950 & 453.771
Hist.: PH 4-2010, f. & cert. ef. 2-16-10

333-124-0010
Civil Penalties

(1) The Authority may impose a civil penalty on:

(a) A tanning facility for violations of ORS 431.925 through 431.955 or any rules in divisions 100, 103, 111, 119 and this chapter.

(b) An X-ray machine registrant for a violation of ORS 453.605 through 453.807 or any rules in division 100, 101, 103, 106, 108, 111, 112, 115, 120, 122, 123 of this chapter, and this division.

(c) A radioactive materials licensee for a violation of ORS 453.605 through 453.807 or any rules in divisions 100, 102, 103, 105, 109, 111, 113, 116, 117, 118, 120, 121 of this chapter, and this division.

(2) For a first violation, unless the violation poses a serious public health threat, the Authority shall provide a tanning facility, X-ray machine registrant or radioactive materials licensee with a Notice of Violation that explains the violation and informs the facility, registrant or licensee of the violation and that it must be corrected within a time frame specified in the Notice, or the facility, registrant or licensee may be subject to a civil penalty.

(3) For violations that pose a significant public health threat, or for second or subsequent violations of any level of severity, the Authority may, but is not required to, issue a Notice of Violation as described in section (2) of this rule prior to issuing a Notice of Imposition of Civil Penalty.

(4) Each day that a facility, registrant or licensee is in violation is considered a new violation until the facility, registrant or licensee is in compliance.

(5) Each device that is out of compliance with applicable statutes or rules is a separate violation.

(6) A civil penalty will be imposed based on the severity of the violation and whether it is a first or repeat offense.

(a) Level 1 violation: A violation that has the potential to cause a significant health and safety problem or has caused a significant health and safety problem.

(b) Level 2 violation: A violation that has the potential to cause a moderate health and safety problem or has caused a moderate health and safety problem.

(c) Level 3 violation: A violation that has the potential to cause a minor health and safety problem or has caused a minor health and safety problem.

(d) Level 4 violation: A violation that, if it continues, could result in a condition that may cause a health and safety problem.

(e) Level 5 violation: An action that violates a statute or rule but will not result in a direct health and safety problem. (Minor statutory or administrative rule infraction)

(7) Civil penalty amounts are as follows, except as provided in section (8) of this rule:

(a) Level 1 violation, first offense: $200.00.

(b) Level 1 violation, second offense: $350.00.

(c) Level 1 violation, third and subsequent offenses: $500.00.

(d) Level 2 violation, first offense: $150.00.
(e) Level 2 violation, second offense: $200.00.
(f) Level 2 violation, third and subsequent offenses: $250.00.
(g) Level 3 violation: $100.00.
(h) Level 3 violation, second offense: $150.00.
(i) Level 3 violation, third and subsequent offenses: $200.00.
(j) Level 4 violation, first offense: $75.00.
(k) Level 4 violation, second offense: $100.00.
(l) Level 4 violation, third and subsequent offenses: $125.00.
(m) Level 5 violation, first offense: $50.00.
(n) Level 5 violation, second offense: $75.00.
(o) Level 5 violation, third and subsequent offenses: $100.00.

(8) For failure to properly pay registration or licensing fee in whole within 30 days of the due date, the registrant or licensee will be subject to a civil penalty of:

(a) Three percent of the applicable fee outlined in division 103 of these rules per day per device for the first 30 days, followed by;

(b) Five percent of the applicable fee outlined in division 103 of these rules per day per device for the next 30 days, followed by;

(c) Ten percent of the applicable fee outlined in division 103 of these rules per day per device for the next 30 days or subsequent periods and calculated from the due date until the registration or licensing fee is paid in full.

(9) The Authority will issue a Notice of Intent to Assess Civil Penalties and the Notice will explain the right of the facility to request a hearing, in accordance with ORS 183.745.

Stat. Auth.: ORS 431.262, 431.950 & 453.771
Stats. Implemented: ORS 431.262, 431.950 & 453.771
Hist.: PH 4-2010, f. & cert. ef. 2-16-10

DIVISION 125

MATERIALS SAFETY AND SECURITY

333-125-0001
Nationally Tracked Sources

(1) Purpose and Scope. This rule outlines the reporting requirements for any licensees that possess an aggregated category 1 or category 2 quantity of radioactive material listed in Appendix A to 10 CFR Part 37 to report to the National Source Tracking System (NSTS). The mission of the NSTS is to track category 1 and category 2 radioactive materials from manufacturing through their disposal, decay, or exportation.

(2) Reports of Transactions. Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in subsections (2)(a) through (2)(e) of this rule for each type of transaction.

(a) Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction report. The report must include the following information:

(A) The name, address, and license number of the reporting licensee;

(B) The name of the individual preparing the report;

(C) The manufacturer, model, and serial number of the source;

(D) The radioactive material in the source;

(E) The initial source strength in becquerels (curies) at the time of manufacture; and

(F) The manufacture date of the source.

(b) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction report. The report must include the following information:

(A) The name, address, and license number of the reporting licensee;

(B) The name of the individual preparing the report;

(C) The name and license number of the recipient facility and the shipping address;

(D) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the sources;

(E) The radioactive material in the source;

(F) The initial or current source strength in becquerels (curies);

(G) The date for which the source strength is reported;

(H) The shipping date;

(I) The estimated time of arrival date; and

(J) For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked sources.

(c) Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(A) The name, address, and license number of the reporting licensee;

(B) The name of the individual preparing the report;

(C) The name, address, and license number of the person that provided the source:

(D) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(E) The radioactive material in the source;

(F) The initial or current source strength in becquerels (curies);

(G) The date for which the source strength is reported;

(H) The date of receipt; and

(I) For material received under a Uniform Low-Level radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

(d) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(A) The name, address, and license number of the reporting licensee;

(B) The name of the individual preparing the report;

(C) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(D) The radioactive material in the source;

(E) The initial or current source strength in becquerels (curies);

(F) The date for which the source strength is reported; and

(G) The disassemble date of the source.

(e) Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(A) The name, address, and license number of the reporting licensee;

(B) The name of the individual preparing the report;

(C) The waste manifest number;

(D) The container identification with the nationally tracked source;

(E) The date of disposal; and

(F) The method of disposal.

(f) The reports discussed in subsections (2)(a) through (2)(e) of this rule must be submitted by the close of the next business day after the transactions. The report must be submitted to the National Source Tracking System by using:

(A) The online National Source Tracking System;

(B) Electronically using a computer readable format;

(C) By facsimile;

(D) By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

(E) By telephone with follow up by facsimile or mail.

(g) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within five business days of the discovery of the error or missed transaction.

Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by subsections (2)(a) through (2)(e) of this rule. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

(h) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by January 31, 2009. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009. The information may be submitted by using any of the methods identified by paragraph (2)(f)(A) through (2)(f)(E) of this rule. The initial inventory report must include the following information:

(A) The name, address, and license number of the reporting licensee;

(B) The name of the individual preparing the report;

(C) The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;

(D) The radioactive material in the sealed source;

(E) The initial or current source strength in becquerels (curies); and

(F) The date for which the source strength is reported.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material

333-125-0005
Purpose and Scope

(1) OAR 333-125-0005 through 333-125-0200 contains the physical protection program requirements for any licensees that possess an aggregated category 1 or category 2 quantity of radioactive material listed in Appendix A to 10 CFR Part 37. These requirements provide reasonable assurance of the security of category 1 or 2 quantities of radioactive material by protecting these materials from theft or diversion. Specific requirements for access to material, use of material, transfer of material, and transport of material are included. No provision of this division authorizes the possession of licensed material.

(2) Background investigations, access control program and physical protection during use requirements apply to any person who possesses or uses at any site, an aggregated category 1 or category 2 quantity of radioactive material.

(3) Physical protection in transit applies to any person who under the rules in this division:

(a) Transports or delivers to a carrier for transport in a single shipment, a category 1 or category 2 quantity of radioactive material; or

(b) Imports or exports a category 1 or category 2 quantity of radioactive materials. The rules that establish the physical protection program apply to the domestic portion of the transport.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0010
Definitions

(1) "Access control" means a system for allowing only approved individuals to have unescorted access to the security zone and for ensuring that all other individuals are subject to escorted access.

(2) "Aggregated" means accessible by the breach of a single physical barrier that shall allow access to radioactive material in any form, including any devices that contain the radioactive material, when the total activity equals or exceeds a category 2 quantity of radioactive material.

(3) "Approved individual" means an individual whom the licensee has determined to be trustworthy and reliable for unescorted access in accordance with OAR 333-125-0020 through 333-125-0095 and who has completed the training required by OAR 333-125-0115.

(4) "Background investigation" means the investigation conducted by a licensee or applicant to support the determination of trustworthiness and reliability.

(5) "Category 1 quantity" means a quantity of radioactive material meeting or exceeding the category 1 threshold in Table 1 of Appendix A, Part 37. This is determined by calculating the ratio of the total activity of each radionuclide to the category 1 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity shall be considered a category 1 quantity. Category 1 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

(6) "Category 2 quantity" means a quantity of radioactive material meeting or exceeding the category 2 threshold but less than the category 1 threshold in Table 1 of Appendix A, Part 37. This is determined by calculating the ratio of the total activity of each radionuclide to the category 2 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity shall be considered a category 2 quantity. Category 2 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

(7) "Diversion" means the unauthorized movement of radioactive material subject to the physical protection program to a location different from the material's authorized destination inside or outside of the site at which the material is used or stored.

(8) "Escorted access" means accompaniment while in a security zone by an approved individual who maintains continuous direct visual surveillance at all times over an individual who is not approved for unescorted access.

(9) "Fingerprint orders" means the orders issued by the U.S. Nuclear Regulatory Commission or the legally binding requirements issued by Agreement States that require fingerprints and criminal history records checks for individuals with unescorted access to category 1 and category 2 quantities of radioactive material or safeguards information-modified handling.

(10) "Local law enforcement agency (LLEA)" means a public or private organization that has been approved by a federal, state, or local government to carry firearms and make arrests, and is authorized and has the capability to provide an armed response in the jurisdiction where the licensed category 1 or category 2 quantity of radioactive material is used, stored, or transported.

(11) "Lost or missing licensed material" means licensed material whose location is unknown. It includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

(12) "Mobile device" means a piece of equipment containing licensed radioactive material that is either mounted on wheels or casters, or otherwise equipped for moving without a need for disassembly or dismounting; or designed to be hand carried. Mobile devices do not include stationary equipment installed in a fixed location.

(13) "Movement control center" means an operations center that is remote from transport activity and maintains position information on the movement of radioactive material, receives reports of attempted attacks or thefts, provides a means for reporting incidents to appropriate agencies and can request and coordinate appropriate aid.

(14) "Nationally Tracked Source" means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of radioactive material listed in 10 CFR Part 20, Appendix E. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded in a solid form and that is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel rod, or fuel pellet.

(15) "No-later-than arrival time" means the date and time that the shipping licensee and receiving licensee have established as the time to initiate an investigation if the shipment has not arrived at the receiving facility. The no-later-than arrival time may not be more than six hours after the estimated arrival time for shipments of category 2 quantities of radioactive material.

(16) "Reviewing official" means the individual who shall make the trustworthiness and reliability determination of an individual to determine whether the individual may have, or continue to have, unescorted access to the category 1 or category 2 quantities of radioactive materials that are possessed by the licensee.

(17) "Sabotage" means deliberate damage, with malevolent intent, to category 1 or 2 quantity of radioactive material, a device that contains a category 1 or 2 quantity of radioactive material, or the components of the security system.

(18) "Safe haven" means a readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for the local law enforcement authorities.

(19) "Security zone" means any temporary or permanent area determined and established by the licensee for the physical protection of category 1 or category 2 of radioactive material.

(20) "Telemetric position monitoring system" means a data transfer system that captures information by instrumentation and measuring devices about the location and status of a transport vehicle or package between the departure and destination locations.

(21) "Trustworthiness and reliability" means the characteristics of an individual considered dependable in judgment, character, and performance, such that unescorted access to category 1 or category 2 quantities of radioactive material by that individual does not constitute an unreasonable risk to the public health and safety or security. A determination of trustworthiness and reliability for this purpose is based upon the results from a background investigation.

(22) "Unescorted access" means solitary access to an aggregated category 1 or category 2 quantity of radioactive material or the devices that contain the material.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0015
Specific Exemptions

(1) A licensee that possesses radioactive waste that contains category 1 or category 2 of radioactive material is exempt from the requirements of OAR 333-125-0020 through OAR 333-125-0190. Except that any radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg (4,409 lbs) is not exempt from the requirements within this division.

(2) The licensee shall implement the following requirements to secure the radioactive waste:

(a) Use continuous physical barriers that allow access to the radioactive waste only through established access control points;

(b) Use a locked door or gate with monitored alarm at the access control point;

(c) Assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred:

(A) Immediately notify LLEA and request an emergency response upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste that contains category 1 or category 2 quantities of radioactive materials; and

(B) As soon as reasonably possible, the licensee shall contact:

(i) The Oregon Health Authority, Radiation Protection Services 24-hour response line at (971) 673-0490; or

(ii) The Oregon Emergency Response System at 1-800-452-0311.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

Background Investigations and Access Control Program

333-125-0020
Personnel Access Authorization Requirements for Category 1 and 2 Quantities

(1) Each licensee that possesses an aggregated quantity of radioactive materials at or above the category 2 threshold shall establish, implement, and maintain an access authorization program in accordance with OAR 333-125-0020 through 333-125-0095.

(2) An applicant for a new license and each licensee that shall become newly subject upon application for modification of its license shall implement the requirements of OAR 333-125-0020 through 333-125-0095, as appropriate, before taking possession of an aggregated category 1 or category 2 of radioactive material.

(3) Any licensee that has not previously implemented the Security Orders or has been subject to the provisions of OAR 333-125-0020 through 333-125-0095 shall implement the provisions of those rules before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

(4) General performance objective. The licensee's access authorization program must ensure that the individuals specified in section (5) of this rule are trustworthy and reliable.

(5) Applicability. Licensees shall subject the following individuals to an access authorization program:

(a) Any individual whose assigned duties require unescorted access to category 1 or category 2 quantities of radioactive material or to any device that contains the radioactive material; and

(b) Reviewing officials.

(6) Licensees need not subject the categories of individuals listed in OAR 333-125-0085 subsections (1)(a) through (m) to the investigation elements of the access authorization program.

(7) Licensees shall approve for unescorted access to category 1 or category 2 quantities of radioactive material only those individuals with job duties that require unescorted access to category 1 or category 2 quantities of radioactive material.

(8) Licensees may include individuals needing access to safeguards information-modified handling under 10 CFR Part 73 in the access authorization program under OAR 333-125-0020 through 333-125-0095.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0025
Access Authorization Program Requirements

(1) Granting unescorted access authorization. Licensees shall implement the following requirements under OAR 333-125-0020 through 333-125-0095 for granting initial or reinstated unescorted access authorization:

(a) Individuals who have been determined to be trustworthy and reliable, shall complete the security training required by OAR 333-125-0105 before being allowed unescorted access to category 1 or category 2 of radioactive material.

(b) Reviewing officials shall be the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to category 1 or category 2 of radioactive material possessed by the licensee.

(c) Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. The fingerprints of the named reviewing official must be taken by a law enforcement

agency, federal or state agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a state to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every 10 years in accordance with OAR 333-125-0065.

(2) Reviewing officials must be permitted to have unescorted access to category 1 or category 2 quantities of radioactive materials and access to the licensee's safeguards information or safeguards information-modified handling, if the licensee possesses safeguards information or safeguards information-modified handling.

(3) Reviewing officials cannot approve other individuals to act as reviewing officials.

(4) A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:

(a) The individual has undergone a background investigation that included fingerprinting and an FBI criminal history records check and has been determined to be trustworthy and reliable by the licensee; or

(b) The individual is subject to a category listed in OAR 333-125-0085.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0030
Informed Consent

(1) Licensees may not initiate a background investigation without the informed and signed consent of the subject individual. The consent must include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. Before a final adverse determination, the licensee shall provide the individual with an opportunity to correct any inaccurate or incomplete information that is developed during the background investigation. Licensees do not need to obtain signed consent from those individuals that meet the requirements of OAR 333-125-0065. A signed consent must be obtained prior to any reinvestigation.

(2) The subject individual may withdraw his or her consent at any time. Licensees shall inform the individual that:

(a) If an individual withdraws his or her consent, the licensee may not initiate any elements of the background investigation that were not in progress at the time the individual withdrew his or her consent; and

(b) The withdrawal of consent for the background investigation is sufficient cause for denial or termination of unescorted access authorization.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0035
Personal History Disclosure

Any individual who is applying for unescorted access authorization shall disclose the personal history information that is required by the licensee's access authorization program for the reviewing official to make a determination of the individual's trustworthiness and reliability. Refusal to provide, or the falsification of, any personal history information required by this division is sufficient cause for denial or termination of unescorted access.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0040
Determination Basis

(1) The reviewing official shall determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access authorization based on an evaluation of all of the information collected to meet the requirements within this division.

(2) The reviewing official may not permit any individual to have unescorted access until the reviewing official has evaluated all of the information collected to meet the requirements of this division and determined that the individual is trustworthy and reliable. The reviewing official may deny unescorted access to any individual based on information obtained at any time during the background investigation.

(3) The licensee shall document the basis for concluding whether or not there is reasonable assurance that an individual is trustworthy and reliable.

(4) The reviewing official may terminate or administratively withdraw an individual's unescorted access authorization based on information obtained after the background investigation has been completed and the individual had been granted unescorted access authorization.

(5) Licensees shall maintain a list of persons currently approved for unescorted access authorization. When a licensee determines that a person no longer requires unescorted access or has become ineligible to meet access authorization requirements, the licensee shall remove the person from the approved list as soon as possible, but no later than seven working days, and take prompt measures to ensure that the individual is unable to have unescorted access to the material.

(6) The licensee shall take prompt immediate measures to ensure that the individual is unable to have unescorted access to the material.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0045
Access Authorization Program Procedures

Licensees shall develop, implement, and maintain written procedures for implementing the access authorization program. The procedures must include provisions for the notification of individuals who are denied unescorted access. The procedures must include provisions for the review, at the request of the affected individual, of a denial or termination of unescorted access authorization. The procedures must contain a provision to ensure that the individual is informed of the grounds for the denial or termination of unescorted access authorization and allow the individual an opportunity to provide additional relevant information.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0050
Right to Correct and Complete Information

(1) Prior to any final adverse determination, licensees shall provide each individual subject to this division with the right to complete, correct, and explain information obtained as a result of the licensee's background investigation. Confirmation of receipt by the individual of this notification must be maintained by the licensee for a period of one year from the date of the notification.

(2) If an individual reviewing their criminal history record believes that it is incorrect or incomplete in any respect and wishes to change, correct, update, or explain anything in the record, the individual may initiate challenge procedures.

(3) Challenge procedures include direct application by the individual challenging the record to the law enforcement agency that contributed the questioned information or a direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Federal Bureau of Investigation, Criminal Justice Information Services (CJIS) Division, ATTN: SCU, Mod. D-2, 1000 Custer Hollow Road, Clarksburg, WV 26306 as set forth in 28 CFR 16.30 through 16.34. In the latter case, the Federal Bureau of Investigation (FBI) will forward the challenge to the agency that submitted the data, and will request that the agency verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division makes any changes necessary in accordance with the information supplied by that agency. Licensees must provide at least 10 days for an individual to initiate action to challenge the results of an FBI criminal history records check after the record being made available for his or her

review. The licensee may make a final adverse determination based upon the criminal history records only after receipt of the FBI's confirmation or correction of the record.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0055

Records

(1) The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for three years from the date the individual no longer requires unescorted access to category 1 or category 2 radioactive materials.

(2) The licensee shall retain a copy of the current access authorization program procedures as a record for three years after the procedure is no longer needed. If any portion of the procedure is superseded, the licensee shall retain the superseded materials for three years after the records have been amended.

(3) The licensee shall retain the list of persons approved for unescorted access authorization for three years after the list is superseded or replaced.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0060
Initial Investigation

(1) Before allowing an individual unescorted access to materials and devices containing category 1 or category 2 radioactive materials, licensees shall complete a background investigation of the individual seeking unescorted access authorization. The scope of the investigation must encompass at least the seven years preceding the date of the background investigation or since the individual's 18th birthday, whichever is shorter.

(2) The background investigation must include at a minimum:

(a) Fingerprinting and an FBI identification and criminal history records check in accordance with OAR 333-125-0075 through 333-125-0080;

(b) Verification of true identity. Licensees shall verify the true identity of the individual who is applying for unescorted access authorization to verify that the applicant is who he or she claims to be. A licensee shall review official identification documents such as driver's license; passport; government identification; certificate of birth issued by the state, province, or country of birth and compare the documents to personal information data provided by the individual to identify any discrepancy in the information.

(A) Licensees shall document the type, expiration, and identification number of the identification document, or maintain a photocopy of identifying documents on file in accordance with OAR 333-125-0090; and

(B) Licensees shall certify in writing that the identification was properly reviewed, and shall maintain the certification and all related documents for review upon inspection.

(c) Employment history verification. Licensees shall complete employment and military history verification. Licensees shall verify the individual's employment with each previous employer for the most recent seven years before the date of application.

(d) Verification of education. Licensees shall verify that the individual participated in the education process during the claimed period.

(e) Character and reputation determination. Licensees shall complete reference checks to determine the character and reputation of the individual who has applied for unescorted access authorization. Unless other references are not available, reference checks may not be conducted with any person who is known to be a close member of the individual's family, including but not limited to the individual's spouse, parents, siblings, or children, or any individual who resides in the individual's permanent household. Reference checks under this division must be limited to whether the individual has been and continues to be trustworthy and reliable.

(A) The licensee shall also, to the extent possible, obtain independent information to corroborate that provided by the individual such as seeking references not supplied by the individual; and

(B) If a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide information or indicates an inability or unwillingness to provide information within a time frame deemed appropriate by the licensee but at the least after 10 business days of the request or if the licensee is unable to reach the entity, the licensee shall document the refusal, unwillingness or inability in the record of investigation; and attempt to obtain the information from an alternate source.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15; PH 25-2016, f. 8-26-16, cert. ef. 9-1-16

333-125-0065
Grandfathering

(1) Individuals who have been determined to be trustworthy and reliable for unescorted access to category 1 or category 2 quantities of radioactive material under the Fingerprint Orders may continue to have unescorted access to category 1 and category 2 quantities of radioactive materials without further investigation. These individuals shall be subject to the reinvestigation requirement outlined in OAR 333-125-0070.

(2) Individuals who have been determined to be trustworthy and reliable under the provisions of 10 CFR Part 73 or the security orders for access to safeguards information, safeguards information-modified handling, or risk-significant material, may have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation.

(3) The licensee shall document that the individual was determined to be trustworthy and reliable under the provisions of 10 CFR Parts 73 or a security order. Security order, in this context, refers to any order that was issued by the NRC that required fingerprints and an FBI criminal history records check for access to safeguards information, safeguards information-modified handling, or risk significant material such as special nuclear material or large quantities of uranium hexafluoride. These individuals shall be subject to the reinvestigation requirement per OAR 333-125-0070.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0070
Reinvestigation

(1) Licensees shall conduct a reinvestigation every 10 years for any individual with unescorted access to category 1 or category 2 quantities of radioactive material.

(2) The reinvestigation shall consist of fingerprinting, FBI identification, and criminal history records check in accordance with OAR 333-125-0075 through 333-125-0080.

(3) The reinvestigations must be completed within 10 years of the date on which these elements were last completed.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0075
Requirements for Criminal History Records Checks of Individuals Granted Unescorted Access

(1) General Performance Objective and Requirements. Except for those individuals listed in OAR 333-125-0085 and those individuals grandfathered under OAR 333-125-0065, each licensee subject to the provision of this division shall fingerprint each individual who is to be permitted unescorted access to category 1 and category 2 quantities of radioactive material.

(2) Licensees shall transmit all collected fingerprints to the NRC for transmission to the FBI. The licensee shall use the information received from the FBI as part of the required background investigation to determine whether to grant or deny unescorted access to category 1 or category 2 quantities of radioactive material for that individual.

(3) The licensee shall notify each affected individual that their fingerprints will be used to secure a review of their criminal history record, and shall inform the individual of the procedures for revising the record or adding explanations to the record.

(4) Fingerprinting is not required if a licensee is reinstating an individual's unescorted access if:

(a) The individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of the individual's unescorted access authorization; and

(b) The previous access was terminated under favorable conditions.

(5) Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to category 1 or category 2 radioactive material, access to safeguards information, or safeguards information-modified handling by another licensee, based upon a background investigation conducted under OAR 333-125-0020 through 333-125-0095 or the Nuclear Regulatory Commission's Fingerprint Orders or 10 CFR Part 73. An existing criminal history check file may be transferred to another licensee who is conducting a criminal history check for an individual requesting unescorted access in accordance with OAR 333-125-0090(3).

(6) Licensees shall use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to category 1 or category 2 quantities of radioactive materials, access to safeguards information, or safeguards information-modified handling.

(7) Prohibitions: Licensees may not base a final determination to deny an individual unescorted access authorization to category 1 or category 2 quantities of radioactive materials solely on the basis of information received from the FBI involving:

(a) An arrest more than one year old for which there is no information of the disposition of the case; or

(b) An arrest that resulted in dismissal of the charge or an acquittal.

(8) Licensees may not use information received from a criminal history records check obtained under this division in a manner that can infringe upon the rights of any individual under the First Amendment of the Constitution of the United States, nor shall licensees use the information in any way that can discriminate among individuals on the basis of race, religion, national origin, gender, or age.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0080
Procedures for Processing of Fingerprint Checks

(1) For the purpose of complying with OAR 333-125-0020 through 333-125-0095, licensees shall submit to the U.S. Nuclear Regulatory Commission, Director, Division of Facilities and Security, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop T-03B46M, Rockville, Maryland 20852, one completed, legible standard fingerprint card (Form FD-258, ORIMDNR-COOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling 1-630-829-9565, or by electronic mail to FORMS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at http://www.nrc.gov/site-help/e-submittals.html.

(2) Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." For guidance on making electronic payments, contact the Security Branch, Division of Facilities and Security at 301-415-7513. Combined payment for multiple applications is acceptable. The Commission publishes the amount of the fingerprint check application fee on the NRC's public website. (To find the current fee amount, go to the Electronic Submittals page at http://www.nrc.gov/site-help/e-submittals.html and see the link for the Criminal History Program under Electronic Submission Systems.)

(3) The Commission shall forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0085
Relief from Fingerprinting, Identification, and Criminal History Record Checks and Other Elements of Background Investigations for Designated Categories of Individuals Permitted Unescorted Access to Certain Radioactive Materials

(1) Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, and other elements of the background investigation are not required for the following individuals prior to granting unescorted access to category 1 or category 2 quantities of radioactive materials:

(a) An employee of the Commission or of the Executive Branch of the U.S. Government who has undergone fingerprinting for a prior U.S. Government criminal history records check;

(b) A member of Congress;

(c) An employee of a member of Congress or Congressional committee who has undergone fingerprinting for a prior U.S. Government criminal history records check;

(d) The Governor of a state or his or her designated state employee representative;

(e) Federal, state, or local law enforcement personnel;

(f) State Radiation Control Program Directors and State Homeland Security Advisors or their designated state employee representatives;

(g) Agreement State employees conducting security inspections on behalf of the NRC under an agreement executed under section 274.i. of the Atomic Energy Act;

(h) Representatives of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S. and IAEA Safeguards Agreement who have been certified by the NRC;

(i) Emergency response personnel who are responding to an emergency;

(j) Commercial vehicle drivers for road shipments of category 1 and 2 quantities of radioactive material;

(k) Package handlers at transportation facilities such as freight terminals and railroad yards;

(L) Any individual who has an active federal security clearance, provided that he or she makes available the appropriate documentation. Written confirmation from the agency or employer that granted the federal security clearance or reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material; and

(m) Any individual employed by a service provider licensee for which the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to category 1 or category 2 quantities of radioactive material. Written verification from the service provider must be provided to the licensee. The licensee shall retain the documentation for a period of three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

(2) Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, are not required for an individual who has had a favorably adjudicated U.S. Government criminal history records check within the last five years, under a comparable U.S. Government program involving fingerprinting and an FBI identification and criminal history records check provided that he or she makes available the appropriate documentation. Written confirmation from the agency or employer that reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material. These programs include, but are not limited to:

(a) National Agency Check;

(b) Transportation Worker Identification Credentials (TWIC) under 49 CFR Part 1572;

(c) Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances under 27 CFR Part 555;

(d) Health and Human Services security risk assessments for possession and use of select agents and toxins under 42 CFR Part 73;

(e) Hazardous Material security threat assessment for hazardous material endorsement to commercial driver's license under 49 CFR Part 1572; and

(f) Customs and Border Protection's Free and Secure Trade (FAST) Program.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0090
Protection of Information

(1) Each licensee who obtains background information on an individual under OAR 333-125-0020 through 333-125-0095 shall establish and maintain a system of files and written procedures for protection of the record and the personal information from unauthorized disclosure.

(2) The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his or her representative, or to those who have a need to have access to the information in performing assigned duties in the process of granting or denying unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling. No individual authorized to have access to the information may disseminate the information to any other individual who does not have a need to know.

(3) The personal information obtained on an individual from a background investigation may be provided to another licensee:

(a) Upon the individual's written request to the licensee holding the data to disseminate the information contained in his or her file; and

(b) The recipient licensee verifies information such as name, date of birth, social security number, gender, and other applicable physical characteristics.

(4) The licensee shall make background investigation records obtained under OAR 333-125-0020 through 333-125-0095 available for examination by an authorized representative of the NRC to determine compliance with the regulations and laws.

(5) The licensee shall retain all fingerprint and criminal history records (including data indicating no record) received from the FBI, or a copy of these records if the individual's file has been transferred, on an individual for three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0095
Access Authorization Program Review

(1) Each licensee shall be responsible for the continuing effectiveness of the access authorization program. Each licensee shall ensure that access authorization programs are reviewed to confirm compliance with the requirements within OAR 333-125-0020 through 333-125-0095 and that comprehensive actions are taken to correct any noncompliance that is identified. The review program shall evaluate all program performance objectives and requirements. Each licensee shall annually review the access program content and implementation.

(2) The results of the reviews, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the access authorization program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

(3) Review records must be maintained for three years.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

Physical Protection Requirements During Use

333-125-0100
Security Program

(1) Applicability: Each licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material shall establish, implement, and maintain a security program in accordance with the requirements outlined in this rule through OAR 333-125-0155.

(a) An applicant for a new license and each licensee that becomes newly subject to the requirements of OAR 333-125-0100

through 333-125-0155 upon application for modification of its license shall implement the requirements of OAR 333-125-0100 through 333-125-0155 as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.

(b) Any licensee that has not previously implemented the Security Orders or been subject to the provisions OAR 333-125-0100 through 333-125-0155 shall provide written notification to the Authority at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

(2) General performance objective: Each licensee shall establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to category 1 or category 2 quantities of radioactive material.

(3) Program features: Each licensee's security program must include the program features, as appropriate, described in OAR 333-125-0105 through 333-125-0150.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15; PH 25-2016, f. 8-26-16, cert. ef. 9-1-16

333-125-0105
General Security Program Requirements

(1) Security plan. Each licensee identified in OAR 333-125-0100(1) shall develop a written security plan specific to its facilities and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by this division. The security plan must, at a minimum:

(a) Describe the measures and strategies used to implement the requirements of OAR 333-125-0100 through 333-125-0155; and

(b) Identify the security resources, equipment, and technology used to satisfy the requirements of this division.

(2) The security plan must be reviewed and approved by the individual with overall responsibility for the security program.

(3) A licensee shall revise its security plan as necessary to ensure the effective implementation of the Authority' requirements. The licensee shall ensure that:

(a) The revision has been reviewed and approved by the individual with overall responsibility for the security program; and

(b) The affected individuals are instructed on the revised plan before the changes

are implemented.

(4) The licensee shall retain a copy of the current security plan as a record for three years after the security plan is no longer required. If any portion of the plan is superseded, the licensee shall retain the superseded material for three years after the record is superseded.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0110
Security Program Implementation Plan

(1) The licensee shall develop and maintain a written implementation plan that provides procedures on how the requirements of the security plan will be met.

(2) The implementation plan's procedures and revisions must be approved in writing by the individual with overall responsibility for the security program.

(3) The licensee shall retain a copy of the implementation plan's current procedures as a record for three years after the implementation plan is no longer needed. Superseded portions of the plan's procedures must be retained for three years after the record is superseded.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0115
Security Program Training

(1) Each licensee shall conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The training must include instruction in:

(a) The licensee's security program and procedures to secure category 1 or category 2 quantities of radioactive material, and in the purposes and functions of the security measures employed;

(b) The responsibility to report promptly to the licensee any condition that causes or may cause a violation of the Authority's requirements;

(c) The responsibility of the licensee to report promptly to the local law enforcement agency and licensee any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material; and

(d) The appropriate response to security alarms.

(2) In determining those individuals who shall be trained on the security program, the licensee shall consider each individual's assigned activities during authorized use and response to potential situations involving actual or attempted theft, diversion, or sabotage of category 1 or category 2 quantities of radioactive material. The extent of the training must be commensurate with the individual's potential involvement in the security of category 1 or category 2 quantities of radioactive material.

(3) Refresher training must be provided at a frequency not to exceed 12 months and when significant changes have been made to the security program. This training must include:

(a) Review of the training requirements in section (1) of this rule and any changes made to the security program since the last training;

(b) Reports on any relevant security issues, problems, and lessons learned;

(c) Relevant results of NRC inspections; and

(d) Relevant results of the licensee's program review and testing and maintenance.

(4) The licensee shall maintain records of the initial and refresher training for three years from the date of the training. The training records must include dates of the training, topics covered, and a list of the licensee's personnel in attendance, and related information.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0120
Security Program, Protection of Information

(1) Except as provided in section (9) of this rule, licensees authorized to possess category 1 or category 2 quantities of radioactive material shall secure from public disclosure and limit access to their security and implementation plans, and the list of individuals that have been approved for unescorted access.

(2) Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of the security and implementation plans.

(3) Before granting an individual access to the security plan or implementation plans, the licensee shall:

(a) Evaluate an individual's need to know of the security or implementation plans; and

(b) If the individual has not been authorized for unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in OAR 333-125-0060(2)(b) through (2)(e)(B).

(4) Licensees need not subject the following individuals to the background investigation elements for protection of information:

(a) The categories of individuals listed in OAR 333-125-0085(1)(a) through (m); or

(b) Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in OAR 333-125-0060(2)(b) through (2)(e)(B) has been provided by the security service provider.

(5) The licensee shall document the basis for concluding that an individual is trustworthy and reliable and allowed access to the security and implementation plans.

(6) Licensees shall maintain a list of persons currently approved for access to the security and implementation plans. When a licensee determines that a person no longer needs access to the security and implementation plans, or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than seven working days, and take prompt measures to ensure that the individual is unable to obtain the security plan or implementation procedures.

(7) When not in use, the licensee shall store its security and implementation plans in a manner to prevent unauthorized access. Information stored in non-removable electronic form must be password protected.

(8) The licensee shall retain as a record for three years after the document is no longer needed:

(a) A copy of the information protection procedures; and

(b) The list of individuals approved for access to the security plan or implementing procedures.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15; PH 25-2016, f. 8-26-16, cert. ef. 9-1-16

333-125-0125
Local Law Enforcement Agency Coordination (LLEA)

(1) A licensee subject to OAR 333-125-0100 through 333-125-0155 shall coordinate, to the extent practicable, with a LLEA for responding to threats to the licensee's facility, including any necessary armed response. The information provided to the LLEA must include:

(a) A description of the facilities and the category 1 and category 2 quantities of radioactive materials along with a description of the licensee's security measures that have been implemented to comply with OAR 333-125-0100 through 333-125-0155; and

(b) A notification that the licensee will request a timely armed response by the LLEA to any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of material.

(2) The licensee shall notify the Authority and the NRC regional office at U.S. Nuclear Regulatory Commission, Region IV, Division of Nuclear Materials Safety, 1600 E. Lamar Blvd., Arlington, TX 76011–4511; where electronic mail is appropriate, it shall be addressed to RidsRgn4MailCenter.Resource@nrc.gov.within three business days if:

(a) The LLEA has not responded to the request for coordination within 60 days of the coordination request; or

(b) The LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities.

(3) The licensee shall document its efforts to coordinate with the LLEA. The documentation must be kept for three years.

(4) The licensee shall coordinate with the LLEA at least every 12 months, or when changes to the facility design or operation adversely affect the potential vulnerability of the licensee's material to theft, sabotage, or diversion.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0130
Security Zones

(1) Licensees shall ensure that all aggregated category 1 and category 2 quantities of radioactive material are used or stored within licensee-established security zones. Security zones may be permanent or temporary.

(2) Temporary security zones must be established as necessary to meet the licensee's transitory or intermittent business activities, such as periods of maintenance, source delivery, and source replacement.

(3) Security zones must, at a minimum, allow unescorted access only to approved individuals through:

(a) Isolation of category 1 and category 2 quantities of radioactive materials by the use of continuous physical barriers that allow access to the security zone only through established access control points. A physical barrier is a natural or man-made structure or formation sufficient for the isolation of the category 1 or category 2 quantities of radioactive material within a security zone; or

(b) Direct control of the security zone by approved individuals at all times; or

(c) A combination of continuous physical barriers and direct control.

(4) For category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, the licensee shall, at a minimum, provide sufficient individuals approved for unescorted access to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow such activities.

(5) Individuals not approved for unescorted access to category 1 or category 2 quantities of radioactive material must be escorted by an approved individual when in a security zone.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0135
Monitoring, Detection, and Assessment

(1) Licensees shall establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into its security zones. Licensees shall provide the means to maintain continuous monitoring and detection capability in the event of a loss of the primary power source, or provide for an alarm and response in the event of a loss of this capability to continuously monitor and detect unauthorized entries.

(2) Monitoring and detection must be performed by:

(a) A monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility; or

(b) Electronic devices for intrusion detection alarms that will alert nearby facility personnel; or

(c) A monitored video surveillance system; or

(d) Direct visual surveillance by approved individuals located within the security zone; or

(e) Direct visual surveillance by a licensee designated individual located outside the security zone.

(f) A licensee subject to OAR 333-125-0100 through 333-125-0155 shall also have a means to detect unauthorized removal of the radioactive material from the security zone. This detection capability must provide:

(A) For category 1 quantities of radioactive material, immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. Such immediate detection capability must be provided by:

(i) Electronic sensors linked to an alarm; or

(ii) Continuous monitored video surveillance; or

(iii) Direct visual surveillance.

(g) For category 2 quantities of radioactive material, weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.

(3) Assessment. Licensees shall immediately assess each actual or attempted unauthorized entry into the security zone to determine whether the unauthorized access was an actual or attempted theft, sabotage, or diversion.

(4) Personnel communications and data transmission. For personnel and automated or electronic systems supporting the licensee's monitoring, detection, and assessment systems, licensees shall:

(a) Maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems; and

(b) Provide an alternative communication capability for personnel, and an alternative data transmission and processing capability, in the event of a loss of the primary means of communication or data transmission and processing. Alternative communications and data transmission systems may not be subject to the same failure modes as the primary systems.

(5) Response. Licensees shall immediately respond to any actual or attempted unauthorized access to the security zones, or actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material at licensee facilities or temporary job sites. For any unauthorized access involving an actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material, the licensee's response shall include requesting, without delay, an armed response from the LLEA.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0140
Maintenance and Testing

(1) Each licensee subject to OAR 333-125-0100 through 333-125-0155 shall implement a maintenance and testing program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in operable condition and are capable of performing their intended function when needed. The equipment relied on to meet the security requirements of this division must be inspected and tested for operability and performance at the manufacturer's suggested frequency. If there is no manufacturer's suggested frequency, the testing must be performed at least annually not to exceed 12 months.

(2) The licensee shall maintain records on the maintenance and testing activities for three years.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0145
Requirements for Mobile Devices

(1) Each licensee that possesses mobile devices containing category 1 or category 2 quantities of radioactive material must have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee.

(2) For devices in or on a vehicle or trailer, unless the health and safety requirements for a site prohibit the disabling of the vehicle, the licensee shall utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee. Licensees shall not rely on the removal of an ignition key to meet this requirement.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0150
Security Program Review

(1) Each licensee shall be responsible for the continuing effectiveness of the security program. Each licensee shall ensure that the security program is reviewed to confirm compliance with the requirements of this division and that comprehensive actions are taken to correct any noncompliance that is identified. The review must include the radioactive material security program content and implementation. Each licensee shall periodically (at least annually) review the security program content and implementation procedures.

(2) The results of the review, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the security program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

(3) The licensee shall maintain the review documentation for three years.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0155
Reporting of Events

(1) The licensee shall immediately notify the LLEA after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of a category 1 or category 2 quantity of radioactive material. As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response to the event, the licensee shall notify the Authority by telephone at (971) 673-0490. In no case shall the notification to the Authority be later than four hours after the discovery of any attempted or actual theft, sabotage, or diversion.

(2) The licensee shall assess any suspicious activity related to possible theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material and notify the LLEA as appropriate. As soon as possible but not later than four hours after notifying the LLEA, the licensee shall notify the Authority by telephone at (971) 673-0490.

(3) The initial telephonic notification required by section (1) of this rule must be followed within a period of 30 days by a written report submitted to the Authority. The report must include sufficient information for Authority analysis and evaluation, including identification of any necessary corrective actions to prevent future instances.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

Physical Protection in Transit

333-125-0165
Additional Requirements for Transfer of Category 1 and Category 2 Quantities of Radioactive Material

(1) A licensee transferring a category 1 or category 2 quantity of radioactive material to a licensee of the Commission or an Agreement State shall meet the license verification provisions listed in subsections (a) through (c) below instead of those listed in OAR 333-102-0330(4).

(a) Any licensee transferring category 1 quantities of radioactive material to a licensee of the Commission or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred and that the licensee is authorized to receive radioactive material at the location requested for delivery. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

(b) Any licensee transferring category 2 quantities of radioactive material to a licensee of the Commission or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

(c) In an emergency where the licensee cannot reach the license issuing authority and the license verification system is non-

functional, the licensee may accept a written certification by the transferee that it is authorized by license to receive the type, form, and quantity of radioactive material to be transferred. The certification must include the license number, current revision number, issuing agency, expiration date, and for a category 1 shipment the authorized address. The licensee shall keep a copy of the certification. The certification must be confirmed by use of the NRC's license verification system or by contacting the license issuing authority by the end of the next business day.

(2) The transferor shall keep a copy of the verification documentation as a record for three years.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0170
Applicability of Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material During Transit

The shipping licensee shall be responsible for meeting the requirements of OAR 333-125-0165 through 333-125-0190 unless the receiving licensee has agreed in writing to arrange for the in-transit physical protection required under OAR 333-125-0165 through 333-125-0190.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0175
Preplanning and Coordination of Shipment of Category 1 or Category 2 Quantities of Radioactive Material

(1) Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 1 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall:

(a) Preplan and coordinate shipment arrival and departure times with the receiving licensee;

(b) Preplan and coordinate shipment information with the Governor or the Governor's designee of any state through which the shipment will pass to:

(A) Discuss the state's intention to provide law enforcement escorts; and

(B) Identify safe havens; and

(C) Document the preplanning and coordination activities.

(2) Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 2 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. The licensee shall document the coordination activities.

(3) Each licensee who receives a shipment of a category 2 quantity of radioactive material shall confirm receipt of the shipment with the originator. If the shipment has not arrived by the no-later-than arrival time, the receiving licensee shall notify the originator.

(4) Each licensee, who transports or plans to transport a shipment of a category 2 quantity of radioactive material, and determines that the shipment will arrive after the no-later-than arrival time provided pursuant to section (2) of this rule, shall promptly notify the receiving licensee of the new no-later-than arrival time.

(5) The licensee shall retain a copy of the documentation for preplanning and coordination and any revision thereof, as a record for three years.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0180
Advance Notification of Shipment of Category 1 Quantities of Radioactive Material

(1) As specified in sections (1) and (2) of this rule, each licensee shall provide advance notification to the Authority and the Governor of a state, or the Governor's designee, of the shipment of licensed material in a category 1 quantity, through or across the boundary of the state, before the transport, or delivery to a carrier for transport of the licensed material outside the confines of the licensee's facility or other place of use or storage.

(a) Procedures for submitting advance notification. The notification must be made to the Authority and to the office of each appropriate Governor or Governor's designee. The contact information, including telephone and mailing addresses, of Governors and Governors' designees, is available on the NRC's website at https://scp.nrc.gov/special/designee.pdf. . A list of the contact information is also available upon request from the Director, Division of Material Safety, State, Tribal, and Rulemaking Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001.(b) A notification delivered by mail must be postmarked at least seven days before transport of the shipment commences at the shipping facility.

(c) A notification delivered by any means other than mail must reach NRC at least four days before the transport of the shipment commences and must reach the office of the Governor or the Governor's designee at least four days before transport of a shipment within or through the state.

(2) Information to be furnished in advance notification of shipment. Each advance notification of shipment of category 1 quantities of radioactive material must contain the following information, if available at the time of notification:

(a) The name, address, and telephone number of the shipper, carrier, and receiver of the category 1 radioactive material;

(b) The license numbers of the shipper and receiver;

(c) A description of the radioactive material contained in the shipment, including the radionuclides and quantity;

(d) The point of origin of the shipment and the estimated time and date that shipment will commence;

(e) The estimated time and date that the shipment is expected to enter each state along the route;

(f) The estimated time and date of arrival of the shipment at the destination; and

(g) A point of contact, with a telephone number, for current shipment information.

(3)(a) Revision notice. The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the Governor of the state or the Governor's designee and to the Authority.

(b) A licensee shall promptly notify the Governor of the state or the Governor's designee of any changes to the information provided in accordance with sections (2) and (3) of this rule. The licensee shall also immediately notify the NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 of any such changes.

(4) Cancellation notice. Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the Governor of each state or to the Governor's designee previously notified and to the Authority. The licensee shall send the cancellation notice before the shipment has commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being cancelled.

(5) Records. The licensee shall retain a copy of the advance notification, any revision and cancellation notices as a record for three years after the notification has been made.

(6) Protection of information. State officials, state employees, and other individuals, whether or not licensees of the U.S Nuclear Regulatory Commission or an Agreement State, who receive schedule information of the kind specified in section (2) of this rule shall protect that information against unauthorized disclosure.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15; PH 25-2016, f. 8-26-16, cert. ef. 9-1-16

333-125-0185
Requirements for Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material During Shipment

(1)(a) Shipments by road. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(A) Ensure that movement control centers are established that maintain position information from a remote location. These control centers must monitor shipments 24 hours a day, seven days a week, and have the ability to communicate immediately, in an emergency, with the appropriate law enforcement agencies.

(B) Ensure that redundant communications are established that allow the transport to contact the escort vehicle (when used) and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication.

(C) Ensure that shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. A movement control center must provide positive confirmation of the location, status, and control over the shipment. The movement control center must be prepared to promptly implement preplanned procedures in response to deviations from the authorized route or a notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.

(D) Provide an individual to accompany the driver for those highway shipments with a driving time period greater than the maximum number of allowable hours of service in a 24 hour duty day as established by the Department of Transportation Federal Motor Carrier Safety Administration. The accompanying individual may be another driver.

(E) Develop written normal and contingency procedures to address:

(i) Notifications to the communication center and law enforcement agencies;

(ii) Communication protocols. Communication protocols must include a strategy for the use of authentication codes and duress codes and provisions for refueling or other stops, detours, and locations where communication is expected to be temporarily lost;

(iii) Loss of communications; and

(iv) Responses to an actual or attempted theft or diversion of a shipment.

(b) Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall ensure that drivers, accompanying personnel, and movement control center personnel have access to the normal and contingency procedures.

(c) Each licensee that transports category 2 quantities of radioactive material shall maintain constant control and surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance.

(d) Each licensee who delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

(A) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it may arrive at the next point of control.

(B) Use carriers that maintain constant control and surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(C) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

(2)(a) Shipments by rail. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(A) Ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-party, or railroad communications center. The communications center shall provide positive confirmation of the location of the shipment and its status. The communications center shall implement preplanned procedures in response to deviations from the authorized route or to a notification of actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.

(B) Ensure that periodic reports to the communications center are made at preset intervals.

(b) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

(A) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it may arrive at the next point of control.

(B) Use carriers that maintain constant control or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(C) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

(3) Investigations:

(a) Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall immediately conduct an investigation upon the discovery that a category 1 shipment is lost or missing.

(b) Each licensee who makes arrangements for the shipment of category 2 quantities of radioactive material shall immediately conduct an investigation, in coordination with the receiving licensee, of any shipment that has not arrived by the designated no-later-than arrival time.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0190
Reporting of Events

(1) The shipping licensee shall notify the appropriate LLEA, and the NRC's Operations Center by telephone at (301) 816-5100 within one hour of its determination that a shipment of category 1 quantities of radioactive material is lost or missing. The appropriate LLEA is the law enforcement agency in the area of the shipment's last confirmed location. During the investigation required by OAR 333-125-0185(3), the shipping licensee shall provide agreed upon updates to the NRC's Operations Center on the status of the investigation.

(2) The shipping licensee shall notify the NRC's Operations Center by telephone at (301) 816-5100, within four hours of its determination that a shipment of category 2 quantities of radioactive material is lost or missing. If, after 24 hours of its determination that the shipment is lost or missing, the radioactive material has not been located and secured, the licensee shall immediately notify the NRC's Operations Center.

(3) The shipping licensee shall notify the designated LLEA along the shipment route as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment or suspicious activities related to the theft or diversion of a shipment of a category 1 quantity of radioactive material. As soon as possible after notifying the LLEA, the licensee shall notify the NRC's Operations Center by telephone at (301) 816-5100 upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment of category 1 radioactive material.

(4) The shipping licensee shall notify the NRC's Operations Center by telephone at (301) 816-5100 as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment of a category 2 quantity of radioactive material.

(5) The shipping licensee shall notify the NRC's Operations Center by telephone at (301) 816-5100 and the LLEA as soon as possible upon recovery of any lost or missing category 1 quantities of radioactive material.

(6) The shipping licensee shall notify the NRC's Operations Center by telephone at (301) 816-5100 as soon as possible upon recovery of any lost or missing category 2 quantities of radioactive material.

(7) The initial telephonic notification required by sections (1) through (4) of this rule must be followed within a period of 30 days by a written report submitted to the Authority. A written report is not required for notifications on suspicious activities required by sections (3) and (4) of this rule. The report must set forth the following information:

(a) A description of the licensed material involved, including kind, quantity, and chemical and physical form;

(b) A description of the circumstances under which the loss or theft occurred;

(c) A statement of disposition, or probable disposition, of the licensed material involved;

(d) Actions that have been taken, or will be taken, to recover the material; and

(e) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

(8) Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0195
Form of Records

Each record required by this rule must be legible throughout the retention period. The record may be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0200
Record Retention

Licensees shall maintain the records that are required by the regulations in this division for the period specified by the appropriate regulation. If a retention period is not otherwise specified, these records must be retained until the Authority terminates the facility's license. All records related to this division may be destroyed upon the Authority terminating the facility's license.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.635
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

DIVISION 150

FOOD SANITATION RULES

Definitions and Administration

333-150-0000
Food Sanitation Rule

(1) Authority and Purpose. This rule establishes definitions, sets standards for management and personnel, food protection, and equipment and facilities, water supply, sewage disposal, provides for food establishment plan review, and employee restriction to safeguard public health and provide consumers food that is safe, unadulterated, and honestly presented.

(2) Incorporation by Reference. The requirements in the U.S. Public Health Service, Food and Drug Administration (FDA), Food Code 2009, Chapters 1 through 8 are adopted and incorporated by reference.

(3) Deletions. The following sections, paragraphs or subparagraphs of the 2009 FDA Food Code are deleted in their entirety: 2-102.11(C)(8)(b), 2-102.20, 2-103.11(K), 3-202.18(A)(1)(a)–(e), 4-301.12(C)(5), (D) and (E), 4-501.115, 4-603.16(B) and (C), 4-603.17(B)(1), 8-302.11, 8-302.14(E), 8-401.10(B), 8-401.20, 8-402.20(A)(3), 8-402.40, 8-406.11, 8-501.40 and Annex 1 through 8.

(4) Definitions. Adopt paragraph 1-201.10(B) with the following amendments and additions to read:

(a) "Accredited program":

(A) Means a food protection manager certification program that has been evaluated and listed by an accrediting agency as conforming to national standards for organizations that certify individuals or approved by the Oregon Health Authority (Authority) or Oregon Department of Agriculture.

(B) Refers to the certification process and is a designation based upon an independent evaluation of factors such as the sponsor's mission; organizational structure; staff resources; revenue sources; policies; public information regarding program scope, eligibility requirements, re-certification, discipline and grievance procedures; and test development and administration.

(C) Does not refer to training functions or educational programs.

(b) "Assembly" means the act of putting together foods that do not require further preparation. This includes but is not limited to placing a hot dog on a bun, or placing beans, lettuce, and cheese on a tortilla.

(c) "Authority" means the Oregon Health Authority.

(d) "Base of Operation" means the licensed restaurant, commissary or warehouse that services a mobile unit or vending operation.

(e) "Benevolent Meal Site" means:

(A) A periodic food service operation run by a benevolent organization that provides food to the needy or indigent without charge; and

(B) The meal service does not operate from a permanent kitchen facility.

(f) "Catering" means the preparation of food in an approved food establishment and the transportation of the food for service and consumption at some other site.

(g) "Close" means to summarily stop the operation of a food establishment pursuant to ORS 624.073 and 624.370.

(h) "Code" shall have the same meaning as administrative rule.

(i) "Combination Food Service Establishment" means any food establishment located within a single structure or at a single site, and which is engaged in activities subject to licensing or inspecting requirements of both the Authority and the Oregon Department of Agriculture, and the regulated activities are common to the same operator.

(j) "Commercial warewashing machine" means a machine designed and manufactured specifically for use in a food service establishment such as a restaurant and not for domestic or light-commercial purposes.

(k) "Commissary" means a commissary catering establishment, restaurant, or any other place in which, food, beverage, ingredients, containers, or supplies are kept, handled, packaged, prepared or stored, and from which vending machines or mobile units are serviced. A licensed commissary may only be used for catering if licensed mobile food units or vending machines are serviced by the establishment as specified in ORS 624.310.

(L) "Complete Inspection" means any inspection conducted at the election of the licensing agency evaluating all items on the inspection form.

(m) "Cut leafy greens" means fresh leafy greens whose leaves have been cut, shredded, sliced, chopped, or torn. The term "leafy greens" includes iceberg lettuce, romaine lettuce, leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage, kale, arugula and chard. The term "leafy greens" does not include herbs such as cilantro or parsley. The term "cut" does not mean removing and discarding exterior leaves.

(n) "Director" means the Director of the Oregon Health Authority or Oregon Department of Agriculture or authorized representative.

(o) "Disclosure" means a written statement that clearly identifies the animal-derived foods which are, or can be ordered, raw, undercooked, or without otherwise being processed to eliminate pathogens, or items that contain an ingredient that is raw, undercooked, or without otherwise being processed to eliminate pathogens.

(p) "Food establishment" means:

(A) An operation that prepares, assembles, packages, serves, stores, vends, or otherwise provides food for human consumption; or

(B) Any room, building, structure or place, used or intended for use, or operated for storing, preparing, compounding, manufacturing, processing, freezing, packaging, distributing, handling, salvaging or displaying food; or

(C) The ground upon which such place or business is operated or used and so much ground adjacent thereto as is also used in carrying on the business of the establishment. The Authority or Department of Agriculture may prescribe additional areas or places which, although they may not be contiguous or adjacent to the above area or establishment, may be included therein; or

(D) Vehicles, machinery, equipment, utensils, tools, fixtures, implements, and all other articles or items, used in operating or carrying on the business of a food establishment.

(q) "Food establishment" regulated by the Oregon Health Authority includes but is not limited to:

(A) Bars, bed and breakfast facilities, cafeterias if open to the public, catered feeding locations, caterers, coffee shops, commissaries, conveyance used to transport people, hospitals if open to the public, hotels, microbreweries, motels, private clubs if open to the public, restaurants, satellite sites, senior citizen centers, snack bars, taverns, vending locations, warehouses (associated with a mobile food unit), or similar food facilities.

(B) An operation that is conducted in a mobile food unit, temporary food establishments, or permanent facility or location; where consumption is on or off premises; and regardless of whether there is a charge for the food.

(C) The premises of a fraternal, social, or religious organization where food is prepared for the public.

(D) School food service that is provided by a private person, business, or organization; and that serve persons other than enrolled students, invited guests or staff.

(E) That relinquishes possession of food to a consumer directly through a restaurant takeout order.

(r) "Food establishment" regulated by the Oregon Department of Agriculture includes but is not limited to:

(A) Markets, food banks, warehouses (distribution), wineries, microbreweries, grocery stores or other food facilities;

(B) An establishment that predominantly sells foods that are not for immediate consumption, such as take and bake pizza, whole pies and cakes, loaves of bread, and pre-made dinners that must be cooked or reheated;

(C) An establishment that offers only prepackaged or bulk foods that are not potentially hazardous;

(D) A produce stand that offers fresh fruits and vegetables;

(E) A food processing plant;

(F) Mobile food units that are operated by an Oregon Department of Agriculture licensed establishment and located on the property of the Oregon Department of Agriculture licensed establishment;

(G) Outdoor cooking and beverage dispensing area operated by a market that is located on the property of the market and is under the jurisdiction of the Oregon Department of Agriculture; or

(H) Food prepared in a private home that is licensed as a domestic processor.

(s) "Food establishment" does not include:

(A) A private home where food is prepared or served for family and guests, and where the public is not invited.

(B) A private home that receives catered or home-delivered food.

(C) An establishment or organization that prepares or sells the following food items for immediate consumption only:

(i) Candy, candied apples and non-potentially hazardous confections;

(ii) Commercially prepackaged ice cream and frozen desserts sold in individual servings;

(iii) Commercially pickled products, commercially processed jerky, nuts, nutmeats, popcorn, and prepackaged foods such as potato chips, pretzels, and crackers;

(iv) Unopened commercially bottled and canned non-potentially hazardous beverages to include alcoholic beverages;

(v) Coffee and tea, with non-potentially hazardous ingredients;

(vi) Non-potentially hazardous hot or cold beverages prepared from individually packaged powdered mixes and commercially bottled water, not to include fresh squeezed juice;

(vii) Non-potentially hazardous foods or beverages provided by a non-food service business or organization as a courtesy for no charge to customers; and

(viii) Other food items as determined by the Authority or the Oregon Department of Agriculture.

(D) An establishment or organization that prepares or sells the following food items for immediate consumption at an event that are obtained from a licensed food service or processing establishment or prepared onsite:

(i) Non-potentially hazardous baked goods;

(ii) A benevolent organization that serves privately donated breads, rolls, pies, cakes, doughnuts or other pastries not having potentially hazardous (TCS) fillings;

(iii) An establishment or organization exempt under this subparagraph must post a notice in public view that states: "NOTICE: Food served at this location may not have been inspected by the regulatory authority."

(E) Private vehicles used for home deliveries.

(F) Personal chef who prepares food for an individual or private party.

(G) Continental breakfast served by a traveler's accommodation licensed under ORS Chapter 446 and that is limited to the following: individual or bulk dispensed containers of commercially prepared juices; commercially prepared non-potentially hazardous pastries; whole uncut fresh fruit with peel, and coffee and tea with non-potentially hazardous ingredients.

(H) Food service that is provided by a state, county, or other governmental entity.

(I) School food service that is provided by a state, county, or other governmental entity; or is providing food to students, teachers, other school staff, and invited guests.

(J) Any person holding a "one-day, special retail beer or special retail wine license" for a private residence; or anyone who possesses a "temporary" license from the Oregon Liquor Control Commission who serves alcoholic beverages to the public, but

serves only foods exempted under 1-201.10(B) of the 2009 FDA Food Code and uses single-service articles.

(K) A bed and breakfast facility with two or less rooms for rent on a daily basis.

(L) Home delivery of grocery orders.

(M) Institutions that do not serve the public.

(N) Produce stands located on a farmer's own property wherein only produce grown by the farmer is sold and no food processing is done as specified in OAR 603-025-0030(2).

(O) Farm Direct Marketers as defined in OAR 603-025-0225(6).

(P) A domestic processor licensed by the Oregon Department of Agriculture that sells only prepackaged and labeled food at a farmer's market.

(t) "Food processing plant" means a commercial operation or a domestic kitchen licensed by the Oregon Department of Agriculture that manufactures, packages, labels, or stores food for human consumption.

(u) "Integral" means that all equipment associated with a mobile unit must be rigidly and physically attached to the unit without restricting the mobility of the unit while in transit. This does not preclude the use of a barbecue unit in conjunction with a Class IV mobile food unit.

(v) "License" means the same as permit for the purposes of this rule.

(w) "License holder" means the same as permit holder for the purposes of this rule.

(x) "Maximum Contaminant Level (MCL)" means the maximum allowable level of a contaminant in water for consumption delivered to the users of a system, except in the case of turbidity where the maximum allowable level is measured at the point of entry to the distribution system.

(y) "Meat" means the flesh of animals used as food including the dressed flesh of cattle, swine, sheep, or goats and other edible animals, except fish, poultry, and wild game animals as specified under subparagraphs 3-201.17(A)(3), (4) and (5) of the 2009 FDA Food Code.

(z) "Mobile Food Unit" means any vehicle that is self-propelled or that can be pulled or pushed down a sidewalk, street, highway or waterway, on which food is prepared, processed or converted or which is used in selling and dispensing food to the ultimate consumer.

(aa) "Outdoor Beverage Dispensing Operation" means an outdoor area on the premises of a food establishment where beverages are dispensed to consumers.

(bb) "Outdoor Cooking Operation" means an outdoor area on the premises of a food establishment where food is cooked for service to consumers.

(cc) "Personal Chef" means an individual that provides cooking services to private individuals or private groups. A personal chef may purchase food from an approved source, but may not store or prepare food in advance. A personal chef may use their own equipment, utensils and spices.

(dd) "Preparation" means the process whereby food is transformed into a consumable form. This includes, but is not limited to, slicing or dicing vegetables, grating cheese, portioning foods, slicing sandwiches, blending foods, or cooking or reheating foods.

(ee) "Priority item" means a provision in this code whose application contributes directly to the elimination, prevention or reduction to an acceptable level, hazards associated with foodborne illness or injury and there is no other provision that more directly controls the hazard.

(A) "Priority item" includes items with a quantifiable measure to show control of hazards such as cooking, reheating, cooling, and handwashing.

(B) "Priority item" is an item that is denoted in this code with a superscript P-^{P}; and

(C) "Priority item" is an item that carries a weight of five points on the Food Service Inspection Report or Inspectional Guide and is considered a critical violation as referenced in ORS Chapter 624.

(ff) "Priority foundation item" means a provision in this code whose application supports, facilitates or enables one or more priority items.

(A) "Priority foundation item" includes an item that requires the purposeful incorporation of specific actions, equipment or procedures by industry management to attain control of risk factors that contribute to foodborne illness or injury such as personnel training, infrastructure or necessary equipment, HACCP plans, documentation or record keeping, and labeling.

(B) "Priority foundation item" is an item that is denoted in this code with a superscript Pf-^{Pf}; and

(C) "Priority foundation item" is an item that carries a weight of three points on the Food Service Inspection Report or Inspectional Guide and is considered a critical violation as referenced in ORS Chapter 624.

(gg) "Quarterly Sampling" means a sample is taken and submitted according to the following schedule: 1st Quarter is January 1 through March 31, 2nd Quarter is April 1 through June 30, 3rd Quarter is July 1 through September 30 and the 4th Quarter is October 1 through December 31.

(hh) "Raw-to-Finish" means cooking foods that are potentially hazardous when in a raw state to a finished, edible state. This practice includes, but is not limited to, cooking raw hamburgers or barbecuing raw meats.

(ii) "Recheck Inspection" means:

(A) An inspection to determine whether specified corrections have been made or alternative procedures maintained for violations identified in previous inspections; or

(B) An inspection to determine whether specific corrections have been maintained for critical violations creating a significantly increased risk for foodborne illness. Recheck inspections may also be referred to as reinspections or follow-up inspections.

(jj) "Repeat violation" means a violation of a rule which is the same specific problem or process as indicated on the Food Service Inspection Report occurring in two consecutive semi-annual inspections.

(kk) "Sample" means a three ounce or less portion of a food or beverage.

(ll) "Semi-annual inspection" means an unannounced complete inspection conducted twice during the calendar year; one in each half of the year, but not less than 90 days or more than 270 days apart.

(mm) "Temporary food establishment" means the same as ORS 624.010(4) (10) and (11).

(nn) "Transport Vehicle" means a vehicle used to transport foods or utensils from the base of operation to a mobile food unit.

(oo) "Utensil" means a food-contact implement or container used in the storage, preparation, transportation, dispensing, sale, or service of food, such as kitchenware or tableware that is multiuse, single-service, or single-use; gloves used in contact with food; temperature sensing probes of food temperature measuring devices; trays used with highchairs; and probe-type price or identification tags used in contact with food.

(pp) "Vehicle" means any device in, upon or by which any person or property is or may be transported or drawn upon a public highway, and includes vehicles that are propelled or powered by any means. This definition includes watercraft.

(qq) "Violation" means any condition which fails to meet a requirement of ORS Chapter 624 or this rule.

(rr) "Violations creating an imminent danger to public health" means those priority item violations in which at least one of the following conditions exits:

(A) Food and drink is spoiled, unwholesome, or contaminated with pathogenic or fecal organisms, toxic chemicals, insect or rodent parts or excreta, or other harmful substances or articles;

(B) Potentially hazardous foods have been kept at temperatures above 41 degrees Fahrenheit and below 135 degrees Fahrenheit for four hours or more;

(C) A food employee has a reportable disease or medical condition under subpart 2-201 of the 2009 FDA Food Code.

(ss) "Violations creating a potential danger to public health" means all priority and priority foundation item violations other than those that create an imminent danger to public health.

(tt) "Violations creating a significantly increased risk for foodborne illness" include:

(A) Potentially hazardous foods at improper temperatures;

(B) Cross contamination of raw to ready-to-eat foods; and

(C) Poor personal hygiene and handwashing.

(uu) "Warehouse" means any place where food, utensils, single-service articles, cleaning or servicing supplies for vending machines, mobile units, or commissaries are stored.

(vv) "Wild Fresh Mushroom" means a mushroom that has not been processed, dried or cultivated.

(5) Amendments to Federal Regulation. The following amendments or additions are made to the 2009 FDA Food Code, as adopted and incorporated by reference. All references to part, subpart, sections, paragraphs and subparagraphs relate to the 2009 FDA Food Code:

(a) Amend section 2-102.11(B) to read: Being a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program or a training program approved by the Oregon Health Authority or Oregon Department of Agriculture;Pf

(b) Adopt paragraphs 2-102.11(A) and (C) without changes.

(c) Amend section 2-201.11 to read: Responsibility of Person in Charge.

(A) The permit holder shall require food employees to report to the person in charge information about their health and activities as they relate to diseases that are transmissible through food. A food employee or conditional employee shall report the date of onset of symptoms, diagnosis of an illness, or of a diagnosis without symptoms that are listed under 2-201.12.P

(B) The person in charge shall notify the regulatory authority that a food employee is:

(i) Jaundice;Pf or

(ii) Diagnosed with an illness listed in 2-201.12.Pf

(C) A food employee shall:

(i) Report to the person in charge if they have been diagnosed with an illness or are experiencing symptoms specified under 2-201.12;P

(ii) Report to the person in charge if they have been living in the same household or working in a setting where there is a confirmed disease outbreak with an illness specified under 2-201.12;P and

(iii) Comply with exclusions and restrictions specified under section 2-201.12.P

(d) Amend section 2-201.12 to read: Exclusions and Restrictions.

(A) The person in charge shall exclude or restrict a food employee from a food establishment in accordance with the following:

(i) Except when the symptom is from a noninfectious condition, exclude a food employee that has any of the following signs or symptoms caused by illness, infection, or other source that is associated with an acute illness:

(I) Vomiting;P

(II) Diarrhea;P

(III) Sore throat with fever;P or

(IV) Jaundice.P

(B) Exclude or restrict a food employee that has a lesion containing pus such as a boil or infected wound that is open or draining and is:

(i) On the hands or wrists, unless an impermeable cover such as a finger cot protects the lesion and a single use glove is worn over the impermeable cover;P

(ii) On exposed portions of the arms, unless the lesion is protected by an impermeable cover;P or

(iii) On other parts of the body, unless the lesion is covered by a dry, durable, tight-fitting bandage.P

(C) Exclude a food employee from a food establishment if the food employee is diagnosed by a health practitioner or presumptive with:

(i) Norovirus;P

(ii) Hepatitis A virus;P

(iii) Shigella spp.;P

(iv) Enterohemorrhagic or Shiga Toxin-Producing Escherichia coli;P or

(v) Salmonella Typhi.P

(e) Amend section 2-201.13 to read: Removal of Exclusions and Restrictions. The person in charge shall adhere to the following conditions when removing, adjusting, or retaining the exclusion or restriction of a food employee:

(A) Restrictions or exclusions on persons diagnosed or presumptive with Hepatitis A, shigellosis or Shiga-toxigenic Escherichia coli (STEC) or Salmonella typhi infection shall not be lifted until a licensed laboratory has determined that the employee is free of pathogens in accordance with OAR 333-019-0014(4) and 333-019-0046. Such restrictions may be waived or modified at the discretion of the local public health authority.P

(B) Except as specified in (A) of section 2-201.13, the person in charge may remove a restriction or exclusion specified under 2-201.12 if the restricted person:

(i) Is free of the symptoms specified under 2-201.12(A)(1)-(3) for 24 hours;P or

(ii) Provides to the person in charge written medical documentation from a health practitioner that states the symptom is from a noninfectious condition;P or

(iii) The person in charge obtains approval from the local public health authority.P

(C) Reinstate a food employee who was diagnosed or presumptive with an infection from Norovirus if the person in charge obtains approval from the local public health authority and one of the following conditions is met:

(i) The food employee provides to the person in charge written medical documentation from a health practitioner stating the food employee is free of a Norovirus infection;P or

(ii) The food employee's symptoms of vomiting or diarrhea have resolved and more than 48 hours have passed since the food employee became asymptomatic;P or

(iii) The food employee did not develop symptoms and more than 48 hours have passed since the food employee was diagnosed.P

(f) Amend section 2-301.13 to read: Double Handwashing.

(A) After defecating, contacting body fluids and discharges, or handling waste containing fecal matter, body fluids, or body discharges, and before beginning or returning to work, food employees shall wash their hands twice using the cleaning procedure specified in section 2-301.12.P

(B) Except when one handwashing lavatory is allowed under paragraph 5-203.11(A), after using the toilet facility food employees shall wash their hands twice, first at a handwashing lavatory in the toilet facility and again at a handwashing lavatory in the food preparation area.P

(g) Amend paragraph 2-301.14(H) to read: Before donning gloves for working with food unless a glove change is not the result of glove contamination.P

(h) Amend section 2-301.16 to read:

(A) A hand antiseptic and a chemical hand antiseptic solution used as a hand dip shall be used according to labeled directions, be approved for use with food, and be applied to hands that are cleaned as specified under section 2-301.12.Pf

(B) A chemical hand antiseptic solution used as a hand dip shall be maintained clean and at a strength equivalent to at least 100 mg/L chlorine.Pf

(i) Amend paragraph 2-401.11(A) to read: Eating, Drinking, or Using Tobacco. Except as specified in paragraph (B) of section 2-401.11, an employee may not eat, drink, or use any form of tobacco except in designated areas where the contamination of exposed food; clean equipment, utensils, and linens; unwrapped single-service and single-use articles; or other items needing protection can not result.Pf

(j) Amend section 2-401.12 to read: Discharges from the Eyes, Nose, and Mouth. Food employees experiencing persistent sneezing, coughing, or a runny nose that causes discharges from the eyes, nose, or mouth may not work with exposed food; clean equipment, utensils, and linens; or unwrapped single-service or single-use articles.Pf

(k) Amend paragraph 2-402.11(A) to read: Employees shall use effective hair restraints to prevent the contamination of food or food-contact surfaces.

(L) Amend paragraph 2-403.11(A) to read: Except as specified in paragraph (B) of section 2-403.11, food employees may not care for or handle animals that may be present such as patrol dogs, service animals, or pets that are allowed as specified in 6-501.115(B)(2)-(5) and (E).Pf

(m) Amend paragraph 3-201.11(B) to read: Except as specified in paragraphs (J), (K) and (L) of section 3-201.11, food prepared in a private home may not be used or offered for human consumption in a food establishment.P

(n) Add paragraph 3-201.11(H) to read: Game meat which has been donated to a charitable organization and has been inspected and processed as provided in ORS 619.095 may be served for human consumption by that charitable organization.P

(o) Add paragraph 3-201.11(I) to read: Except as required in 3-201.11(A) through (H) of the 2009 FDA Food Code and in accordance with ORS 624.116, any person, business or volunteer group may donate food to a benevolent organization that meets the requirements in ORS 624.101. The Internal Revenue Service (IRS) may issue a "letter of determination" that should be used as the basis for assessing compliance with benevolent status of ORS 624.101. The person, business or volunteer group making the donation shall inspect the food to ensure its fitness for human consumption and discard all food that is unwholesome. The following donated food items are approved for use by benevolent organizations:

(A) Commercially prepared foods, canned goods, and milk products, marine and freshwater fishery products or meat animals; i.e., cattle, sheep, goats, equine, swine, poultry or rabbits obtained from facilities licensed by the Oregon Department of Agriculture or the Oregon Health Authority according to ORS Chapters 603, 616, 621, 622, 624, 625 and 635;P

(B) Home baked bread, rolls, pies, cakes, doughnuts or pastries not having perishable fillings, icings, toppings or glazes;P

(C) Fresh fruit and produce from private gardens or commercial growers;P

(D) Salvageable food which has lost the label or which has been subjected to possible damage due to accident, fire, flood, adverse weather or similar cause. Reconditioning of salvageable food shall be conducted according to the Model Food Salvage Code recommended by the Association of Food and Drug Officials and U.S. Department of Health and Human Services;P

(E) Other food as may be approved by the Oregon Health Authority upon prior notification by the donator or benevolent organization;

(F) Unless alternative language has been approved by the regulatory authority, a notice shall be posted in public view that says: "NOTICE: Food served at this location may not have been inspected by the regulatory authority."Pf

(p) Add paragraph 3-201.11(J) to read: Privately donated breads, rolls, pies, cakes, doughnuts or other pastries not having perishable fillings, icings, toppings or glazes may be used in temporary food establishments operated by benevolent organizations for fund-raising events, provided they meet the requirements under 3-201.11(I)(iv).P

(q) Add paragraph 3-201.11(K) to read: Food prepared in a private home that is licensed as a home processor by the Oregon Department of Agriculture.P

(r) Add paragraph 3-201.11(L) to read: A Benevolent Meal Site may serve food prepared by volunteers in an unlicensed kitchen under the following conditions:

(A) Volunteers must obtain a food handler certificate as required in OAR chapter 333, division 175. If the food is prepared by a group of people at the same location, only the person supervising the food preparation shall be required to obtain a certificate. The person supervising the food preparation shall be at the preparation site at all times;

(B) Volunteers that provide only non-potentially hazardous baked goods as allowed under paragraph (J) of section 3-201.11 or whole, uncut fresh fruits and vegetables are exempt from the food handler certification requirement.

(C) The organization sponsoring the Benevolent Meal Site must obtain a signed statement from the volunteers that they have reviewed and will follow the requirements of section 3-201.11. The signed statement must include the volunteer's name, contact information and the kinds of food donated;

(D) The signed statement shall be maintained at the Benevolent Meal Site and be available for review.

(E) Food Preparation and Service:

(i) The following foods may not be provided: home-canned or home processed foods, wild mushrooms, wild game, shellfish, sport-caught fish, raw milk, raw animal foods, eggs from non-commercial sources, unpasteurized juices, and water and ice from unapproved water systems;P

(ii) Except whole, uncut fresh fruit and vegetables and non-potentially hazardous baked goods as described under paragraph (J) of section 3-201.11, leftover food prepared by volunteers must be returned to the volunteer or discarded.P

(iii) Food obtained from licensed establishments may be donated to other facilities if the food is held under proper temperature control and protected from contamination during serving;

(iv) At least one portable handwashing facility as described in paragraph 5-203.11(C) shall be provided at the service location;Pf

(v) Self-service of food is limited to prepackaged items and condiments dispensed in a sanitary manner;

(vi) A statement must be posted at the meal site in public view that states: "Notice: Food served at this location may not have been inspected by the regulatory authority."Pf

(vii) Food must be stored, prepared, handled, transported and served in a manner that is consistent with the food safety requirements in these rules.

(s) Amend section 3-201.16 to read:

(A) Except as specified in (B), identification of mushroom species picked in the wild shall have a written buyer specification which is to remain on file in the food establishment for a minimum of 90 days from the date of sale or service.Pf This written specification shall include:

(i) Identification by the scientific name and the common name of the mushroom species;Pf

(ii) Identification in the fresh state;Pf

(iii) The name and contact information of the person who identified the mushroom and the mushroom seller;Pf and

(iv) A statement as to the qualifications and training of the identifier, specifically related to mushroom identification.Pf

(B) Paragraph (A) of 3-201.16 does not apply to cultivated wild mushroom species that are grown, harvested, and processed in an operation that is regulated by the food regulatory agency that has jurisdiction over the operation.

(C) The food establishment that sells, uses or serves mushrooms picked in the wild shall ensure the mushrooms are conspicuously identified by a label, placard, or menu notation that states:

(i) The common and usual name of the mushroom;Pf and

(ii) The statement "Wild mushrooms: not an inspected product".Pf

(t) Add subparagraph 3-201.17(A)(5) to read: Except as specified in (A)(1) through (4) of section 3-201.17:

(A) Game meat donated to a charitable organization and inspected by employees of the Oregon Department of Agriculture, Oregon Department of Fish and Wildlife, or State Police as provided for in ORS 619.095 may be served for human consumption by that charitable organization.P

(B) As used in subparagraph (A) of section 3-201.17:

(i) Charitable organization means the Department of Human Services, Oregon Health Authority, Oregon Youth Authority,

Department of Corrections institutions, low-income nutritional centers, public school nutritional centers, senior nutritional centers, state hospitals and other charitable organizations or public institutions approved by the Oregon Department of Fish and Wildlife.

(ii) Game meat includes antelope, bighorn sheep, deer, elk, moose and mountain goat.

(u) Add section 3-201.18 to read: Outdoor Cooking and Beverage Dispensing Operations.

(A) Outdoor cooking and beverage dispensing by a food establishment shall be allowed as a part of the operation when conducted on the premises of the food establishment.Pf

(B) Enclosure of an outdoor cooking and beverage dispensing operation is not required unless necessary to protect food from contamination. The outdoor cooking and beverage dispensing operation must be designed to protect food, equipment, utensils, single-use articles and other items from contamination when not in operation.

(C) Outdoor cooking and beverage dispensing operations must be equipped with or located adjacent to a plumbed handwashing sink. Outdoor cooking and beverage dispensing operations that are not permanently constructed may provide a handwashing system that meets the requirements of 5-203.11(C) if approved by the regulatory authority.Pf

(D) Outdoor cooking shall be limited to the use of a barbeque, hearth oven, tandoori oven, barbeque pit or other similar cooking equipment. The use of equipment such as flat top grills or griddles, woks, steamtables or other cooking, storage or holding devices designed or intended to be used inside of a food service establishment is not allowed.Pf

(E) Other than cooking food, no preparation, assembly, storage or service of food may be done at the outdoor cooking operation. Non-potentially hazardous (non-TCS) condiments may be dispensed at the outdoor cooking operation.Pf

(F) Employees or consumers may be served directly from the outdoor cooking operation if the food is portioned for immediate service. Consumers may not serve themselves from an outdoor cooking operation.

(G) Outdoor beverage dispensing may include alcoholic and other beverages. Consumers may serve themselves from beverage dispensing equipment that meets the requirements of 4-204.13.

(H) Outdoor cooking and beverage dispensing operations must be monitored by food service employees.

(I) Section 3-201.18 does not preclude the service of foods prepared inside the establishment to consumers at outdoor seating areas.

(v) Add paragraph (E) to 3-202.14 to read: Raw milk from goats and sheep that is in compliance with the labeling requirements in OAR 603-024-0543 and the standards defined in OAR 603-024-0041 may be sold in licensed Oregon Department of Agriculture establishments.P

(w) Add subparagraph (C)(3) to 3-203.11 to read: If the establishment serves raw or undercooked shucked molluscan shellfish for immediate consumption, container label information must be maintained in the establishment for 90 days.Pf

(x) Amend section 3-301.11 to read:

(A) Food employees shall wash their hands as specified under sections 2-301.12 and 2-301.13.

(B) Food employees shall minimize bare hand contact with food and shall use suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment.P/Pf

(y) Amend paragraph 3-304.12(F) to read: In a container of water if the container is cleaned at a frequency specified under subparagraph 4-602.11(D)(7); and

(A) The water is maintained at a temperature of 135 degrees Fahrenheit or above; or

(B) At 41 degrees Fahrenheit or less.

(z) Add paragraph 3-304.15(E) to read: The use of latex gloves in food service establishments is prohibited.

(aa) Amend section 3-304.17 to read:

(A) Except as specified in paragraph (C) of section 3-304.17, a take-home food container returned to a food establishment may not be refilled at a food establishment with a potentially hazardous food (time/temperature control for safety food).

(B) Except as specified in paragraph (C) of section 3-304.17, a take-home food container refilled with non-potentially hazardous (non-TCS) food shall be cleaned as specified under paragraph 4-603.17(B).

(C) Notwithstanding paragraphs (A) and (B) of section 3-304.17, personal take-out beverage containers, such as thermally insulated bottles, non-spill coffee cups, and promotional beverage glasses, may be refilled by employees or the consumer with a beverage that is a potentially hazardous food (time/temperature control for safety food) if refilling is a contamination-free process as specified under paragraphs 4-204.13(A), (B), and (D).

(bb) Amend section 3-306.11 to read: Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling, or washing by the consumer before consumption, food on display shall be protected from contamination by the use of packaging; counter, service line, or salad bar food guards; display cases; or other effective means.Pf

(cc) Amend section 3-306.12 to read: Condiments, Protection.

(A) Condiments shall be protected from contamination by being kept in dispensers that are designed to provide protection, protected food displays provided with the proper utensils, original containers designed for dispensing, or individual packages or portions.Pf

(B) Condiments at a vending machine location shall be in individual packages or provided in dispensers that are filled at an approved location, such as the food establishment that provides food to the vending machine location, a food processing plant that is regulated by the agency that has jurisdiction over the operation, or a properly equipped facility that is located on the site of the vending machine location.Pf

(dd) Add section 3-307.12 to read: Protection from Contamination, Use of Private Vehicles for Food Deliveries.

(A) Private vehicles may be used for food deliveries if the food is packaged so that it is protected from contamination under Part 3-3 of the 2009 FDA Food Code, and adequate means are provided for maintaining proper food temperatures under section 3-501.16.

(B) Private vehicles shall not be used in any activity that is incompatible with safe and sanitary transportation of food.

(ee) Amend paragraph 3-401.12(C) to read: Heated to a temperature of at least 74 degrees Celsius (165 degrees Fahrenheit) in all parts of the food.P

(ff) Amend paragraph 3-401.14(D) to read: Prior to sale or service, cooked using a process that heats all parts of the food to a temperature and for a time that complies with one of the methods based upon the food being cooked as specified in 3-401.11.P

(gg) Amend subparagraph 3-401.14(F)(5) to read: Describe how foods, after initial heating but prior to cooking as specified in paragraph (D) of section 3-401.14, are to be separated from ready-to-eat foods as specified under 3-302.11(A).Pf

(hh) Amend paragraph 3-402.11 to read:

(A) Except as specified in paragraph (B) of this section, before service or sale in ready-to-eat form, raw, raw-marinated, partially cooked, or marinated-partially cooked fish shall be:

(i) Frozen and stored at a temperature of -20 degrees Celsius (-4 degrees Fahrenheit) or below for a minimum of 168 hours (seven days) in a freezer;P or

(ii) Frozen at -35 degrees Celsius (-31 degrees Fahrenheit) or below until solid and stored at -35 degrees Celsius (-31 degrees Fahrenheit) or below for a minimum of 15 hours;P

(iii) Frozen at -35 degrees Celsius (-31 degrees Fahrenheit) or below until solid and stored at -20 degrees Celsius (-4 degrees Fahrenheit) or below for a minimum of 24 hours.P

(B) Paragraph (A) of this section does not apply to:

(i) Molluscan Shellfish;

(ii) Tuna of the species Thunnus alalunga, Thunnus albacares (Yellowfin tuna), Thunnus atlanticus, Thunnus maccoyii (Bluefin tuna, Southern), Thunnus obesus (Bigeye tuna), or Thunnus thynnus (Bluefin tuna, Northern), or fish species that are listed in

the FDA Fish and Fisheries Products Hazards and Control Guidance, Potential Species-Related & Process Related Hazards and parasites are not a hazard; or

(iii) Aquacultured fish, such as salmon, that:

(I) If raised in open water, are raised in net-pens; or

(II) Are raised in land-based operations such as ponds or tanks; and

(III) Are fed formulated feed, such as pellets, that contains no live parasites infective to the auqacultured fish.

(iv) Fish eggs that have been removed from skein and rinsed.

(ii) Amend section 3-402.12 (B) to read: If the fish are frozen by a supplier, a written agreement or statement from the supplier stipulating that the fish supplied are frozen to a temperature and for a time specified under section 3-402.11 may substitute for the records specified under paragraph (A) of section 3-402.12.Pf

(A) Each invoice received from the supplier shall state the specific fish by species that have been frozen to meet the requirements for parasite destruction specified under section 3-402.11.Pf

(B) The written agreement or statement from the supplier must be updated at least once per year.Pf

(jj) Amend paragraph 3-501.15(B) to read: When placed in cooling or cold holding equipment, food containers in which food is being cooled shall be:

(A) Arranged in the equipment to provide maximum heat transfer through the container walls;Pf and

(B) Loosely covered, or uncovered if protected from overhead contamination as specified under subparagraph 3-305.11(A)(2), during the cooling period to facilitate heat transfer from the surface of the food.Pf

(kk) Amend subparagraph 3-501.17(A) to read: Except when packaging food using a reduced oxygen packaging method as specified under section 3-502.12, and except as specified in paragraphs (D) and (E) of section 3-501.17, refrigerated, ready-to-eat food (time/temperature control for safety food) prepared and held in a food establishment for more than 24 hours shall be clearly marked to indicate the date or day by which the food shall be consumed on premises, sold, or discarded when held at a temperature of 5 degrees Celsius (41 degrees Fahrenheit) or less for a maximum of seven days. The day of preparation shall count as Day 1.Pf

(ll) Amend paragraph 3-501.19(B) to read: If time without temperature control is used as the public health control up to a maximum of four hours.

(mm) Adopt subparagraphs 3-501.19(B)(1)-(4) as written.

(nn) Add subparagraph 3-603.11(B)(3) to read: Food service establishments that serve predominantly raw foods may disclose those items that are not served raw or do not require cooking before consumption.Pf

(oo) Add paragraph 3-701.11(E) to read: Potentially hazardous foods (TCS) that have been kept at temperatures above 41 degrees Fahrenheit or below 135 degrees Fahrenheit for more than four hours shall be discarded.P

(pp) Amend paragraph 4-101.17(A) to read: Except as specified in paragraphs (B), (C), (D) and (E) of section 4-101.17, wood and wood wicker may not be used as a food-contact surface.

(qq) Add paragraph 4-101.17(E) to read: Untreated wood planks, such as cedar, may be used as a cooking surface for grilling or baking.

(rr) Amend section 4-204.14 to read: Vending Machine, Vending Stage Closure. The dispensing compartment of a vending machine including a machine that is designed to vend prepackaged snack food that is not potentially hazardous (time/temperature control for safety food) shall be equipped with a self-closing door or cover if the machine is:

(A) Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment; or

(B) Available for self-service during hours when it is not under the full-time supervision of a food employee.

(ss) Amend paragraph 4-301.12(A) to read: Except as specified in paragraphs (C) and (F) of section 4-301.12, a sink with at least three compartments shall be provided for manually washing, rinsing, and sanitizing equipment and utensils.Pf

(tt) Amend subparagraph 4-301.12(C)(5) to read: In establishments licensed by the Oregon Department of Agriculture, two-compartment sinks as specified in paragraphs (D) and (E) of section 4-301.12.

(uu) Add paragraphs 4-301.12(F), (G) and (H) to read: (F) A commercial warewashing machine is allowed in lieu of a manual warewashing sink as required in section 4-301.12.

(A) For mobile food units:

(i) Class I, II and III mobile food units are not required to provide warewashing facilities on the unit, if adequate facilities exist at the commissary.Pf

(ii) Multiple or disposable utensils may be used for food handling on the unit. There shall be at the beginning of each day's business a sufficient supply of clean utensils necessary to properly prepare, assemble, or dispense the food. For mobile food units that do not have a warewashing sink on the unit, this supply shall consist of at least one of each type of utensil for every two hours of operation. If the unit operates less than four hours in a day, the unit shall provide a minimum of two sets of each type of utensil. Utensils shall not be used if they become contaminated.Pf

(iii) Class IV mobile food units must provide a sink with at least three compartments.Pf

(B) For temporary food establishments:

(i) Temporary food establishments are not required to provide warewashing facilities on the premises if multiple utensils are provided as specified in subparagraph (G)(2) of section 4-301.12 and the operator uses a licensed restaurant or commissary as a base of operation.Pf

(vv) Amend subparagraph 4-602.11(D)(7) to read: In-use utensils are intermittently stored in a container of water in which the water is maintained at 57 degrees Celsius (135 degrees Fahrenheit) or more or 5 degrees Celsius (41 degrees Fahrenheit) or less and the utensils and container are cleaned at least every 24 hours or at a frequency necessary to preclude accumulation of soil residues.

(ww) Amend section 4-603.16 to read: Washed utensils and equipment shall be rinsed so that abrasives are removed and cleaning chemicals are removed or diluted through the use of water by using one of the following procedures.

(xx) Adopt paragraphs 4-603.16(A), (D) and (E) as written.

(yy) Amend section 4-603.17 to read:

(A) Except as specified in paragraphs (B) and (C) of this section, returned empty containers intended for cleaning and refilling with food shall be cleaned and refilled in a regulated food processing plant. P

(B) A food-specific container for beverages may be refilled at a food establishment if:

(i) The design of the container and of the rinsing equipment and the nature of the beverage, when considered together, allow effective cleaning at home or in the food establishment;

(ii) Facilities for rinsing before refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system;

(iii) The consumer-owned container returned to the food establishment for refilling is refilled for sale or service only to the same consumer; and

(iv) The container is refilled by:

(I) An employee of the food establishment, or

(II) The owner of the container if the beverage system includes a contamination-free transfer process that can not be bypassed by the container owner.

(C) Consumer-owned containers that are not food-specific may be filled at a water vending machine or system.

(zz) Amend section 5-102.11 to read: Except as specified under section 5-102.12(A), water from a public water system shall meet 40 CFR 141 – National Primary Drinking Water Regulations and OAR chapter 333, division 061.P The following drinking water standards apply to licensed food establishments that are not regulated under OAR chapter 333, division 061:

(A) General Sampling Requirements:

(i) All samples required by this rule must be analyzed and collected as prescribed by OAR 333-061-0036(1)(a) and (b).P

(ii) All samples required by this rule must be analyzed by a laboratory accredited by the Oregon Environmental Laboratory Accreditation Program (ORELAP) and must be handled and documented in accordance with ORELAP standards.P

(iii) Samples submitted to laboratories for analysis shall be clearly identified with the name of the water system, facility license number, sampling date, time, sample location identifying the sample tap, the name of the person collecting the sample and whether it is a routine or a repeat sample.P

(I) Routine: These are samples collected from established sampling locations within a water system at specified frequencies to satisfy monitoring requirements as prescribed in this rule;P

(II) Repeat: These are samples collected as a follow-up to a routine sample that is positive for coliform bacteria or that exceeds the maximum contaminant level for nitrate as specified in OAR 333-061-0030(1);P

(iv) Reporting: All sample results must be submitted to the regulatory authority by the 10th of the month following the end of the applicable sampling period.P

(v) The regulatory authority may collect additional samples to determine compliance with applicable requirements of these rules.P

(B) Sampling for coliform bacteria:

(i) For seasonal establishments, one sample must be collected prior to the operational period of the facility and each subsequent calendar quarter while open to the public. A minimum of two samples shall be required for coliform, regardless of length of operation.P

(ii) For year round facilities, facilities utilizing surface water sources must collect one sample every month. Facilities utilizing groundwater sources must collect one sample every calendar quarter.P

(iii) Domestic kitchens licensed by the Oregon Department of Agriculture must test annually for coliform bacteria. If water is a major ingredient of the product, then additional water testing may be required by the regulatory authority, not to exceed the standards listed in this rule.

(C) Sampling for chemicals:

(i) Every facility must collect one arsenic sample before beginning operation for the first time. This requirement does not apply to facilities that were previously regulated under OAR chapter 333, division 061 and that have sampling results from samples collected prior to January 1, 2003.P

(ii) Every facility must collect one nitrate sample every year while open to the public.P

(D) Additional sampling may be required for coliform bacteria, arsenic, or nitrate at the discretion of the regulatory authority. It is the responsibility of the operator to correct any problems or deficiencies and to assure that water provided to the public does not present a risk to public health.P

(E) MCL Violations: An item is not considered a violation until confirmed by a second sample collected within 24 hours. For coliform bacteria, four repeat samples must be collected within 24 hours of the original positive sample.P

(i) Total coliform: Facilities must report samples positive for total coliform to the regulatory authority within 24 hours of being notified of the sample results.P

(ii) Fecal coliform: Facilities must report samples positive for E. coli to the regulatory authority within 24 hours of being notified of the sample results.P

(I) Facilities must publish public notification for this potential acute health risk as prescribed by OAR 333-061-0042.P

(II) An alternative procedure approved by the regulatory authority must be in place before serving the public.P

(iii) Facilities must report samples that exceed the MCL for nitrate as specified in OAR 333-061-0030(1) to the regulatory authority within at least 24 hours.P

(I) Public notification is required.P

(II) Bottled water must be provided to the public upon request.P

(F) Public Notice: All public notification must be posted conspicuously on site and must include:

(i) A description of the violation or situation of concern;P

(ii) Corrective actions taken to improve water quality;P

(iii) Any potential adverse health effects;P

(iv) The population at risk;P

(v) The alternative measures in place to provide safe drinking water.P

(G) Surface Water Sources: New facilities with surface water sources not regulated under OAR chapter 333, division 061 shall not be licensable after January 1, 2005. Facilities existing prior to January 1, 2005 in compliance with OAR 333-061-0032 may continue to operate.P

(H) Plan Review: All new facilities that are not regulated by OAR chapter 333, division 061 must submit plans to the regulatory authority for review prior to operation. Existing facilities must submit plans to the regulatory authority for review prior to construction or major modification of the system. Systems regulated prior to January 1, 2003 by OAR chapter 333, division 061 are not required to re-submit plans. Plan review must be conducted in accordance with the procedures specified in OAR 333-061-0060.P

(aaa) Add paragraph 5-103.11(C) to read: Hot and cold or tempered water must be provided at all handwashing sinks in the establishment.Pf

(bbb) Amend section 5-104.12 to read:

(A) Water meeting the requirements specified under subparts 5-101, 5-102, and 5-103 of the 2009 FDA Food Code shall be made available for a mobile facility, for a temporary food establishment without a permanent water supply, and for a food establishment with a temporary interruption of its water supply through:

(i) A supply of containers of commercially bottled drinking water;Pf

(ii) One or more closed portable water containers;Pf

(iii) An enclosed vehicular water tank;Pf

(vi) An on-premises water storage tank;Pf or

(v) Piping, tubing, or hoses connected to an adjacent approved source.Pf

(B) If approved by the local public health authority, water for single-event temporary food establishments without a permanent water supply may be obtained from a well that has been tested for coliform bacteria within 60 days prior to the event. The local public health authority may require additional testing or an evaluation of the well and premises as part of the approval process. Sampling, reporting and correction of MCL violations shall be in accordance with the applicable provisions of 5-102.11.Pf

(C) The regulatory authority may grant a temporary variance from requirements of subparts 5-101, 5-102, and 5-103 of the 2009 FDA Food Code by continuing or re-issuing previously issued permits where:

(i) Failure to comply with the code requirements is due to a failure of a community, municipal or public utility water supply system to meet the regulatory authority's requirements;

(ii) The regulatory authority is satisfied that necessary remedial action is ongoing or reasonably imminent in connection with such water supply system; and

(iii) Continuance or re-issuance of the permit is conditional upon the carrying out of such remedial action and the provision of such other measures by the certificate or license holder which will in the judgment of the regulatory authority afford reasonable interim protection to the public health including, but not limited to, adequate warnings to public and personnel as to the safety of the water delivered to the premises from the distribution system and notice of measures to avoid use or consumption of such water or to render it safe for consumption; adequate warnings as to the need for supervision of children and others needing supervision against use of such water; provision of alternative potable water and adequate notification as to its availability; and measures to avoid the use and the availability of water on the premises.Pf

(ccc) Amend paragraph 5-203.11(A) to read: Except as specified in (B),(C), (D) and (E) of section 5-203.11, at least one handwashing sink or the number of handwashing sinks necessary for

their convenient use by employees in areas specified under section 5-204.11 shall be provided. Food establishments opened prior to July 1, 1965 are exempt from this requirement provided that employees can meet the requirements under sections 2-301.12 and 2-301.13.Pf

(ddd) Amend paragraph 5-203.11(C) to read: An adequate number of handwashing stations shall be provided for each temporary food establishment to include:

(A) A minimum of one enclosed container that has a minimum water capacity of five gallons;Pf

(B) A spigot that can be opened to provide a constant flow of water;Pf

(C) Soap;Pf

(D) Water;Pf

(E) Paper towels;Pf and

(F) A collection container for wastewater with a minimum capacity of five gallons.Pf

(eee) Add paragraph 5-203.11(D) and (E) to read: (D) For mobile food units:

(A) Class II, III and IV mobile food units must provide a handwashing sink;Pf

(B) Notwithstanding paragraph 5-203.11(D)(i), Class II and III mobile food units licensed prior to September 4, 2012 may provide a handwashing system as described in paragraph (C) of section 5-203.11 if by January 1, 2018 the unit is upgraded to meet the requirements in paragraph 5-203.11(D)(i). There must be a minimum initial volume of five gallons of water available for handwashing at the beginning of the workday.Pf

(C) Outdoor cooking and beverage dispensing operations must be equipped with or located adjacent to a plumbed handwashing sink. Outdoor cooking and beverage dispensing operations that are not permanently constructed may provide a handwashing system that meets the requirements of paragraph 5-203.11(C) if approved by the regulatory authority.Pf

(fff) Amend section 5-203.12 to read:

(A) Except as specified in paragraph (B) of section 5-203.12, toilet facilities shall be installed according to ORS 455.010 through 455.895 (2010 Oregon Structure Specialty Code) for the number of toilets.Pf

(B) Food establishments with occupancy of 15 or less to include both employees and patrons may have only one toilet fixture and adjacent lavatory on the premises.

(C) Mobile food units shall provide toilet facilities as provided for in section 6-402.11.Pf

(ggg) Add section 5-203.13 (C) to read: For mobile food units, if wet mopping is used as a method for cleaning the floor, then a separate sink must be provided in the unit for cleaning mops and cleaning tools and for the disposal of mop water or similar liquid wastes.

(hhh) Amend paragraph 5-203.15(A) to read: If not provided with an air gap as specified under 5-202.13, a dual check valve with an intermediate vent preceded by a screen of not less than 100 mesh to 25.4 mm (100 mesh to 1 inch) shall be installed upstream from a carbonating device and downstream from any copper in the water supply line.P

(iii) Amend section 5-302.16 to read: A food grade hose shall be used for conveying drinking water from a water tank and shall be:

(jjj) Adopt paragraphs 5-302.16(A) through (E) as written.

(kkk) Add section 5-305.11 to read: Water System Requirements.

(A) A Class IV mobile food unit must have a potable water system under pressure. The system must be of sufficient capacity to furnish enough hot and cold water for food preparation, warewashing, and handwashing, and the requirements of these rules. This supply must consist of a minimum of five gallons of water for handwashing, and 30 gallons or twice the volume of the three-compartment sink, whichever is greater, of water for warewashing.P

(B) Class II and III mobile food units must have a water supply that provides sufficient water for food preparation, handwashing, warewashing or any other requirements as set forth in these rules. If warewashing is conducted on the unit, a minimum of 30 gallons or twice the volume of the three-compartment sink, whichever is greater, of water must be dedicated for this purpose. A minimum of five gallons of water must be provided for handwashing.P

(C) Except relating to handwashing as provided for in subparagragh 5-203.11(D)(2), all mobile food units must be designed with integral potable and waste water tanks on board the unit. A mobile unit may connect to water and sewer if it is available at the operating location, however, the tanks must remain on the unit at all times.Pf

(lll) Add paragraph 5-401.11(C) to read: For a mobile food unit selling only beverages, such as coffee, espresso, or soda, and where most of the potable water supply is used in the product, the waste water retention tank may be at least one half the volume of the potable water storage tank. This determination must be made by the regulatory authority.

(mmm) Amend section 5-402.14 to read: Sewage and other liquid wastes shall be removed from a mobile food establishment at an approved waste servicing area or by a sewage transport vehicle in such a way that a public health hazard or nuisance is not created.Pf

(A) Mobile food units that generate only gray water liquid wastes may hand-carry those wastes to a specific disposal location approved by the regulatory authority.

(B) The waste transport container must be designed and intended to hold and transport gray water without leaks or spills and have a capacity no greater than 20 gallons.Pf

(nnn) Amend subparagraph 6-101.11(B)(2) to read: Walls and ceilings may be constructed of a material that protects the interior from the weather and windblown dust and debris. Benevolent meal sites, as defined in paragraph 1-201.10(B), are exempt from the requirement to provide ceilings or overhead protection.

(ooo) Amend paragraph 6-202.15(E) to read: Paragraph (D) of section 6-202.15 does not apply:

(A) If flying insects or other pests are absent due to the location of the establishment, the weather, or other limiting condition; and

(B) The establishment develops a pest management plan to control the presence of flying insects or other pests. The pest management plan must be approved by the regulatory authority prior to implementation.Pf

(ppp) Amend section 6-202.19 to read: Exterior walking and driving surfaces shall be graded to drain if required by law.

(qqq) Amend section 6-202.110 to read: Outdoor Refuse Areas, Drainage. Outdoor refuse areas shall be constructed in accordance with law and shall be designed and maintained to prevent the accumulation of liquid waste that results from the refuse and from cleaning the area and waste receptacles.

(rrr) Amend section 6-202.111 to read: Except under a domestic kitchen license issued by the Oregon Department of Agriculture, a private home, a room used as living or sleeping quarters, or an area directly opening into a room used as living or sleeping quarters may not be used for conducting food establishment operations.P

(sss) Amend section 6-402.11 to read:

(A) Except for paragraphs (B) through (F) of section 6-402.11, toilet rooms shall be conveniently located and accessible to employees during all hours of operation and shall be an integral part of the building.

(B) A food service establishment may be approved without an integral toilet room under the following conditions:

(i) An integral toilet room is not required by law; and

(ii) A toilet room is located within 500 feet of the food establishment; and

(iii) A written agreement is in place that allows the use of the toilet room; or

(iv) The food service establishment is located in an outdoor mall or shopping center.

(C) Toilet facilities for the customer are required only in establishments constructed or extensively remodeled after May 11, 1974,

(D) Food establishments limited to drive-in or handout service are not required to provide toilet rooms facilities for the customer.

(E) For mobile food units:

(i) On board toilet facilities are not applicable to most mobile food units. If the unit is not so equipped, then the mobile food unit must operate within one-quarter mile or a five-minute walk of an accessible restroom facility. Mobile food units that operate on a designated route, and which do not stop at a fixed location for more than two hours during the workday, shall be exempt from this rule.

(ii) Mobile food units that do not provide on board restroom facilities must have restroom facilities that shall be accessible to employees during all hours of operation. The restroom facilities must have a handwashing system that meets the requirements of sections 5-202.12, 6-301.11, 6-301.12, 6-301.20 and 6-302.11. Employees may use a restroom located in a private home or a portable toilet to satisfy this requirement.

(F) Food service establishments that are constructed in or adjacent to a single family residence are not required to provide a separate restroom for employees, if a restroom in the residence is available during all hours of operation. The restroom facility must meet the requirements of sections 5-202.12, 6-301.11, 6-301.12, 6-301.20 and 6-302.11.

(ttt) Amend section 6-501.111 to read: Controlling Pests.

(A) The premises shall be maintained free of insects, rodents, and other pests.[Pf] The presence of insects, rodents, and other pests shall be controlled to minimize their presence on the premises by:

(i) Routinely inspecting incoming shipments of food and supplies;

(ii) Routinely inspecting the premises for evidence of pests;

(iii) Using methods, if pests are found, such as trapping devices or other means of pest control as specified under sections 7-202.12, 7-206.12, and 7-206.13;[Pf] and

(iv) Eliminating harborage conditions.

(uuu) Amend section 6-501.115 to read: Prohibiting Animals.

(A) Except as specified in paragraph (B), (C), (D) and (E) of section 6-501.115, live animals may not be allowed on the premises of a food establishment.

(B) A food establishment shall permit the use of a service animal by an individual with a disability on its premises unless the service animal poses a direct threat to the health and safety of others.

(i) For purposes of section 6-501.115 the term "direct threat" means a significant risk to the health or safety of others that cannot be eliminated by modification of policies, practices, or procedures or by provision of auxiliary aids or services.

(ii) In determining whether a service animal poses a direct threat to the health or safety of others, a food establishment must make an individualized assessment, based on reasonable judgment that relies on the best available objective evidence, to ascertain: The nature, duration, and severity of the risk; the probability that the potential injury will actually occur; and whether reasonable modifications of policies, practices, or procedures will mitigate the risk.

(iii) A food establishment may ask an individual with a disability to remove a service animal from the premises if:

(I) The animal is out of control and the animal's handler does not take effective action to control it; or

(II) The animal is not housebroken.

(C) Live animals may be allowed in the following situations if the contamination of food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles can not result:

(i) Edible fish or decorative fish in aquariums, shellfish or crustacea on ice or under refrigeration, and shellfish and crustacean in display tank systems;

(ii) Patrol dogs accompanying police or security officers in offices and dining, sales, and storage areas, and sentry dogs running loose in outside fenced areas;

(iii) Pets in the common dining areas of group residences at times other than during meals if:

(I) Effective partitioning and self-closing doors separate the common dining areas from food storage or food preparation areas;

(II) Condiments, equipment, and utensils are stored in enclosed cabinets or removed from the common dining areas when pets are present; and

(III) Dining areas including tables, countertops, and similar surfaces are effectively cleaned before the next meal service.

(iv) In areas that are not used for food preparation, storage, sales, display, or dining, in which there are caged animals or animals that are similarly restricted, such as in a variety store that sells pets or a tourist park that displays animals.

(D) Live or dead fish bait may be stored if contamination of food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles can not result.

(E) Pet dogs may be allowed in outside seating areas of a food establishment under the following conditions:

(i) The food establishment prepares written procedures that include:

(I) A diagram of the outdoor area to be designated as available to consumers with pet dogs;[Pf]

(II) The establishment's procedure for ensuring that employees do not touch, pet or otherwise handle pet dogs and for immediately cleaning accidents involving dog waste. The procedure must also describe the location of materials and equipment necessary to clean up accidents involving dog waste;[Pf] and

(III) The establishment's procedure for notifying employees and consumers of the requirements of this paragraph.[Pf]

(ii) Pet dogs may not come into contact with serving dishes, utensils and tableware. Pet dogs are also not allowed on chairs, tables and other furnishings.[Pf]

(iii) Employees and consumers may not provide food to pet dogs.[Pf]

(iv) Pet dogs must be on a leash and under control of the consumer at all times.[Pf]

(v) At no time may pet dogs be permitted to travel through the indoor or non-designated outdoor portions of the food establishment.[Pf]

(vvv) Amend subparagraph 7-202.12(A)(4) to read: Additional conditions that may be established by the regulatory authority;[P] and

(www) Add paragraph 8-101.10(C) to read: Plans submitted shall be reviewed and commented on by an environmental health specialist registered in accordance with ORS Chapter 700.

(xxx) Amend section 8-103.10 to read:

(A) The Authority may grant a variance from requirements of this code as follows:

(i) Where it is demonstrated to the satisfaction of the Authority that strict compliance with the rule would be highly burdensome or impractical due to special condition or cause;

(ii) Where the public or private interest in the granting of the variance is found by the Authority to clearly outweigh the interest of the application of uniform rules; and

(iii) Where such alternative measures are provided which in the opinion of the Authority will provide adequate public health and safety protection.

(B) Such variance authority is not conferred upon any Local Public Health Authority notwithstanding contractual authority in administration and enforcement of the food service statutes and rules;

(C) The applicant must include all necessary information to support the variance request, which may include, but is not limited to, required testing, challenge data and research results;

(D) If a variance is granted, the regulatory authority shall retain the information specified under section 8-103.11 in its records for the food establishment;

(E) The Authority shall review variances at least triennially;

(F) Revocation or denial of the variance request shall be subject to the appeal process provided under ORS Chapter 183.

(yyy) Add paragraph 8-103.11(D) to read: If required by the regulatory authority, provide documentation that a recognized process authority has reviewed the variance request and approved the process. Any necessary or required training or documentation must be successfully completed prior to variance approval.[Pf]

(zzz) Add paragraph 8-201.11(D) to read: Notwithstanding paragraphs (A) through (C) of section 8-201.11, vending machines having the sanitary approval of the National Automatic Merchandizing Association shall be exempt from the requirement to submit plans for review and approval.

(aaaa) Amend paragraph 8-302.14(A) to read: The name, mailing address, telephone, number, and signature of the person applying for the permit and the name, mailing address, and location of the food establishment;

(bbbb) Amend paragraph 8-303.30(C) to read: Advisement of the applicant's right of appeal and the process and time frames for appeal that are provided under ORS Chapter 183.

(cccc) Amend paragraph 8-304.10(A) to read: (A) At the time a permit is first issued, the regulatory authority shall provide to the permit holder information on how to obtain a copy of this code so that the permit holder is notified of the compliance requirements and the conditions of retention, as specified under section 8 304.11, that are applicable to the permit.

(dddd) Amend subparagraph 8-304.11(G)(2) to read: The regulatory authority directs the replacement to meet current code requirements after the food establishment has been closed for a minimum of six consecutive months, or

(eeee) Amend paragraph 8-304.11(I) to read: Accept notices issued and served by the regulatory authority as may be authorized under ORS Chapters 183 and 624; and

(ffff) Amend paragraph 8-304.11(J) to read: Be subject to the administrative, civil, injunctive, and criminal remedies as may be authorized under ORS Chapters 183 and 624.

(gggg) Amend paragraph 8-401.10(C) to read: For temporary food establishments:

(A) Except for subparagraph (C)(2) of section 8-401.10, the regulatory authority shall inspect at least once during the operation of a temporary food establishment.

(B) For benevolent single-event temporary food establishments, the regulatory authority shall either:

(i) Inspect; or

(ii) Provide a consultation.

(hhhh) Amend paragraph 8-403.10(A) and (B) to read:

(A) Administrative information about the food establishment's legal identity, street and mailing addresses, type of establishment and operation as specified under 8-302.14(C), inspection date, and employee food handler certificates; and

(B) Specific factual observations of violative conditions or other deviations from this code that require correction by the permit holder including:

(i) Failure of the person in charge to demonstrate the knowledge of foodborne illness prevention, application of HACCP principles, and the requirements of this code as specified under section 2-102.11;

(ii) Failure of food employees, conditional employees, and the person in charge to report a disease or medical condition as specified under section 2-201.11;

(iii) Nonconformance with priority items or priority foundation items of this code;

(iv) Failure of the appropriate food employees to demonstrate their knowledge of, and ability to perform in accordance with, the procedural, monitoring, verification, and corrective action practices required by the regulatory authority as specified under section 8-103.12;

(v) Failure of the person in charge to provide records required by the regulatory authority for determining conformance with a HACCP plan as specified under subparagraph 8-201.14(D)(6); and;

(vi) Nonconformance with critical limits of a HACCP plan.

(iiii) Amend section 8-403.20 to read: The regulatory authority shall specify on the inspection report form the time frame for correction of the violations as specified under sections 8-404.11, and 8-405.11.

(jjjj) Amend paragraph 8-405.11(B) to read: Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the regulatory authority may agree to or specify a longer time frame, not to exceed 14 calendar days after the inspection, for the permit holder to correct violations of a priority item or priority foundation item or HACCP plan deviations.

(kkkk) Amend paragraph 8-501.20(C) to read: (C) Closing the food establishment by summarily suspending a permit to operate as may be provided under ORS Chapter 624.

(llll) Amend paragraph 8-501.30(C) to read: (C) States that the suspected food employee or the permit holder may request an appeal hearing by submitting a timely request as provided under ORS Chapter 183.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 624.041, 624.355

Stats. Implemented: ORS 624.041, 624.355

Hist.: HD 20-1986, f. 12-22-86, ef. 2-2-87; HD 6-1989, f. 9-6-89, cert. ef. 9-7-89; HD 10-1992, f. 10-2-92, cert. ef. 10-5-92; HD 19-1994, f. & cert. ef. 7-1-94; HD 16-1995, f. 12-28-95, cert. ef. 1-1-96; OHD 24-2001, f. 10-31-01, cert. ef. 1-1-02; OHD 11-2002, f. & cert. ef. 8-7-02; PH 5-2004(Temp), f. & cert. ef. 2-13-04 thru 7-30-04; PH 15-2004, f. & cert. ef. 4-9-04; PH 1-2005, f. & cert. ef. 1-14-05; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06; PH 3-2008, f. & cert. ef. 3-5-08; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

DIVISION 157

INSPECTION AND LICENSING PROCEDURES

333-157-0000
Inspection Form Procedures

(1) The Local Public Health Authority shall document violations observed during any sanitation inspection by including the following information on the form approved by the Authority:

(a) The number of the related item on the inspection form;

(b) The point value associated with the item including penalty additions;

(c) Oregon Administrative Rule or Oregon Revised Statute number violated; and

(d) A brief statement of the specific problem and required corrections.

(2) Calculation of Points:

(a) Three point priority foundation items shall be given an additional three point weight when a repeat violation is observed.

(b) Five point priority items shall be given an additional five point weight when a repeat violation is observed.

(c) Additional points shall accumulate and be added to the value of uncorrected items that are repeat violations.

(d) Each three point priority foundation item can accumulate to six points.

(e) Each five point priority item can accumulate to 10 points.

(3) Violations creating a potential danger to public health shall be recorded as in section (1) of this rule and shall specify:

(a) Any alternative procedure as may be approved, the time limit for its use, and that the alternative procedure must be implemented immediately; and

(b) The corrections to be made and the time limit by which the corrections shall be made. In the case where an alternative procedure has not been approved, the time limit by which the correction must be made shall be within but not to exceed 14 days.

(4) Violations creating an imminent or present danger to public health shall be recorded as required in sections (1) and (3) of this rule except when no alternative procedure is approved, the correction shall be required immediately.

(5) If a restaurant obtains a sanitation score of less than 70 upon an unannounced complete inspection, the operator or person in charge shall be notified by a statement on the inspection form that the restaurant shall be closed, if the score of another complete inspection conducted within 30 days is not 70 or above.

(6) Violations creating a significantly increased risk for food borne illness shall require a recheck inspection if found on consec-

utive complete inspections, and for the purposes of enforcement shall be considered uncorrected.

(7) If a restaurant is ordered closed, the closure order as designated by the Authority shall be attached to the inspection form and delivered to the operator or person in charge.

Stat. Auth.: ORS 624.100
Stats. Implemented: ORS 624.100 – 624.130
Hist.: HD 20-1986, f. 12-22-86, ef. 2-2-87; HD 19-1994, f. & cert. ef. 7-1-94; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-157-0010
Approved Alternative Procedures

(1) An alternative procedure may be approved on a temporary basis for a designated time period, if in the judgment of the environmental health specialist the procedure provides interim health and safety protection equal to that provided by the rule. The environmental health specialist may extend the designated time period if justified by unforeseen circumstances. Such an alternative procedure shall not authorize or condone any priority item or priority foundation item violation.

(2) All alternative procedures that have been approved shall be implemented immediately.

Stat. Auth.: ORS 624.100
Stats. Implemented: ORS 624.100 – 624.130
Hist.: HD 20-1986, f. 12-22-86, ef. 2-2-87; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-157-0020
Public Notice of Restaurant Sanitation

(1) The notice of restaurant sanitation shall be based upon the sanitation score calculated on the inspection form at the end of each unannounced complete inspection and shall be posted at a customary entrance to the establishment. If, upon recheck inspection, any priority item or priority foundation item violation listed on the inspection form is not corrected within the designated time limit, the notice of restaurant sanitation posted at the end of the unannounced complete inspection shall be removed, the notice of closure posted, and closure action taken.

(2) A notice of restaurant sanitation that states that the establishment "Complied with the Acceptable Sanitation Standards" shall be assigned to a restaurant that obtains a sanitation score of 70 or more in an unannounced complete inspection provided all priority item and priority foundation item violations have been corrected or remedied by approved alternative procedures. Upon recheck inspection, any uncorrected priority item or priority foundation item violations shall cause the notice of restaurant sanitation to be removed, the notice of closure to be posted, and closure action taken.

(3) A notice of restaurant sanitation that states that the establishment "Failed to Comply with the Acceptable Sanitation Standards" shall be assigned to a restaurant that obtains a sanitation score of less than 70 in an unannounced complete inspection provided all priority item and priority foundation item violations have been corrected or remedied by approved alternative procedures. Such a notice of restaurant sanitation shall remain until the facility is closed or until a sanitation score of 70 or more is obtained upon another inspection conducted within 30 days.

Stat. Auth.: ORS 624.073
Stats. Implemented: ORS 624.085
Hist.: HD 20-1986, f. 12-22-86, ef. 2-2-87; HD 19-1988, f. 7-27-88, cert. ef. 10-1-88; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-157-0025
Communication and Compliance Protocols

Communication and compliance protocols will be provided by the Assistant Director to operators of non-complying food service facilities. This communication will convey current and potential compliance actions, and will include the appropriate use of correspondence, meetings, and officials notices.

Stat. Auth.: ORS 624.041
Stats. Implemented: ORS 624.041
Hist.: HD 19-1994, f. & cert. ef. 7-1-94

333-157-0027
Increased Inspection Schedule

(1) Any restaurant that fails to obtain a minimum acceptable sanitation score of 70 or more for two consecutive, unannounced semi-annual inspections shall be subject to an increased inspection schedule.

(2) Except as provided in section (4) of this rule, this schedule will consist of one complete unannounced inspection a quarter (three month period) as well as any re-check inspections required. This inspection schedule shall begin in the quarter immediately following the second consecutive score of less than 70.

(3) The increased inspection schedule will revert to semi-annual inspections after the facility has obtained four (4) consecutive scores of 70 or above.

(4) At the Assistant Director's option, one of the four required inspections may be an inspection using Hazard Analysis and Critical Control Point (HACCP) principles, as defined in these rules. HACCP based inspections may be announced. Participation by a restaurant in a HACCP-based inspection shall be the equivalent of a score of 70 or above for the purposes of this rule.

(5) The inspecting agency may assess a fee for each quarterly inspection required under this rule of up to one-half of the annual licensing fee otherwise assessable to the restaurant.

Stat. Auth.: ORS 624.100
Stats. Implemented: ORS 624.100 – 624.130
Hist.: HD 14-1995, f. 12-28-95, cert. ef. 1-1-96; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06

333-157-0030
Closure of Restaurants

(1) If the administrator closes a restaurant, a statement by the Authority ordering closure and specifying the reasons therefore, and signed by the administrator, shall be attached to the inspection form and delivered to the operator or person in charge:

(a) When a restaurant is closed, the administrator shall post the notice of closure at a customary entrance;

(b) No person except the administrator shall remove or alter this notice;

(c) No person shall operate a restaurant that has been closed.

(2) If a violation which creates an imminent or present danger to public health is not corrected immediately or an approved alternative procedure is not initiated immediately by the operator, the restaurant shall be closed.

(3) If a violation which creates a potential danger to public health has not been corrected within the designated time limit, the restaurant shall be closed.

(4) When a restaurant has been closed because a priority item or priority foundation item violation(s) has not been corrected, it may be reopened after 24 hours if:

(a) A recheck inspection by the administrator confirms that all priority item and priority foundation item violations have been corrected; and

(b) A closure dismissal order designated by the Authority is delivered to the operator or person in charge; and

(c) The closed sign previously posted is removed by the administrator;

(d) A restaurant may be reopened earlier than 24 hours following a voluntary meeting attended by the restaurant operator or person in charge, the administrator, and the inspecting environmental health specialist, at which the provisions of subsections (4)(a) through (c) of this rule are demonstrated to be met;

(e) A restaurant closed and reopened as described in this subsection shall be assigned a notice of restaurant sanitation based on the sanitation score of the unannounced complete inspection that identified the priority item and priority foundation item violations causing the closure.

(5) If a restaurant has obtained a sanitation score of less than 70 on two consecutive complete inspections conducted within 30 days as described in OAR 333-157-0000(5), it shall be closed.

(6) When a restaurant has been closed for failure to obtain a minimum acceptable sanitation score of 70 or more, it may be reopened after 24 hours if:

(a) The operator submits a written plan of correction, specifying the corrections to be made and time limits for their completion, which would achieve a sanitation score of 80 points by the next semi-annual inspection; and

(b) The plan of correction is approved by the administrator; and

(c) A complete inspection after the restaurant has been closed produces a sanitation score of 70 or more.

(d) A closure dismissal order designated by the Authority is delivered to the operator or person in charge; and

(e) The closed sign previously posted is removed by the administrator;

(f) A restaurant may be reopened earlier than 24 hours following a voluntary meeting attended by the restaurant operator or person in charge, the administrator, and the inspecting environmental health specialist, at which the provision of subsections (6)(a) through (e) of this rule are demonstrated to be met;

(g) A restaurant closed and reopened as described in this subsection shall be assigned a notice of restaurant sanitation based on the sanitation score of the complete inspection performed while the restaurant was closed.

(7) Appeals of closures are contested cases pursuant to ORS Chapter 183.

(8) Operators whose facilities have been closed for failure to obtain a minimum acceptable sanitation score of 70 or more, or for failure to correct repeat priority item or priority foundation item violations must agree in writing, as part of reopening the restaurant, to:

(a) Enroll in and successfully complete an approved food manager training course; or

(b) In the event that an extraordinary situation exists whereby an approved food manager training course is not available to the operator, the administrator shall make provision for an alternative type of food manager training using criteria approved by the Authority.

Stat. Auth.: ORS 624.100
Stats. Implemented: ORS 624.100 – 624.130
Hist.: HD 20-1986, f. 12-22-86, ef. 2-2-87; HD 19-1994, f. & cert. ef. 7-1-94; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-157-0040
Display of Public Notice of Restaurant Sanitation

It shall be unlawful for any restaurant to display a Public Notice of Restaurant Sanitation other than the one awarded by the administrator. It shall be unlawful for anyone except the administrator to post, change, remove, or deface a Public Notice of Restaurant Sanitation.

Stat. Auth.: ORS 624.060 & 624.073
Stats. Implemented: ORS 624.060 & 624.073
Hist.: HD 20-1986, f. 12-22-86, ef. 2-2-87; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-157-0045
Civil Penalties

(1) The Authority or a Local Public Health Authority may impose civil penalties on any person for the following willful violations:

(a) Operation of a restaurant, bed and breakfast facility or vending machine without a current license to do so from the Authority or the Local Public Health Authority;

(b) Failure to cease operation of a restaurant, bed and breakfast facility or vending machine that has been closed due to uncorrected priority item violations. This authority shall be limited to those priority item violations identified as creating an imminent or present danger to public health and defined in OAR 333-150-0000 Section 1-201.10.

(2) For the purposes of section (1) of this rule, the term 'willful' means intentional or deliberate.

(3) The maximum civil penalty for each of the violations listed in section (1) of this rule is $500 per day of violation.

(4) Civil penalties shall be imposed in the manner provided by ORS Chapter 183 or the equivalent.

Stat. Auth.: ORS 624.100
Stats. Implemented: ORS 624.100 – 624.130
Hist.: HD 15-1995, f. 12-28-95, cert. ef. 1-1-96; OHD 18-2002, f. 12-4-02, cert. ef. 1-1-03; PH 5-2004(Temp), f. & cert. ef. 2-13-04 thru 7-30-04; PH 15-2004, f. & cert. ef. 4-9-04; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-157-0070
Licensing

Any license issued by the Authority pursuant to ORS Chapter 624 shall expire and may be reinstated on December 31 of each year; except for temporary restaurant licenses issued pursuant to ORS 624.082, 624.084 and 624.086.

Stat. Auth.: ORS 624.100
Stats. Implemented: ORS 624.100 – 624.130
Hist.: HD 20-1986, f. 12-22-86, ef. 2-2-87; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-157-0073
Temporary Restaurant Definitions

(1) "Intermittent temporary restaurant" means an establishment:

(a) That operates temporarily at a specific location in connection with multiple public gatherings, entertainment events, food product promotions or other events, at least two of which are arranged for by different oversight organizations; and

(b) Where food is prepared or served for consumption by the public.

(2) "Operational review" means the examination of a plan of operation for an establishment in order to ensure that the proposed operation conforms with applicable sanitation standards.

(3) "Oversight organization" means an entity responsible for organizing, managing or otherwise arranging for a public gathering, entertainment event, food product promotion or other event, including but not limited to ensuring the availability of water, sewer and sanitation services.

(4) "Seasonal temporary restaurant" means an establishment:

(a) That operates at a specific location in connection with multiple public gatherings, entertainment events, food product promotions or other events that are arranged for by the same oversight organization; and

(b) Where food is prepared or served for consumption by the public.

(5) "Single-event temporary restaurant" means an establishment:

(a) That operates in connection with a single public gathering, entertainment event, food product promotion or other event; and

(b) Where food is prepared or served for consumption by the public.

(6) "Substantial menu alteration" means a change of menu that increases the complexity of the menu of a seasonal temporary restaurant and intermittent temporary restaurant operation. For purposes of these rules, an increase in complexity occurs when the menu moves from:

(a) Service of ready-to-eat foods that requires no further preparation or cooking; to

(b) Foods that are prepared or cooked on-site and served directly to the consumer that day; to

(c) Foods that must be prepared in the operation in advance and reheated or cooled over the course of multiple days of operation.

Stat. Auth.: ORS 624.041
Stats. Implemented: ORS 624.038, 624.041, 624.082 & 624.084
Hist.: PH 3-2012, f. 2-29-12, cert. ef. 3-1-12

333-157-0077
Temporary Restaurant Licensing and Inspection

(1) A person may not operate a single-event, intermittent or seasonal temporary restaurant without first procuring a license to do so from the Local Public Health Authority.

(2)(a) Application for an intermittent or seasonal temporary restaurant license shall be in writing in the form prescribed by the Authority and shall contain the name and address of the applicant, the specific location of the intermittent or seasonal temporary restaurant, a description of the public gatherings, entertainment

events, food product promotions or other events to be served by the intermittent or seasonal temporary restaurant, an operational review and any other information the Authority may require. In addition to the application the applicant for an intermittent or seasonal temporary restaurant license shall pay to the Local Public Health Authority the appropriate license fee under ORS 624.490.

(b) The Local Public Health Authority shall issue a license to a benevolent organization to operate a single-event temporary restaurant if the benevolent organization has notified the Local Public Health Authority orally or in writing that the benevolent organization intends to operate a single-event temporary restaurant. A Local Public Health Authority may not charge a benevolent organization a license fee or inspection fee for a single-event temporary restaurant.

(3)(a) Intermittent and seasonal temporary restaurants must complete and submit an operational plan for review by the Local Public Health Authority prior to obtaining a license and operation of the establishment.

(b) Intermittent and seasonal temporary restaurants that do not complete an operational plan prior to operation may operate under one or more single-event temporary licenses until the operational plan can be completed and approved.

(c) After the operational plan has been completed by the Local Public Health Authority, another operational plan is not required for subsequent licenses, unless deemed necessary by the Local Public Health Authority.

(4) The single-event, intermittent or seasonal temporary restaurant license shall be posted in a conspicuous place on the premises of the licensee.

(5) An intermittent temporary restaurant license shall expire 30 days after issuance.

(6) A seasonal temporary restaurant license shall expire 90 days after issuance.

(7) A single-event temporary restaurant license shall terminate 30 days after issuance unless within 30 days the single-event temporary restaurant is discontinued or moved from the specific location for which the license was issued.

(8) An intermittent or seasonal temporary license shall terminate immediately if:

(a) The intermittent or seasonal temporary restaurant prepares or serves food for consumption by the public that is not in connection with a public gathering, entertainment event, food product promotion or other event held by an oversight organization;

(b) The location of the intermittent or seasonal temporary restaurant changes; or

(c) The menu is substantially altered as defined by OAR 333-157-0073(6).

(d) If a licensed operation undergoes a substantial menu alteration, then a new license and completed operational plan is required.

(9) If the license of an intermittent or seasonal temporary restaurant is terminated under section (8) of this rule, the intermittent or seasonal temporary restaurant may reapply for a license in accordance with section (2) of this rule.

(10) The Local Public Health Authority may suspend, deny or revoke a single-event, intermittent or seasonal temporary restaurant license if it appears, after a reasonable time has been given for correction of a sanitation violation, that the applicant does not meet applicable minimum sanitation standards as described in ORS 624.010 through 624.121 or in OAR 333-150-0000. Any suspension, denial or revocation action shall be taken in accordance with ORS Chapter 183.

(11) The Local Public Health Authority may conduct a reinspection of a seasonal or intermittent temporary restaurant if a priority item or priority foundation item violation is uncorrected and a separate follow-up visit is necessary to determine compliance.

(12) A seasonal or intermittent temporary restaurant that has uncorrected priority item and priority foundation item violations and for which an alternative procedure has not been approved shall be closed in accordance with ORS 624.096.

(13) The renewal of a single-event, intermittent or seasonal temporary restaurant license shall be in accordance with section (2) of this rule.

Stat. Auth.: ORS 624.041
Stats. Implemented: ORS 624.038, 624.041, 624.082 & 624.084
Hist.: PH 3-2012, f. 2-29-12, cert. ef. 3-1-12; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-157-0080
Fees

(1) Fees for eating and drinking establishments and other food service activities subject to ORS Chapter 624 shall be as specified in ORS Chapter 624.

(2) Any restaurant providing food or beverage solely to children, elderly persons, indigent or other needy populations shall not be required to pay a restaurant license fee to the Authority if such restaurant is:

(a) Operated by a benevolent organization as defined in ORS 624.101; and

(b) The patrons or recipients are not required to pay the full cost of the food or beverage.

(3) A restaurant that meets the criteria in section (2) of this rule must still obtain a restaurant license and must comply with OAR 333-150-0000.

Stat. Auth.: ORS 624.100
Stats. Implemented: ORS 624.100 – 624.130
Hist.: HD 20-1986, f. 12-22-87, ef. 2-2-87; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

DIVISION 158

COMBINATION FOOD SERVICE FACILITIES

Combination Facilities Engaged in Activities Subject to Regulation by the Oregon Department of Agriculture and by the Oregon Health Authority

333-158-0000
Licensing and Inspections

The licensing of combination facilities shall be the responsibility of either the Authority or the Oregon Department of Agriculture in accordance with the following criteria:

(1) The establishments subject to these rules are those combination facilities as defined in OAR 333-150-0000 1-201.10(B).

(2) A determination shall be made for each firm covered in OAR 333-150-0000 1-201.10(B) as to which agency shall inspect and license. The determination shall be based upon which agency has statutory responsibility and authority for the predominant activities of the firm.

(3) In those instances where it is determined that either a full or limited service restaurant or other activity for which the Authority has authority, is predominant, the Authority shall perform the inspectional and licensing responsibilities to the exclusion of the Oregon Department of Agriculture.

(4) In those instances where it is determined that the bakery, retail grocery, food processing or other activities for which the Oregon Department of Agriculture has authority, is predominant, the Oregon Department of Agriculture shall perform the inspectional and licensing responsibilities to the exclusion of the Authority.

(5) The determination of the predominant activity at any combination facility subject to this agreement shall be made first by the field environmental health specialists. If agreement is not reached, then it shall be referred to program supervisors of the Local Public Health Authority and the Oregon Department of Agriculture for a determination of predominant activity. If an agreement is not reached among the Local Public Health Authority and the Oregon Department of Agriculture, or if a licensed facility disagrees with the determination, the matter may be appealed to an arbitration panel composed of the administrator of the Food and Dairy Division (or appointee), the administrator of the Center for Health Protection (or appointee), and one representative each from the Conference of Local Health Officials, an association representing the restaurant industry and an association representing the retail

grocery industry. The decision of this panel shall be final except as provided in section (6) of this rule.

(6) Any licensee wishing to contest the determination of predominance by agencies may produce records of gross annual sales to support the protest and be heard by the Local Public Health Authority in accordance with ORS Chapter 183.

(7) Notwithstanding sections (2) through (6) of this rule, if the Local Public Health Authority and the Oregon Department of Agriculture agree that the complexity rather than the predominance of food processing activities should determine the regulating agency, inspectional and licensing responsibilities may be transferred to the Oregon Department of Agriculture to the exclusion of the Local Public Health Authority.

Stat. Auth.: ORS 624.530
Stats. Implemented: ORS 624.530
Hist.: HD 20-1986, f. 12-22-86, ef. 2-2-87; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-158-0010
Applicability of Rules

(1) Any facility licensed and inspected by the Authority, pursuant to OAR 333-158-0000 through 333-158-0030, shall be subject to the applicable rules under OAR chapter 333 of the Authority for all activities subject to ORS Chapter 624. The facility shall also be subject to the applicable statutes and rules under ORS 616 and 625, and OAR 603-021-0010, 603-021-0015, 603-021-0021, 603-021-0022, 603-021-0025, 603-021-0612, 603-025-0010 through 603-025-0040, 603-025-0080 through 603-025-0190 and 603-025-0220 of the Oregon Department of Agriculture, which are hereby adopted by reference.

(2) Any facility licensed and inspected by the Oregon Department of Agriculture, pursuant to OAR 333-158-0000 through 333-158-0030, shall be subject to the applicable rules under OAR chapter 603 of the Oregon Department of Agriculture for all activities subject to statutes administered by the Oregon Department of Agriculture and ORS Chapter 624.

Stat. Auth.: ORS 624.530
Stats. Implemented: ORS 624.530
Hist.: HD 20-1986, f. 12-22-86, ef. 2-2-87; HD 2-1997, f. & cert. ef. 1-23-97; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06

333-158-0020
Licenses and Permits

Licenses and permits issued pursuant to these rules shall be subject to the statutes of the licensing and inspecting agency, including fees and legal remedies, and shall be deemed to satisfy the licensing statutes of the other agency.

Stat. Auth: ORS 624.530
Stats. Implemented: ORS 624.530
Hist.: HD 20-1986, f. 12-22-86, ef. 2-2-87

333-158-0030
Periodic Review

At least annual re-evaluations of predominance shall be made by the regulating agencies and changes in jurisdiction shall be made where indicated

Stat. Auth.: ORS 624.530
Stats. Implemented: ORS 624.530
Hist.: HD 20-1986, f. 12-22-86, ef. 2-2-87

DIVISION 160

DESTRUCTION OF FOOD UNFIT FOR HUMAN CONSUMPTION

333-160-0000
Destruction and Embargo of Mishandled, Adulterated or Spoiled Food and Beverage

Whenever the Authority finds food or beverage for which there is probable cause to believe is adulterated, mishandled, spoiled, or otherwise potentially dangerous to health, the Authority shall immediately notify the person in charge that the product is hazardous; and shall request immediate destruction of the product. If the person in charge agrees, the food or beverage shall be destroyed or removed in a manner specified by the Authority:

(1) If the person in charge will not agree to destruction, an embargo order shall be placed on the food or beverage. The order shall include:

(a) A statement of the reasons for the embargo;

(b) A description of the products, their location and the amount of product embargoed;

(c) The date and time of day when the order is issued, and the signature of the inspecting Environmental Health Specialist.

(2) The product shall be marked, sealed, isolated, and otherwise identified as required by the Authority to ensure that it remains off sale and is not moved prior to final disposition of the embargo.

(3) After placement of an embargo order, samples may be taken for testing by the Authority.

(4) If the order of embargo does not include a notice of hearing; within 48 hours of the placement of an embargo, the person in charge shall be notified in writing that a hearing on the embargo order will be held if requested in writing within ten (10) days of the delivery of the notice.

(5) If a hearing is requested, it shall be held in accordance with ORS 183 and the model rules of the Attorney General for contested cases.

(6) If no hearing is requested as provided in section (4) of this rule, a default order for destruction shall be issued to the person in charge.

(7) Destruction or removal of embargoed product shall be done only under the direct supervision of the Authority. Denaturation may be required where it is necessary to render the product unpalatable or to identify it as unfit for human consumption.

(8) Violation of any embargo or destruction order or removal of any product under embargo is grounds for closure of the facility, revocation or denial of license or criminal penalties provided under ORS 624.990.

Stat. Auth.: ORS 624.070
Stats. Implemented: ORS 624.070
Hist.: HD 20-1986, f. 12-22-86, ef. 2-2-87; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06

DIVISION 162

MOBILE FOOD UNITS, COMMISSARIES AND WAREHOUSES

333-162-0020
Mobile Food Units, General Requirements

(1) Mobile food units shall comply with the applicable requirements in OAR 333-150-0000 and these rules. The Authority may impose additional requirements to protect against health hazards related to the conduct of the mobile food unit operation and may prohibit the sale of potentially hazardous food.

(2) There are four types of mobile food units:

(a) Class I. These mobile food units can serve only intact, packaged foods and non-potentially hazardous drinks. No preparation or assembly of foods or beverages may take place on the unit. Non-potentially hazardous beverages must be provided from covered urns or dispenser heads only. No dispensed ice is allowed;

(b) Class II. These mobile food units may serve foods allowed under Class I and provide hot and cold holding display areas from which unpackaged foods are displayed. Self-service by customers of unpackaged foods is not allowed. Preparation, assembly or cooking of foods is not allowed on the unit;

(c) Class III. These mobile food units may serve any food item allowed under Class I and II mobile food units, and may cook, prepare and assemble food items on the unit. However, cooking of raw animal foods on the unit is not allowed;

(d) Class IV. These mobile food units may serve a full menu.

(3) All operations and equipment shall be an integral part of the mobile food unit. This does not preclude the use of a barbecue unit used in conjunction with a Class IV mobile food unit. The barbecue, however, may only be used under the following conditions:

(a) It must be used in close proximity to the mobile food unit;

(b) Food shall only be cooked on the barbecue. Processing, portioning, preparation, or assembly of food must be conducted from inside the mobile food unit; and

(c) A handwashing system shall be provided adjacent to the barbecue as specified in OAR 333-150-0000 section 5-203.11(C).

(4) Mobile food unit operators may provide seating for customers if a readily accessible restroom is provided. The restroom must have a handwashing facility that provides hot and cold running water and meets the requirements of OAR 333-150-0000 sections 6-301.11, 6-301.12, 6-301.20 and 6-302.11.

(5) Auxiliary storage may be provided if it is limited to impervious, nonabsorbent, covered containers stored in such a manner as to preclude contamination or infestation. Auxiliary storage shall be limited to items necessary for that day's operation. No self-service, assembly or preparation activities may occur from auxiliary storage containers.

Stat. Auth.: ORS 624.390
Stats. Implemented: ORS 624.390
HD 7-1994, f. & cert. ef. 2-24-94; HD 10-1997, f. & cert. ef. 7-8-97; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-162-0030
Mobile Unit Operation, General

Mobile food units shall remain mobile at all times during operation. The wheels of the unit shall not be removed from the unit at the operating location. A removable tongue may be allowed if the tongue can be removed with the use of only simple tools and the tools are available on the unit at all times.

Stat. Auth.: ORS 624.390
Stats. Implemented: ORS 624.390
HD 7-1994, f. & cert. ef. 2-24-94; HD 10-1997, f. & cert. ef. 7-8-97; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06

333-162-0040
Base of Operation

(1) Mobile food units shall operate from a licensed restaurant, commissary or warehouse.

(2) If only prepackaged goods are sold, a warehouse may be accepted in lieu of a commissary.

(3) Notwithstanding section (1) of this rule, self-contained mobile food units may not be required to have a base of operation if the unit contains all the equipment and utensils necessary to assure the following:

(a) Maintaining proper hot and cold food temperatures during storage and transit;

(b) Providing adequate facilities for cooling and reheating of foods;

(c) Providing adequate handwashing facilities;

(d) Providing adequate warewashing facilities and assuring proper cleaning and sanitizing of the unit;

(e) Obtaining food and water from approved sources;

(f) Sanitary removal of waste water and garbage at approved locations.

(4) The ability to operate without a base of operation shall be determined by the regulatory authority.

(5) A mobile food unit may not serve as a commissary for another mobile food unit or as the base of operation for a caterer.

Stat. Auth.: ORS 624.390
Stats. Implemented: ORS 624.390
Hist.: HD 20-1986, f. 12-22-86, ef. 2-2-87; HD 17-1993, f. & cert. ef. 10-14-93; HD 10-1997, f. & cert. ef. 7-8-97; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06

333-162-0280
Food Transportation, General

(1) During transportation, food and food utensils shall be kept in covered containers or completely wrapped or packaged so as to be protected from contamination. Foods in original individual packages do not need to be overwrapped or covered if the original package is sealed.

(2) Food shall be maintained at required temperatures at all times during transport. Mobile food units that do not maintain food at temperatures required in OAR 333-150-0000 section 3-501.16 may be required to provide an on board power source, such as a battery or generator, to assure maintenance of food at proper temperatures during transit.

(3) Transport vehicles shall not be used in activities incompatible with safe and sanitary food service operations.

Stat. Auth.: ORS 624.390
Stats. Implemented: ORS 624.390
Hist.: HD 10-1997, f. & cert. ef. 7-8-97; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06

333-162-0680
Overhead Protection

Overhead protection shall be provided for mobile food units that are operated outdoors and where food is not covered at all times. The overhead protection shall consist of, but not be limited to, roofing, ceilings, awnings, or umbrellas. Overhead protection is not required for barbecue units that have a lid or covering that will protect foods from contamination. The overhead protection must be easily cleanable.

Stat. Auth.: ORS 624.390
Stats. Implemented: ORS 624.390
Hist.: HD 10-1997, f. & cert. ef. 7-8-97; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06

Inspection and Licensing Procedures Mobile Food Units, Commissaries and Warehouses

333-162-0880
Licensing Procedure

(1) All procedures shall be in accordance with ORS Chapter 624 in the licensure of mobile food units, commissaries and warehouses. Any license issued by the Authority pursuant to ORS 624.320 shall expire and may be reinstated on December 31 of each year.

(2) A permanent license number shall be assigned each operator of mobile food units by the regulatory authority.

(3) Each mobile food unit shall be clearly marked with the licensee's name or a distinctive identifying symbol. The lettering shall be at least two inches in height and of a color contrasting with the background color. If a symbol is used, it shall be at least 12 inches in diameter or of an equivalent size. An accurate scale drawing or photograph of the symbol shall be filed with the regulatory authority.

(4) Each mobile food unit shall be clearly marked with a number for purposes of identifying each unit on inspection reports and other communications.

(5) Stored units are not subject to licensure.

(6) All vehicles used as mobile food units shall be kept in good repair and in a sanitary condition while in use.

Stat. Auth.: ORS 624.390
Stats. Implemented: ORS 624.390
Hist.: HD 10-1997, f. & cert. ef. 7-8-97; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-162-0890
Inspection Form Procedures

(1) Violations that are observed during any sanitation inspection by the Local Public Health Authority shall be described in the space provided on a form approved by the Authority by citing the Oregon Revised Statute or Oregon Administrative Rule number violated, and by giving a brief statement of the specific problem and required corrections.

(2) Priority item or priority foundation item violations shall result in closure of a mobile food unit, commissary or warehouse if the administrator determines that an imminent danger to public health exists, and that the violation cannot be corrected immediately or an approved alternative procedure has not been implemented. For priority item or priority foundation item violations not resulting in closure, the time limit by which the correction must be made shall be within but not to exceed 14 days.

(3) Violations other than those specified in section (2) of this rule shall be corrected by the next semi-annual inspection.

(4) If a mobile food unit, commissary or warehouse is ordered closed, the reason for closure shall be stated on the inspection form and signed by the administrator.

Stat. Auth.: ORS 624.390
Stats. Implemented: ORS 624.390

Hist.: HD 10-1997, f. & cert. ef. 7-8-97; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-162-0910
Closure of Mobile Food Units, Commissaries or Warehouses

(1) If the administrator closes a mobile food unit, commissary or warehouse, a statement by the Authority shall be made on the inspection form specifying the reasons for closure. The inspection form must be signed and delivered to the operator or person in charge within 24 hours.

(2) When a mobile food unit is closed, the administrator shall post the inspection report on the unit. When a commissary or warehouse is closed, the administrator shall post the inspection report inside the facility. No person except the administrator shall remove or alter this inspection report, or operate a mobile food unit that has been closed.

(3) If a priority item or priority foundation item violation presenting an imminent danger to public health is not corrected immediately or an approved alternative procedure has not been implemented, the mobile food unit, commissary or warehouse shall be closed.

(4) If a priority item or priority foundation item violation that does not result in immediate closure at the time of the semi-annual inspection has not been corrected within the designated time limit, the mobile food unit, commissary or warehouse shall be closed.

(5) When a mobile food unit, commissary or warehouse has been closed because a priority item or priority foundation item violation has not been corrected, it may be reopened if a recheck inspection by the administrator confirms that all priority item or priority foundation item violations have been corrected.

(6) The administrator shall, if requested, hold a hearing in accordance with ORS Chapter 183.

Stat. Auth.: ORS 624.390
Stats. Implemented: ORS 624.390
Hist.: HD 10-1997, f. & cert. ef. 7-8-97; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-162-0920
Plan Review

(1) Newly constructed or extensively remodeled mobile food units, commissaries and warehouses must undergo plan review and a pre-operational inspection. Mobile food units having the sanitary approval of a recognized qualified, independent testing laboratory, or approved by the Authority may be accepted without the submission of plans.

(2) Approval from the administrator to operate after the plan review process does not preclude obtaining required permits or approvals from other agencies or jurisdictions of concern.

(3) Mobile food unit operators must obtain approval from the administrator to add to or change menu items served from the mobile food unit;P

(4) Mobile food units that operate on a fixed route must provide an itinerary to the regulatory authority prior to licensure and at the beginning of each licensing period. Mobile food units operating at a specific or multiple locations shall provide a list of all locations to the regulatory authority.

Stat. Auth.: ORS 624.390
Stats. Implemented: ORS 624.390
Hist.: HD 10-1997, f. & cert. ef. 7-8-97; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-162-0940
Warehouses

(1) If only prepackaged goods are sold, a warehouse may be accepted in lieu of a commissary.

(2) Warehouses shall be required to meet only those rules necessary to prevent the contamination of stored foods, single-service articles, utensils and equipment. In general, warehouses shall be exempt from the rules relating to finished walls, ceilings or storage bases, light colored surfaces, restrooms, lavatories and utility facilities, provided foods are protected from contamination from dust, insects, rodents, flooding, drainage, or other contaminants.

(3) Handling of unpackaged foods, dishwashing and ice making are prohibited in a warehouse.

(4) The Assistant Director may impose additional requirements as deemed necessary to prevent the contamination of stored foods, single-service articles, utensils, and equipment.

Stat. Auth.: ORS 624.390
Stats. Implemented: ORS 624.390
Hist.: HD 10-1997, f. & cert. ef. 7-8-97; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06

333-162-0950
Memorandum of Commissary or Warehouse Usage/Verification

A Memorandum of Commissary or Warehouse Usage/Verification shall be on file with the administrator for mobile units using a licensed food service facility as a commissary or warehouse. This memorandum shall be on a form approved by the Authority, and be updated at least once per year.

Stat. Auth.: ORS 624.390
Stats. Implemented: ORS 624.390
Hist.: HD 10-1997, f. & cert. ef. 7-8-97; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-162-1005
Civil Penalties

(1) The Authority or a Local Public Health Authority may impose civil penalties on any person for the following willful violations:

(a) Operation of a mobile food unit, commissary, or warehouse without a current license to do so from the Authority or Local Public Health Authority;

(b) Failure to cease operation of a mobile food unit, commissary, or warehouse that has been closed due to uncorrected priority item violations. This authority shall be limited to those priority item violations identified as creating an imminent or present danger to public health and defined in OAR 333-150-0000 section 1-201.10(B).

(2) For the purposes of section (1) of this rule, the term 'willful' means intentional or deliberate.

(3) The maximum civil penalty for each of the violations listed in section (1) of this rule is $500 per day of violation.

(4) Civil penalties shall be imposed in the manner provided by ORS Chapter 183 or the equivalent.

Stat. Auth.: ORS 624.992
Stats. Implemented: ORS 624.992
Hist.: HD 10-1997, f. & cert. ef. 7-8-97; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

DIVISION 170

BED AND BREAKFAST FACILITIES

333-170-0000
Definitions

As used in OAR 333-170-0000 to and including 333-170-0130:

(1) "Appurtenant Structure" means a building that belongs to, is accessory or incident to, adjacent, appended or annexed to a single family residence. The single family residence and appurtenant structure must be on the same tax lot. Appurtenant structure includes but is not limited to a carriage house, garage, livery, pool or cabana building, guest cottage, bunkhouse, or similar building converted for human occupancy.

(2) "Bed and Breakfast Facility" means any establishment located in a structure designed for a single family residence and structures appurtenant thereto, regardless of whether the owner or operator of the establishment resides in any of the structures, which:

(a) Has more than two rooms for rent on a daily basis to the public;

(b) Offers a breakfast meal as part of the cost of the room;

(c) Serves one breakfast meal a day to guests, staff and owners, only.

(3) "Breakfast Meal" is the meal served to guests during the a.m. or morning hours each day.

(4) "Designated Employees' Restroom" means toilet room with handwashing lavatory accessible to employees only, during breakfast meal preparation and service.

(5) "Guests' Restroom" means toilet room located in the area of the guest rooms.

Stat. Auth.: ORS 624.100
Stats. Implemented: ORS 624.100
Hist.: HD 6-1988, f. & cert. ef. 4-4-88; HD 23-1988(Temp), f. & cert. ef. 9-23-88; HD 2-1989, f. & cert. ef. 1-31-89; HD 2-1992, f. 3-24-92, cert. ef. 3-30-92

333-170-0010
Application of Rules

(1) Except as otherwise set forth in ORS 624.041 and these rules, bed and breakfast facilities shall meet the applicable requirements in OAR 333-150-0000 of the Oregon Food Sanitation Rules.

(2) If more than nine bedrooms or accommodations for 19 or more persons are available on a daily basis, commercial grade dishwashing and separate refrigeration equipment must be provided.

Stat. Auth.: ORS 624.100
Stats. Implemented: ORS 624.100
Hist.: HD 6-1988, f. & cert. ef. 4-4-88; HD 2-1992, f. 3-24-92, cert. ef. 3-30-92; OHD 11-2002, f. & cert. ef. 8-7-02; PH 5-2004(Temp), f. & cert. ef. 2-13-04 thru 7-30-04; PH 15-2004, f. & cert. ef. 4-9-04; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-170-0020
Animal Restrictions

Bed and Breakfast Facilities shall be exempt from the provisions of OAR 333-150-0000 section 6-501.115 provided, however, that no live animal, bird, or turtle will be kept or allowed in any portion of the premises where food for the registered guests of the establishment is stored, prepared, served, offered for sale, or given away. Aquariums and aviaries shall be allowed if enclosed so as not to create a public health problem.

Stat. Auth.: ORS 624.041
Stats. Implemented: ORS 624.041
Hist.: HD 6-1988, f. & cert. ef. 4-4-88; OHD 11-2002, f. & cert. ef. 8-7-02; PH 5-2004(Temp), f. & cert. ef. 2-13-04 thru 7-30-04; PH 15-2004, f. & cert. ef. 4-9-04

333-170-0030
Equipment Replacement

Bed and Breakfast Facilities shall meet the provisions of OAR 333-150-0000 section 8-304.11 (G) and (H) except that replacement equipment and new equipment acquired after the effective date of these Bed and Breakfast rules may be of residential design, construction and installation. The equipment must be in good repair, capable of being maintained in a sanitary condition, have nontoxic food-contact surfaces and meet all other requirements of these rules.

Stat. Auth.: ORS 624.041
Stats. Implemented: ORS 624.041
Hist.: HD 6-1988, f. & cert. ef. 4-4-88; OHD 11-2002, f. & cert. ef. 8-7-02; 5-2004(Temp), f. & cert. ef. 2-13-04 thru 7-30-04; PH 15-2004, f. & cert. ef. 4-9-04

333-170-0040
Employee Change Rooms

Bed and Breakfast Facilities shall be exempt from the provisions of OAR 333-150-0000 sections 6-305.11, 6-403.11 (B) and 6-501.110 provided, however, that no person shall change clothes, store clothing or personal effects in any area used for the storage or preparation of food or for utensil washing or storage.

Stat. Auth.: ORS 624.041
Stats. Implemented: ORS 624.041
Hist.: HD 6-1988, f. & cert. ef. 4-4-88; OHD 11-2002, f. & cert. ef. 8-7-02; 5-2004(Temp), f. & cert. ef. 2-13-04 thru 7-30-04; PH 15-2004, f. & cert. ef. 4-9-04

333-170-0050
Dishwashing

(1) All food service utensils and equipment shall be scraped, cleaned, and/or sanitized as circumstances of use require.

(2) Bed and Breakfast Facilities shall comply with provisions of OAR 333-150-0000 for manual and/or mechanical cleaning and sanitizing of equipment and utensils, however, at the option of the owner or operator a domestic or homestyle dishwasher may be used provided the following performance criteria can be met:

(a) The dishwasher must effectively remove physical soil from all surfaces of dishes;

(b) The dishwasher must sanitize dishes either by the application of enough accumulative heat or by the application of adequate chemical solutions to the surface of the dish;

(c) Machines relying on heat for sanitizing shall produce heat unit equivalents in the final rinse and drying cycles which comply time and temperature relationships or equivalents listed in **Table 1** (155° F. minimum):

TABLE 1
155° F — 150 seconds
161° F — 30 seconds
165° F — 15 seconds
170° F — 5 seconds

(d) If machine or water line mounted thermometers which indicate temperature of the final rinse water as it enters the manifold are not provided, the operator shall provide and daily use a registering thermometer or thermopaper to check the temperature at the dish surface during the final sanitizing rinse and drying cycles;

(e) The dishwasher must be installed and operated according to manufacturer's instructions for the highest level of sanitization possible when sanitizing Bed and Breakfast Facilities' utensils; a copy of the instructions must be available on the premises at all times;

(f) The pressure of the final rinse water supplied to the dishwasher shall not be less than 15 nor more than 25 pounds per square inch, (psi);

(g) There shall be sufficient area or facilities such as portable dish tubs and drain boards for the proper handling of soiled utensils prior to washing and of cleaned utensils after sanitization so as not to interfere with safe food handling, handwashing and the proper use of dishwashing facilities.

Stat. Auth.: ORS 624.041
Stats. Implemented: ORS 624.041
Hist.: HD 6-1988, f. & cert. ef. 4-4-88; OHD 11-2002, f. & cert. ef. 8-7-02; 5-2004(Temp), f. & cert. ef. 2-13-04 thru 7-30-04; PH 15-2004, f. & cert. ef. 4-9-04

333-170-0060
Plumbing

Notwithstanding provisions of OAR 333-150-0000 sections 5-202.11 and 5-402.11, existing food preparation sinks and mechanical dishwashers in Bed and Breakfast Facilities are not required to have indirect sewer connections. However, any new food preparation sinks or dishwashers installed after the effective date of these rules or existing installations in which backflow has been demonstrated may be required to comply with the Oregon State Plumbing Specialty Code. In existing food preparation sinks which are directly plumbed and where food is placed in the sink below the rim then food must be placed in a container where the rim is above the flood rim of the sink. Bed and Breakfast Facilities shall meet OAR 333-150-0000 section 5-203.14, in preventing contamination of the potable water system. New plumbing in a Bed and Breakfast Facility shall be installed and maintained in accordance with the Oregon State Plumbing Specialty Code.

Stat. Auth.: ORS 624.041

Stats. Implemented: ORS 624.041
Hist.: HD 6-1988, f. & cert. ef. 4-4-88; OHD 11-2002, f. & cert. ef. 8-7-02; 5-2004(Temp), f. & cert. ef. 2-13-04 thru 7-30-04; PH 15-2004, f. & cert. ef. 4-9-04; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06

333-170-0070
Ventilation

Bed and Breakfast Facilities shall be exempt from the provisions of OAR 333-150-0000 sections 6-304.11 and 6-501.14(A), however, in the event that the inspecting sanitarian determines that sufficient ventilation must be mechanical in nature, such ventilation shall be installed and operated according to state and local code.

Stat. Auth.: ORS 624.041
Stats. Implemented: ORS 624.041
Hist.: HD 6-1988, f. & cert. ef. 4-4-88; OHD 11-2002, f. & cert. ef. 8-7-02; 5-2004(Temp), f. & cert. ef. 2-13-04 thru 7-30-04; PH 15-2004, f. & cert. ef. 4-9-04

333-170-0080
Construction

In Bed and Breakfast Facilities, only new and replacement walls and ceilings (or their coverings), constructed after the effective date of these rules need comply with OAR 333-150-0000 sections 6-201.11, 6-201.16 and 6-201.17 provided, however, that all walls and ceilings (and their coverings) must be in good repair and maintained in a clean and sanitary condition.

Stat. Auth.: ORS 624.041
Stats. Implemented: ORS 624.041
Hist.: HD 6-1988, f. & cert. ef. 4-4-88; OHD 11-2002, f. & cert. ef. 8-7-02; 5-2004(Temp), f. & cert. ef. 2-13-04 thru 7-30-04; PH 15-2004, f. & cert. ef. 4-9-04

333-170-0090
Utility Facilities

Bed and Breakfast Facilities shall be exempt from the provisions of OAR 333-150-0000 sections 5-203.13 and 6-306.10 provided, however, that hot water must be available for janitorial purposes. The use of handwashing lavatories, utensil-washing or equipment-washing or food preparation sinks for this purpose is prohibited.

Stat. Auth.: ORS 624.041
Stats. Implemented: ORS 624.041
Hist.: HD 6-1988, f. & cert. ef. 4-4-88; OHD 11-2002, f. & cert. ef. 8-7-02; 5-2004(Temp), f. & cert. ef. 2-13-04 thru 7-30-04; PH 15-2004, f. & cert. ef. 4-9-04

333-170-0100
Food Storage

Bed and Breakfast Facilities shall be exempt from the 333-150-0000 sections 6-202.111 and 6-202.112. However, no sleeping accommodations shall be allowed in any area where utensils are washed or where food is stored, prepared, or served.

Stat. Auth.: ORS 624.041
Stats. Implemented: ORS 624.041
Hist.: HD 6-1988, f. & cert. ef. 4-4-88; OHD 11-2002, f. & cert. ef. 8-7-02; 5-2004(Temp), f. & cert. ef. 2-13-04 thru 7-30-04; 5-2004(Temp), f. & cert. ef. 2-13-04 thru 7-30-04; PH 15-2004, f. & cert. ef. 4-9-04

333-170-0110
Food Source

All food intended for consumption by guests shall meet the Oregon Department of Agriculture requirements as being obtained from an approved source. The use of home canned foods and meat and dairy products from unapproved sources is prohibited, and the storage of such food items shall not be allowed in any area where food is prepared or served to guests.

Stat. Auth.: ORS 624.041
Stats. Implemented: ORS 624.041
Hist.: HD 6-1988, f. & cert. ef. 4-4-88; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-170-0120
Laundry Facilities

Bed and Breakfast Facilities shall be exempt from the provisions of OAR 333-150-0000 section 4-803.13 provided that food service laundry be laundered and stored separately from guest or resident laundry and laundry operations are separated from food preparation areas.

333-170-0130
Toilet and Handwashing Facilities

Toilet and handwashing facilities in bed and breakfast facilities shall comply with OAR 333-150-0000 of the Oregon Food Sanitation Rules except as follows:

(1) Bed and breakfast facilities are exempt from OAR 333-150-0000 sections 5-203.12 and 6-402.11 provided an employee restroom can be designated during meal preparation and service, and guests' restrooms are available. New toilet facilities shall be installed according to the Oregon State Plumbing Specialty Code.Pf

(2) Notwithstanding OAR 333-150-0000 section 4-501.16, handwashing facilities may be designated at a sink compartment used for dishwashing provided this sink is not being used to store or wash soiled dishes or prepare food during food preparation and service. Handwashing facilities, in the kitchen, shall be available at all times during food preparation and service. If facility operation results in handwashing facilities being unavailable, then a separate handwashing lavatory in the food preparation area shall be required.Pf

(3) Handwashing signs are required to be properly posted at all sinks designated for employee handwashing.

(4) Guests' restrooms not designated for food service worker use do not need to comply with Oregon Food Sanitation Rules.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 624.041
Stats. Implemented: ORS 624.041
Hist.: HD 6-1988, f. & cert. ef. 4-4-88; OHD 11-2002, f. & cert. ef. 8-7-02; 5-2004(Temp), f. & cert. ef. 2-13-04 thru 7-30-04; PH 15-2004, f. & cert. ef. 4-9-04; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

DIVISION 175

FOOD HANDLER TRAINING

333-175-0001
Purpose

The food handler training program rules set fees and address requirements for successful completion of a food handler training program and issuance of the certificate. Additionally, these rules set out general provisions regarding food handler training programs and provide guidelines for the relationship between the Oregon Health Authority, Local Public Health Authorities and Designated Agents.

Stat. Auth.: ORS 624.570
Stats. Implemented: ORS 624.570
Hist.: PH 21-2004, f. & cert. ef. 6-18-04

333-175-0011
Program Description — General

The program is a Authority-approved food handler training program provided through mechanisms such as self-training, computer-based training, or instructor-led training. The goal of the food handler training program is to provide food handlers with a basic understanding of food safety that will assist the manager or person in charge to direct the food handler in preparing and serving food safely. A certificate of program completion confirms that the food handler met the learning objectives.

Stat. Auth.: ORS 624.570
Stats. Implemented: ORS 624.570
Hist.: PH 21-2004, f. & cert. ef. 6-18-04; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06

333-175-0021
Definitions

(1) "Approved" means approved by the Oregon Health Authority.

(2) "Assessment" means to determine whether the food worker understood the concepts represented by the learning objectives. The assessment used by the program providers must be provided or approved by the Authority.

(3) "Authority" means the Oregon Health Authority, Foodborne Illness Prevention Program.

(4) "Certificate of Program Completion" confirms that a person has successfully completed the food handler training program.

(5) "Certified Food Manager" means that a manager has successfully completed an Authority-approved food manager program.

(6) "Computer-Based Training" means self-training through the use of a computer program or the Internet.

(7) "Designated Agent" means an individual or organization who/that has been authorized by the Oregon Health Authority or Local Public Health Authority to provide a food handler training program and issue certificates of program completion.

(8) "Food Handler" means those persons involved in the supervision or preparation or service of food in a restaurant or food service facility licensed under ORS 624.020 or 624.320. This includes, but is not limited to, managers, cooks, wait staff, dishwashers, bartenders and bus persons.

(9) "Local Public Health Authority" means those counties to which the Oregon Health Authority has entered into an Intergovernmental Agreement under ORS 624.510.

(10) "Program" means an Authority-approved food handler training program.

(11) "Program Provider" means the Oregon Health Authority, Local Public Health Authority or a Designated Agent.

(12) "Self-Training" means a training process wherein the individual learns without the presence or intervention of a trainer or instructor.

(13) "Trainer" means the person actively delivering food handler training to learners.

Stat. Auth.: ORS 624.570
Stats. Implemented: ORS 624.570
Hist.: PH 21-2004, f. & cert. ef. 6-18-04; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 11-2011, f. & cert. ef. 10-27-11

333-175-0031
Food Handler Training

(1) All food handlers employed in a restaurant, bed and breakfast, mobile unit, commissary, warehouse or vending operation must obtain a certificate of program completion from the Oregon Health Authority, Local Public Health Authority or a Designated Agent within 30 days after the date of hire. A food handler must maintain a current certificate of program completion as long as they are employed as a food handler.

(2) A food handler certificate of program completion expires three years after the date of issuance. When a food handler's certificate of program completion expires, the food handler must successfully complete the program and pay the appropriate fee.

(3) The Oregon Health Authority and Local Public Health Authority may provide food handler training themselves, through a Designated Agent or both.

(4) At least one person involved in the preparation or service of food in a temporary restaurant who has a valid certificate of program completion must be present at all times during the operation of the facility.

(5) A facility listed in section (1) of this rule that is operated by a benevolent organization must have at least one person with a valid food handler certificate of program completion present at all times during the preparation and service of food. This person is responsible for supervising and educating all workers in the sanitary practices used in food service.

Stat. Auth.: ORS 624.570
Stats. Implemented: ORS 624.570
Hist.: PH 21-2004, f. & cert. ef. 6-18-04; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06

333-175-0041
Minimum Standards for Program Providers

(1) In order for the Oregon Health Authority or Local Public Health Authority to appoint a Designated Agent, the individual or organization must demonstrate that they have sufficient experience in food safety, food science or food service to be knowledgeable in all areas of the food handler training curriculum, and at a minimum

are a certified food manager or registered environmental health specialist as defined by ORS 700. This staff member must be reasonably involved in the operation or administration of the training program delivery.

(2) Program providers must also have:

(a) The ability to provide training and an assessment; and

(b) The ability to safeguard the training and assessment materials.

(3) The Local Public Health Authority exercising duties pursuant to ORS 624.510 shall ensure that food handler training programs are provided within their jurisdiction. The Local Public Health Authority or Oregon Health Authority who authorized a Designated Agent is responsible for the proper program administration and delivery.

Stat. Auth.: ORS 624.570

Stats. Implemented: ORS 624.570

Hist.: PH 21-2004, f. & cert. ef. 6-18-04; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06

333-175-0051

Content of Food Handler Training Programs

The concept of foodborne illness shall be introduced. The training shall address personal hygiene, contamination, and temperature control to reinforce the notion that the food handler's behaviors can prevent foodborne illness. The following learning objectives must be included in the food handler training program:

(1) Foodborne Illness.

(a) The food handler shall be able to describe foodborne illness as an illness resulting from eating contaminated food.

(b) The food handler shall know food contaminated with organisms (known to cause illness) does not look, smell or taste different from food not contaminated.

(c) The food handler shall know that symptoms vary and may include diarrhea, vomiting, fever, cramping and nausea.

(d) The food handler shall know that depending on the cause, symptoms may develop in a few minutes to several days. Symptoms may last several days and can result in death.

(e) The food handler shall know that foodborne illness is caused by organisms known to cause illness, or is caused by chemicals.

(2) The Role of the Food Handler in Foodborne Illness.

(a) The food handler shall be able to describe the five major mistakes that cause foodborne illness. The five major mistakes are:

(A) Inadequate handwashing;

(B) Employees working while ill;

(C) Cross contamination;

(D) Inadequate final cooking temperatures; and

(E) Inadequate temperature control (allowing foods to be in the danger zone).

(b) The food handler shall be able to describe the activities performed by food handlers that prevent foodborne illness from happening. The activities that prevent foodborne illness are:

(A) Proper handwashing every time hands may have become contaminated;

(B) Food handlers working only when healthy;

(C) Storing and handling of foods in a manner to prevent contamination;

(D) Cook each animal product to its required final cooking temperature; and

(E) Maintaining hot and cold temperatures (keeping foods out of the danger zone).

(3) The Role of Management.

(a) The food handler shall know that the manager sets the tone of what food safety activities occur or don't occur within the facility.

(b) The food handler shall know that the food service management is responsible for training and ensuring that food handlers practice the activities that prevent foodborne illness.

(4) Handwashing.

(a) The food handler shall be able to identify the following as the correct technique for handwashing:

(A) Use warm water and soap;

(B) Scrub hands thoroughly (approximately 15-20 seconds); and

(C) Dry hands with single-use towel, cloth towel roll or air dryer.

(b) The food handler shall be able to identify the following situations for when food handlers must wash their hands:

(A) After handling raw food;

(B) After smoking, eating, or drinking;

(C) After handling dirty dishes or garbage;

(D) After cleaning or using other toxic materials; and

(E) Before putting on gloves.

(c) The food handler shall be able to identify the following situations for when food handlers must wash their hands twice:

(A) After using the toilet and again when entering the work area (double handwash);

(B) After blowing nose, sneezing, coughing, or touching eyes, nose or mouth (double handwash);

(C) Before starting work (double handwash); and

(D) Anytime hands come into contact with bodily fluids including cuts and burns (double handwash).

(d) The food handler shall know that food service gloves are capable of spreading germs and do not substitute for proper handwashing.

(e) The food handler shall know that smoking, eating, and chewing tobacco is prohibited in food preparation and food and utensil storage areas.

(5) Employee Illness.

(a) The food handler shall know to call the person in charge at the food service facility when ill with diarrhea, vomiting, fever, jaundice or sore throat with fever.

(b) The food handler shall know to not work in the food service facility while ill with these symptoms.

(c) The food handler shall know after experiencing vomiting or diarrhea that he or she must not work in food service for 24 hours after symptoms have gone.

(d) The food handler shall know to not handle food with an infected cut or infected burn on the hands and wrists, unless an impermeable cover protects the lesion and a single-use glove is worn over the impermeable cover.

(6) Contamination and Cross Contamination.

(a) The food handler shall be able to define and identify physical contamination as foreign objects accidentally introduced into food. Food items may arrive already contaminated with dirt, and pebbles.

(b) The food handler shall be able to define and identify cross contamination as happening when microorganisms are transferred from one food or surface to another food.

(c) The food handler shall be able to identify methods to prevent cross contamination such as wash, rinse, and sanitize utensils, work surfaces and equipment between uses.

(d) The food handler shall be able to identify the following storage conditions that shall minimize the potential for cross contamination:

(A) Store raw meats below and completely separate from ready-to-eat food in refrigeration units;

(B) Store chemicals, cleansers and pesticides completely separate from food, utensils, and single service items; and

(C) Properly label all chemicals, cleansers and pesticides.

(7) Final Cooking Temperature. The food handler shall be able to identify that cooking to the recommended temperature will kill disease-causing germs.

(8) Temperature Control.

(a) The food handler shall be able to identify that potentially hazardous food will support bacterial growth when held at temperatures between 41 degrees Fahrenheit and 135 degrees Fahrenheit. The danger zone is any temperature between 41 degrees Fahrenheit and 135 degrees Fahrenheit.

(b) The food handler shall be able to identify that food being cooled or heated must move through the danger zone as rapidly as possible.

(c) The food handler shall be able to identify 135 degrees Fahrenheit as the proper temperature for hot holding potentially hazardous food.

(d) The food handler shall be able to identify 41 degrees Fahrenheit as the proper temperature for cold holding.

(e) The food handler shall know that you cannot make food safe to eat when food has been in the danger zone for four hours or more.

Stat. Auth.: ORS 624.570
Stats. Implemented: ORS 624.570
Hist.: PH 21-2004, f. & cert. ef. 6-18-04; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-175-0061
Administration of Food Handler Training Program

(1) Program providers may provide the food handler training program through a trainer-led class and assessment, self-training materials and assessment or other method approved by the Authority.

(2) The Authority must provide or approve all food handler training program materials, including instructional delivery methods, materials and assessment tools based on criteria established by the Authority.

(3) Each food handler training assessment must determine that the food worker met the learning objectives stated in OAR 333-175-0051.

(4) When being assessed, food handlers may refer to the training manual or printed text. Food handlers may also refer to handwritten notes developed onsite during training.

(5) Upon successful completion of the program, the food handler must be allowed to keep the food handler training materials distributed.

(6) Workers with special needs may be allowed the option to take the assessment orally on specific job duties or to receive assistance in reading the assessment.

(7) A restricted certificate of program completion may be issued according to Authority guidelines.

(a) The certificate must identify the specific duties that may be performed by this individual;

(b) Removal of the restrictions can be accomplished by successfully completing the food handler training program. The food handler will then be issued a new certificate of program completion.

(8) Program providers, if requested, must provide food handlers specific feedback on the assessment questions missed.

(9) Program providers will ensure that a knowledgeable person is available to answer questions about the assessment and program content. It is not necessary that the knowledgeable person be present at all times to answer questions.

(10) Program providers will rotate the written assessment versions at least quarterly.

(11) At least triennially or when deemed necessary, the Oregon Health Authority or Local Public Health Authority that approved the Designated Agent will perform an onsite review of the training programs. The review will examine:

(a) Written assessment security, including rotation, physical security, and compliance with availability of reference materials during assessment;

(b) Instructor qualification and availability of qualified assistance for individuals with questions on the training materials.

(12) Annually, program providers will submit information to the Authority on the number of assessments taken for the year and the number of assessments passed by assessment type (e.g., language, written, oral, and online).

(13) Failure to follow rules may result in the removal of the ability of a program provider to provide food worker training:

(a) Upon failure to follow rules, unless immediately correctable, the program provider will develop a remediation plan. The Local Public Health Authority or the Oregon Health Authority that approved the training will follow up within 90 days to ensure that the program provider is in compliance with training requirements. The Local Public Health Authority or the Oregon Health Authority may allow for additional time to achieve compliance with the training requirements;

(b) Continued failure to achieve compliance with the training requirements will result in the termination of the program provider's training approval.

(14) Program provider shall take reasonable measures to ensure identity of food worker being assessed.

Stat. Auth.: ORS 624.570
Stats. Implemented: ORS 624.570
Hist.: PH 21-2004, f. & cert. ef. 6-18-04; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06

333-175-0071
Requirements for Food Handler Training Program Qualifications

(1) Any trainer providing food handler training must either be a Registered Environmental Health Specialist, Registered Environmental Health Specialist Trainee or have a current certificate of completion from an approved food manager training course or the equivalent as determined by the Authority.

(2) Trainer requirements do not apply when food handlers are trained using self-training materials.

Stat. Auth.: ORS 624.570
Stats. Implemented: ORS 624.570
Hist.: PH 21-2004, f. & cert. ef. 6-18-04; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06

333-175-0081
Successful Completion of Food Handler Training Program

(1) In order to receive a certificate of program completion, a food handler must pass the written assessment with a minimum score of 75%.

(2) If a person successfully completes a food handler training program and pays the appropriate fee, the program provider shall issue a certificate of program completion.

Stat. Auth.: ORS 624.570
Stats. Implemented: ORS 624.570
Hist.: PH 21-2004, f. & cert. ef. 6-18-04; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06

333-175-0091
Reciprocity and Equivalency

(1) A food handler certificate of program completion is valid statewide.

(2) Any person who has a current certification from an Authority-approved food manager training program or is registered as an Environmental Health Specialist or Environmental Health Specialist Trainee as required in ORS Chapter 700 need not obtain a food handler certificate of program completion.

(3) To be accepted in lieu of a food handler certificate of program completion, a food manager certification must be renewed every five years.

Stat. Auth.: ORS 624.570
Stats. Implemented: ORS 624.570
Hist.: PH 21-2004, f. & cert. ef. 6-18-04; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06; PH 12-2012, f. 8-30-12, cert. ef. 9-4-12

333-175-0101
Fees

(1) Program providers may charge a fee up to a maximum of $10 per person for the administration of the program and the issuance of a certificate of program completion.

(2) Program providers shall not require a fee of any food handler listed in OAR 333-175-0091.

(3) Program providers may charge a fee for food handler materials and deduct the cost from the food handler training and certificate of program completion as long as the total cost does not exceed $10 to each individual.

(4) Notwithstanding sections (1) and (3) of this rule, program providers may assess a new program fee each time a participant takes or retakes all or part of a program or certification assessment.

(5) Program providers may charge a fee not to exceed $5 for duplicate certificates of program completion.

Stat. Auth.: ORS 624.570
Stats. Implemented: ORS 624.570

Hist.: PH 21-2004, f. & cert. ef. 6-18-04; PH 14-2006, f. 6-27-06, cert. ef. 7-1-06

333-175-0111
General

(1) Upon request by the Oregon Health Authority or a Local Public Health Authority, a licensee of a facility licensed under ORS 624.020 or 624.320 shall make available the certificate of program completion for each food handler in the licensed facility. For purposes of complying with this rule, the licensee may keep photocopies of the food handler certificates of program completion.

(2) If a food handler uses their food manager training program certification in lieu of a food handler certificate of program completion, the licensee shall make available to the inspecting authority the food handler's food manager training certification.

(3) Consistent with civil rights and disability laws, all program providers will make reasonable accommodations for training workers with disabilities, including the issuing of restricted certificates of program completion, and providing culturally, developmentally, and linguistically appropriate training.

(4) The Local Public Health Authority that approves a Designated Agent must provide the Oregon Health Authority with the name, address and telephone number of the individual or organization that has been approved. Such notification must be in writing and must occur before the Designated Agent can commence training and/or certification of food workers.

Stat. Auth.: ORS 624.570
Stats. Implemented: ORS 624.570
Hist.: PH 21-2004, f. & cert. ef. 6-18-04

DIVISION 200

EMERGENCY MEDICAL SERVICES AND SYSTEMS

333-200-0000
Purpose

The purpose of these rules is to establish the procedures and standards for the development and maintenance of a comprehensive statewide trauma system as set forth under ORS 431.575 through 431.671.

Stat. Auth.: ORS 431.611
Stats. Implemented: ORS 431.575 – ORS 431.671
Hist.: HD 17-1985(Temp), f. & ef. 9-20-85; HD 5-1987, f. & ef. 6-26-87; PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-200-0010
Definitions

As used in OAR 333-200-0000 through 333-200-0295:

(1) "Area Trauma Advisory Board" (ATAB) means an advisory group appointed by the Authority for each established trauma area to represent providers of trauma care and members of the public.

(2) "Authority" means the Oregon Health Authority.

(3) "Categorization" means a process for determining the level of a hospital's trauma care capability and commitment which allows any hospital which meets criteria to receive trauma patients.

(4) "Communications Coverage Area" means a geographic region representing a primary radio service area for emergency medical communications. When primary service areas substantially overlap they will be considered as one coverage area.

(5) "Coordinated Care Organization" has the meaning given that term in OAR 410-141-0000.

(6) "Designation" means a competitive process for determining the level of a hospital's trauma care capability and commitment, allowing the Division to select a limited number of hospitals which meet criteria to receive trauma patients.

(7) "Division" means the Public Health Division of the Oregon Health Authority.

(8) "Emergency Medical Condition" means a medical condition that manifests itself by symptoms of sufficient severity that a prudent layperson possessing an average knowledge of health and medicine would reasonably expect that failure to receive immediate medical attention would place the health of a person, or a fetus, in the case of a pregnant woman, in serious jeopardy.

(9) "Emergency Medical Services Agency" (EMS Agency) has the meaning given that term in OAR 333-265-0000.

(10) "Emergency Medical Responder" means a person who is licensed by the Division as an Emergency Medical Responder.

(11) "Emergency Medical Services Provider" (EMS Provider) means a person who is licensed by the Division as an Emergency Medical Responder or an Emergency Medical Technician.

(12) "Emergency Medical Technician" (EMT) means a person who is licensed by the Division as an Emergency Medical Technician.

(13) "Glasgow Coma Scale" (GCS) means an internationally recognized scoring system for the assessment of head injury severity and degree of coma.

(14) "Hospital" has the meaning set forth in ORS 442.015(15).

(15) "Hospital Catchment Area" means a geographic region representing a primary service area for hospitals. When primary service areas substantially overlap they shall be considered as one catchment area.

(16) "Injury Severity Score" (ISS) means a method for quantifying the degree of anatomic injury. As described in Baker, S.P., O'Neill B., Haddon W. Jr., et al: The Injury Severity Score, Journal of Trauma, 1974, 14: 187-196.

(17) "Level I (Regional) Trauma Hospital" means a hospital which is categorized or designated by the Division as having met the trauma hospital resource standards for a Level I hospital, as described in Exhibit 4. Level I hospitals manage severely injured patients, provide trauma related medical education and conduct research in trauma care.

(18) "Level II (Area) Trauma Hospital" means a hospital categorized or designated by the Division as having met the trauma hospital resource standards for a Level II hospital, as described in Exhibit 4. Level II hospitals manage the severely injured patient.

(19) "Level III (Local) Trauma Hospital" means a hospital categorized or designated by the Division as having met the trauma hospital resource standards for a Level III hospital, as described in Exhibit 4. Level III hospitals provide resuscitation, stabilization, and assessment of the severely injured patient and provide either treatment or transfer the patient to a higher level trauma system hospital as described in Exhibit 5.

(20) "Level IV (Community) Trauma Hospital" means a hospital categorized or designated by the Division as having met the hospital resource standards for a Level IV hospital, as described in Exhibit 4. Level IV hospitals provide resuscitation and stabilization of the severely injured patient prior to transferring the patient to a higher level trauma system hospital.

(21) "Managed Health Care Organization" means a health care provider or a group or organization of medical service providers that provide for the delivery of an agreed upon set of medical or referral services for an enrolled group of individuals and families in a defined geographic area at a fixed periodic rate paid per enrolled individual or family.

(22) "Medical Direction" means physician responsibility for the operation and evaluation of prehospital emergency medical care performed by emergency care providers.

(23) "Off-Line Medical Direction" means the direction provided by a physician to prehospital emergency medical care providers through communications such as written protocols, standing orders, education and quality improvement reviews.

(24) "On-Line Medical Direction" means the direction provided by a physician to prehospital emergency medical care providers through radio, telephone, or other real time communication.

(25) "Oregon Trauma Registry" means the trauma data collection and analysis system operated by the Division.

(26) "Prehospital Response Time" means the length of time between the notification of a provider and the arrival of that provider's emergency medical service unit(s) at the incident scene.

(27) "Stabilization" means that, within reasonable medical probability, no material deterioration of an emergency medical condition is likely to occur.

(28) "State Trauma Advisory Board" (STAB) means an advisory group appointed by the Authority to represent providers of trauma care.

(29) "Trauma Patient" means a person who at any time meets field triage criteria for inclusion in the Oregon Trauma System, as described in Exhibit 2 of these rules.

(30) "Trauma System Hospital" means a hospital categorized or designated by the Division to receive and provide services to trauma patients.

(31) "Trauma System Plan" means a document which describes the policies, procedures and protocols for a comprehensive system of prevention and management of traumatic injuries.

(32) "Triage Criteria" means the parameters established to identify trauma patients for treatment in accordance with the trauma system plan. These criteria are set forth in Exhibit 2.

[ED. NOTE: Exhibits & Publications referenced are available from the agency.]

Stat. Auth.: ORS 431.611

Stats. Implemented: ORS 431.611

Hist.: HD 5-1987, f. & ef. 6-26-87; HD 9-1993, f. 6-22-93, cert. ef. 7-1-93; HD 7-1995, f. & cert. ef. 11-6-95; OHD 6-2000, f. & cert. ef. 5-4-00; OHD 6-2001, f. & cert. ef. 4-24-01; PH 16-2012, f. 12-20-12, cert. ef. 1-1-13; PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-200-0020
Objectives of the Trauma System

The objective of the statewide trauma system is to reduce deaths and disabilities which result from traumatic injuries by:

(1) Identifying the causes of traumatic injuries and recommending, promoting, and coordinating prevention activities;

(2) Developing a statewide trauma system plan to assure timely, quality, definitive care through coordinated identification, transportation and treatment of trauma patients:

(a) The statewide trauma system plan shall be composed of seven area plans; and

(b) Each area trauma system plan shall consist of policies, procedures, and protocols which address each of the following trauma system components:

(A) Communication and dispatch;

(B) Responders and prehospital response times;

(C) Medical direction and treatment;

(D) Triage and transportation;

(E) Hospital resources;

(F) Inter-hospital transfers;

(G) Rehabilitation;

(H) Quality improvement;

(I) Education and research;

(J) Prevention; and

(K) Disaster management.

(3) Adopting the standards, policies and procedures necessary to unify area trauma system plans into a statewide trauma system; and

(4) Promoting quality treatment, education, research and prevention of traumatic injuries utilizing as a model **Resources for Optimal Care of the Injured Patient: Committee on Trauma, American College of Surgeons, 2014 and the Guidelines for Field Triage of Injured Patients, Recommendations of the National Expert Panel on Field Triage, 2011; Centers for Disease Control and Prevention, MMWR, January 13, 2012, Vol. 61, No. 1.**

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 431.611

Stats. Implemented: ORS 431.575, 431.609, 431.611, 431.613 & 431.619Hist.: HD 17-1985(Temp), f. & ef. 9-20-85; HD 5-1987, f. & ef. 6-26-87; HD 9-1993, f. 6-22-93, cert. ef. 7-1-93; HD 7-1995, f. & cert. ef. 11-6-95; OHD 6-2000, f. & cert. ef. 5-4-00; OHD 6-2001, f. & cert. ef. 4-24-01; PH 16-2012, f. 12-20-12, cert. ef. 1-1-13; PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-200-0030
State Trauma Advisory Board Functions

(1) The STAB is established in accordance with ORS 431.580.

(2) The STAB shall:

(a) Advise the Division with respect to the development of a comprehensive emergency medical services and trauma system including meeting the objectives established in OAR 333-200-0020;

(b) Advise the Division on the adoption of rules, policies, and procedures regarding the trauma system;

(c) Analyze data related to prevention of injuries, monitoring of the trauma system and recommend improvements where indicated; and

(d) Suggest improvements to the emergency medical services and trauma system.

(3) In satisfying its duties described in section (2) of this rule, the STAB shall:

(a) Make evidence-based decisions that emphasize the standard of care attainable throughout the state and individual communities; and

(b) Seek the advice and input of coordinated care organizations or other managed care organizations.

(4) The Division shall seek the advice of the STAB concerning the approval of area trauma system plans and approval of subsequent protocols for major modifications.

(5) A majority of the members of the STAB shall constitute a quorum in order to conduct business.

(6) Official action taken by the STAB requires the approval of the majority of the members.

Stat. Auth.: ORS 431.611

Stats. Implemented: ORS 431.580 & 431.613

Hist.: HD 17-1985(Temp), f. & ef 9-20-85; HD 5-1987, f. & ef. 6-26-87-93, cert. ef. 71-93; OHD 6-2000, f. & cert. ef. 5-4-00; PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-200-0035
State Trauma Advisory Board Appointments

(1) The STAB shall consist of a minimum of 17 members. These members shall represent each of the seven ATABs. A STAB member may also be a member of an ATAB.

(2) Members of the STAB shall be chosen in accordance with the provisions of ORS 431.580.

(3) Appointment for STAB members shall be as follows:

(a) Terms shall be for four years;

(b) Vacancies shall be filled by the Authority in concurrence with the Governor;

(c) Members may be reappointed but may not serve consecutive terms;

(d) With the exception of Level I trauma hospitals, members may not be appointed from the same trauma hospital in consecutive terms; and

(e) A member serves at the pleasure of the director of the Authority.

(4) The STAB may recommend to the Authority that:

(a) Membership be expanded to improve coordination of the trauma care system; and

(b) Provider specialty positions are considered for board appointment.

(5) A public member who has an economic interest in the provision of emergency medical services or trauma care may not be appointed to serve on the STAB.

Stat. Auth.: ORS 431.580 & 431.611

Stats. Implemented: ORS 431.609

Hist.: OHD 6-2000, f. & cert. ef. 5-4-00; OHD 6-2001, f. & cert. ef. 4-24-01; PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-200-0040
Trauma System Areas

The Division has established seven trauma system areas utilizing county lines, zip codes, township and range, and roads for the purpose of developing, implementing and monitoring the trauma system and not for the purpose of restricting patient referrals. The trauma system areas are illustrated in Exhibit 1 and are:

(1) Area 1: Clackamas County; Clatsop County; Columbia County; Multnomah County; Tillamook County (except zip codes 97122, 97135 and 97149); Washington County; and Yamhill County (zip codes 97115, 97119, 97123, 97132, 97140 and 97148 only);

(2) Area 2: Benton County; Lincoln County; Linn County; Polk County; Marion County; Tillamook County (zip codes 97122, 97135 and 97149 only); and Yamhill County (except zip codes 97115, 97132 and 97148);

(3) Area 3: Coos County; Curry County (zip codes 97450, 97465, and 97476 only); Douglas County; and Lane County;

(4) Area 5: Curry County (zip codes 97406, 97415 and 97444 only); Jackson County; and Josephine County;

(5) Area 6: Gilliam County; Hood River County; Sherman County; and Wasco County (except zip codes 97001, 97057 and 97761);

(6) Area 7: Crook County; Deschutes County; Grant County; Harney County; Jefferson County; Klamath County; Lake County; Wasco County (zip codes 97001, 97057 and 97761 only); and Wheeler County; and

(7) Area 9: Baker County, Malheur County, Morrow County; Umatilla County; Union County; and Wallowa County.

[ED. NOTE: Exhibits referenced are available from the agency.]

Stat. Auth.: ORS 431.611

Stats. Implemented: ORS 431.609

Hist.: HD 17-1985(Temp), f. & ef. 9-20-85; HD 5-1986, f. & ef. 6-26-87; HD 16-1987, f. & ef. 10-9-87; HD 9-1993, f. 6-22-93, cert. ef. 7-1-93; HD 7-1995, f. & cert. ef. 11-6-95; OHD 6-2000, f. & cert. ef. 5-4-00; OHD 6-2001, f. & cert. ef. 4-24-01; PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-200-0050
Area Trauma Advisory Board Functions

(1) Area Trauma Advisory Boards (ATAB) are established in accordance with ORS 431.613;

(2) Each ATAB shall:

(a) Act as liaison between the providers and general public in their area and the STAB and the Division for exchanging information about trauma system issues and developing an area-wide consensus;

(b) Advise the STAB and the Division on the adoption of rules, policies and procedures regarding area trauma system plans;

(c) Recommend to the Division an area trauma system plan which meets the standards and objectives of these rules;

(d) Participate in the promotion and function of the implemented area trauma system plan by making recommendations to the Division and the area trauma care providers; and

(e) Provide an annual report to the Division which describes a review and any recommended modifications of the area trauma system plan.

Stat. Auth.: ORS 431.611

Stats. Implemented: ORS 431.613

Hist.: HD 17-1985(Temp), f. & ef. 9-20-85; HD 5-1987, f. & ef. 6-26-87; HD 9-1993, f. 6-22-93, cert. ef. 7-1-93; HD 7-1995, f. & cert. ef. 11-6-95; OHD 6-2000, f. & cert. ef. 5-4-00; PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-200-0060
Area Trauma Advisory Board Appointments

(1) Each ATAB shall consist of at least 15 members who shall be broadly representative of the trauma area as a whole.

(2) Appointments to the ATABs shall be in accordance with the provisions of ORS 431.613.

(3) Terms of appointment for ATAB members shall be as follows:

(a) Terms shall be for a period of three years;

(b) Vacancies shall be filled by appointment by the Authority in concurrence with the Governor;

(c) Members may serve unlimited terms at the discretion of the Division; and

(d) Members are subject to removal with cause by the Division.

(4) ATABs may recommend to the Division that:

(a) Membership be expanded in order to improve coordination of the area trauma system; and

(b) Provider specialty positions are considered for ATAB appointments.

Stat. Auth.: ORS 431.611

Stats. Implemented: ORS 431.613

Hist.: HD 17-1985(Temp), f. & ef. 9-20-85; HD 5-1987, f. & ef. 6-29-87; HD 9-1993, f. 6-22-93, cert. ef. 7-1-93; HD 7-1995, f. & cert. ef. 11-6-95; OHD 6-2000, f. & cert. ef. 5-4-00; PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-200-0070
Approval of Area Trauma System Plans

(1) Each ATAB shall recommend to the Division an area trauma system plan and, when deemed necessary by the Division or the ATAB, modifications to the plan.

(2) Area trauma system plans shall meet the minimum standards established in OAR 333-200-0080.

(3) The Division may grant waivers from one or more standards contained in OAR 333-200-0080, in an area trauma system plan if the ATAB can demonstrate, or the Division finds that compliance with such standards is inappropriate because of special circumstances which would render compliance unreasonable, burdensome or impractical. Such waivers may be limited in time or may be conditioned as necessary to protect the public welfare.

(4) The Division shall seek the advice of the STAB concerning the approval of area trauma system plans and approval of subsequent proposals for major modifications.

(5) All approved area trauma system plans shall be considered the standard of care for the area covered by the plan.

(6) Each ATAB shall review its area trauma system plan at least once every five years and submit to the Division:

(a) A copy of the plan; and

(b) A description of any proposed changes including a statement about why such changes are necessary.

Stat. Auth.: ORS 431.611

Stats. Implemented: ORS 431.609, 431.611, 431.613

Hist.: HD 5-1987, f. & ef. 6-26-87; HD 9-1993, f. 6-22-93, cert. ef. 7-1-93; HD 7-1995, f. & cert. ef. 11-6-95; OHD 6-2000, f. & cert. ef. 5-4-00; PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-200-0080
Standards for Area Trauma System Plans

Area trauma system plans shall describe how each of the following standards are met or exceeded. Interpretation and implementation of the standards as set forth in this rule shall be in general accordance with the guidelines of the **Resources for Optimal Care of the Injured Patient: Committee on Trauma, American College of Surgeons, 2014**. For the purposes of section (4) of this rule, interpretation and implementation of standards shall be in general accordance with the **Guidelines for Field Triage of Injured Patients, Recommendations of the National Expert Panel on Field Triage, 2011; Centers for Disease Control and Prevention, MMWR, January 13, 2012, Vol. 61, No. 1**:

(1) Communications and Dispatch:

(a) System Access: Residents and visitors in a communications coverage area shall be able to access emergency medical services by calling 9-1-1 as set forth in ORS 403.115;

(b) Dispatch Response: Dispatchers for emergency medical care providers shall have protocols which include pre-arrival patient care instructions and which require the dispatch of the appropriate level of available responding units (Basic, Intermediate or Advanced Life Support) based on medical need;

(c) Special Resources: All emergency medical services dispatchers shall maintain an up-to-date list of available law enforcement agencies, fire departments, air and ground ambulance services, quick response units that respond to an ill or injured person to provide initial emergency medical care prior to transportation by an ambulance and special responders for extrication, water rescue, hazardous material incidents and protocols for their use;

(d) Prehospital/Hospital: Ambulances shall have either a UHF or VHF radio that will provide reliable communications between the ambulance and central dispatch, the receiving hospital, and online medical direction. If the information has to be relayed through the dispatching agency, that agency shall be responsible to relay patient information to the hospital; and

(e) Training: There shall be training and certification standards for all tele-communicators that process telephone requests for or dispatch emergency care providers. The authorization to establish

these standards is the responsibility of the Department of Public Safety Standards and Training in accordance with ORS 181.640.

(2) Responders and Prehospital Response Times:

(a) Ambulance Service Areas (ASAs): The existing ASAs shall be described as well as a summary of the ATAB's efforts to promote each county adopting an ASA plan in accordance with ORS 682.062;

(b) Prehospital Response Times: Trauma system patients shall receive prehospital emergency medical care within the following prehospital response time parameters 90 percent of the time:

(A) Urban area, an incorporated community of 50,000 or more population — 8 minutes;

(B) Suburban area, an area which is not urban and which is contiguous to an urban community. It includes the area within a 10-mile radius of that community's center. It also includes areas beyond the 10-mile radius which are contiguous to the urban community and have a population density of 1,000 or more per square mile — 15 minutes;

(C) Rural area, a geographic area 10 or more miles from a population center of 50,000 or more, with a population density of greater than six persons per square mile — 45 minutes;

(D) Frontier area, the areas of the state with a population density of six or fewer persons per square mile and are accessible by paved roads — 2 hours; and

(E) Search and rescue area, the areas of the state that are primarily forest, recreational or wilderness lands that are not accessible by paved roads or not inhabited by six or more persons on a year round basis. — No established prehospital response time.

(c) Field Command: A uniform policy shall assign responsibility for directing the care of the trauma patient in the prehospital setting in cases of response by multiple providers to assure scene control by the most qualified responder;

(d) Utilization of Air Ambulance: Protocols for the medical direction, activation and utilization of air ambulance service(s) shall be established;

(e) Prehospital Care Report Form: All prehospital emergency care providers shall use a patient care report form as defined in OAR 333-255-0000; and

(f) Utilization of Oregon Trauma System Identification Bracelet: All prehospital emergency medical care providers shall use the official Public Health Division numbered Trauma System Identification Bracelet when the patient meets trauma system entry criteria or is entered into the Trauma System and notify the receiving trauma hospital of the incoming patient. The prehospital emergency medical care provider shall record the number on the patient's prehospital care report.

(3) Medical Direction and Treatment:

(a) Protocols, Policies and Procedures: Providers in each trauma system area shall function under an effective and coordinated set of off-line prehospital trauma protocols and on-line medical direction trauma policies and procedures which address basic, intermediate and advanced levels of care. Off-line treatment protocols shall clearly describe all treatment and transportation procedures and identify those procedures which require on-line medical authorization. Medical direction policies and procedures must assure consistent area-wide coordination, data collection and area-wide quality improvement responsibility;

(b) Hospital Status: In the event that on-line medical direction serves two or more categorized or designated hospitals, there shall be a system for medical direction to continuously determine the current status of hospital trauma care capabilities; and

(c) Physician Qualifications: On-line medical direction physicians must be qualified for this role by virtue of training, experience and interest in prehospital trauma care as demonstrated through emergency medicine and Advanced Trauma Life Support (ATLS) training in accordance with the American College of Surgeons ATLS course.

(4)(a) Triage and Transportation: Triage and transportation protocols shall be written to ensure that patients who at any time meet field triage criteria as set forth in Exhibit 2 will be transported directly to a categorized trauma hospital as described under OAR 333-200-0090. The protocols must be based on field triage criteria (Exhibit 2) and identify the following:

(A) Which patients are appropriate for transport to a Level I, II, III or IV trauma hospital based on the capabilities of the hospitals in the ATAB;

(B) Conditions in which an ambulance may bypass a Level III or IV trauma hospital in order to transport directly to a Level I or II trauma hospital; and

(C) Conditions in which air transport should be considered for transport directly to a Level I or II trauma hospital.

(b) Triage and transportation protocols shall be followed unless otherwise advised by on-line medical direction or under the following circumstances:

(A) If unable to establish and maintain an adequate airway, the patient shall be taken to the nearest hospital to obtain definitive airway control. Upon establishing and maintaining airway control, the patient shall be immediately transferred to a Level I or Level II trauma hospital;

(B) If the scene time plus transport time to a Level I or Level II trauma hospital is significantly greater than the scene time plus transport time to a closer Level III or Level IV trauma hospital;

(C) If the hospital is unable to meet hospital resource standards as defined in Exhibit 4, when there are multiple patients involved, or the patient needs specialty care; or

(D) If on-line medical direction overrides these standards for patients with special circumstances, such as membership in a health maintenance organization, and if the patient's condition permits.

(E) Application of paragraphs (B), (C), and (D) of this subsection must not delay definitive medical or surgical treatment.

(5) Hospital Resources:

(a) Trauma System Hospital Identification: Either the categorization or designation method of identifying trauma system hospitals as described under OAR 333-200-0090(1), (3) and (4) shall be recommended to the Division; and

(b) Resource Criteria: Trauma system hospitals shall meet or exceed the trauma hospital resource standards as set forth in Exhibit 4 and hospital activation criteria as set forth in Exhibit 3. Area criteria that exceed the criteria set forth in Exhibit 4 shall be accompanied by an informational statement of the additional costs that a hospital will incur to meet these standards.

(6) Inter-hospital Transfers:

(a) Identification of Patients: ATAB-wide criteria which meet or exceed any of the criteria set forth in Exhibit 5 of these rules shall be established to identify patients who should be transferred to a Level I or II trauma system hospital or specialty care center.

(b) When it is determined that a patient transfer is warranted:

(A) The transfer shall take place after the stabilization of the patient's emergency medical condition has been provided within the capabilities of the local hospital, which may include operative intervention; and

(B) The transfer to a Level I or II trauma hospital shall not be delayed for diagnostic procedures that have no impact on the transfer process or the immediate need for resuscitation.

(c) In all situations regarding an inter-hospital transfer, the decision to retain or transfer the patient shall be based on medical knowledge, experience and resources available to the patient.

(d) The hospital's trauma performance improvement and patient safety process shall monitor all cases meeting inter-hospital transfer criteria. The Division, through annual reports and site surveys, shall monitor this performance category.

(7) Inter-hospital Transfers with Health Maintenance Organizations:

(a) Trauma system hospitals shall facilitate the transfer of a member of a health maintenance organization or other managed health care organization when the emergency medical condition of the member permits and no deterioration of that condition is likely to result from or occur during the transfer of the patient. Trauma system hospitals shall transfer a patient in accordance with the provisions of ORS 431.611(2)(a) and (b) and any other applicable laws or regulations.

(b) A patient will be deemed stabilized, if the treating physician attending to the patient in the trauma hospital has determined, within reasonable clinical confidence, that the emergency medical condition has been resolved.

(c) Hospitals or health maintenance organizations may not attempt to influence patients and families, prior to the patient's stabilization, into making decisions affecting their trauma treatment by informing them of financial obligations if they remain in the trauma facility.

(d) Health maintenance organizations and non-designated trauma facilities shall report follow-up information to the transferring trauma system hospital and all required data as set forth in the Oregon Trauma Registry Data Dictionary; and

(e) Hospitals or health maintenance organizations that receive or transfer trauma patients shall participate in regional quality improvement activities.

(8) Rehabilitation Resources:

(a) Capabilities for trauma rehabilitation in each trauma system area and transfer procedures to other rehabilitation facilities shall be described; and

(b) Rehabilitation resources for burns, pediatrics, neurotrauma and extended care shall be included.

(9) Quality improvement:

(a) Provisions shall be made for at least quarterly review of medical direction, prehospital emergency medical care and hospital care of trauma cases:

(A) Area-wide criteria for identifying trauma cases for audit shall be described and shall include all trauma related deaths;

(B) Responsibility for identifying and reviewing all trauma cases meeting audit criteria shall be assigned; and

(C) Quarterly reports shall be submitted to the Division by the ATAB or its representative on confidential forms.

(b) The ATAB, STAB, all Area and State Quality Improvement Committee(s) and the Division shall meet in executive session as set forth in ORS 192.660 when discussing individual patient cases; and

(c) No member of any ATAB, the STAB, or any committee, subcommittee or task force thereof, shall disclose information or records protected by ORS 431.627 or 41.675 to unauthorized persons. Any person violating these rules shall be immediately removed by the Division from membership on any trauma system committee, subcommittee or task force thereof.

(10) Education and Research:

(a) Trauma Training: Trauma system hospitals shall provide or assist in the provision of prehospital trauma management courses to all EMS Providers involved in the prehospital emergency medical care of severely injured patients; and

(b) Research: In areas with Level I hospitals, clinical and basic research in trauma and publication of results involving surgical and nonsurgical specialists, nurses, and allied health professionals engaged in trauma care, shall be promoted.

(11) Prevention:

(a) Public Education: Public education and awareness activities shall be developed by trauma system hospitals to increase understanding of the trauma system and injury prevention. These activities shall be appropriate to the size and resources of the area; and

(b) Development and Evaluation: Trauma prevention activities to identify and address area problems shall be supported.

(12) Disaster Management: Provisions for addressing triage of trauma system patients to non-trauma hospitals during a natural or manmade disaster must be addressed and include:

(a) Implementation and termination of the disaster management plan; and

(b) Reporting requirements of the Oregon Trauma Registry and Oregon Trauma Program.

[ED. NOTE: Exhibits & Publications referenced are available from the agency.]

Stat. Auth.: ORS 431.611

Stats. Implemented: ORS 431.609 & 431.611

Hist.: HD 5-1987, f. & ef. 6-26-87; HD 9-1993, f. 6-22-93, cert. ef. 7-1-93; HD 7-1995, f. & cert. ef. 11-6-95; HD 5-1997, f. & cert. ef. 3-12-97; OHD 6-2000, f. & cert. ef. 5-4-00; OHD 6-2001, f. & cert. ef. 4-24-01; PH 16-2012, f. 12-20-12, cert. ef. 1-1-13; PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-200-0090
Trauma Hospital Approval and Categorization

(1) The Division shall approve trauma system hospitals by levels of care capability as defined by the standards contained in Exhibit 4 and by any criteria contained in the approved area plan. Approval will be renewed every three years if the hospital submits an application for renewal, and if the Division's review finds that the hospital continues to meet the prescribed standards in Exhibit 4.

(2) Upon determining the level of a hospital's trauma care capability and whether prescribed hospital resource standards have been met in accordance with OAR 333-200-0080, the Division shall categorize a trauma system hospital as a Level I, Level II, Level III or Level IV trauma hospital. A trauma hospital may also be categorized as a Level I or Level II Pediatric Trauma Center and must meet prescribed pediatric trauma care standards in Exhibit 4. The Division may accept ACS verification in accordance with OAR 333-200-0250.

(3) For area trauma system plans prescribing categorization of hospitals, the Division shall approve all hospitals which meet the standards of the area trauma system plan.

(4) For area trauma system plans prescribing designation of hospitals, the Division shall approve selected hospitals which meet the standards of the area trauma system plan. The Division shall select hospitals based on the assessment that the best interests of the patients of the area are served by the particular applicant and expected patient volume. Competing applicants shall be judged on the on-site survey assessments of which hospital(s) provides the highest quality of compliance with the standards in Exhibit 4.

(5) A trauma system's hospital categorization may be transferable to a successor operator if the successor provides written acknowledgment that the successor will comply with all of the responsibilities and obligations imposed upon the transferor and under these rules including probationary status, and the successor agrees to be substituted in pending proceedings regarding the approval status. The Division may decline, at its discretion, to transfer approval if it reasonably believes the successor cannot meet the standards, rules, policies or protocols set forth in the approved area plan.

(6) A trauma system hospital may, without cause, terminate its trauma system hospital status upon 90-days written notice to the Division and the ATAB's list of interested parties.

[ED. NOTE: Exhibits referenced are available from the agency.]

Stat. Auth.: ORS 431.611

Stats. Implemented: ORS 431.609, 431.611 & 431.627

Hist.: HD 5-1987, f. & ef. 6-26-87; HD 16-1987, f. & ef. 10-9-87; HD 9-1990, f. & cert. ef. 4-25-90; HD 9-1993, f. 6-22-93, cert. ef. 7-1-93; HD 7-1995, f. & cert. ef. 11-6-95; HD 5-1997, f. & cert. ef. 3-12-97; OHD 6-2000, f. & cert. ef. 5-4-00; PH 16-2012, f. 12-20-12, cert. ef. 1-1-13; PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-200-0235
Trauma Hospital Application

(1) Application for a hospital to be categorized as a Level I, II, III or IV trauma hospital shall be submitted in writing on a form prescribed by the Division.

(2) The application process shall provide for at least 60 days in which to complete and submit proposals to the Division with all supporting information and documents.

(3) The Division's evaluation of the application shall include:

(a) A review of the hospital's proposal by the Division or survey team; and

(b) An onsite survey by the Division and survey team of the hospital.

(4) The application shall become the property of the Division and upon completion of the approval process is not subject to disclosure in accordance with ORS 431.627.

(5) The applicant shall have the right to withdraw its application at any time prior to dispositive action by the Division.

Stat. Auth.: ORS 431.611

Stats. Implemented: ORS 431.609, 431.611 & 431.627

Hist.: PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-200-0245
Trauma Survey and Survey Team

(1) In accordance with OAR 333-200-0235, the Division shall conduct an on-site survey using a survey team composed of persons selected by the Division.

(2) No person may serve as a member of the survey team that has any actual or potential personal, organizational or financial conflict of interest in the hospital under consideration.

(3) The Division shall provide the proposed list of survey team members to the applicant prior to conducting a survey. An applicant wishing to contest a member of the survey team shall provide written notice to the Division within 10 calendar days of receiving the proposed list. The written notice must identify concerns and provide information that demonstrates a clear and convincing basis for the concern.

(4) The quality of each hospital's compliance with the standards set forth in Exhibit 4 shall be evaluated during an on-site survey. Members of the survey team shall:

(a) Evaluate medical records, staff rosters and schedules, minutes from quality improvement committee meetings, and other documents relevant to trauma care;

(b) Evaluate equipment and premises;

(c) Conduct informal interviews with hospital personnel; and

(d) Report the findings and interpretations of the survey to the Division.

(5) During an on-site survey, administrative staff, faculty, medical staff, employees and representatives are prohibited from having any contact with any survey team member, except as directed by the Division. A violation of this provision may be grounds for immediate termination of the survey.

(6) The Division may review, inspect, evaluate, and audit patient trauma discharge summaries, trauma patient care logs, trauma patient care records, trauma quality improvement committee minutes and other documents relevant to trauma care of any hospital at any time to verify compliance with trauma system standards as set forth in these rules. The confidentiality of such records shall be maintained by the Division in accordance with state law.

(7) Information gathered during an on-site survey by the survey team including oral and written reports and deliberations shall be confidential in accordance with ORS 431.627(3).

(8) A written report of the on-site survey findings will be provided to the applicant only within 60 days of completing the on-site survey and shall be confidential in accordance with ORS 431.627(3).

[ED. NOTE: Exhibits referenced are available from the agency.]

Stat. Auth.: ORS 431.611

Stats. Implemented: ORS 431.609, 431.611 & 431.627

Hist.: PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-200-0250
Hospitals Seeking Verification from American College of Surgeons

(1) Notwithstanding OAR 333-200-0235 and 333-200-0245, a hospital seeking verification from the American College of Surgeons (ACS) shall submit the following information to the Division:

(a) Notification of intent to seek verification;

(b) Notification of the date and time of the site visit to be conducted by ACS;

(c) A copy of the ACS Preview Review Questionnaire; and

(d) Any additional information necessary to determine compliance with state specific standards.

(2) A Division representative shall be present at the verification site visit and may request additional information to determine compliance with state specific standards.

(3) In accordance with OAR 333-200-0295, the Division shall provide a written report of the on-site survey findings and a corrective action plan shall be submitted by the hospital, if applicable.

(4) A hospital shall submit a copy of the ACS verification report to the Division upon receipt.

(5) The Division may accept ACS verification if the verification is recognized by the Division as addressing the ACS trauma system standards and any additional state standards identified in these rules.

Stat. Auth.: ORS 431.611

Stats. Implemented: ORS 431.609, 431.611 & 431.627

Hist.: PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-200-0255
Waivers

(1) The Division may grant waivers from standards that are established in OAR 333-200-0080, OAR 333-200-0265 or Exhibit 4. Such waivers may be limited in time or may be conditioned as the Division considers necessary to protect the safety and welfare of the public.

(2) If a hospital seeks a waiver to the Division's rules, it must submit a request in writing that includes, at a minimum, the following information:

(a) The specific rule for which a waiver is requested;

(b) The special circumstances relied upon to justify the waiver;

(c) Any alternatives that were considered and the reasons those alternatives were not selected;

(d) How the proposed waiver will maintain or improve patient health and safety without jeopardizing patient health and safety; and

(e) The proposed duration of the waiver.

(3) After reviewing the written request, the Division shall issue its decision in writing.

(4) Applicants may not implement any waiver request until approved in writing by the Division.

[ED. NOTE: Exhibits referenced are available from the agency.]

Stat. Auth.: ORS 431.611

Stats. Implemented: ORS 431.611

Hist.: PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-200-0265
Trauma System Hospital Responsibilities

A trauma system hospital shall:

(1) Be responsible for all expenses incurred by the hospital in planning, developing and participating in the trauma system, including attorney fees and costs;

(2) Be responsible for all expenses incurred when a re-survey of the hospital is conducted by the Division or its designee(s);

(3) Comply with all requirements in these rules, all current state and area trauma system standards, and all policies, protocols and procedures as set forth in the approved area trauma system plan;

(4) Meet or exceed the standards for hospital resources as set forth in Exhibit 4 and hospital activation and transfer criteria as set forth in Exhibits 3 and 5;

(5) Provide the resources, personnel, equipment and response required by these rules;

(6) Provide care to trauma system patients which is consistent with the standards advocated by the Advanced Trauma Life Support Course, American College of Surgeons, Committee on Trauma;

(7) Report to the Oregon Trauma Registry all required data as set forth in the Oregon Trauma Registry Abstract Manual for each and every trauma patient as defined in these rules:

(a) Data must be reported within 60 days of death or discharge of that patient; and

(b) Data shall be submitted in electronic media using a format prescribed by the Division.

(c) The Division may, at its sole discretion, permit data submission by alternative means where use of the Division's prescribed format would impose a severe hardship on the reporting institution.

(8) Participate in evaluation and research studies as prescribed by the Division;

(9) Record patient resuscitation data using the official state trauma resuscitation flow sheet. If using a form other than the official form, that form must contain at least the same information; and

(10) Identify and submit to the Division the name of the individual that will serve as the Trauma Registrar, Trauma Coordinator or Trauma Program Manager, and Trauma Medical Director. Any changes to persons serving in these roles must be reported to the Division within 60 days.

[ED. NOTE: Exhibits & Publications referenced are available from the agency.]

Stat. Auth.: ORS 431.611 & 431.623

Stats. Implemented: ORS 431.609, 431.611 & 431.623, 431.627

Hist.: PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-200-0275
Division Responsibilities

When requested, the Division shall provide statistical reports in formats prescribed by the Division in consultation with the STAB, to the STAB and ATAB Quality Improvement Committees within 90 days of the close of the calendar quarter following receipt of the data submitted pursuant to OAR 333-200-0265(7).

Stat. Auth.: ORS 431.611

Stats. Implemented: ORS 431.611

Hist.: PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-200-0285
Violations

(1) No person, emergency medical service, medical clinic, or hospital shall by any means advertise, assert, represent, offer, provide or imply that such person, service, clinic or hospital is a trauma system hospital or has the capabilities for providing treatment to trauma patients beyond the status for which the approval has been granted.

(2) No trauma system hospital shall in any manner advertise or publicly assert that its trauma approval affects the hospital's care capabilities for non-trauma system patients, nor that the approval should influence the referral of non-trauma system patients.

(3) Where a hospital is greater than three months in arrears in reporting required trauma patient data, the Division may contract with an independent data collection and abstraction service to perform the data collection. The Division shall assess the trauma system hospital for all costs associated with such collection of required data.

Stat. Auth.: ORS 431.611

Stats. Implemented: ORS 431.609, 431.611 & 431.627

Hist.: PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-200-0295
Enforcement

(1) Following an on-site survey, a member of the survey team may conduct an exit conference with the applicant or his or her designee. During the exit conference, a survey team member shall:

(a) Inform the applicant or designee of the preliminary findings of the survey; and

(b) Give the person a reasonable opportunity to submit additional facts or other information to the surveyor in response to those findings.

(2) Following the survey, a determination shall be made and Division staff shall prepare and provide the applicant or his or her designee specific and timely written notice of the findings. An applicant shall have 30 days from receipt of the survey report to request a reconsideration of the categorization.

(3) If during a survey, the survey team documents non-compliance with trauma rules or laws, the deficiencies will be identified in the survey report and the laws alleged to have been violated and the facts supporting the allegation.

(a) A corrective action plan must be mailed to the Division within 45 to 60 calendar days from the date the survey report was received by the applicant.

(b) The Division shall prescribe the time frame an applicant has to correct all deficiencies. The time frame shall be based on the seriousness of the deficiencies and whether any deficiencies affect patient safety.

(c) The Division may determine that a focused review is necessary within one year of the date of the on-site survey in order to determine that the deficiencies identified in the survey report have been corrected.

(4) Upon receipt of the Division's written survey report, an applicant shall be provided an opportunity to dispute any findings including identified deficiencies. If an applicant desires an informal conference to dispute the survey findings, the applicant shall notify the Division in writing within 10 calendar days after receipt of the written survey report. The written request must include a detailed explanation of why the applicant believes the findings are inaccurate.

(5) The Division shall determine if a corrective action plan is acceptable. If the plan of correction is not acceptable to the Division, the Division shall notify the applicant in writing or by telephone:

(a) Identifying which provisions in the plan the Division finds unacceptable;

(b) Citing the reasons the Division finds them unacceptable; and

(c) Requesting that the plan of correction be modified and resubmitted no later than 30 calendar days from the date the letter of non-acceptance was received by the applicant.

(6) The Division may re-survey a trauma system hospital, immediately suspend or revoke a trauma system hospital approval or place a hospital on probation under any of the following circumstances:

(a) Substantial failure, for any reason, of a hospital to comply with these rules, all current state and area trauma system standards, and all policies, protocols and procedures as set forth in the approved area trauma system plan; or

(b) Submission of reports to the Division that are incorrect or incomplete in any material aspect.

(7) Except as set forth in OAR 333-200-0285(3), occasional failure of a trauma system hospital to meet its obligations will not be grounds for probation, suspension or revocation by the Division if the circumstances under which the failure occurred:

(a) Do not reflect an overall deterioration in quality of and commitment to trauma care; and

(b) Are corrected immediately by the hospital.

(8) Failure of a trauma system hospital to timely and accurately report to the Division all data required by rule or statute is grounds for suspension or revocation as a trauma hospital.

(9) A hospital which is dissatisfied with the decision of the Division regarding revocation, suspension, or probation in section (6) or (8) of this rule may request a contested case hearing pursuant to ORS Chapter 183.

Stat. Auth.: ORS 431.611

Stats. Implemented: ORS 431.609, 431.611 & 431.627

Hist.: PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-200-0300
Applicability

(1) A trauma hospital categorized as a Level I, Level II, Level III or Level IV trauma hospital as of January 1, 2016 shall comply with the resource standards prescribed in Exhibit 4 no later than January 1, 2017.

(2) An area trauma system plan shall include revised triage and transportation standards in accordance with OAR 333-200-0080(4) no later than January 1, 2017.

[ED. NOTE: Exhibits referenced are available from the agency.]

Stat. Auth.: ORS 431.611

Stats. Implemented: ORS 431.611

Hist.: PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

DIVISION 205

TRAUMA SYSTEM HOSPITAL DESIGNATION IN TRAUMA AREA # 1

333-205-0000
Purpose

These rules establish standards for the approval and designation of Level I trauma system hospitals in Trauma Area #1. These rules establish standards in addition to OAR 333-200-0000 through 333-200-0295. For all standards addressed in both OAR 333-200-0000 through 333-200-0295 and 333-205-0000 through 333-205-0050,

the rules contained in OAR 333-205-0000 through 333-205-0050 shall apply.

Stat. Auth: ORS 431.611

Stats. Implemented: ORS 431.575 – 431.635

Hist.: HD 6-1987, f. & ef. 6-26-87; PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-205-0010

Designation

(1) The designation method of selecting Level I trauma system hospitals shall be implemented in accordance with the provisions of OAR 333-200-0090(1) and (4), 333-200-0235, and 333-200-0245.

(2) Written notification of the trauma system hospital designation shall be provided to the applicant by the Division. An applicant shall have 30 days from the receipt of notification of non-designation to file a request with the Division for reconsideration.

Stat. Auth: ORS 431.611

Stats. Implemented: ORS 431.609, 431.611 & 431.627

Hist.: HD 6-1987, f. & ef. 6-26-87; PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-205-0020

Hospital Resource Criteria

Trauma system hospitals shall meet or exceed the standards for Hospital Resources as set forth in OAR 333-200-0090, Exhibit 4.

[ED. NOTE: Exhibits referenced are available from the agency.]

Stat. Auth: ORS 431.611

Stats. Implemented: ORS 431.609, 431.611 & 431.627

Hist.: HD 6-1987, f. & ef. 6-26-87; HD 7-1995, f. & cert. ef. 11-6-95; PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-205-0040
Number of Facilities

(1) The Division shall designate a sufficient number of Level I trauma system hospitals to assure resources within ATAB 1 are routinely available to treat at least four major trauma patients within a 90-minute time period. Major trauma means serious injury caused by external forces which results in death or an injury severity score of 16 or greater, a three day hospital length of stay, or requires intensive care admission or major surgical procedure within six hours of hospital admission.

(2) The Division shall designate a maximum of two Level I hospitals and shall not designate any Level III or Level IV hospitals in Clackamas, Multnomah and Washington Counties.

Stat. Auth: ORS 431.611

Stats. Implemented: ORS 431.609, 431.611 & 431.627

Hist.: HD 6-1987, f. & ef. 6-26-87; HD 9-1993, f. 6-22-93, cert. ef. 7-1-93; HD 7-1995, f. & cert. ef. 11-6-95; OHD 6-2000, f. & cert. ef. 5-4-00; PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

333-205-0050
Hospital Designation Criteria

(1) The Division shall utilize criteria as set forth in OAR 333-200-0090(4) and may, in addition, utilize the following criteria for selecting trauma system hospitals:

(a) Locations of major trauma incidents; and

(b) Geographical barriers which impede air or ground transportation.

(2) The Division shall consider the information contained in **Resources for Optimal Care of the Injured Patient: Committee on Trauma American College of Surgeons, 2014**, when interpreting the standards for the purpose of designating trauma system hospitals. This publication is not adopted as part of these rules.

[Publications: Publications referenced are available from the agency.]

Stat. Auth: ORS 431.611

Stats. Implemented: ORS 431.609, 431.611 & 431.627

Hist.: HD 6-1987, f. & ef. 6-26-87; HD 8-1988, f. & cert. ef. 4-28-88; HD 9-1993, f. 6-22-93, cert. ef. 7-1-93; HD 7-1995, f. & cert. ef. 11-6-95; OHD 6-2000, f. & cert. ef. 5-4-00; PH 27-2015, f. 12-8-15, cert. ef. 1-1-16

DIVISION 250

AMBULANCE SERVICE LICENSING

333-250-0000
Effective Date and Preemption

(1) No person shall operate an ambulance service unless issued an ambulance service license by the Oregon Health Authority, Public Health Division.

(2) These rules preempt any local ambulance ordinances and county ambulance service area plans that are in conflict. This rule does not prevent a city or county from establishing requirements more stringent than those set forth in these rules.

Stat. Auth.: ORS 682.015 & 682.215

Stats. Implemented: ORS 682.017 - 682.117, 682.991

Hist.: HD 18-1994, f. 6-30-94, cert. ef. 7-1-94; OHD 7-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07

333-250-0010
Definitions

(1) "Advertise" means to communicate information to the public, or to any person concerned, by any oral, written, or graphic means including, but not limited to, handbills, newspapers, television, billboards, radio, Internet and telephone directories.

(2) "Agent" means a medical or osteopathic physician licensed under ORS Chapter 677, actively registered and in good standing with the Oregon Medical Board, a resident of or actively participating in the area in which the emergency service is located, designated by the supervising physician to provide direction of the medical services of EMS providers as specified in OAR chapter 847.

(3) "Ambulance" or "Ambulance Vehicle" means any privately or publicly owned motor vehicle, aircraft, or watercraft that is regularly provided or offered to be provided for the emergency transportation of persons who are ill or injured or who have disabilities.

(4) "Ambulance Based Clinician" means a registered nurse, physician, or physician assistant who:

(a) Has an active license in Oregon and is in good standing with the Oregon Board of Nursing or the Oregon Medical Board; and

(b) Staffs an ambulance for a licensed ambulance service.

(5) "Ambulance Service" means any person, governmental unit, corporation, partnership, sole proprietorship, or other entity that operates ambulances and that holds itself out as providing prehospital care or medical transportation to persons who are ill or injured or who have disabilities.

(6) "Ambulance Service Area (ASA)" means a geographic area served by one ground ambulance service provider, and may include all or portion of a county, or all or portions of two or more contiguous counties.

(7) "Authority" means the Emergency Medical Services and Trauma Systems Program, within the Oregon Health Authority.

(8) "Business Day" means Monday through Friday when the Authority is open for business, excluding holidays.

(9) "Emergency Care" means the performance of acts or procedures under emergency conditions in the observation, care and counsel of the ill, injured or disabled; in the administration of care or medications as prescribed by a licensed physician, insofar as any of these acts is based upon knowledge and application of the principles of biological, physical and social science as required by a completed course utilizing an approved curriculum in prehospital emergency care. However, "emergency care" does not include acts of medical diagnosis or prescription of therapeutic or corrective measures.

(10) "EMS" means Emergency Medical Services.

(11) "EMS Medical Director" has the same meaning as "Supervising Physician" in ORS 682.025.

(12) "Emergency Medical Services Provider (EMS Provider)" means a person who has received formal training in prehospital and emergency care and is state-licensed to attend to any ill, injured or disabled person. Police officers, fire fighters, funeral home employees and other personnel serving in a dual capacity, one of which meets the definition of "emergency medical services provider" are "emergency medical services providers" within the meaning of ORS Chapter 682.

(13) "EMT-Paramedic" has the same meaning as Paramedic.

(14) "Employee" means any full-time paid or part-time paid person acting within the scope of his or her duties and for or on behalf of an ambulance service.

(15) "Fraud or Deception" means the intentional misrepresentation or misstatement of a material fact, concealment of or failure to make known any material fact or any other means by which misinformation or false impression is knowingly given.

(16) "License" means the documents issued by the Authority to the owner of an ambulance service when the service and its ambulance are found to be in compliance with ORS Chapter 682, OAR chapter 333, division 255 and OAR chapter 333, division 250.

(17) "Non-emergency Care" means the performance of acts or procedures on a patient who is not expected to die, become permanently disabled or suffer permanent harm within the next 24-hours, including but not limited to observation, care and counsel of a patient and the administration of medications prescribed by a physician licensed under ORS Chapter 677, insofar as any of those acts are based upon knowledge and application of the principles of biological, physical and social science and are performed in accordance with scope of practice rules adopted by the Oregon Medical Board in the course of providing prehospital care as defined by this rule.

(18) "Owner" means the person having all the incidents of ownership in an ambulance service or an ambulance or, where the incidents of ownership are in different persons, the person, other than a security interest holder or lessor, entitled to the possession of an ambulance vehicle or operation of an ambulance service under a security agreement or a lease for a term of 10 or more successive days.

(19) "Paramedic" means a person who is licensed by the Authority as a Paramedic.

(20) "Patient" means a person who is ill or injured or who has a disability and who is transported in an ambulance.

(21) "Person" means any individual, corporation, association, firm, partnership, joint stock company, group of individuals acting together for a common purpose, or organization of any kind and includes any receiver, trustee, assignee, or other similar representative thereof.

(22) "Physician" means a person licensed under ORS Chapter 677, actively registered and in good standing with the Oregon Medical Board as a Medical Doctor (MD) or Doctor of Osteopathic Medicine (DO).

(23) "Prehospital Care" means that care rendered by EMS providers as an incident of the operation of an ambulance as defined by ORS Chapter 682 and that care rendered by EMS providers as incidents of other public or private safety duties, and includes, but is not limited to "emergency care" as defined by ORS Chapter 682.

(24) "Prehospital Care Report Form (PCRF)" means an Authority-approved form or electronic field data format that is completed for all patients receiving prehospital assessment, care or transportation to a medical facility.

(25) "Procedure" means a written, dated and signed course of action to carry out a directive. A procedure must be able to answer the questions; who, what, why, when and where.

(26) "Qualified Driver" means someone who is not licensed by the Authority and who meets Authority requirements to operate a ground ambulance.

(27) "Volunteer" means a person who is working without wages and is acting within the scope of his or her duties for an ambulance service, but who may receive reimbursement for personal expenses incurred.

Stat. Auth.: ORS 682.017

Stats. Implemented: ORS 682.017 - 682.117, 682.991

Hist.: HD 18-1994, f. 6-30-94, cert. ef. 7-1-94; OHD 7-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 11-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2013, f. & cert. ef. 1-25-13

333-250-0020

Application Process to Obtain an Ambulance Service License

(1) Every person who furnishes, operates, conducts, maintains, advertises, engages in, proposes to engage in, or professes to engage in the provision of ambulance service must apply for and receive an ambulance service license from the Authority before offering such service to the public.

(2) The applicant for an ambulance service license must possess at least one ambulance, facilities, equipment, and a communications system meeting the requirements of ORS Chapter 682 and OAR chapter 333, division 250. In addition, an applicant must have a sufficient number of EMS providers, a number approved by the Authority, to appropriately staff each ambulance.

(3) An applicant for an ambulance service license must submit an application to the Authority on a form specified by the Authority. A completed application form must contain, at a minimum:

(a) The name and address of the person or public entity owning the ambulance service;

(b) If other than the applicant's true name, the name under which the applicant is doing business;

(c) If for a corporation, a limited partnership, or a limited liability company, attach to the application:

(A) A written statement from the Oregon Secretary of State's Corporation Division that the ambulance service is registered in accordance with the requirements of the Secretary of State's Corporation Division and that the ambulance service is in good standing and has filed all its annual reports, together with filing fees;

(B) The name of the registered agent of the ambulance service that is on file with the Secretary of State's Corporation Division; and

(C) All trade names recorded with the Secretary of State's Corporation Division for this business entity, and if this business entity is a subsidiary, all trade names or names of all other subsidiaries recorded with the Secretary of State's Corporation Division.

(d) If for a public agency, documentation from local city or county authorizing operation as an ambulance service;

(e) A copy of a signed signature authorization form or a power of attorney;

(f) The name of the principal contact person that the ambulance service wants contacted regarding official communications with the Authority, if different than identified in subsection (3)(a) of this rule;

(g) The mailing and actual street address of the principal place of business of the ambulance service and the actual street address of all fixed locations where an ambulance is parked when not in operation;

(h) Proof of financial responsibility as specified in ORS 682.105. Proof must be in the form of a certificate of insurance;

(i) Copies of all licenses issued by the Federal Communications Commission (FCC) for the operation of the ambulance service's communications equipment and radio configuration data as required by the Authority or written authorization from a FCC license holder to use the license holder's frequencies;

(j) If laboratory tests are conducted that require a license, a copy of that license;

(k) A copy of the operator's Air Carrier Operating Certificate, if the service will be operating an air ambulance;

(l) A copy of the operator's US Coast Guard Certificate of Compliance, if the service will be operating a marine ambulance;

(m) Copies of all telephone book yellow pages and the website addresses, where ambulance service advertising appears;

(n) A copy of a Prehospital Care Report Form or electronic field data format, which must be approved by the Authority, if not using the Authority's Prehospital Care Report Form;

(o) Name of the approved EMS medical director;

(p) A roster of all EMS providers, ambulance based clinicians, and qualified drivers in alphabetical order, who shall either operate an ambulance or attend to patients, or both, along with the following information for each employee and volunteer:

(A) The full legal name;

(B) The employment status as either full-time paid, part-time paid or volunteer;

(C) The level of professional license held; and

(D) License numbers, including EMS provider license numbers, driver and pilot license numbers for those persons operating the ambulance.

(q) A list of all ambulances to be operated by the ambulance service under the ambulance service license along with the information required for an ambulance license pursuant to ORS Chapter 682 and these rules;

(r) A statement under the penalties of perjury that certifies the following:

(A) There has been no attempt to knowingly and willfully falsify, conceal, or omit a material fact, or make any false, fictitious, incomplete or fraudulent statements or representations, or make or use any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry for the purpose of obtaining or attempting to obtain an ambulance service license to operate in the State of Oregon. Where an applicant relies on documents submitted by employees, volunteers or agents, the applicant has made a reasonable effort to verify the validity of those documents;

(B) The applicant authorizes any persons or entities, including but not limited to hospitals, institutions, organizations, or governmental entities to release to the Authority any information, files, or records requested by the Authority in connection with the processing of an application; and

(C) Upon receiving an ambulance service license, the licensee authorizes disclosure of information by insurance companies, physicians, health care facilities, including but not limited to hospitals, nursing homes, or free standing medical centers, to the Authority relating to service provided by the ambulance service to those facilities or to patients being taken from or to those facilities.

(s) The completed application must contain the signature(s) of the person(s) having the lawful responsibility for the overall operation of an ambulance service or the person having the power of attorney, or the authorized person empowered to sign on behalf of the ambulance service; and

(t) Such other information as the Authority may reasonably require.

(4) If the applicant's primary ambulance service business office is located in another state, the applicant must:

(a) Meet requirements listed in sections (1) through (3)(t) of this rule; and

(b) Attach copies of their current ambulance service and ambulance license(s) for that state to the application.

(5) The completed application to license an ambulance service must be accompanied by a nonrefundable licensing fee of:

(a) $75, when the service has a maximum of four full-time paid positions; or

(b) $250, when the service has five or more full-time paid positions.

(6) Upon review of the completed initial application and nonrefundable fee, the Authority shall schedule an inspection of the applicant's facilities, records and ambulances. The applicant must successfully complete the inspection to be issued an ambulance service license. A license shall be issued within 10 business days of successful inspection.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: HD 18-1994, f. 6-30-94, cert. ef. 7-1-94; OHD 7-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 11-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2013, f. & cert. ef. 1-25-13

333-250-0030
Issuance of License to Operate an Ambulance Service

(1) When the completed ambulance service license application with the appropriate nonrefundable licensing fee has been received by the Authority, and if it is found that the submitted data, facilities and records comply with the requirements of ORS Chapter 682 and these rules, the Authority shall issue an ambulance service license for the specified ambulance service.

(2) The ambulance service license:

(a) Shall be valid until June 30 of each year, unless sooner revoked or suspended. The initial licensing period may not exceed 15 months;

(b) Shall expire on June 30 of the following year, if a license is applied for and issued between April 1 and June 30; and

(c) Must be conspicuously displayed in the main business office of the ambulance service, or otherwise as directed by the Authority.

(3) Except when specifically exempted by ORS 682.035, an out-of-state ambulance service that operates or advertises in Oregon must be licensed by the Authority. An out-of-state ambulance service is not required to obtain an ambulance service license and ambulance license for the following situations:

(a) Transporting a patient through the state;

(b) Delivering a patient to a medical facility or other location within the state, if the beginning of the transport originated outside of the state;

(c) Picking up a patient at a medical facility or airport within the state for the purpose of transporting the patient to a medical facility or other location outside of the state, unless prohibited by the county's Ambulance Service Area plan; or

(d) In the event of a man-made or natural disaster declared by federal, state or local officials and resulting in the need to utilize all available resources to provide patient care and transportation in the affected area.

(4) If an ambulance service license becomes lost, damaged or destroyed, the licensee must apply for a replacement license. The licensee must submit, to the Authority, the completed application with a $10 nonrefundable fee for each replacement license.

(5) An ambulance service license is not transferable to a new owner of a purchased ambulance service.

(6) When an ambulance service is found to be in non-compliance with ORS Chapter 682 or these rules, the Authority may deny, suspend or revoke an ambulance service license or place the ambulance service on probation.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: HD 18-1994, f. 6-30-94, cert. ef. 7-1-94; OHD 7-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 1-2013, f. & cert. ef. 1-25-13

333-250-0031
Ambulance Service Requirements with Use of Qualified Drivers

(1) If a licensee is using a driver of a ground ambulance who is not licensed as an EMS provider by the Authority, a licensee must ensure the driver has:

(a) A valid driver's license;

(b) Emergency ground ambulance operator's training that meets Authority standards;

(c) Current healthcare provider cardiopulmonary resuscitation (CPR) card or proof of course completion that meets or exceeds the 2010 American Heart Association Emergency Cardiovascular Care (ECC) guidelines or equivalent standards approved by the Authority;

(d) Bloodborne pathogen and infectious disease training that meets or exceeds standards found in OAR chapter 437;

(e) Hazardous materials awareness training that meets or exceeds the Oregon Occupational Safety and Health Division standards found in OAR chapter 437; and

(f) A signed statement by a driver not certified or licensed through the Authority that he or she is:

(A) Not addicted to alcohol or controlled substances and is free from any physical or mental condition that might impair the ability to operate or staff an ambulance; and

(B) Physically capable of assisting in the extrication, lifting and moving of a patient at the direction of an EMS provider.

(2) A licensee must have a certified copy of the qualified driver's license check done through the Oregon Department of Motor Vehicles Automated Reporting System Program or equivalent reporting program as approved by the Authority. If the driver has an out-of-state driver's license, the licensee must obtain an equivalent certified copy from that state, if available and if not available, conduct an annual driving record check. The latest copy must be kept in the driver's personnel file.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: PH 1-2013, f. & cert. ef. 1-25-13

333-250-0040
Ambulance Service Operational Requirements

(1) The licensee must ensure that the service, employees, volunteers and agents:

(a) Comply with all of the requirements of ORS chapter 682, ORS 820.300 through 820.380 and other applicable federal, state and local laws and regulations governing the operation of a licensed ambulance service;

(b) Notify the Authority, upon making initial application or within 14-days of the date of registration, of any new "trading as", "division of", or "doing business as" names utilized by the licensee; and

(c) Transport only patients for which it has the resources to provide appropriate medical care and transportation unless in transfers between medical facilities, the sending or receiving facility has provided medically appropriate life support measures, personnel, and equipment to sustain the patient during the transfer.

(2) The licensee shall document that each employee or volunteer:

(a) Is provided an initial orientation program that addresses, at a minimum, the ambulance service standing orders, ambulance service policies and procedures, driving and operating requirements for ambulance vehicles, and operations of equipment. The initial orientation program must be completed prior to the employee or volunteer being allowed to staff an ambulance; and

(b) Has access to current copies of these rules, and the documents referred to within these rules that are incorporated by reference.

(3) The licensee must have written policies and procedures to carry out daily ambulance service operations including, but not limited to:

(a) Work practice controls for bloodborne pathogens in compliance with OAR chapter 437;

(b) Storage of medications including controlled substances if authorized by the EMS medical director and meeting the requirements of the Oregon Board of Pharmacy in OAR chapter 855 and the US Drug Enforcement Administration found in 21 CFR 1301.75(b);

(c) Destruction of outdated medications including controlled substances if authorized by the EMS medical director and meeting the requirements of the Oregon Board of Pharmacy in OAR chapter 855 and the US Drug Enforcement Administration found in 21 CFR 1307.21;

(d) Notifying the licensee when an employee is impaired by excessive fatigue, illness, injury or other factors that may reasonably be anticipated to constitute a threat to the health and safety of patients or the public;

(e) Reporting of suspected child abuse as required in ORS 419B.005 through 419B.050;

(f) Reporting of suspected elderly abuse as required in ORS 124.050 through 124.095;

(g) Patient rights in accordance with OAR 333-250-0085; and

(h) Providing secure transport for patients in custody in accordance with OAR 309-033-0435, if the licensee has been authorized to perform this service.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: HD 18-1994, f. 6-30-94, cert. ef. 7-1-94; OHD 7-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 11-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2013, f. & cert. ef. 1-25-13; PH 14-2016, f. & cert. ef. 4-28-16

333-250-0041
Ambulance Service Personnel Educational Requirements and Quality Improvement

(1) The licensee shall provide, coordinate, and document the following:

(a) An orientation program for all new EMS providers, ambulance based clinicians and qualified drivers. The initial orientation program must include but is not limited to the subjects listed in OAR 333-250-0040(2)(a); and

(b) The training of all EMS providers and ambulance based clinicians on the:

(A) Proper use of any new equipment, procedure or medication prior to being placed into operation on an ambulance; and

(B) Secure transportation of patients in custody in accordance with OAR 309-033-0437, if the licensee has been authorized to perform this service.

(2) Before the licensee permits a person to staff an ambulance, the licensee shall ensure that the person has current training that includes but is not limited to:

(a) Bloodborne pathogen and infectious disease training that meets or exceeds standards found in OAR chapter 437;

(b) Hazardous materials awareness training that meets or exceeds the Oregon Occupational Safety and Health Division standards found in OAR chapter 437;

(c) Emergency ground ambulance operator's training that meets Authority standards when operating a ground ambulance;

(d) Air medical crew training that meets Authority standards when operating an air ambulance; and

(e) Marine crew training that meets Authority standards when operating a marine ambulance.

(3) The licensee shall ensure that there is verifiable written documentation placed in the employee's or volunteer's training file that the employee or volunteer has completed the training and the documentation shall include when and where the training was obtained.

(4) Any EMS related or required continuing education offered by the licensee or designee must be documented as follows:

(a) A class roster that contains:

(A) Name of the ambulance service;

(B) Full name of the instructor;

(C) Full name of the person attending the class;

(D) Class date;

(E) Class subject; and

(F) Class length; or

(b) A computer-generated printout history of an individual's continuing education record that contains:

(A) The full name of the person attending the class;

(B) Name of the ambulance service;

(C) Class dates;

(D) Class subjects; and

(E) Class lengths.

(5) Documentation required in section (4) of this rule must be maintained in a secure manner with limited access for a minimum of four years.

(6) The licensee must establish a procedure to release copies of all records of continuing education completed by an EMS provider or employee through the service in a verifiable format to the requesting party within five business days of being requested.

(7) The licensee must have a written quality improvement program that is approved by the EMS medical director.

(8) To assist the licensee and the EMS medical director in determining if appropriate and timely emergency medical care was rendered, the ambulance service designated official may request the following information from the hospital receiving the patient as authorized by ORS 682.056:

(a) Patient admit status and unit admitted to;

(b) Any procedure listed in section D04_04 of the National Highway Transportation Safety Administration dataset dictionary, version 2.2.1, and performed on the patient within the first hour of being admitted;

(c) Any medication administered to the patient within the first hour of being admitted; and

(d) Trauma system entry by emergency department staff.

(9) Information provided under section (8) of this rule is considered confidential pursuant to ORS 682.056. Any employee or volunteer participating in a quality improvement session must have a signed confidentiality statement in their personnel file.

(10) If the licensee accepts students for Paramedic internships from an accredited teaching institution, the licensee must:

(a) Have a signed and dated contract with each teaching institution providing internship students; and

(b) Use qualified preceptors, as defined by OAR 333-265-0000, who will be assigned to supervise, document and evaluate the Paramedic interns.

Stat. Auth.: ORS 682.017

Stats. Implemented: ORS 682.017 - 682.117, 682.991

Hist.: OHD 7-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 11-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2013, f. & cert. ef. 1-25-13; PH 14-2016, f. & cert. ef. 4-28-16

333-250-0042
Ambulance Operational Requirements

(1) The licensee must ensure that the service, employees, volunteers and agents providing ground ambulance service:

(a) Comply with all applicable statutes in the 2007-2008 Oregon Motor Vehicle Codes relating to motor vehicle and emergency vehicle operations, ORS 820.300 through 820.380 and ORS Chapter 445.

(b) Successfully complete an emergency vehicle operator's course of instruction prior to independently operating an ambulance. The course must meet or be equivalent to the National Safety Council for Emergency Vehicle Operators Course (CEVO 2 or 3) or National Fire Protection Agency (NFPA) Driver.

(c) Comply with the licensee's procedures.

(2) A licensee shall have a procedure:

(a) Detailing the operation of an ambulance for both emergency and non-emergency situations;

(b) To remove an ambulance from service when the mechanical condition of an ambulance is sufficiently unreliable so as to endanger or potentially endanger the health, safety, or welfare of a patient or crew member;

(c) To handle a mechanical breakdown and to repair or replace a damaged tire or wheel when the ambulance is in operation; and

(d) Detailing what steps are to be followed when an ambulance is involved in an accident. The procedure must include the submission of a legible copy of the Department of Motor Vehicles Accident Report to the Authority within 10 business days of the accident.

(3) The licensee must ensure that the service, employees, volunteers and agents providing air ambulance service:

(a) Comply with the Federal Acquisition Regulation (FAR), 14 CFR Part 135 of the Operating requirements; Commuter and on demand operations and rules governing persons on board such aircraft; and

(b) Successfully complete the 2004 Association of Air Medical Services (AAMS) Guidelines or equivalent. There must also be an annual review of the Air Medical Crew course material, the length of which must be established by the EMS medical director.

(4) A licensee may only utilize an ambulance for the provision of providing ambulance service that has been issued a license by the Authority and that complies with all requirements of ORS Chapter 682, OAR chapter 333, division 255, and these rules.

(5) A licensee must not allow or schedule an employee or volunteer to serve on an ambulance who is impaired by excessive fatigue, illness, injury or other factors that may reasonably be anticipated to constitute a threat to the health and safety of patients or the public.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 682.017

Stats. Implemented: ORS 682.017 - 682.117, 682.991

Hist.: OHD 7-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 11-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2013, f. & cert. ef. 1-25-13

333-250-0043
Ambulance Service Personnel Record Keeping and Reporting Requirements

(1) The licensee must:

(a) Maintain a complete and current personnel file, training file, and medical file for each employee and volunteer, including but not limited to:

(A) Full name;

(B) Current home mailing address;

(C) Affiliation status, listed as either an employee full-time paid, employee part-time paid, volunteer, or agent;

(D) Copies of:

(i) Reportable actions forms as required under OAR 333-250-0043(5);

(ii) Applicable professional certificates or licenses;

(iii) A current driver's license;

(iv) A current pilot's license if the employee or volunteer operates an air ambulance;

(v) A certified court printout of initial driver's license check done through the Oregon Department of Motor Vehicles Automated Reporting System Program or equivalent reporting program as approved by the Authority, and any subsequent reported convictions, accidents or license suspensions. If the driver has an out-of-state driver's license, the licensee must participate in a similar program for that state, if available and if not available, conduct an annual driving record check; and

(vi) Current healthcare provider CPR card or proof of course completion that meets or exceeds the 2010 American Heart Association ECC guidelines or equivalent standards approved by the Authority.

(b) If the licensee contracts with or employs ambulance based clinicians for the purpose of providing advanced level care, the licensee shall ensure that the clinicians:

(A) Meet all of the applicable requirements in OAR chapter 333, division 250;

(B) Have documentation of a current Advanced Cardiac Life Support course or other Authority-approved equivalent course completion;

(C) Have documentation of current Pediatric Advanced Life Support or other Authority-approved equivalent course completion; and

(D) Have documentation of completing a current Prehospital Trauma Life Support, Basic Trauma Life Support, Trauma Emergency Assessment Management or Trauma Nurse Core Course. The Trauma Emergency Assessment Management and Trauma Nurse Core Course must include a supplemental prehospital rapid extrication training session.

(c) Documentation that an employee or volunteer has completed:

(A) An ambulance service initial orientation program that includes requirements set forth in OAR 333-250-0040(2)(a) and (b);

(B) A bloodborne pathogen and infectious disease training course that meets standards found in OAR 437-002-0360 and 437-002-1030 and an annual refresher training course;

(C) A Hazardous Materials Awareness training course that meets or exceeds the Oregon Occupational Safety and Health Division standards found in OAR chapter 437 and an annual refresher training course;

(D) An Authority-approved emergency vehicle operator's course for ground ambulance drivers only. The course must meet or be equivalent to the standards of the National Safety Council for Emergency Vehicle Operators Course, (CEVO II-IIIAMB) or NFPA Driver;

(E) The US Department of Transportation's Air Medical Crew National Standard Curriculum course or equivalent and annual refresher training for persons staffing air ambulances only;

(F) Initial Tuberculosis (TB) screening and any subsequent TB screenings;

(G) Hepatitis-B immunizations or a signed statement of declination;

(H) A signed statement by a driver not certified or licensed through the Authority that they are:

(i) Not addicted to alcohol or controlled substances and are free from any physical or mental condition that might impair the ability to operate or staff an ambulance; and

(ii) Physically capable of assisting in the extrication, lifting and moving of a patient.

(2) A licensee shall have documentation of items listed in section (1) of this rule prior to the employee or volunteer being allowed to independently staff an ambulance. Note: an employee or volunteer must begin the Hepatitis-B immunization series or have a signed statement of declination prior to independently staffing an ambulance.

(3) All records relating to an ambulance service's operations must be retained by the licensee or the licensee's successors or assigns for not less than seven years from the date of implementation, purchase, dispatch, creation or longer if so required by law or regulation. The record keeping mechanism may be in any permanent form including paper or on magnetic media provided that the information can be made readily available for inspection by the Authority.

(4) The licensee must promptly submit to the Authority such information, including survey information that the Authority may reasonably require.

(5) The licensee must submit a completed reportable action form to the Authority, within the times specified, for any of the following actions:

(a) Hiring a new employee or volunteer, within 14 business days;

(b) Terminating or suspending an employee or volunteer for cause, within 14 business days; and

(c) Disciplinary action taken by the licensee or the EMS medical director for unprofessional conduct as listed in OAR 333-265-0000, within 14 business days.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 682.017

Stats. Implemented: ORS 682.017 - 682.117, 682.991

Hist.: OHD 7-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 11-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2013, f. & cert. ef. 1-25-13

333-250-0044

Prehospital Care Report Form or Electronic Field Data Format Completion Requirements

(1) The licensee must complete a PCRF in each instance where an ambulance arrives on the scene and patient contact is initiated.

(2) A complete PCRF or electronic field data format as specified by the Authority must be prepared by ambulance personnel and delivered to appropriate hospital staff at the time patient care is transferred, unless the PCRF is provided electronically under section (3) of this rule.

(3) If a PCRF is provided via electronic format, a licensee shall ensure that personnel verbally relay pertinent patient care information to hospital staff prior to leaving the hospital. A completed electronic report must be submitted to the hospital at a location designated by the hospital within 12 hours of the patient being transported to the hospital.

(4) If the ambulance crew is unable to complete the PCRF at the time patient care is transferred, the ambulance crew may depart after receiving verbal verification from an emergency department employee involved with providing patient care that sufficient patient information has been transferred to support safe and timely continuation of patient care.

(5) The licensee must return the ambulance crew to the hospital when requested by the attending physician for the purpose of obtaining the completed PCRF or additional patient care information. If acceptable to the attending physician, a completed PCRF can be faxed or electronically sent to the hospital;

(6) A licensee must ensure that a PCRF or electronic field data form contains data points as defined by version 2.2.1 of the National Highway Transportation Safety Administration Uniform Pre-Hospital Emergency Medical Services Dataset; and

(a) For any patient meeting the criteria for trauma patient as defined in OAR 333-200-0010(26):

(A) Trauma band number; and

(B) Triage criteria as defined in OAR 333-200-0010, Exhibit 2.

(7) Notwithstanding the requirements in this rule, a completed PCRF or electronic field data form is not required when there is a disaster or a multiple patient incident consisting of more than five patients or the number of patients prescribed in the county's ASA plan, and which results in a single ambulance transporting two stretcher patients at the same time or when an ambulance is required to make more than one trip to and from the incident site. In those situations, a completed triage tag that includes listing of the trauma systems identification bracelet number, recording of the times and results of all vital signs taken and the times, name and dosage of any medication given is acceptable patient care documentation. However, every reasonable attempt must be made by the ambulance personnel or ambulance based clinicians to complete an approved PCRF or electronic field data form for each patient at the conclusion of the incident.

[ED. NOTE: Exhibits referenced are available from the agency.]

Stat. Auth.: ORS 682.017

Stats. Implemented: ORS 682.017 - 682.117, 682.991

Hist.: OHD 7-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 11-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2013, f. & cert. ef. 1-25-13

333-250-0045

Storage, Release and Destruction of Prehospital Care Report Form Requirements

(1) The licensee is responsible for:

(a) Providing secure storage of PCRFs, with limited access to the PCRFs by office and ambulance personnel;

(b) Providing that the PCRFs are organized in a manner that will allow an authorized ambulance service representative to locate a PCRF within a reasonable amount of time, given a patient's name and the date and time of the ambulance call;

(c) Establishing a procedure for when a copy of the PCRF may be released to a medical facility receiving the patient, the patient, the patient's family, the patient's legal guardian, an insurance company, an attorney, a law enforcement officer, or a law enforcement agency;

(d) Protecting the confidentiality of patient information during quality improvement sessions by limiting access to the PCRF and having all persons having access to PCRFs sign a confidentiality statement; and

(e) Establishing a procedure for the method and verification of the destruction of a PCRF:

(A) An ambulance service may not destroy a medical record or report about a patient for 10 years after the record or report is made, or longer if so required by law or regulation unless the patient is notified.

(B) In the case of a minor patient, a medical record or report may not be destroyed until the patient attains the age of majority plus three years or for 10 years after the record or report is made, whichever is later, unless the parent or guardian of the minor patient is notified.

(i) Notification of a minor patient or the parent or guardian of the minor patient of the potential destruction of a prehospital care report must:

(I) Be made by first class mail to the last known address of the patient;

(II) Include the date on which the record of the patient shall be destroyed; and

(III) Include a statement that the record or synopsis of the record, if wanted, must be retrieved at a designated location within 30 days of the proposed date of destruction.

(2) Under no circumstances shall an employee, volunteer or agent make a copy of a PCRF for their own personal record or remove the original or a copy of a completed PCRF from the licensee's files or facilities without having written approval of the licensee.

(3) All PCRFs must be made available for inspection and duplication when requested by the Authority as authorized by ORS 41.675 and 41.685.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: OHD 7-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 11-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2013, f. & cert. ef. 1-25-13

333-250-0046
Ambulance Service Communications and Dispatching Operational Requirements

(1) The licensee is responsible for:

(a) Having a valid license from the Federal Communications Commission (FCC) to operate an EMS radio on assigned frequencies, or proper authorization from another agency holding a valid FCC license to operate on designated radio frequencies;

(b) Having 24-hour-a-day phone answering and dispatching capabilities or having a signed agreement or contract with a recognized primary or secondary Public Safety Answering Point (PSAP), who will provide telephone answering and emergency dispatching services;

(c) Providing a reliable means of alerting and communicating with an ambulance crew before, during and after an ambulance call;

(d) Immediately routing all emergency calls received from the public on any of the licensee's 10-digit telephone number to the primary PSAP. When a licensee receives a request for an emergency ambulance and the licensee is a recognized secondary PSAP, the licensee shall dispatch the ambulance and notify the primary PSAP for coordination of other emergency responder agencies;

(e) Ensuring that any request for an ambulance received on the licensee's 10-digit telephone number is answered by a live person or that there is an answering machine referring the caller to the appropriate emergency telephone number; and

(f) Maintaining ambulance dispatch records as prescribed in ORS 820.330 and 820.340. The records must be kept by the licensee or the licensee must have a signed agreement with the PSAP, service or agency that provides telephone answering and dispatching services that they will maintain and make available copies of the official dispatch records for a minimum of seven years.

(2) When the licensee employs dispatchers for the purpose of answering the telephone, taking information regarding the need for an ambulance and dispatching the ambulance, the dispatcher must have written documentation of completing:

(a) The Department of Public Safety Standards and Training's Emergency Medical Dispatcher's Course or equivalent; and

(b) Four hours of annual refresher training for dispatchers that meets the standards set forth by the Department of Public Safety Standards and Training.

(3) Air ambulance must meet Federal Acquisition Regulation (FAR), 14 CFR Part 135 of the Operating requirements; Commuter and on demand operations and rules governing persons on board such aircraft.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: OHD 7-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 11-2010, f. 6-30-10, cert. ef. 7-1-10

333-250-0047
Ambulance Service EMS Medical Director Operational Requirements

(1) The licensee must have a single EMS medical director except:

(a) When the licensee operates in non-contiguous counties, then the licensee may have one EMS medical director in each non-contiguous county of operation; or

(b) Where a county or regional EMS system prescribes that multiple agencies within a county or region must have a governmentally appointed EMS medical director, that agency may have a different EMS medical director in contiguous counties. In this event, the signed agreement or contract may be between the EMS medical director and the county or regional EMS system.

(2) The licensee must ensure that the EMS medical director:

(a) Meets the requirements and duties as prescribed in OAR 847-035-0020 through 847-035-0030;

(b) Has a written set of treatment protocols for each level of service offered by the licensee; and

(c) Has a signed and dated agreement or contract with the licensee.

(3) When an EMS medical director authorizes the administration of controlled substances, the EMS medical director must have on file with the licensee:

(a) A US Drug Enforcement Administration License listing the name of the ambulance service and address where the controlled substances are stored when not on an ambulance; and

(b) A signed and dated procedure as to the amount stored on the ambulance and how controlled substances will be stored, accessed, recorded, administered, destroyed and secured. It is the responsibility of the EMS medical director to ensure that the procedure meets the minimum US Drug Enforcement Administration requirements found in 21 CFR 1301.75(b).

(4) The licensee must notify the Authority in writing of:

(a) The denial, suspension, or voluntary surrender of an EMS medical director's medical license or US Drug Enforcement Administration license within 72 hours; and

(b) A change in the EMS medical director, 21 days prior to the change.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: OHD 7-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 11-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2013, f. & cert. ef. 1-25-13

333-250-0048
Ambulance Service Ambulance Personnel Operational Requirements

(1) The licensee must ensure that the service, employees, volunteers and agents meet the personnel requirements as prescribed in these rules.

(2) The licensee must not schedule or allow an employee or volunteer to serve on an ambulance who is impaired by excessive fatigue, illness, injury or other factors that may reasonably be anticipated to constitute a threat to the health and safety of patients or the public.

(3) The licensee shall require each person staffing an ambulance or providing prehospital emergency or non-emergency care to display his or her level of licensure on the outermost garment of his or her usual work uniform at all times while staffing an ambulance or rendering patient care, and shall make reasonable efforts to display this information under other circumstances.

(4) The licensee shall ensure that any EMS providers, ambulance based clinicians or qualified drivers:

(a) Are trained to properly operate all ambulances and equipment that he or she is authorized to use; and

(b) Are physically capable and have the ability to lift and move patients and assist in extrication of patients when necessary.

(5) The licensee shall not permit employees or volunteers to operate an ambulance, equipment, or have patient contact if:

(a) They are taking any medications that could impair safe operation and handling of the ambulance, equipment, or patient; or

(b) The employee or volunteer has consumed any alcoholic beverages within the last eight hours.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: OHD 7-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 11-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2013, f. & cert. ef. 1-25-13

333-250-0049
Ambulance Service Housing of Personnel, Ambulance and Equipment Operational Requirements

(1) The licensee must provide:

(a) An area where an employee or volunteer working a 24-hour shift may sleep or rest;

(b) An area equipped with adequate toilet, hand-washing and shower facilities with hot and cold running water, antiseptic soap and clean towels for hand and body drying. If the ambulance service facility does not have shower facilities, the licensee must have a signed agreement or contract with a medical facility or other entity to make available shower facilities to ambulance personnel for the purpose of showering after coming in contact with medical or other biohazardous waste;

(c) Separate areas for clean and soiled linen receptacles in accordance with the applicable Oregon Occupational Safety and Health Division and other rules governing the handling of special medical wastes;

(d) A designated secure area for storing, or an alternate method and a procedure for identification and storage of, all medications which are deteriorated, outdated, misbranded, adulterated or otherwise unfit for use. This area or procedure must provide for the physical separation of defective supplies so that products are not confused with usable products. Security procedures for unusable medications, fluids and controlled substances must be the same as for usable supplies;

(e) A separate area to place clearly marked "out of service" malfunctioning patient care equipment until the equipment has been repaired or replaced or enforces a procedure for an alternate method of identification and storage to assure that defective equipment will not be used; and

(f) A reasonable inventory of patient care equipment, supplies and medications, properly secured, or in the alternative, a signed agreement with a medical facility that the medical facility will provide the patient care equipment, supplies, and medications.

(2) A licensee shall ensure that:

(a) Controlled substances, when authorized by the EMS Medical Director, are stored, accessed, inventoried, administered, destroyed and secured in a manner consistent with the signed and dated procedure established by the EMS Medical Director. The procedure must be in accordance with the regulations promulgated by the US Drug Enforcement Administration (DEA) found in 21 CFR 1301.75(b).

(b) A copy of the EMS Medical Director's DEA license is maintained in a secure manner, inaccessible to the public, at each fixed ambulance location where controlled substances are stored other than in the ambulance.

(c) Pharmacological and medical supplies with expiration dates affixed thereon by the manufacturer or packager are removed from service no later than the expiration date. Expired pharmacological and medical supplies must be disposed of in accordance with applicable laws and regulations.

(d) Medications and equipment are stored in a manner that protects viability and proper operation; and

(e) Ambulances available for or subject to a call are maintained to allow immediate starting of the engine and to prevent medications and medical supplies from becoming environmentally degraded.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: OHD 7-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 11-2010, f. 6-30-10, cert. ef. 7-1-10

333-250-0050
Request for Variance from Standards

(1) The licensee may request a variance from the standards established in ORS 820.330 to 820.380, ORS Chapter 682 and these rules when:

(a) The licensee believes that compliance with a rule is inappropriate because of special circumstances which would render compliance unreasonable, burdensome, or impractical due to special conditions or causes, or because compliance would result in substantial curtailment of necessary ambulance service; and

(b) A city ordinance or county ASA plan exists, and the licensee has presented his or her request for a variance to the local city or county governing body and that body has given their approval for the proposed variance.

(2) A written request for a variance must be made to the Authority. The Authority may not grant a variance that may cause danger or harm to the public or to persons operating or staffing the ambulance. A written variance request must include:

(a) Justification for the variance request; and

(b) A detailed and realistic plan to resolve the need for a future variance.

(3) The request for variance may be presented to the State Emergency Medical Service Committee at a regularly scheduled meeting. The Public Health Director or designee, after considering the Committee's recommendation, when requested, may grant a variance:

(a) A variance shall be granted for a period of time as prescribed by the Authority; and

(b) A subsequent variance may only be granted when the licensee has demonstrated to the Authority, insofar as possible, adequate progress in resolving the need for the initial variance as described in the plan.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: HD 18-1994, f. 6-30-94, cert. ef. 7-1-94; OHD 7-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 1-2013, f. & cert. ef. 1-25-13

333-250-0060
Right of Entry and Inspection of an Ambulance Service and Ambulance

(1) The Authority may conduct an inspection for the purpose of evaluating the eligibility of an ambulance service or an ambulance to receive or retain a license and to ensure the health, safety, and welfare of the persons who utilize ambulances. Ambulance services that acquire and maintain current status with a nationally recognized EMS service program accreditation entity that meets or exceeds Oregon requirements may be exempted from the inspection process. A copy of the inspection report from the nationally recognized EMS service program accreditation entity must be filed with the Authority for approval.

(2) Routine inspections of an ambulance service or an ambulance must be scheduled with the management of the ambulance service at least 72 hours in advance of the inspection unless

otherwise mutually agreed upon by the Authority and the ambulance service representative.

(3) Investigative inspections for the purpose of ensuring continued compliance with ORS Chapter 682 and these rules do not require giving advanced notice to the licensee.

(4) In conducting an inspection or interview, the Authority representative must:

(a) Identify him or herself by presenting the Authority identification to the owner, manager, or ranking employee or volunteer present at the site of an inspection or interview;

(b) Inform the ambulance service representative of the purpose for the inspection or interview; and

(c) Inform the ambulance service representative when the inspection or interview has been completed and the results of the inspection only.

(5) The Authority may make photographic or video-graphic documentation as part of an inspection for or an investigation of non-compliance with ORS Chapter 682 and these rules.

(6) Failure of the licensee to produce records for inspection or to permit examination of equipment and facilities by the Authority shall be grounds for the denial, suspension or revocation of an ambulance service or ambulance license.

(7) The Authority may accept local city or county governing body inspections that meet or exceed requirements outlined in ORS Chapter 682 and OAR chapter 333, divisions 250 and 255 in lieu of an inspection by the Authority.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: HD 18-1994, f. 6-30-94, cert. ef. 7-1-94; OHD 7-2001, f. & cert. ef. 4-24-01l: PH 2-2007, f. & cert. ef. 2-1-07; PH 11-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2013, f. & cert. ef. 1-25-13

333-250-0070
Denial, Suspension, or Revocation of an Ambulance Service License or Placing an Ambulance Service on Probation

(1) Conduct subjecting an ambulance service to discipline means conduct unbecoming a person who is either applying for or holds an ambulance service license and is detrimental to the best interest of the public and includes, but is not limited to the conduct listed in this rule.

(2) The Authority may, in accordance with the provisions of ORS Chapter 183, deny, suspend, or revoke an ambulance service license or ambulance license. The Authority may also place an ambulance service on probation, the terms of which shall be established by the Authority. In addition to or in lieu of probation, suspension or revocation, the Authority may cite an ambulance service for a violation and request corrective action.

(3) An individual, firm, partnership, limited liability company, corporation, association, or organization shall be considered in violation of ORS Chapter 682 and these rules if the Authority determines that the individual, firm, partnership, limited liability company, corporation, association, or organization has done any of the following:

(a) Been convicted of a crime, including conviction of Medicare or Medicaid fraud, relating adversely to the person's capability of owning or operating an ambulance service;

(b) Violated ORS Chapter 682 or any of these rules, which poses a significant threat to the health and safety of the public;

(c) Made a material omission or misrepresentation of facts on an application for a license or waiver, or in response to an inquiry or investigation. This includes fraud or deceit in obtaining or attempting to obtain a license or waiver or in any other transaction with the Authority;

(d) Failed to employ or contract for an approved EMS medical director, or to operate under the direction of an EMS medical director appointed by an appropriate governmental authority;

(e) Failed to have medical equipment and supplies required for operation at the highest level of service provided;

(f) Lent a license, borrowed, or used the license of another, or knowingly aided or abetted the improper granting of a license;

(g) Defaced, altered, removed or obliterated any portion of any official entry upon a license, licensing decal, or waiver issued by the Authority;

(h) Refused to respond to or render prehospital emergency care as required by protocol because of a patient's race, sex, creed, national origin, sexual preference, age, handicap, medical problem, or financial inability to pay;

(i) Failed to promptly notify the Authority of a change of ownership, or to report any matter the reporting of which is required by ORS 682.220(4);

(j) Disclosed medical or other confidential information;

(k) Altered or inappropriately destroyed medical records;

(l) Willfully prepared or filed false reports or records, or induced another to do so;

(m) Engaged in a pattern of any of the following:

(A) Incompetence, negligence or misconduct in operating the ambulance service or in providing emergency medical care and transportation to patients;

(B) Abuse or abandonment of patients;

(C) Failure to comply with the county ASA plan, area trauma plan, or other lawfully promulgated policies, plans, or procedures;

(D) Failure to meet response time standards as prescribed by the county ASA plan or if no ASA plan is in effect, the area trauma plan;

(E) Misuse or misappropriation of medications or medical materials; and

(F) Other conduct determined by the Authority to pose a significant threat to the public health and safety and the well being of ambulance patients.

(n) Failed to comply with the minimum personnel requirements or failed to have the required equipment in working order on an ambulance as prescribed in these rules;

(o) Had a continuing pattern of violations over a period of two or more years;

(p) Failed to submit a reasonable timetable to correct the violations cited by the Authority;

(q) Interfered with the performance of the Authority's duties; and

(r) Failed to pay all applicable licensing fees or civil penalties set by the Authority.

(4) Upon receipt of a sufficient written or verbal complaint describing specific violations of ORS Chapter 682 or any other relevant statute or rule, the Authority shall initiate an investigation of the allegations. The Authority does not have jurisdiction over and shall not take action on complaints that relate solely to rates charged a patient by an ambulance service.

(5) When an ambulance, upon inspection by the Authority, manifests evidence of a mechanical or equipment deficiency, which poses a significant threat to the health or safety of patients or crew, the Authority shall immediately suspend that ambulance from operation. No ambulance that has been suspended from operation may be operated until the licensee has certified and the Authority has confirmed that all of the violations have been corrected.

(6) The Authority shall confirm by inspection or other appropriate means that all violations have been corrected within 48 hours of notification by the licensee. The licensee must notify the Authority of corrections by personal telephone contact (voice mail messages will suffice), or facsimile, or in person during normal business hours. Notifications received by facsimile outside of business hours will be considered received the next business day. Telephonic notifications shall be deemed received at the time actual voice contact between the licensee and the Authority's ambulance service licensing program representative or designee is established.

(7) In the event that a license is suspended or revoked, the licensee must cease ambulance service operations and no person except the Authority may permit or cause the service to continue.

(8) The licensee must return all indications of licensing, including certificates and the remains of ambulance license decals to the Authority by registered mail, posted within 48 hours of

either receipt of notification of suspension or revocation or the effective date of revocation, whichever is later.

(9) The Authority shall notify applicable local government, county ASA administrator, and supervising physician of the suspension or revocation of an ambulance service license, or the placing of a service on probation.

(10) The Authority may assess civil penalties up to $5000 per violation against any entity or person licensed under these rules or subject to licensure under these rules for a violation of ORS Chapter 682 or these rules.

(11) If a principal owner of an ambulance service has had its ambulance service license revoked, following the opportunity for a hearing as provided by ORS Chapter 183, that person may not be eligible to apply for or hold an ambulance service license for a period of two years from the date of revocation as specified in ORS Chapter 682.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: HD 18-1994, f. 6-30-94, cert. ef. 7-1-94; OHD 7-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 11-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2013, f. & cert. ef. 1-25-13

333-250-0080
Surrender of License to Operate an Ambulance Service

(1) An ambulance service license is non-transferable.

(2) When the owner sells or closes an ambulance service, the owner must:

(a) Provide a minimum 30-days written notice of the intent to cease operation to the Authority;

(b) Provide the required notice as prescribed in the county ASA plan to the county health department and the ASA authority in which the ambulance service operates; and

(c) Take such other actions as may be determined to be necessary by the Authority or the county health, or the ASA authority to assure the smooth transition to a new ambulance service provider, including but not limited to permitting the continued operation of the existing provider for more than the required period of legal notice or making equipment and supplies available to an interim ambulance service provider.

(3) Within 10 days of final closing of the ambulance service sale, the owner must return the ambulance service license to the Authority.

(4) An owner may not terminate the ambulance service business or otherwise cease operations in contravention of any provisions, rules or ordinances established under the provision of ORS Chapter 682.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: HD 18-1994, f. 6-30-94, cert. ef. 7-1-94; OHD 7-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 1-2013, f. & cert. ef. 1-25-13

333-250-0085
Patient Rights for Emergency Medical Care and Transportation

(1) An ambulance service licensed by the Authority shall maintain written policies and procedures regarding patient rights.

(2) A statement of patient rights shall be distributed to each employee or volunteer and made available in the business office and in each satellite location.

(3) The statement of patient rights shall include, but is not limited to, the following:

(a) Access to appropriate emergency medical care and transportation without regard to race, ethnicity, religion, age, gender, sexual orientation, or disability;

(b) EMS providers will be considerate and respectful to all patients regardless of status;

(c) Opportunity to refuse any medical care or transportation to a medical facility when informed about the care to be provided and the risks associated with refusing medical care or transportation;

(d) Transportation to a clinically appropriate medical facility of the patient's choice without questioning ability to pay. The agency may elect to transport to a closer, appropriate medical facility if a patient's facility of choice:

(A) Is unreasonable due to unsafe conditions; or

(B) Requires an ambulance to be taken out of service for an unreasonable amount of time;

(e) When appropriate, opportunity to request private transport, for example from a friend or family member;

(f) Patient's health information will be protected in accordance with state and federal privacy laws;

(g) Opportunity to receive, upon request, medical information relating to the care or transport provided by EMS providers;

(h) Opportunity to receive, upon request, a reasonable explanation of any charges for emergency medical care provided by EMS providers or for ambulance services; and

(i) Information on how and where to file a complaint about the services performed is posted and available.

(4) Notwithstanding subsection (3)(d) of this rule, a licensed ambulance service may transport a patient against the patient's wishes if it is determined that the patient is incapacitated to make decisions based upon illness, injury or age.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: PH 14-2016, f. & cert. ef. 4-28-16

333-250-0100
Advertising of an Ambulance Service

(1) The licensee may advertise only when the ambulance service and ambulance meets the requirements of ORS Chapter 682 and these rules.

(2) If the licensee does not provide the level of service advertised, the license may be denied, suspended or revoked in accordance with the provisions of ORS Chapter 183 for failure to comply.

(3) No licensee shall advertise or promote the use of any telephone number other than "9-1-1" for emergency ambulance service.

(4) A licensee which offers non-emergency service may advertise its non-emergency or business telephone number for other than emergency use, provided that in any print, audio or video advertising the phrase "FOR EMERGENCIES -- CALL 9-1-1" is provided. When using the phrase "FOR EMERGENCIES -- CALL 9-1-1" in print, it must be in bold-faced type at least one and one-half times the point size in which the non-emergency or business telephone number is displayed.

(5) Contents of ambulance service advertising must include:

(a) The legal name of the ambulance service indicated on the license issued by the Authority;

(b) If the licensee advertises 24-hours-a-day operation, the ambulance service must provide uninterrupted service 24-hours-a-day, 7 days-a-week, 365 days-a-year; and

(c) If the licensee provides service for only a portion of a 24-hour day or week, any advertising must specify the hours and days of operation.

(6) Advertising materials disclosure upon request. The licensee must maintain copies of all print, audio, video, and all other types of advertisements for one year after use and distribution have ceased, and must make those copies available to the Authority upon request.

(7) Novelty or promotional items which are not distributed to the general public do not meet the definition of advertisement.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: HD 18-1994, f. 6-30-94, cert. ef. 7-1-9; OHD 7-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 1-2013, f. & cert. ef. 1-25-13

DIVISION 255

AMBULANCE LICENSING

333-255-0000
Definitions

(1) "Advanced Emergency Medical Technician (AEMT)" means a person who is licensed by the Authority as an Advanced Emergency Medical Technician.

(2) "Ambulance" or "Ambulance Vehicle" means any privately or publicly owned motor vehicle, aircraft, or watercraft that is regularly provided or offered to be provided for the emergency transportation of persons who are ill or injured or who have disabilities.

(3) "Ambulance Based Clinician" means a Registered Nurse, Physician, or Physician Assistant who:

(a) Has an active license in Oregon and is in good standing with the Oregon Board of Nursing or the Oregon Medical Board; and

(b) Staffs an ambulance for a licensed ambulance service.

(4) "Ambulance Service" means any person, governmental unit, corporation, partnership, sole proprietorship, or other entity that operates ambulances and that holds itself out as providing prehospital or medical transportation to persons who are ill or injured or who have disabilities.

(5) "Ambulance Service Area (ASA)" means a geographic area served by one ground ambulance service provider, and may include all or portion of a county, or all or portions of two or more contiguous counties.

(6) "Authority" means the Emergency Medical Services and Trauma Systems Program, within the Oregon Health Authority.

(7) "Business day" means Monday through Friday when the Authority is open for business, excluding holidays.

(8) "Emergency Care" means the performance of acts or procedures under emergency conditions in the observation, care and counsel of the ill, injured or disabled; in the administration of care or medications as prescribed by a licensed physician, insofar as any of these acts is based upon knowledge and application of the principles of biological, physical and social science as required by a completed course utilizing an approved curriculum in prehospital emergency care. However, "emergency care" does not include acts of medical diagnosis or prescription of therapeutic or corrective measures.

(9) "EMS" means Emergency Medical Services.

(10) "EMS Medical Director" has the same meaning as "Supervising Physician" in ORS 682.025.

(11) "Emergency Medical Responder (EMR)" means a person who is licensed by the Authority as an Emergency Medical Responder.

(12) "Emergency Medical Services Provider (EMS Provider)" means a person who has received formal training in prehospital and emergency care and is state-licensed to attend to any ill, injured or disabled person. Police officers, fire fighters, funeral home employees and other personnel serving in a dual capacity, one of which meets the definition of "emergency medical services provider" are "emergency medical services providers" within the meaning of ORS Chapter 682.

(13) "Emergency Medical Technician (EMT)" means a person who is licensed by the Authority as an Emergency Medical Technician.

(14) "EMT-Basic" has the same meaning as Emergency Medical Technician.

(15) "EMT-Intermediate" means a person who is licensed by the Authority as an EMT-Intermediate.

(16) "EMT-Paramedic" has the same meaning as Paramedic.

(17) "In Operation" means the time beginning with the initial response of the ambulance and ending when the ambulance is available to respond to another request for service. An ambulance that transports a patient becomes available to respond when the care of the patient has been transferred.

(18) "License" means the documents issued by the Authority to the owner of an ambulance service when the service and its ambulances are found to be in compliance with ORS Chapter 682, OAR chapter 333, division 250 and OAR chapter 333, division 255.

(19) "Non-emergency Care" means the performance of acts or procedures on a patient who is not expected to die, become permanently disabled or suffer permanent harm within the next 24-hours, including but not limited to observation, care and counsel of a patient and the administration of medications prescribed by a physician licensed under ORS Chapter 677, insofar as any of those acts are based upon knowledge and application of the principles of biological, physical and social science and are performed in accordance with scope of practice rules adopted by the Oregon Medical Board in the course of providing prehospital care as defined by this rule.

(20) "Owner" means the person having all the incidents of ownership in an ambulance service or an ambulance or, where the incidents of ownership are in different persons, the person, other than a security interest holder or lessor, entitled to the possession of an ambulance vehicle or operation of an ambulance service under a security agreement of a lease for a term of 10 or more successive days.

(21) "Paramedic" means a person who is licensed by the Authority as a Paramedic.

(22) "Patient" means a person who is ill or injured or who has a disability and who is transported in an ambulance.

(23) "Person" means any individual, corporation, association, firm, partnership, joint stock company, group of individuals acting together for a common purpose, or organization of any kind and includes any receiver, trustee, assignee, or other similar representatives thereof.

(24) "Physician" means a person licensed under ORS Chapter 677, actively registered and in good standing with the Oregon Medical Board as a Medical Doctor (MD) or Doctor of Osteopathic Medicine (DO).

(25) "Physician Assistant (PA)" means a person licensed under ORS Chapter 677, actively registered and in good standing with the Oregon Medical Board.

(26) "Prehospital Care" means that care rendered by EMS providers as an incident of the operation of an ambulance as defined by ORS Chapter 682 and that care rendered by EMS providers as incidents of other public or private safety duties, and includes, but is not limited to "emergency care" as defined by ORS Chapter 682.

(27) "Prehospital Care Report Form (PCRF)" means an Authority-approved form or electronic field data format that is completed for all patients receiving prehospital assessment, care or transportation to a medical facility.

(28) "Qualified Driver" means someone who is not licensed by the Authority and who meets Authority requirements to operate a ground ambulance.

(29) "Registered Nurse (RN)" means a person licensed under ORS Chapter 678, actively registered and in good standing with the Oregon Board of Nursing.

(30) "Rural Ambulance Service" means ambulance service located in an area where all geographic areas are 10 or more miles from the centroid of a population center of 40,000 or more.

(31) "Sanitary" means being free from all body fluids, dirt, dust, grease or other extraneous matter.

(32) "Scope of Practice" means the maximum level of emergency or non-emergency care that an emergency medical technician may provide.

(33) "Specialty Care Transport (SCT)" means interfacility transportation of a critically injured or ill beneficiary by a ground ambulance vehicle, including medically necessary supplies and service, at a level of service beyond the scope of the Paramedic. SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area, for example nursing, emergency medicine, respiratory care, cardiovascular care, or a Paramedic with additional training. Any skill or medication in addition to or not found in the Department of Transportation curriculum for Paramedics would be defined as additional training and is defined by the EMS medical director.

(34) "Standing Orders" means the written detailed procedures for medical or trauma emergencies issued by the EMS medical director to be performed by appropriate certificate holders or licensees in conformance with the scope of practice and level of licensure.

Stat. Auth.: ORS 682.017

Stats. Implemented: ORS 682.017 - 682.117, 682.991

Hist.: HD 63, f. 6-6-74, ef. 6-25-74; HD 1-1981, f. & ef. 1-14-81; Renumbered from 333-023-0600; HD 19-1984, f. & ef. 9-10-84; HD 16-1986, f. & ef. 9-9-86; HD 9-1987, f. & ef. 7-21-87; HD 19-1991, f. & cert. ef. 10-18-91; HD 8-1993, f. 6-22-93, cert. ef. 7-1-93; HD 18-1994, f. 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0000; OHD 5-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 12-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2013, f. & cert. ef. 1-25-13

333-255-0010
Application Process to Obtain an Ambulance License

(1) An ambulance service owner that wishes to obtain an ambulance license must apply for and receive an ambulance license from the Authority before placing an ambulance into operation.

(2) The Authority shall issue an ambulance license to the owner of an ambulance service that is not subject to disqualification from licensure for any reason specified in ORS Chapter 682, OAR chapter 333, division 250 or these rules. The ambulance service owner must:

(a) Have a current ambulance service license;

(b) Have paid the fees required by ORS Chapter 682 and these rules;

(c) Agree to comply with all applicable federal, state and local laws and regulations governing the operation of a licensed ambulance; and

(d) Submit a completed application in a form specified by the Authority in accordance with ORS 682.045 and these rules.

(3) An application for an air ambulance license must be made on an Authority-approved form containing at a minimum:

(a) The name and address of the person or public entity owning the aircraft;

(b) If other than the applicant's true name, the name under which the applicant is doing business;

(c) The description of the ambulance:

(A) Indication if the aircraft was purchased from an ambulance service in Oregon;

(B) Type of aircraft:

(i) Fixed-wing; or

(ii) Rotary-wing.

(C) Number of engines;

(D) Make of aircraft;

(E) Model of aircraft;

(F) Year of manufacture;

(G) Federal Aviation Authority (FAA) registration number;

(H) Whether a major repair or alteration has been made to the aircraft, and if so, a FAA Form 337 must be on file in the licensee's office for each repair or alteration made;

(I) Aircraft colors:

(i) Fuselage;

(ii) Stripe; and

(iii) Lettering.

(J) Insigne name, monogram or other distinguishing characteristics. A photo of the air ambulance may be submitted to show these characteristics.

(4) An application for a ground ambulance must be made on an Authority-approved form containing at a minimum:

(a) The name and address of the person or public entity owning the ambulance;

(b) If other than the applicant's true name, the name under which the applicant is doing business;

(c) The description of the ambulance:

(A) Whether the ground ambulance was purchased from an ambulance service in Oregon;

(B) Make of vehicle;

(C) Model type of vehicle;

(D) Year of manufacture;

(E) Whether the vehicle is a remounted chassis;

(F) Conversion manufacturer;

(G) Vehicle Identification Number;

(H) Vehicle license plate number;

(I) Mileage at the time of licensing;

(J) Ambulance colors:

(i) Body;

(ii) Stripe; and

(iii) Lettering.

(K) Insigne name, monogram or other distinguishing characteristics. A photo of the ground ambulance may be submitted to show these characteristics.

(d) A copy of the ground ambulance manufacturers authenticated Star-of-Life certificate or Final Stage Vehicle Manufacturing Certification of compliance;

(A) A previously owned ambulance must have, at a minimum, a January 1, 1995, Star-of-Life certificate; or

(B) A newly constructed ambulance must have at a minimum a Star-of-Life certificate or a Final Stage Vehicle Manufacturing Certificate of compliance.

(5) A completed application for the licensing of a marine ambulance must contain, at a minimum:

(a) The name and address of the person or public entity owning the ambulance;

(b) If other than the applicant's true name, the name under which the applicant is doing business;

(c) The description of the ambulance:

(A) Whether the marine craft was purchased from an ambulance service in Oregon;

(B) Whether the patient-care area is covered or uncovered;

(C) Number of engines;

(D) Type of engines:

(i) Inboard;

(ii) Outboard; or

(iii) Both inboard and outboard.

(E) Make of marine craft;

(F) Model of marine craft;

(G) Year of manufacture;

(H) Marine craft registration number;

(I) Marine craft license plate number;

(J) Ambulance colors:

(i) Hull;

(ii) Stripe; and

(iii) Lettering.

(K) Insigne name, monogram or other distinguishing characteristics. A photo of the marine ambulance may be submitted to show these characteristics.

(d) A signed and dated statement that the application contains truthful information.

(6) The completed ambulance license application must be submitted to the Authority with a nonrefundable ambulance licensing fee of:

(a) $45, when the service has a maximum of four full-time paid positions; and

(b) $80, when the service has five or more full-time paid positions.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist. HD 18-1994, f. 6-30-94, cert. ef. 7-1-94; OHD 5-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 12-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2013, f. & cert. ef. 1-25-13

333-255-0020
Issuance of License to Operate an Ambulance

(1) When the completed ambulance license application with a nonrefundable ambulance license fee as specified in OAR 333-255-0010(6)(a) or (6)(b) has been received by the Authority and if it is found that the submitted data complies with the requirements of ORS Chapter 682 and these rules, the Authority shall issue an ambulance license for the specified ambulance within 10 business days.

(2) The ambulance license:

(a) Shall be valid until June 30 of each year, unless sooner revoked or suspended. The initial licensing period may not exceed 15 months;

(b) If issued between April 1 and June 30, shall expire on June 30 of the following year; and

(c) Must be conspicuously displayed in the operator's or patient compartment of the ambulance, or otherwise as directed by the Authority.

(3) Except when specifically exempted by ORS 682.035 and OAR 333-250-0030(3)(a) through (3)(d), an out-of-state licensed ambulance that operates in Oregon must be licensed by the Authority:

(a) An ambulance license shall be granted when the ambulance is currently licensed in another state, the standards of which meet or exceed those of Oregon; and

(b) The owner submits to the Authority:

(A) A completed Oregon ambulance license application;

(B) A non-refundable ambulance licensing fee as specified in OAR 333-255-0010(6)(a) or (6)(b); and

(C) A copy of the current home-state ambulance license.

(4) An ambulance license is not transferable to a replacement ambulance or to a new owner.

(5) An ambulance license shall be issued to an owner of an ambulance used as a reserve, so long as the ambulance meets all construction and mechanical requirements at the time of manufacture. A reserve ambulance shall not be required to have patient care equipment on-board at all times. However, when the ambulance is placed in operation, it must meet all ambulance licensing requirements.

(6) If an ambulance license becomes lost, damaged or destroyed, the licensee must obtain an application for a replacement license from the Authority. The licensee must submit the completed application with a nonrefundable fee of $10 to the Authority for each replacement license and shall receive a replacement license within 10 business days.

(7) When an ambulance is found to be in non-compliance with ORS Chapter 682 or these rules, the Authority may deny, suspend or revoke the ambulance license as authorized by ORS 682.220.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist. HD 63, f. 6-6-74, ef. 6-25-74; HD 1-1981, f. & ef. 1-14-81; Renumbered from 333-023-0605; HD 19-1984, f. & ef. 9-10-84; HD 16-1986, f. & ef. 9-9-86; HD 19-1991, f. & cert. ef. 10-18-91; HD 18-1994, f. 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0005; OHD 5-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 1-2013, f. & cert. ef. 1-25-13

333-255-0030
Denial, Suspension or Revocation of an Ambulance License

(1) The Authority may, in compliance with proper administrative procedures as prescribed in ORS Chapter 183, deny, suspend, or revoke an ambulance license issued under these rules, or an ambulance service license issued under OAR 333-250-0030, if the Authority determines:

(a) A violation of ORS Chapter 682 or of these rules has occurred that poses a significant threat to the health and safety of the public or an applicant does not meet the requirements of ORS Chapter 682 or these rules;

(b) The ambulance owner makes a material omission or misrepresentation of facts on an application for a license or waiver, or in response to an inquiry or investigation. This includes the intentional misrepresentation or misstatement of a material fact, concealment of or failure to make known any material fact or any other means by which misinformation or false impression is knowingly given or deceit in obtaining or attempting to obtain a license or waiver or in any other transaction with the Authority;

(c) Defacing, altering, removing or obliterating any portion of any official entry upon a license, licensing decal, or waiver issued by the Authority;

(d) Failure to have the appropriate personnel, medical equipment and supplies required for operation at the highest level of service provided when the ambulance is in operation as prescribed by these rules;

(e) When an ambulance, upon inspection by the Authority, manifests evidence of a mechanical or equipment deficiency that poses a significant threat to the health or safety of patients or crew, the Authority shall immediately suspend that ambulance from operation. No ambulance that has been suspended from operation may be operated as an ambulance until the licensee has certified and the Authority has confirmed that the deficiency has been corrected; and

(f) Other reasons determined by the Authority to pose a significant threat to the Authority and safety and the well being of patients.

(2) The licensee must return all indications of licensing, including certificates and the remains of ambulance license decals to the Authority by registered mail, posted within 48 hours of either receipt of notification of suspension or revocation or the effective date of revocation, whichever is later.

(3) The Authority must provide appropriate public notification of the suspension or revocation of an ambulance license.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist. HD 19-1991, f. & cert. ef. 10-18-91; HD 18-1994, f. 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0006; OHD 5-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 12-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2013, f. & cert. ef. 1-25-13

333-255-0040
Surrender of License to Operate an Ambulance

(1) The ambulance license in the owner's possession must be surrendered to the Authority immediately upon notification by the Authority of the suspension or revocation of an ambulance service or ambulance license, or upon the sale of an ambulance, or upon the termination of operations.

(2) An ambulance license is non-transferable. When the owner sells, trades, or donates an ambulance, or terminates the business, the licensee must notify the Authority within 10 days of the transaction by listing the date that the sale was completed and the full name and address of the purchaser of the ambulance on the back of the ambulance license and surrendering all ambulance licenses for that ambulance to the Authority.

(3) When an ambulance is decommissioned and not sold to another licensed ambulance service, the owner of the ambulance shall be responsible for the removal of the ambulance license decals. Ambulance license decals shall be returned to the Authority within 10 business days. In addition to the removal of the ambulance license decals, the owner of the vehicle shall remove any emblems or markings as defined in OAR 333-255-0060(5) identifying the vehicle as an ambulance.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist. HD 63, f. 6-6-74, ef. 6-25-74; HD 1-1981, f. & ef. 1-14-81; Renumbered from 333-023-0610; HD 19-1984, f. & ef. 9-10-84; HD 16-1986, f. & ef. 9-9-86; HD 19-1991, f. & cert. ef. 10-18-91; HD 18-1994, f. 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0010; OHD 5-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 1-2013, f. & cert. ef. 1-25-13; PH 1-2013, f. & cert. ef. 1-25-13

333-255-0050
Right of Entry and Inspection of an Ambulance

(1) The Authority may conduct an inspection of an ambulance vehicle for the purpose of evaluating the eligibility of an ambulance service to receive or retain an ambulance license and to ensure the health, safety, and welfare of the persons who utilize ambulances. The ambulance service may be exempted from the inspection process if;

(a) The ambulance service is accredited by a nationally recognized EMS service program accreditation entity that meets or exceeds Oregon requirements. A copy of the inspection report from the nationally recognized EMS service program accreditation entity must be filed with the Authority for approval; or

(b) The ambulance service and ambulance has undergone inspections from a governmental agency or state designee. A copy of the inspection report from the governmental agency or state designee must be filed with the Authority for approval.

(2) Initial and routine inspections of an ambulance must be scheduled with the management of the ambulance service at least 72 hours in advance of the inspection unless otherwise mutually agreed upon by the Authority and ambulance service representative.

(3) Inspections for the purpose of investigating a complaint do not require giving advanced notice to the licensee. Unless the

Authority gives written approval, no person may give advanced notice of an unannounced inspection.

(4) Upon request of the Authority, an ambulance service owner, manager, employee, volunteer or agent must, at a reasonable time and without delay, permit entry by the Authority onto all premises housing an ambulance for the purpose of an ambulance inspection. No one, including but not limited to, the owner, the manager, employees, volunteers, and agents, may impede the Authority in conducting a lawful inspection of an ambulance to evaluate compliance with ORS Chapter 682 and these rules.

(5) In conducting an inspection, the Authority must:

(a) Identify him or herself by presenting Authority identification to the owner, manager, ranking employee, or volunteer present at the site of an inspection;

(b) Inform the ambulance service representative of the purpose for the inspection; and

(c) Inform the ambulance service representative when the inspection has been completed and the results of the inspection.

(6) The Authority may inspect an ambulance at any reasonable time including, but not limited to, whenever the ambulance is present at the ambulance service office or any satellite-office location.

(7) The Authority shall conduct an inspection without impeding patient care or unreasonably delaying patient transport unless, in the judgment of the Authority, the lack of properly operating patient care equipment, the safety condition of the ambulance, or the patient care being rendered is detrimental or is reasonably likely to be detrimental to the patient's health, safety, or welfare.

(8) When an ambulance is found to be in violation with ORS Chapter 682 or these rules, and requires a second or subsequent on-site inspection, the Authority may impose a civil penalty as authorized in ORS 682.224:

(a) A subsequent on-site inspection must be conducted and passed on the same day as the initial inspection if the ambulance is to remain available for operation;

(b) If the subsequent on-site inspection reveals that all violations have not been corrected and those violations constitute an immediate danger or threat to the public, the Authority may immediately suspend the ambulance license. The suspension shall remain in force until all violations have been corrected;

(c) The Authority shall immediately notify the county health department and the administrator of the county ASA plan of any ambulance license suspension; and

(d) A copy of the completed inspection form shall be given to a representative of the ambulance service and one copy each shall be sent to the county health department and administrator of the county ASA plan.

(9) An Authority representative may accompany an ambulance crew on a call for the purpose of evaluating compliance with the requirements of ORS Chapter 682 and these rules.

(10) The Authority shall have the authority to make photographic or video-graphic documentation as part of an inspection for or investigation of non-compliance with ORS Chapter 682 and these rules.

(11) Failure of the licensee to produce records for inspection or to permit examination of an ambulance or patient care equipment by the Authority shall be grounds for the denial, suspension or revocation of an ambulance license.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist. HD 18-1994, f. 6-30-94, cert. ef. 7-1-94; OHD 5-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 1-2013, f. & cert. ef. 1-25-13

333-255-0060
Ground Ambulance Construction Criteria

(1) The construction criteria for a new ground ambulance shall comply with June 1, 2008 Federal Specifications for the Star-of-Life Ambulance Certification. Copies of the specifications are available through the Authority.

(2) The construction criteria for a previously owned ambulance must comply with the November 1, 1994 Federal Specifications for the Star-of-Life Ambulance Certification, or standards as defined by the Final Stage Vehicle Manufacturing Certification of compliance. Copies of the specifications are available through the Authority.

(3) The construction criteria for remounting a Type I or Type III ambulance is:

(a) The patient compartment must have been built after November 1, 1994; and

(b) The remounting must be done by a recognized ambulance manufacturer, a recognized vehicle modifier, a remount center, or licensee with an established in-house remount program. The agency doing the remounting must utilize current nationally recognized vehicle modification techniques and industry standard parts and components. The agency doing remounting shall provide a notarized statement that the structural integrity of the specific patient compartment was not compromised during the remounting, and the remounting has not invalidated the Star-of-Life Certification or Final Stage Vehicle Manufacturing Certificate of compliance.

(4) A licensee may establish an in-house remount program by obtaining the necessary training, appropriate equipment and facilities to remount a vehicle to the described standard.

(5) The owner of an ambulance must select an exterior color, emblems, and markings for the ambulance that will ensure the prompt recognition of that vehicle as an ambulance. All ambulance vehicles shall be clearly identified by appropriate emblems and markings on the front, side, roof, and rear of the vehicle.

(a) The size, number and locations of the "Star-of-Life" emblems are:

(A) Sides — a 12 to 16-inch emblem must be located on the left and right side panels.

(B) Roof — a 32-inch emblem must be located on the roof.

(b) The size, number and locations of the word "AMBULANCE" are:

(A) Front — centered, in block letters, not less than four inches high, must be in mirror image and centered above the grille;

(B) Rear — in block letters of not less than six inches in height and centered on the rear door panels or an approved alternative; and

(C) Acceptable alternatives for the word "AMBULANCE" includes generic terms that do not connote any particular level of service, limited to "MEDIC UNIT", "FIRE MEDIC UNIT", "EMERGENCY MEDICAL SERVICES", "EMS UNIT" or other phrases as the Authority, in its sole discretion, may permit.

(c) The locations of additional markings are:

(A) An ambulance shall display the service or organization name or logo on the vehicle;

(B) An ambulance may not display on its exterior any level of service which is not provided at all times when that ambulance is in operation.

(6) An ambulance in operation and a reserve ambulance must be reasonably equipped and maintained, and maintenance records must be kept and made available for inspection by the Authority. An ambulance must be equipped with the following items in satisfactory working condition:

(a) Audio/visual devices must be in compliance with the Star-of-Life Certification or the Final Stage Vehicle Manufacturing Certificate of compliance;

(b) An ambulance shall comply with Federal Motor Vehicle Safety Standards (FMVSS) and Department of Transportation (DOT) vehicle equipment standards for the ambulance at the time of manufacture;

(c) In case of dual batteries, batteries located in the engine compartment must have heat shields. If the batteries are located elsewhere, they must be sealed off from the occupants' compartment in a ventilated area.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: HD 63, f. 6-6-74, ef. 6-25-74; HD 1-1981, f. & ef. 1-14-81; Renumbered from 333-023-0655; HD 16-1986, f. & ef. 9-9-86; HD 19-1991, f. & cert. ef. 10-18-91; HD 18-1994, f. 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0055; OHD 5-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 12-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2013, f. & cert. ef. 1-25-13

333-255-0070
Ground Ambulance Operating Requirements

(1) In order to operate a ground ambulance a licensee shall:

(a) Have a qualified driver that meets the qualifications in OAR chapter 333, division 250;

(b) Have EMS providers or other qualified licensed health care professionals staffing the ambulance, as required by OAR chapter 333, division 250.

(c) Ensure that the appropriate equipment is available and in satisfactory working condition, stored in a sanitary and secure manner that protects the viability and safe operation of medications and equipment, including but not limited to:

(A) Installed medical oxygen cylinder with a capacity of at least 3,000 liters and having not less than 500 psi:

(i) The installed medical oxygen cylinder must be located in a vented compartment; and

(ii) The compartment shall not be utilized for storage of any non-secured equipment. No combustible items shall be stored in the oxygen compartment.

(B) Oxygen pressure regulator:

(i) The oxygen must be delivered by a single-stage regulator which is set to at least 50 psi;

(ii) The pressure regulator controls must be accessible from inside the patient compartment; and

(iii) The pressure regulator or other display must be visible from inside the patient compartment.

(C) Oxygen flow meter, mounted — 2:

(i) The flow meter must be readable from the EMT seat and squad bench; and

(ii) The flow meter must be adjustable over a minimum range of 0 to 15 liters per minute.

(D) Portable medical oxygen cylinder with a capacity of at least 300 liters and having not less that 500 psi:

(i) The oxygen must be delivered by a yoke regulator with a pressure gauge and non-gravity-dependent flow meter that is visible and accessible to the medical personnel; and

(ii) The flow meter must be adjustable over a minimum range of 0 to 15 liters per minute.

(E) Spare portable oxygen cylinder that is full, tagged, sealed and securely mounted;

(F) Oxygen non-rebreathing masks with tubing:

(i) Pediatric — 2; and

(ii) Adult — 3.

(G) Oxygen nasal cannula with tubing that is transparent and disposable, adult — 3;

(H) Bag-valve-mask ventilation device with reservoir. The device must:

(i) Have a standard universal adapter;

(ii) Be operable with or without an oxygen supply;

(iii) Be manually operated and self-refilling; and

(iv) Have bag-valve-mask ventilation devices with reservoir that are transparent and semi-rigid in assorted sizes to include adult, child, and newborn/infant.

(I) Pharyngeal esophageal airway devices in assorted sizes with agency supervising physician approval;

(J) Oxygen Saturation Monitor;

(K) Endtidal CO2 detection device in assorted sizes;

(L) Oropharyngeal airways in assorted sizes to include adult, child, and newborn/infant;

(M) Nasopharyngeal airways in assorted sizes;

(N) Two suction apparatus. Suction apparatus:

(i) Shall be electrically powered or battery powered with pressure regulator.

(ii) If battery powered, shall have enough back-up batteries to maintain suction during routine transport.

(O) Adequate supply of wide-bore tubing, commercial rigid pharyngeal curved suction tips and flexible suction catheters sized from infant to adult;

(P) Collection canisters, either disposable or sealable liners, with adequate capacity.

(Q) Cardiac monitoring equipment including, at a minimum, a portable battery operated automatic external defibrillator (AED) or semi-automatic defibrillator with pediatric capabilities and sufficient pediatric accessories for proper operation on a pediatric patient.

(R) A wheeled stretcher:

(i) Capable of securely fastening to the ambulance body;

(ii) Having a minimum of three restraining devices and an upper torso (over the shoulder) restraint;

(iii) Containing a standard size waterproof foam mattress; and

(iv) Capable of having the head of the stretcher tilted upwards to a 60-degree semi-sitting position.

(S) At least one folding stretcher, the number required based on the stretcher-carrying capacity of the ambulance, or an additional long backboard:

(i) Capable of securely fastening to the squad bench when carrying a patient; and

(ii) Having a minimum of three restraining devices and an upper torso (over the shoulder) restraint.

(T) Fracture immobilization equipment, including but not limited to:

(i) Traction splints in assorted adult sizes or adult child combination;

(ii) Extremity splints in assorted sizes;

(iii) Extrication collars in assorted pediatric through adult sizes;

(iv) Scoop stretcher, folding or non-folding type with necessary restraining devices with sufficient supplies for head immobilization;

(v) Short backboard or equivalent with necessary restraining devices with sufficient supplies for head immobilization;

(vi) Long backboard with necessary restraining devices with sufficient supplies for head immobilization;

(vii) Pediatric backboard with necessary restraining straps with sufficient supplies for head immobilization;

(viii) Bandages and dressings in assorted sizes, sterile and non-sterile; and

(ix) Adhesive or hypo-allergenic tape in assorted sizes.

(U) Miscellaneous equipment, including but limited to:

(i) Emesis containers;

(ii) Stethoscope, pediatric and adult;

(iii) Aneroid sphygmomanometer in assorted sizes;

(iv) Bandage shears;

(v) Hypothermia thermometer;

(vi) Disposable obstetrical kit;

(vii) Chemical heat and cold packs assorted;

(viii) Urinals, female and male, one each;

(ix) Bedpan;

(x) Set of extremity restraining devices;

(xi) Blood glucose level testing kit or blood glucose level test strips;

(xii) Medications and fluids authorized for Basic Life Support (BLS) use as required by the EMS medical director; and

(xiii) Linen supplies and replacements sufficient to cover wheeled stretchers.

(V) Personal protection equipment sufficient for crew and patient(s), including but not limited to:

(i) Non-latex disposable gloves;

(ii) Disposable face masks;

(iii) Protective eyewear;

(iv) Disposable isolation gowns;

(v) Commercial antimicrobial hand cleanser;

(vi) Surface cleaning disinfectant;

(vii) Sharps container for the patient care compartment and a separate container for each kit that contains needles; and

(viii) Infectious waste disposal bags.

(W) Security and rescue equipment, including but not limited to:

(i) Fire extinguisher, 5lb. (2A-10BC type) — mounted and readily accessible in either the driver's or patient compartment;

(ii) Road flares, red colored chemical lights, the number and burning time to equal at least 180 minutes, or a minimum of six reflective triangles;

(iii) Flashlight;

(iv) Leather gloves sufficient for crew;

(v) Reflective vests for each crew member;

(vi) HEPA mask for each crew member; and

(vii) Adequate extrication equipment for agencies that provide initial response without the response of other rescue apparatus or equipment.

(X) The 2008 Department of Transportation Emergency Response Guidebook, (Initial Response to Hazardous Materials Incidents);

(Y) Triage tags — 25;

(Z) Oregon Trauma Systems Identification Bracelets — 5;

(AA) Prehospital Care Report Forms or electronic field data form;

(BB) A copy of BLS standing orders dated within one year and signed by the EMS medical director;

(CC) A universal "No Smoking" sign conspicuously displayed in the driver's and patient compartment; and

(DD) A universal "Fasten Seatbelt" sign conspicuously displayed in the driver's compartment.

(2) An ambulance shall have two-way radio communication equipment to provide reliable contact between the ambulance and central dispatch, the receiving hospital, and online medical direction.

Stat. Auth.: ORS 682.017

Stats. Implemented: ORS 682.017 - 682.117, 682.991

Hist. HD 63, f. 6-6-74, ef. 6-25-74; HD 1-1981, f. & ef. 1-14-81; Renumbered from 333-023-0650; HD 14-1981(Temp), f. & ef. 8-7-81; HD 19-1984, f. & ef. 9-10-84; HD 16-1986, f. & ef. 9-9-86; HD 9-1987, f. & ef. 7-21-87; HD 19-1991, f. & cert. ef. 10-18-91, Renumbered from 333-028-0051 & 333-028-0052; HD 8-1993, f. 6-22-93, cert. ef. 7-1-93; HD 18-1994, f. 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0050; OHD 5-2001, f. & cert. ef. 2-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 12-2010, f. 6-30-10, cert. ef. 7-1-10; PH 16-2010(Temp), f. & cert. ef. 7-16-10 thru 1-1-11; PH 1-2011, f. & cert. ef. 1-6-11; PH 1-2013, f. & cert. ef. 1-25-13

333-255-0071
Ground Ambulance Operating Requirements When Providing Intermediate Level Care

(1) A ground ambulance in operation and providing intermediate life support care must have at a minimum the following staffing:

(a) A qualified driver, an EMT or above, and an advanced emergency medical technician or EMT-Intermediate; or

(b) A driver who is licensed at least at an EMT level and an advanced emergency medical technician.

(2) Notwithstanding section (1) of this rule a rural ambulance service as that term is defined in OAR 333-255-0000(30) is permitted to operate a ground ambulance providing intermediate level care with a qualified driver and one AEMT or an EMT-Intermediate if the rural ambulance service:

(a) Notifies the county responsible in writing for the applicable ASA of the reduced staffing and the county notifies the ambulance service in writing that it does not object to the reduced staffing;

(b) Notifies the licensee's supervising physician in writing of the reduced staffing and the supervising physician notifies the ambulance service in writing that he or she does not object to the reduced staffing; and

(c) Provides, to the Authority in writing by certified mail, the following:

(A) A description of efforts made to comply with the staffing requirements in section (1) of this rule; and

(B) A copy of the county's notice that it does not object.

(3) If a rural ambulance service is operating with reduced staffing pursuant to section (2) of this rule and the ambulance service responds to a call with reduced staffing, a copy of the PCHR must be sent to the Authority within 14 days of responding to the call.

(4) A rural ambulance service operating with reduced staffing pursuant to section (2) of this rule must make a continuous effort to attempt to comply with the staffing requirements in section (1) of this rule and comply with the requirements of section (2) of this rule annually.

(5) A ground ambulance must meet all requirements specified in OAR 333-255-0070.

(6) A ground ambulance in operation and providing intermediate level care must have the following items in satisfactory working condition, kept in a sanitary manner, stored in a secure manner and be readily accessible to the medical personnel:

(a) All items specified in OAR 333-255-0070;

(b) Cardiac Monitoring Equipment:

(A) A portable battery powered manual monitor defibrillator capable of recording ECG reading;

(B) ECG electrodes, adult and pediatric;

(C) Hands-free defibrillation patches, adult and pediatric or defibrillation paddles, adult and pediatric;

(D) Contact gel if using paddles;

(E) Patient cables — 2; and

(F) ECG paper.

(c) Any physiologic isotonic crystalloid solution or combinations thereof — 6000 cc in any size containers;

(d) Medications and fluids authorized for use by an AEMT or EMT-Intermediate as required by the EMS medical director. Storage of controlled substances in an ambulance must adhere to the signed and dated procedures as specified in OAR 333-250-0047(3)(a) and (b);

(e) Vascular access devices:

(A) Over-the-needle catheters in assorted sizes 24-gauge through 14-gauge; and

(B) Specifically-designed needles or device with needles for intraosseous infusions.

(f) A copy of standing orders for AEMTs and/or EMT-Intermediates dated within one year and signed by the EMS medical director.

Stat. Auth.: ORS 682.017

Stats. Implemented: ORS 682.017 - 682.117, 682.991

Hist.: OHD 5-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 12-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2011, f. & cert. ef. 1-6-11; PH 1-2013, f. & cert. ef. 1-25-13

333-255-0072
Ground Ambulance Operating Requirements When Providing Advanced Level Care

(1) A ground ambulance in operation and providing advanced life support care must have at a minimum the following staffing:

(a) A qualified driver, an EMT or above, and a Paramedic, RN, PA or physician who is trained in prehospital emergency medical care; or

(b) A driver who is licensed at least at an EMT level and a Paramedic.

(2) Notwithstanding section (1) of this rule a rural ambulance service as that term is defined in OAR 333-255-0000(30) is permitted to operate a ground ambulance providing advanced level care with a qualified driver and one Paramedic, RN, PA, or physician if the rural ambulance service:

(a) Notifies the county responsible in writing for the applicable ASA of the reduced staffing and the county notifies the ambulance service in writing that it does not object to the reduced staffing;

(b) Notifies the licensee's supervising physician in writing of the reduced staffing and the supervising physician notifies the ambulance service in writing that he or she does not object to the reduced staffing; and

(c) Provides, to the Authority in writing by certified mail, the following:

(A) A description of efforts made to comply with the staffing requirements in section (1) of this rule; and

(B) A copy of the county's notice that it does not object.

(3) If a rural ambulance service is operating with reduced staffing pursuant to section (2) of this rule and the ambulance service responds to a call with reduced staffing, a copy of the PCHR must be sent to the Authority within 14 days of responding to the call.

(4) A rural ambulance service operating with reduced staffing pursuant to section (2) of this rule must make a continuous effort to attempt to comply with the staffing requirements in section (1) of

this rule and comply with the requirements of section (2) of this rule annually.

(5) A person who is at the Paramedic license level, or an RN, PA or physician who is trained in prehospital emergency medical care must be in the patient compartment when a patient is receiving advanced life support care.

(6) When a RN, PA or physician is staffing an ambulance in lieu of a Paramedic and providing advanced level life support care he or she must have:

(a) A current American Heart Association "Health Care Provider," American Red Cross "Basic Life Support for the Professional Rescuer" or other Authority-approved equivalent cardiopulmonary resuscitation (CPR) course completion document;

(b) A current Advanced Cardiac Life Support course or other Authority-approved equivalent completion document;

(c) A pediatric advanced life support course or other Authority-approved equivalent completion document;

(d) A Prehospital Trauma Life Support, Basic Trauma Life Support, Trauma Emergency Assessment Management or Trauma Nurse Core Course completion document. The Trauma Emergency Assessment Management and Trauma Nurse Core Course must include a supplemental prehospital rapid extrication training session;

(e) The ability to properly assist in extricating, lifting and moving a patient;

(f) Not consumed any alcoholic beverages in the eight hours prior to working on an ambulance; and

(g) Not be taking any medications that could impair the giving of proper patient care.

(7) A ground ambulance must meet all requirements specified in OAR 333-255-0070.

(8) Advanced life support patient care equipment. A ground ambulance in operation and providing advanced level care must have the following advanced life support equipment in satisfactory working condition, kept in a sanitary manner and which is readily accessible to medical personnel:

(a) All items specified in OAR 333-255-0070;

(b) Nasogastric tubes in assorted sizes;

(c) Cardiac monitoring equipment as specified in OAR 333-255-0071(2)(b);

(d) Advanced airway care equipment:

(A) Laryngoscope handle and assorted blade sizes, adult and pediatric;

(B) Spare dated batteries for the laryngoscope handle;

(C) Spare bulbs for the laryngoscope blades;

(D) Endotracheal tubes in assorted sizes, adult and pediatric;

(E) Magill Forceps — adult and child;

(F) Intubation stylettes — adult and child;

(G) Endtidal CO2 detection device;

(H) Oxygen saturation monitor; and

(I) Chest decompression equipment.

(e) Sterile intravenous agents and medications authorized by the EMS medical director;

(f) Vascular access devices:

(A) Over-the-needle catheters in assorted sizes 24-gauge through 14-gauge; and

(B) Specifically-designed needles or device designed for intraosseous infusions.

(g) Storage of controlled substances in an ambulance must adhere to the signed and dated procedures as specified in OAR 333-250-0047(3)(a) and (b); and

(h) A copy of standing orders for Paramedics or ambulance based clinicians dated within one year and signed by the EMS medical director.

Stat. Auth.: ORS 682.017

Stats. Implemented: ORS 682.017 - 682.117, 682.991

Hist.: OHD 5-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 12-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2011, f. & cert. ef. 1-6-11; PH 1-2013, f. & cert. ef. 1-25-13

333-255-0073

Ground Ambulance Operating Requirements When Providing Only Specialty Level Care

(1) A ground ambulance in operation and providing only specialty level care during inter-facility transfers must have a minimum staff of two qualified persons as defined by the Center for Medicare Services or additional staff, the number and type, requested by the transferring physician:

(a) A qualified driver who complies with the requirements specified in OAR chapter 333, division 250; and

(b) A person who is at the Paramedic license level, RN, PA, physician or other qualified persons who have additional specialty care training and who must be in the patient compartment when a patient is receiving specialty level care.

(2) A ground ambulance must meet all requirements specified in OAR 333-255-0072.

(3) The Paramedics, RNs, PAs, physicians or other qualified persons must have the:

(a) Training to properly operate all patient care equipment carried on an ambulance, including specialty care equipment necessary to care for the patient during the transfer;

(b) Training to do titration of intravenous medications necessary to care for the patient during transfer; and

(c) Ability to properly assist in lifting and moving a patient.

(4) The personnel staffing an ambulance must not:

(a) Have consumed any alcoholic beverages in the eight hours prior to working on an ambulance; and

(b) Be taking any medications that could impair the giving of proper patient care.

(5) A ground ambulance in operation and providing only specialty level care must have the following patient care equipment in a satisfactory working condition, stored in a sanitary and secure manner, and be readily accessible to the medical personnel:

(a) All patient care equipment specified in OAR 333-255-0072; and

(b) Any other patient care equipment or supplies anticipated or required for patient care.

Stat. Auth.: ORS 682.017

Stats. Implemented: ORS 682.017 - 682.117, 682.991

Hist.: OHD 5-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 12-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2011, f. & cert. ef. 1-6-11; PH 1-2013, f. & cert. ef. 1-25-13

333-255-0079
Exception to the Two Person Staffing Requirement

(1) The Authority may, on application from any full volunteer or part volunteer ambulance service, authorize an exception to the two-person requirement as prescribed by ORS 682.068 and OAR 333-255-0070(1), 333-255-0071(1) or 333-255-0072(1) if provisions acceptable to the Authority have been made to assure timely arrival of the two-person crew as required by ORS 682.068 and OAR 333-255-0070(1), 333-255-0071(1) or 333-255-0072(1).

(2) A full volunteer or part volunteer ambulance service making application for an exception under this rule must submit an application to the Authority in a format prescribed by the Authority:

(a) The application must be approved by the EMS medical director of the ambulance service, the governing body of each municipality for which the exception is being requested and by the county ambulance service planning authority. The application must contain written approval of all such bodies prior to submission to the Authority;

(b) An application for an exception to this provision must provide for and include a description of:

(A) An alerting system which shall make known to the intended responders the location of the emergency and either two-way radio communication between responders such that response can be coordinated by responding personnel, or a fixed schedule of assigned personnel, with designation of the parties who are to respond directly to the scene of an emergency and parties who are to operate the ambulance;

(B) Personnel who respond directly to the scene of an emergency must be individually equipped with equipment necessary to provide initial patient care, including uniform or personal protective clothing, disposable gloves and a pocket ventilation mask or other appropriate ventilatory adjuncts;

(C) Copies of approved standard operating procedures or general orders which address the number of personnel to respond to the scene, organizational policies regarding the operation of motor vehicles by personnel responding to the scene and prohibiting entry into dangerous scenes; and

(D) A method of assuring that neither of the following shall be permitted to occur:

(i) An ambulance driven by a person not licensed as an EMT arrives at an emergency scene but an EMT or higher fails to arrive or arrives substantially later than the responding ambulance; or

(ii) An ambulance driven by an EMT or higher arrives at the scene but no other qualified driver, as specified by these rules, arrives at the scene to operate the ambulance.

(c) Whenever possible, an agency operating under an exception to the general rule granted pursuant to this rule must endeavor to assure that a qualified driver who is not licensed at least to the EMT level is trained to the EMR level and meets the requirements for a qualified driver as specified in OAR 333-250-0031.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: OHD 5-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 1-2013, f. & cert. ef. 1-25-13

333-255-0080
Air Ambulance Configuration and Survival Equipment Requirements

(1) An air ambulance in operation must be in compliance with all Federal Aviation Administration (FAA) regulations contained in Part 135, and ORS Chapter 682, and must be maintained and maintenance records must be kept and made available for inspection by the Authority:

(a) The aircraft must have:

(A) A climate control system to prevent temperature extreme that would adversely affect patient care;

(B) Interior lighting, so that patient care can be given and patient status monitored without interfering with the pilot's vision. The cockpit must be sufficiently isolated, by protective barrier, to minimize in-flight distraction or interference;

(C) At least one outlet per patient and current for 110 volts (50/60 cycle) alternating current or other current which is capable of operating all electrically-powered medical equipment;

(D) A back-up source of electric current or batteries capable of operating all electrically-powered life support equipment for one-hour;

(E) An adequate door to allow loading and unloading of a patient without rotating the patient and stretcher more than 30 degrees about the longitudinal (roll) axis or 45 degrees about the lateral (pitch) axis;

(F) A configuration that allows the medical personnel access to the patient in order to begin and maintain treatment modalities. There must always be complete access to the patient's head and upper body for effective airway management;

(G) The stretcher and medical equipment placed in a manner that shall not impede rapid egress by personnel or patient from the aircraft;

(H) Communications equipment to ensure both internal crew and air-to-ground exchange of information between individuals and agencies appropriate to the mission. Scene response aircraft must be able to communicate with EMS and law enforcement personnel at the scene; and

(I) An installed self-activating emergency locator transmitter.

(b) The aircraft must have survival equipment for crew members and patient consisting of:

(A) Clothes for the season and area to be served;
(B) Thermal (space) blanket;
(C) Plastic tarp, at least 5' x 7';
(D) Signal mirror;
(E) Compass;
(F) Canned smoke signal, or flare pistol and flares or pencil-flares;
(G) Large flashlight;
(H) Orange signal banner;
(I) Noise maker (whistle);
(J) Drinkable water or intravenous fluid;
(K) Tea;
(L) Salt and sugar;
(M) Beef jerky or granola bars;
(N) Waterproof matches; and
(O) Fire extinguisher (ABC rating).

(2) The aircraft owner who does not own their medical equipment or employ their medical personnel, must have on file with the Authority a copy of the signed and dated agreement or contract with the agency that does provide either the medical personnel or medical equipment to be used on the air ambulance. The signed and dated agreement or contract must be filed annually or whenever substantive changes are made, whichever is more frequent.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: HD 63, f. 6-6-74, ef. 6-25-74; HD 1-1981, f. & ef. 1-14-81; Renumbered from 333-023-0650; HD 14-1981(Temp), f. & ef. 8-7-81; HD 19-1984, f. & ef. 9-10-84; HD 16-1986, f. & ef. 9-9-86; HD 9-1987, f. & ef. 7-21-87; HD 19-1991, f. & cert. ef. 10-18-91, Renumbered from 333-028-0050(3); HD 18-1994, f. 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0051; OHD 5-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 1-2013, f. & cert. ef. 1-25-13

333-255-0081
Air Ambulance Operating Requirements for Prearranged Inter-Facility Transfers

(1) Fixed-wing aircraft in operation and providing prearranged inter-facility transfers requiring basic level care must have a minimum staff of two persons:

(a) A pilot adhering to all regulations set forth in FAA Part 135 for air medical transport; and

(b) One Paramedic, RN, PA or physician having:

(A) Documentation that at least one member of the medical crew has successfully completed the 2004 Association of Air Medical Services (AAMS) Curriculum Guidelines or equivalent. The curriculum must include emergency care procedures, aircraft safety and altitude physiology. There must be written documentation of an annual review of the Air Medical Crew course material. The

length and content of the review must be established by the EMS medical director and be kept on file with the ambulance service;

(B) A current American Heart Association "Health Care Provider", American Red Cross "Basic Life Support for the Professional Rescuer" or other Authority-approved equivalent CPR course completion document;

(C) The ability to properly assist in lifting and moving a patient; and

(D) The knowledge to properly operate all patient care equipment that may be used.

(2) Fixed or rotary-wing aircraft in operation and providing pre-arranged inter-facility transfers requiring advanced life support care must have a minimum staff of two persons:

(a) A pilot adhering to all regulations set forth in FAA Part 135 for air medical transport; and

(b) One Paramedic, RN, PA or physician meeting the requirements specified in paragraph (1)(b)(A) through (1)(b)(D) of this rule.

(3) Fixed or rotary-wing aircraft in operation and providing pre-arranged inter-facility transfers requiring specialty level care must have a minimum staff of two persons:

(a) A pilot adhering to all regulations set forth in FAA Part 135; and

(b) One Paramedic, RN, PA, physician or other qualified person(s), who must:

(A) Meet the requirements specified in paragraph (1)(b)(A) through (1)(b)(D) of this rule;

(B) Have documentation of completing additional specialty care training as defined by the EMS medical director;

(C) Have training to properly operate specialty care equipment necessary to care for the patient during the transfer; and

(D) Have training to do titration of intravenous medications necessary to care for the patient during the transfer.

(4) An air ambulance in operation and providing specialty level care must have the following patient care equipment in a satisfactory working condition, stored in a sanitary and secure manner, and be readily accessible to the medical personnel:

(a) All patient care equipment specified in subsection (7)(a) through (7)(k) of this rule;

(b) All patient care equipment specified in OAR 333-255-0082(2)(d) through (2)(i); and

(c) Any other patient care equipment required during the transfer.

(5) When an inter-facility transfer is requested, a representative from the ambulance service must contact the attending physician at the sending facility, prior to the transfer, to determine which type of aircraft; fixed-wing, rotary-wing, pressurized or non-pressurized, is needed based on the patient's medical condition and which additional equipment and personnel are required.

(6) Patient Care Equipment. The following patient care equipment, in satisfactory working condition and kept in a sanitary manner, is required on all air ambulance flights. The equipment may be kept separate from the aircraft in modular pre-packaged form, so as to be available for rapid loading, easy securing and easy access aboard the aircraft:

(a) Medical oxygen cylinders and regulators:

(A) Medical oxygen cylinder with a capability of at least 600 liters and having not less than 500psi:

(i) The oxygen cylinder(s) must be securely fastened to the aircraft while in flight;

(ii) The oxygen must be delivered by a yoke regulator with a pressure gauge and a non-gravity-dependent flow meter that is visible and accessible to the medical personnel; and

(iii) The flow meter must be adjustable over a minimum range of 0 to 15 liters per minute.

(B) A spare portable oxygen cylinder that is full, tagged, sealed, and securely mounted.

(b) Medical oxygen administration equipment:

(A) Oxygen non-rebreathing masks with tubing:

(i) Pediatric — 2; and

(ii) Adult — 2.

(B) Oxygen nasal cannula with tubing that is transparent and disposable, adult —2;

(C) Bag-valve-mask ventilation device with reservoir. The device must:

(i) Have a standard universal adapter (15 mm tracheal tube/22 mm mask);

(ii) Be operable with or without an oxygen supply;

(iii) Be manually operated and self-refilling;

(iv) Have valves that operate effectively at temperatures down to 0° F;

(v) Have bag-valve-mask ventilation devices with reservoir that are transparent and semi-rigid in assorted sizes to include adult, child, and newborn/infant.

(c) Airway maintenance devices:

(A) Pharyngeal esophageal airway devices in assorted sizes;

(B) Endtidal CO2 detection device in assorted sizes;

(C) Oropharyngeal airways in assorted sizes to include adult, child, and newborn/infant; and

(D) Nasal airways in assorted sizes.

(d) Suction equipment:

(A) Portable suction aspirator:

(i) The unit must be either a self-contained battery or oxygen-powered unit that can operate continuously for 20 minutes and is rechargeable or be a manually-powered unit;

(ii) The unit must be capable of developing a minimum vacuum of 300 mm Hg within four seconds after the suction tube is closed;

(iii) The unit must provide a free air flow of at least 20 liters per minute;

(iv) The unit must be adjustable for use on children and intubated patients;

(v) The unit must include at least a 300 ml collection bottle; and

(vi) A secondary suction apparatus.

(B) Suction connecting tubing and catheters:

(i) Suction connecting tubing that is at least one-quarter of an inch in diameter, translucent and will not kink or collapse under high suction — 2; and

(ii) Suction catheters in assorted sizes and types for adult, child, and newborn/infant.

(e) Stretcher. The stretcher must:

(A) Be securely fastened to the aircraft in accordance with FAA Part 135; and

(B) Have a minimum of three restraining devices and an upper torso (over the shoulder) restraint.

(f) Miscellaneous equipment:

(A) Emesis containers;

(B) Stethoscope, adult and pediatric;

(C) Aneroid sphygmomanometer in assorted sizes:

(D) Bandage shears;

(E) Hypothermia thermometer;

(F) Chemical heat and cold packs, assorted;

(G) Blood glucose level testing kit or blood glucose level test strips;

(H) Urinals, female and male, one each;

(I) Bed pan (Exempt from rotary-wing aircraft); and

(J) Set of extremity restraining devices.

(g) Personal protection equipment sufficient for crew and patient(s) including:

(A) Disposable gloves;

(B) Disposable face masks;

(C) Protective eyewear;

(D) Disposable isolation gowns;

(E) Hand cleaning solution or foam;

(F) Surface cleaning disinfectant;

(G) Sharps container for each kit that contains needles; and

(H) Infectious waste disposal bags.

(h) Linen supplies and replacements to cover stretcher;

(i) Prehospital Care Report Form or electronic field data form;

(j) A copy of standing orders for EMS providers, RNs and PAs dated within one year and signed by the EMS medical director; and

(k) A universal "No Smoking" sign must be conspicuously displayed in the cockpit and patient compartment.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: OHD 5-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 12-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2013, f. & cert. ef. 1-25-13

333-255-0082
Air Ambulance Operating Requirements for Scene Response

(1) Rotary-wing aircraft in operation and providing scene response care must have a minimum staff of two persons:

(a) A pilot adhering to all regulations set forth in FAA Part 135; and

(b) One Paramedic, RN, PA, or physician having:

(A) Documentation that at least one member of the medical crew successfully completed the 2004 Association of Air Medical Services (AAMS) Curriculum Guidelines or equivalent. The curriculum must include emergency care procedures, aircraft safety and altitude physiology. There must be written documentation of an annual review of the Air Medical Crew course material. The length and content of the review must be established by the EMS medical director and be kept on file with the ambulance service;

(B) The ability to properly assist in extricating, lifting and moving a patient; and

(C) The knowledge to properly operate all patient care equipment that may be used.

(2) The following prehospital scene patient care equipment is required on all prehospital scene responses:

(a) All patient care equipment specified in OAR 333-255-0081(7)(a) through (7)(k);

(b) Fracture immobilization equipment:

(A) Traction splints in assorted adult or adult-child combination;

(B) Extremity splints in assorted sizes;

(C) Extrication collars in assorted pediatric through adult sizes;

(D) Short backboard or equivalent with necessary restraining devices with sufficient supplies for head immobilization;

(E) Long backboard with necessary restraining devices with sufficient supplies for head immobilization;

(F) Scoop stretcher with necessary restraining devices with sufficient supplies for head immobilization; and

(G) Pediatric backboard with necessary restraining devices with sufficient supplies for head immobilization.

(c) Bandages and dressings in assorted sizes, sterile and non-sterile;

(d) Adhesive or hypo-allergenic tape in assorted sizes;

(e) Cardiac monitoring equipment:

(A) Manual monitor/defibrillator;

(B) Monitoring electrodes, infant and adult;

(C) Patient cables — 2; and

(D) ECG paper.

(f) Advanced airway care equipment:

(A) Laryngoscope handle and assorted blade sizes, adult and pediatric;

(B) Spare dated batteries for the laryngoscope handle;

(C) Spare bulbs for the laryngoscope blades;

(D) Endotracheal tubes in assorted sizes, adult and pediatric;

(E) Magill Forceps, child and adult;

(F) Intubation stylettes, child and adult;

(G) Endtidal CO2 detection device;

(H) Oxygen saturation monitor; and

(I) Chest decompression kit.

(g) Sterile intravenous agents and medications authorized by the EMS medical director;

(h) Vascular access devices:

(A) Over-the-needle catheters in assorted sizes 24-gauge through 14-gauge; and

(B) Specifically-designed needles for intraosseous infusions.

(i) Nasogastric tubes in assorted sizes;

(j) Storage of controlled substances in an ambulance must adhere to the signed and dated procedures as specified in OAR 333-250-0047(3)(a) and (3)(b);

(k) Oregon Trauma System's Identification Bracelets — 5;

(l) Miscellaneous equipment:

(i) The 2008 Department of Transportation Emergency Response Guidebook (Initial Response to Hazardous Materials Incidents); and

(ii) A copy of standing orders for Paramedics, RNs and PAs dated within one year and signed by the EMS medical director.

(3) In a prehospital resuscitation, when no other practical means of transportation, including any other properly equipped license-holder, is reasonably available, a license-holder may deviate from the rules to the extent necessary to meet the rescue situation.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: OHD 5-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 12-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2013, f. & cert. ef. 1-25-13

333-255-0090
Marine Ambulance Configuration and Survival/Rescue Equipment Requirements

(1) A marine ambulance in operation must be in compliance with all the requirements which relate to marine ambulances, any applicable federal navigation regulations, ORS Chapter 682, and these rules. Maintenance records must be kept and made available for inspection by the Authority:

(2) Marine craft size and configuration. The marine craft must be of sufficient size to accommodate, at a minimum, the operator, two EMS providers, one patient, and the required supplies and equipment and be configured to allow full access to the patient. The marine craft must have:

(a) Adequate lighting, so that patient care can be given and patient status be monitored;

(b) At least one outlet per patient and current for 110 volts (50/60 cycle) alternating current or other current which is capable of operating all electrically-powered medical equipment;

(c) An adequate door or opening to allow loading and unloading of the patient without rotating the patient and stretcher more than 30 degrees about the longitudinal (roll) axis or 45 degrees about the lateral (pitch) axis;

(d) A configuration that allows the medical personnel access to the patient in order to begin and maintain treatment modalities. There must always be complete access to the patient's head and upper body for effective airway management; and

(e) The stretcher or litter and medical equipment placed in a manner that must not impede rapid egress by personnel or patient from the marine craft.

(3) Marine craft equipment. A marine craft ambulance must have the following items in good working condition:

(a) Anchor with line that is three times the maximum depth of water in areas of usual operation;

(b) Docking fenders — 2;

(c) Mooring lines — 2;

(d) Self or mechanical bailer;

(e) Search light with a minimum of 200,000 candle power of illumination;

(f) Swim harness and 75-foot tethering line;

(g) Waterproof flashlight, six volt minimum;

(h) Navigational charts for service area and navigational aids, including a compass;

(i) A cold water protection device for each crew member;

(j) Life jackets — 2 adult and 2 child; and

(k) Boat hook with minimum of 10 foot capability.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: HD 63, f. 6-6-74, ef. 6-25-74; HD 1-1981, f. & ef. 1-14-81; Renumbered from 333-023-0650; HD 14-1981(Temp), f. & ef. 8-7-81; HD 19-1984, f. & ef. 9-10-84; HD 16-1986, f. & ef. 9-9-86; HD 9-1987, f. & ef. 7-21-87; HD 19-1991, f. & cert. ef. 10-18-91, Renumbered from 333-028-0050(4) & (5); HD 18-1994, f. 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0052; OHD 5-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 1-2013, f. &

cert. ef.
1-25-13

333-255-0091
Marine Ambulance Operating Requirements When Providing Basic Level Care

(1) A marine ambulance in operation and providing basic level care must have a staff of at least two persons:

(a) An operator, who:

(A) Has a valid US Coast Guard pilot's license;

(B) Operates the marine ambulance in compliance with any applicable marine craft statutes;

(C) Has not consumed any alcoholic beverages in the eight hours prior to operating an ambulance; and

(D) Is not taking any medications that could impair the safe operation of the ambulance.

(b) A person who is at or above the EMT license level who must be with the patient at all times. The person at or above the EMT level attending the patient must:

(A) Not have consumed any alcoholic beverages in the eight hours prior to working on an ambulance; and

(B) Not be taking any medications that could impair the giving of proper patient care.

(c) If the operator is not a licensed EMS provider, the operator must meet the requirements specified in paragraphs (1)(a)(A) through (1)(a)(D) of this rule and meet the requirements of a qualified driver specified in OAR 333-250-0031.

(2) Basic life support care equipment. A marine ambulance in operation and providing basic level care must have the following patient care equipment in a satisfactory working condition, kept in a sanitary manner, stored in a secure manner and be readily accessible to the medical personnel:

(a) Medical oxygen cylinders and regulators:

(A) Medical oxygen cylinder with a minimum capacity of 600 liters;

(i) The oxygen must be delivered by a yoke regulator with a pressure gauge and a non-gravity-dependent flow meter that is visible and accessible to the medical personnel; and

(ii) The flow meter must be adjustable over a minimum range of 0 to 15 liters per minute.

(B) A spare portable oxygen cylinder that is full, tagged, sealed and securely mounted.

(b) Medical oxygen administration equipment:

(A) Oxygen non-rebreathing masks with tubing:

(i) Pediatric — 2; and

(ii) Adult — 2.

(B) Oxygen nasal cannulas with tubing that are transparent and disposable, adult — 2;

(C) Bag-valve-mask ventilation device with reservoir. The device must:

(i) Have a standard universal adapter (15 mm tracheal tube/22 mm mask);

(ii) Be operable with or without an oxygen supply;

(iii) Be manually operated and self-refilling;

(iv) Have valves that operate effectively at temperatures down to 0° F; and

(v) Have bag-valve-mask ventilation devices with reservoir that are transparent and semi-rigid in assorted sizes to include adult, child, and newborn/infant.

(c) Airway maintenance devices:

(A) Pharyngeal esophageal airway devices in assorted sizes if the EMS medical director approved use;

(B) Endtidal CO2 detection device in assorted sizes;

(C) Oropharyngeal airways in assorted sizes to include adult, child and newborn/infant; and

(D) Nasal airways in assorted sizes.

(d) Suction equipment:

(A) Portable suction aspirator:

(i) The unit must be either a self-contained battery or oxygen-powered unit that can operate continuously for 20 minutes and is rechargeable or be a manually-powered unit;

(ii) The unit must be capable of developing a minimum vacuum of 300 mm Hg within four seconds after the suction tube is closed;

(iii) The unit must provide a free air flow of at least 20 liters per minute;

(iv) The unit must be adjustable for use on children and intubated patients;

(v) The unit, including at least a 300 ml collection bottle; and

(vi) A secondary suction apparatus.

(B) Suction connecting tubing and catheters:

(i) Suction connecting tubing that is at least one-quarter of an inch in diameter, translucent and will not kink or collapse under high suction — 2; and

(ii) Suction catheters that are in assorted sizes and types for adult, child and newborn/infant.

(e) Cardiac monitoring equipment: Automatic or semi-automatic defibrillator. The unit must be capable of operating independently of an electrical outlet, and delivering total defibrillation energy sufficient to meet the number of shocks and power settings prescribed in the EMS medical director's standing orders and be inclusive of the 2005 American Heart Association guidelines for emergency cardiac care or equivalent standards as approved by the Authority.

(f) Stretcher. The stretcher must:

(A) Be a plastic or metal basket stretcher with a four-point bridle;

(B) Have a locking mechanism which can be securely fastened to the craft below the gunwale level; and

(C) Have a minimum of four restraining devices, one of which shall be a torso (over the shoulder) restraint.

(g) Fracture immobilization equipment:

(A) Traction splints in assorted adult sizes or adult/child combination;

(B) Extremity splints in assorted sizes;

(C) Extrication collars in assorted pediatric through adult sizes;

(D) Short backboard or equivalent with necessary restraining devices with sufficient supplies for head immobilization;

(E) Long backboard with necessary restraining devices with sufficient supplies for head immobilization; and

(F) Pediatric backboard with necessary restraining devices with sufficient supplies for head immobilization.

(h) Bandages and dressings in assorted sizes, sterile and non-sterile;

(i) Adhesive or hypo-allergenic tape in assorted sizes;

(j) Miscellaneous equipment:

(A) Emesis containers;

(B) Stethoscope, pediatric and adult;

(C) Aneroid sphygmomanometer in assorted sizes:

(D) Bandage shears;

(E) Hypothermia thermometer;

(F) Disposable obstetrical kit;

(G) Chemical heat and cold packs assorted;

(H) Urinals, female and male, one each;

(I) Bed pan;

(J) Set of extremity restraining devices; and

(K) Blood glucose level testing kit or blood glucose level testing strips.

(k) Personal protection equipment sufficient for crew and patient(s) including:

(A) Disposable gloves;

(B) Disposable face masks;

(C) Protective eyewear;

(D) Disposable isolation gowns;

(E) Hand cleaning solution or foam;

(F) Surface cleaning disinfectant;

(G) Sharps container for the patient compartment and a separate container for each kit that contains needles;

(H) Infectious waste disposal bags; and

(I) The 2008 Department of Transportation — Emergency Response Guidebook (Initial Response to Hazardous Materials Incidents.)

(l) Medications and fluids authorized for use by an EMT as required by the EMS medical director;

(m) Linen supplies and replacements sufficient to cover stretchers;

(n) Communication equipment. Communications equipment must consist of a VHF/FM marine radio with at least 25 watts of power. In addition, the radio must have the capability to have reliable contact between the marine ambulance and a ground or air ambulance and with a hospital having online medical direction;

(o) Prehospital Care Report Form or electronic field data;

(p) Oregon Trauma System Identification Bracelets — 5;

(q) A copy of standing orders for EMTs dated within one year and signed by the EMS medical director; and

(r) A universal "No Smoking" sign conspicuously displayed in the pilot's and patient area.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117 & 682.991
Hist.: OHD 5-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 12-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2013, f. & cert. ef. 1-25-13

333-255-0092
Marine Ambulance Operating Requirements When Providing Intermediate Level Care

(1) A marine ambulance in operation and providing intermediate life support care must have a minimum staff of two persons:

(a) An operator who complies with the requirements specified in OAR 333-255-0091(1)(a)(A) through (1)(a)(D) or (1)(c)(A) through (1)(c)(D); and

(b) A person who is at or above the AEMT license level and who must be with the patient at all times. If the qualified driver is not a licensed EMT, then a second EMT must be available for patient care both in the marine ambulance or on scene.

(2) Intermediate life support care equipment. A marine ambulance in operation and providing intermediate level care must have the following patient care equipment in a satisfactory working condition, kept in a sanitary manner, stored in a secure manner and be readily accessible to the medical personnel:

(a) All of the items specified in OAR 333-255-0091(2)(a) through (2)(r);

(b) Any physiologic isotonic crystalloid solution or combinations thereof — 6000 cc in any size containers;

(c) Medications and fluids authorized for use by an AEMT or EMT-Intermediate as required by the EMS medical director;

(d) Vascular access devices:

(A) Over-the-needle catheters in assorted sizes 24 gauge through 14 gauge; and

(B) Specifically-designed needles for intraosseous infusions.

(e) A copy of standing orders for AEMTs and/or EMT-Intermediates dated within one year and signed by the EMS medical director.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: OHD 5-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 12-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2013, f. & cert. ef. 1-25-13

333-255-0093
Marine Ambulance Operating Requirements When Providing Advanced Level Care

(1) A marine ambulance in operation and providing advanced level care must have a minimum staff of two persons:

(a) An operator who complies with the requirements specified in OAR 333-255-0091(1)(a)(A) through (1)(a)(D) or (1)(c)(A) through (1)(c)(D); and

(b) A person who is at the Paramedic license level or an RN, PA or physician who is trained in prehospital emergency medical care must be attending to the patient when a patient is receiving advanced life support care. If the operator is not a licensed EMT, then a second EMT must be available for patient care both on the marine ambulance and on scene. The Paramedic, RN, PA, physician, or other qualified personnel must:

(A) Not have consumed any alcoholic beverages in the eight hours prior to working on an ambulance; and

(B) Not be taking any medications that could impair the giving of proper patient care.

(c) When a RN, PA or physician is staffing an ambulance in lieu of a Paramedic and is providing advanced level care he or she must have:

(A) A current American Heart Association "Health Care Provider", American Red Cross "Basic Life Support for the Professional Rescuer" or other Authority-approved equivalent CPR course completion document;

(B) A current Advanced Cardiac Life Support course or other Authority-approved equivalent completion document;

(C) A pediatric advanced life support course or other Authority-approved equivalent completion document;

(D) A Prehospital Trauma Life Support, Basic Trauma Life Support, Trauma Emergency Assessment Management or Trauma Nurse Core Course completion document. The Trauma Emergency Assessment Management and Trauma Nurse Core Course must include a supplemental prehospital rapid extrication training session;

(E) The ability to properly assist in extricating, lifting and moving a patient; and

(F) The knowledge to properly operate all patient care equipment that may be used.

(2) A marine ambulance in operation and providing advanced level care must have the following advanced life support patient care equipment in a satisfactory working condition, kept in a sanitary manner and which is readily accessible to medical personnel:

(a) All items specified in OAR 333-255-0091(2)(a) through (2)(r);

(b) Cardiac monitoring equipment:

(A) Manual monitor/defibrillator;

(B) Monitoring electrodes, infant and adult;

(C) Patient cables — 2; and

(D) ECG paper.

(c) Advanced airway care equipment:

(A) Laryngoscope handle and assorted blade sizes, adult and pediatric;

(B) Spare dated batteries for the laryngoscope handle;

(C) Spare bulbs for the laryngoscope blades;

(D) Endotracheal tubes in assorted sizes, adult and pediatric;

(E) Magill Forceps, adult and child;

(F) Intubation stylettes, adult and pediatric;

(G) Endtidal CO2 detection device; and

(H) Chest decompression equipment.

(d) Sterile intravenous agents and medications authorized by the EMS medical director;

(e) Vascular access devices:

(A) Over-the-needle catheters in assorted sizes 14-gauge through 24-gauges; and

(B) Specifically-designed needles for intraosseous infusions.

(f) Nasogastric tubes in assorted sizes;

(g) The storage of controlled substances in a marine ambulance must adhere to the procedure specified in OAR 333-250-0047(2)(a) and (b); and

(h) A copy of standing order for Paramedics, RNs and PAs dated within one-year and signed by the EMS medical director.

(3) The special equipment required for a marine ambulance may be kept separate from the craft in modular watertight and buoyant containers for rapid loading and easy access aboard the marine craft.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017 - 682.117, 682.991
Hist.: OHD 5-2001, f. & cert. ef. 4-24-01; PH 2-2007, f. & cert. ef. 2-1-07; PH 1-2013, f. & cert. ef. 1-25-13

DIVISION 260

COUNTY AMBULANCE SERVICE AREA PLANS

333-260-0000
County and State Relationship

The following rules reflect the Division's interpretation of 1989 Oregon Laws Chapter 722. The adoption and amendment of ambulance service plans and the establishment of ambulance service areas are a matter for regulation by county government within the parameters of relevant statutes and these rules.

Stat. Auth.: ORS 682.205, 682.215, 682.275, 682.315, 682.325, 682.335 & 682.345
Stats. Implemented: ORS 682.205, 682.215, 682.275, 682.315, 682.325, 682.335 & 682.345
Hist.: HD 11-1990, f. & cert. ef. 5-7-90; HD 18-1994, f. 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0095

333-260-0010
Definitions

As used in these rules:

(1) "Ambulance" means any privately or publicly owned motor vehicle, aircraft, or marine craft operated by a Division-licensed ambulance service and that is regularly provided or offered to be provided for the emergency and non-emergency transportation of persons suffering from illness, injury or disability.

(2) "Ambulance Service" means any individual, partnership, corporation, association, governmental agency or other entity that holds a Division-issued ambulance service license to provide emergency and non-emergency care and transportation to sick, injured or disabled persons.

(3) "Ambulance Service Area (ASA)" means a geographic area which is served by one ambulance service provider, and may include all or a portion of a county, or all or portions of two or more contiguous counties.

(4) "Ambulance Service Plan (Plan)" means a written document, which outlines a process for establishing a county emergency medical services system. A plan addresses the need for and coordination of ambulance services by establishing ambulance service areas for the entire county and by meeting the other requirements of these rules. Approval of a plan shall not depend upon whether it maintains an existing system of providers or changes the system. For example, a plan may substitute franchising for an open-market system.

(5) "Ambulance Service Provider" means a licensed ambulance service that responds to 9-1-1 dispatched calls or provides pre-arranged non-emergency transfers or emergency or non-emergency inter-facility transfers.

(6) "County Government or County Governing Body (County)" means a Board of County Commissioners or a County Court.

(7) "Division" means the Public Health Division, Oregon Health Authority.

(8) "Emergency Medical Service (EMS)" means those pre-hospital functions and services whose purpose is to prepare for and respond to medical and traumatic emergencies, including rescue and ambulance services patient care, communications and evaluation.

(9) "Notification Time" means the length of time between the initial receipt of the request for emergency medical service by either a provider or an emergency dispatch center (9-1-1), and the notification of all responding emergency medical service personnel.

(10) "Provider" means any public, private or volunteer entity providing EMS.

(11) "Response Time" means the length of time between the notification of each provider and the arrival of each provider's emergency medical service unit(s) at the incident scene.

Stat. Auth.: ORS 682.205, 682.215, 682.235, 682.275, 682.315, 682.325, 682.335 & 682.345
Stats. Implemented: ORS 682.205, 682.215, 682.235, 682.275, 682.315, 682.325, 682.335 & 682.345
Hist.: HD 16-1986, f. & ef. 9-9-86; HD 11-1990, f. & cert. ef. 5-7-90; HD 18-1994, f. 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0100; OHD 8-2001, f. & cert. ef. 4-24-01

333-260-0020
Procedures for Adoption and Approval of Ambulance Service Plans

(1) A county may obtain technical assistance from the Division as available in developing and amending an ambulance service plan.

(2) A county that does not have a Division-approved plan on July 19, 1989, must adopt and submit a plan by December 31, 1990. A county that has a Division-approved plan that does not meet the requirements of these rules must adopt and submit an amended plan by June 30, 2003. This requirement may be met by a plan submitted in conjunction with another contiguous county or counties. A Division-approved plan which is currently in effect, remains in effect until one of the following occurs:

(a) An amended plan is approved by the Division;

(b) There is a failure to submit an amended plan pursuant to this subsection; or

(c) Where an amended plan was required to be submitted pursuant to this subsection and such amended plan was disapproved by the Division, if 120 days have elapsed since such disapproval and no new amended plan has been adopted and submitted to the Division for approval.

(3) After March 31, 2001, a county must submit a plan or amendment(s) to the Division using the following format:

1. CERTIFICATION BY GOVERNING BODY OF COUNTY AMBULANCE SERVICE PLAN
2. OVERVIEW OF COUNTY (DEMOGRAPHIC AND GEOGRAPHIC DESCRIPTION)
3. DEFINITIONS;
4. BOUNDARIES;
(a) ASA Map(s) with Response Time Zones:
(b) ASA Narrative Description:
(c) Map(s) Depicting "9-1-1," Fire Districts and Incorporated Cities:
(d) Alternatives Considered to Reduce Response Times.
5. SYSTEM ELEMENTS:
(a) 9-1-1 Dispatched Calls;
(b) Pre-arranged Non-emergency Transfers and Inter-facility Transfers;
(c) Notification and Response Times;
(d) Level of Care;
(e) Personnel;
(f) Medical Supervision;
(g) Patient Care Equipment;
(h) Vehicles;
(i) Training;
(j) Quality Improvement;
(A) Structure:
(B) Process:
(C) Sanctions for Non Compliant Personnel or Providers:
6. COORDINATION
(a) The Entity That Shall Administer and Revise the ASA Plan;
(b) Complaint Review Process;
(c) Mutual Aid Agreements;
(d) Disaster Response;
(A) County Resources Other Than Ambulances;
(B) Out of County Resources;
(C) Mass-Casualty Incident Plan;
(D) Response to Terrorism;
(e) Personnel and Equipment Resources;
(A) Non-transporting EMS Provider;
(B) Hazardous Materials;
(C) Search and Rescue;
(D) Specialized Rescue;
(E) Extrication;
(f) Emergency Communication and System Access;
(A) Telephone;
(B) Dispatch Procedures;
(C) Radio System;
(D) Emergency Medical Services Dispatcher Training.
7. PROVIDER SELECTION:
(a) Initial Assignment;
(b) Reassignment;
(c) Application for an ASA;
(d) Notification of Vacating an ASA;
(e) Maintenance of Level of Service;
8. COUNTY ORDINANCES AND RULES:

(4) Procedures for the Division's review of a plan submitted under section (3) of this rule are set forth in ORS 682.205(6). Except for the time frames, plans submitted prior to April 1, 2001,

but not yet approved by the Division shall be processed in the same manner.

(5) The Division's approval of a plan or amendments is limited to determining whether there has been compliance with these rules.

(6) A county is required to amend their plan, if necessary, to comply with any amendments made in ORS Chapter 682 or OAR chapter 333, divisions 250, 255 or 260. The Division shall notify the county in writing each time an amendment is made in either the statute or administrative rules that may affect the plan. Anytime a county plan is amended, the county must submit a copy of the amended plan to the Division.

(7) The Division shall review each county plan no less than once every five years to ensure compliance with the statutes and administrative rules pertaining to a county ambulance service area plan. The Division shall notify the county of the results of the review.

(8) The Division may seek the advice of the State Emergency Medical Service Committee concerning plan compliance with these rules.

Stat. Auth.: ORS 682.205, 682.215, 682.275, 682.315, 682.325, 682.335 & 682.345

Stats. Implemented: ORS 682.205, 682.215, 682.275, 682.315, 682.325, 682.335 & 682.345

Hist.: HD 16-1986, f. & ef. 9-9-86; HD 9-1987, f. & ef. 7-21-87; HD 11-1990, f. & cert. ef. 5-7-90; HD 18-1994, f. 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0105; OHD 8-2001, f. & cert. ef. 4-24-01

333-260-0030
Subjects to be Considered in an Ambulance Service Plan

(1) A county is required to include in a plan, each of the subjects or items set forth in these rules and to address and consider each of those subjects or items in the adoption process.

(2) The plan submitted to the Division for approval must contain a certification signed by the governing body of the county that:

(a) Each subject or item contained in the plan was addressed and considered in the adoption of the plan;

(b) In the governing body's judgment, the ASAs established in the plan provides for the efficient and effective provision of ambulance services; and

(c) To the extent they are applicable, the county has complied with ORS 682.205(2)(3) and 682.335 and existing local ordinances and rules.

Stat. Auth.: ORS 682.205, 682.215, 682.275, 682.315, 682.325, 682.335 & 682.345

Stats. Implemented: ORS 682.205, 682.215, 682.275, 682.315, 682.325, 682.335 & 682.345

Hist.: HD 16-1986, f. & ef. 9-9-86; HD 11-1990, f. & cert. ef. 5-7-90; HD 18-1994, f. 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0110; OHD 8-2001, f. & cert. ef. 4-24-01

333-260-0040
Boundaries

(1) The entire county must be included in a plan. One or more ASAs may be established in a plan. The county or contiguous counties are solely responsible for establishing all ASA boundaries within the county's jurisdiction.

(2) A map showing ASA boundaries and response time zones must be included in the plan, along with a narrative description of each ASA.

(3) A map depicting all "9-1-1," fire district and incorporated city boundaries within the county must be included in the plan.

(4) The plan must describe the major alternatives considered, if any, for reducing the effects of artificial and geographical barriers on response times.

Stat. Auth.: ORS 682.205, 682.215, 682.275, 682.315, 682.325, 682.335 & 682.345

Stats. Implemented: ORS 682.205, 682.215, 682.275, 682.315, 682.325, 682.335 & 682.345

Hist.: HD 16-1986, f. & ef. 9-9-86; HD 11-1990, f. & cert. ef. 5-7-90; HD 18-1994, f. 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0115; OHD 8-2001, f. & cert. ef.

333-260-0050
System Elements

(1) The following system elements must be addressed and considered in the county's plan for each ASA:

(a) 9-1-1 dispatched calls;

(b) Pre-arranged non-emergency transfers and inter-facility transfers, by June 30, 2003;

(c) Notification and response times;

(d) Level of care, ranging from basic life support to advanced life support;

(e) Personnel for first response vehicles and ambulances;

(f) Medical supervision of all medically trained emergency response personnel;

(g) Patient care equipment for first response vehicles and ambulances;

(h) Vehicle, vehicle equipment and safety requirements;

(i) Initial and continuing education training for emergency response personnel; and

(j) Quality improvement.

(2) Notification and response times must be addressed and considered in the plan as follows:

(a) Notification times must be expressed in terms of percent of calls which do not exceed a specified number of minutes;

(b) Response times must be expressed in terms of percent of calls which do not exceed a specified number of minutes; and

(c) Multiple response time standards may be established within the ASA to accommodate climate, weather, access, terrain, staffing and other factors as determined by the county.

(3) The plan must address and consider a quality improvement program which at a minimum:

(a) Monitors compliance with pertinent statutes ordinances and rules;

(b) Monitors compliance with standards for prehospital provider notification times, response times and patient care; and

(c) Provides for problem resolution and legal sanctions for non compliant personnel or providers of the plan provisions.

Stat. Auth.: ORS 682.205, 682.215, 682.275, 682.315, 682.325, 682.335 & 682.345

Stats. Implemented: ORS 682.205, 682.215, 682.275, 682.315, 682.325, 682.335 & 682.345

Hist.: HD 16-1986, f. & ef. 9-9-86; HD 11-1990, f. & cert. ef. 5-7-90; HD 18-1994, f. 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0120; OHD 8-2001, f. & cert. ef. 4-24-01

333-260-0060
Coordination

The county may delegate authority for development and administration of the plan to an intergovernmental body. The plan must address and consider:

(1) A process for the county to receive input from prehospital care consumers, providers and the medical community.

(2) Mutual aid agreements for ambulance responses from outside of the service area and responses to other service areas to meet the need for service in unusual circumstances.

(3) Ambulance service providers' responsibilities in the event of a disaster, including: coordination with county resources and determination of methods for obtaining out-of-county resources other than ambulances, a process for adoption of a mass-casualty incident plan that is recognized and approved by the county's emergency management administration.

(4) Personnel and equipment resources in addition to the ambulance provider for response to incidents involving but not limited to:

(a) Hazardous Materials;

(b) Search and Rescue;

(c) Specialized Rescue; and

(d) Extrication.

(5) Emergency radio and telephone communications systems for the county. Mechanisms for the following must be in operation or scheduled for implementation:

(a) Access to the Emergency Medical Services System centralized emergency telephone numbers;

(b) Dispatch of ambulances staffed in accordance with the plan and other emergency resources based on emergency medical protocols; and

(c) U.S. Department of Transportation, National Highway Traffic Safety Administration, Emergency Medical Services Dispatcher: National Standard Curriculum or equivalent training for all emergency medical services dispatchers.

Stat. Auth.: ORS 682.205, 682.215, 682.275, 682.315, 682.325, 682.335 & 682.345

Stats. Implemented: ORS 682.205, 682.215, 682.275, 682.315, 682.325, 682.335 & 682.345

Hist.: HD 16-1986, f. & ef. 9-9-86; HD 11-1990, f. & cert. ef. 5-7-90; HD 18-1994, f. 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0125

333-260-0070
Provider Selection

(1) The county is solely responsible for designating and administering the process of selecting an ambulance service provider.

(2) The plan must address and consider a process for:

(a) Assigning and reassigning of an ambulance service provider to an ASA;

(b) Responding to an application by a provider for an ASA;

(c) Responding to notification that an ASA is being vacated; and

(d) Maintaining the existing level of service after notification that a provider is vacating an ASA.

(3) The county shall designate one emergency ambulance provider for each ASA. The county may designate one or more non-emergency ambulance provider for each ASA.

Stat. Auth.: ORS 682.205, 682.215, 682.275, 682.315, 682.325, 682.335 & 682.345

Stats. Implemented: ORS 682.205, 682.215, 682.275, 682.315, 682.325, 682.335 & 682.345

Hist.: HD 16-1986, f. & ef. 9-9-86; HD 11-1990, f. & cert. ef. 5-7-90; HD 18-1994, f. 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0130; OHD 8-2001, f. & cert. ef. 4-24-01

DIVISION 265

EMERGENCY MEDICAL SERVICES PROVIDERS

333-265-0000
Definitions

(1) "Advanced Emergency Medical Technician (AEMT or Advanced EMT)" means a person who is licensed by the Authority as an Advanced Emergency Medical Technician.

(2) "Ambulance Service" means any person, governmental unit, corporation, partnership, sole proprietorship, or other entity that operates ambulances and holds itself out as providing prehospital care or medical transportation to sick, injured or disabled persons.

(3) "Authority" means the Emergency Medical Services and Trauma Systems Program, within the Oregon Health Authority.

(4) "Business day" means Monday through Friday when the Authority is open for business, excluding holidays.

(5) "Candidate" means an applicant that has completed training in an emergency medical services provider course and has not yet been licensed by the Authority.

(6) "Clinical Experience (Clinical)" means those hours of the curriculum that synthesize cognitive and psychomotor skills and are performed under a preceptor.

(7) "Continuing Education" means education required as a condition of licensure under ORS Chapter 682 to maintain the skills necessary for the provision of competent prehospital care. Continuing education does not include attending EMS related business meetings, EMS exhibits or trade shows.

(8) "Didactic Instruction" means the delivery of primarily cognitive material through lecture, video, discussion, and simulation by program faculty.

(9) "Direct Medical Oversight" means real-time direct communication by a physician who is providing direction to an emergency medical services provider during a patient encounter.

(10) "Direct Visual Supervision" means that a person qualified to supervise is at the patient's side to monitor the emergency medical services provider in training.

(11) "Emergency Care" means the performance of acts or procedures under emergency conditions in the observation, care and counsel of the ill, injured or disabled; in the administration of care or medications as prescribed by a licensed physician, insofar as any of these acts is based upon knowledge and application of the principles of biological, physical and social science as required by a completed course utilizing an approved curriculum in prehospital emergency care. However, "emergency care" does not include acts of medical diagnosis or prescription of therapeutic or corrective measures.

(12) "EMS" means Emergency Medical Services.

(13) "EMS Medical Director" has the same meaning as "Supervising Physician" in ORS 682.025.

(14) "Emergency Medical Responder (EMR)" means a person who is licensed by the Authority as an Emergency Medical Responder.

(15) "Emergency Medical Services (EMS) Agency" means any person, partnership, corporation, governmental agency or unit, sole proprietorship or other entity that utilizes emergency medical services providers to provide prehospital emergency or non-emergency care. An emergency medical services agency may be either an ambulance service or a nontransporting service.

(16) "Emergency Medical Services Provider (EMS Provider)" means a person who has received formal training in prehospital and emergency care and is state-licensed to attend to any ill, injured or disabled person. Police officers, fire fighters, funeral home employees and other personnel serving in a dual capacity, one of which meets the definition of "emergency medical services provider" are "emergency medical services providers" within the meaning of ORS Chapter 682.

(17) "Emergency Medical Technician (EMT)" means a person who is licensed by the Authority as an Emergency Medical Technician.

(18) "EMT-Basic" has the same meaning as Emergency Medical Technician.

(19) "EMT-Intermediate" means a person who is licensed by the Authority as an EMT-Intermediate.

(20) "EMT-Paramedic" has the same meaning as Paramedic.

(21) "Exam Evaluator" is a person who attends an EMS provider practical examination and who objectively observes and records each student's performance consistent with the standards of the National Registry of EMTs.

(22) "First Responder" has the same meaning as Emergency Medical Responder.

(23) "In Good Standing" means a person who is currently licensed in Oregon, who does not have any restrictions placed on his or her license, or who is not on probation with the licensing agency for any reason.

(24) "Key party" means immediate family members and others who would be reasonably expected to play a significant role in the health care decisions of the patient or client and includes, but is not limited to, the spouse, domestic partner, sibling, parent, child, guardian and person authorized to make health care decisions of the patient or client.

(25) "Licensing Officer" is a person who is responsible for conducting an Emergency Medical Technician (EMT) or EMT-Intermediate practical examination in a manner consistent with the standards of the National Registry for EMTs and the Authority.

(26) "Non-Emergency Care" means the performance of acts or procedures on a patient who is not expected to die, become permanently disabled or suffer permanent harm within the next 24-hours, including but not limited to observation, care and counsel of a patient and the administration of medications prescribed by a physician licensed under ORS Chapter 677, insofar as any of those acts are based upon knowledge and application of the principles of biological, physical and social science and are performed in accordance with scope of practice rules adopted by the Oregon Medical

Board in the course of providing prehospital care as defined by this rule.

(27) "Paramedic" means a person who is licensed by the Authority as a Paramedic.

(28) "Patient" means a person who is ill or injured or who has a disability and who is transported in an ambulance.

(29) "Person" means any individual, corporation, association, firm, partnership, joint stock company, group of individuals acting together for a common purpose, or organization of any kind and includes any receiver, trustee, assignee, or other similar representatives thereof.

(30) "Prehospital Care" means that care rendered by an EMS provider as an incident of the operation of an ambulance as defined by ORS Chapter 682 and that care rendered by an EMS provider as an incident of other public or private safety duties, and includes, but is not limited to "emergency care" as defined by ORS Chapter 682.

(31) "Preceptor" means a person approved by an accredited teaching institution and appointed by the EMS agency, who supervises and evaluates the performance of an EMS provider student during the clinical and field internship phases of an EMS provider course. A preceptor must be a physician, physician assistant, registered nurse, or EMS provider with at least two years field experience in good standing at or above the level for which the student is in training.

(32) "Protocols" has the same meaning as standing orders.

(33) "Reciprocity" means the manner in which a person may obtain Oregon EMS provider licensure when that person is licensed in another state and certified with the National Registry.

(34) "Scope of Practice" means the maximum level of emergency or non-emergency care that an EMS provider may provide that is set forth by the rules adopted by the Oregon Medical Board.

(35) "Skills Lab" means those hours of the curriculum that provides the student with the opportunity to develop the skills for the level of training obtained.

(36) "Standing Orders" means the written protocols that an EMS provider follows to treat patients when direct contact with a physician is not maintained.

(37) "Successful completion" means having attended 85 percent of the didactic and skills instruction hours (or makeup sessions) and 100 percent of the clinical and field internship hours, and completing all required clinical and internship skills and procedures and meeting or exceeding the academic standards for those skills and procedures.

(38) "Teaching Institution" means a two-year community college or four-year degree granting college or a licensed vocational school that is accredited by the Office of Career and Technical Education, or the Department of Community Colleges and Workforce Development/Oregon Department of Education.

(39) "Unprofessional Conduct" has the meaning given that term in ORS 682.025.

(40) "Volunteer" means a person who is not compensated for their time to staff an ambulance or rescue service, but who may receive reimbursement for personal expenses incurred.

Stat. Auth.: ORS 682.025 & 682.215
Stats. Implemented: ORS 682.017 - 682.991
Hist.: HD 18-1994, 6-30-94, cert. ef. 7-1-94; HD 8-1995, f. & cert. ef. 11-6-95; OHD 9-2001, f. & cert. ef. 4-24-01; PH 10-2008. f. & cert. ef. 6-16-08; PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12; PH 1-2013, f. & cert. ef. 1-25-13

333-265-0010
Application for Approval of EMT, AEMT, EMT-Intermediate, and Paramedic Courses

(1) The Authority is responsible for approving EMT, AEMT, and Paramedic courses.

(2) EMT, AEMT, and Paramedic courses must be offered by a teaching institution accredited by the Oregon Department of Education or the Oregon State Board of Higher Education and must meet the standards established by the Oregon Department of Education in OAR chapter 581, division 49.

(3) Notwithstanding section (2) of this rule, the Authority may allow a hospital to conduct an EMT course if there is no training available at a teaching institution in a rural part of the state. A hospital that wishes to conduct an EMT course in a rural area must send a request to the Authority in writing explaining why there is a need and why there is no training available in its area. The Authority will inform the hospital in writing whether it has permission to conduct the EMT course.

(4) EMT, AEMT, and Paramedic courses must meet the requirements prescribed by the Authority in OAR 333-265-0014.

(5) EMT, AEMT, and Paramedic courses must be taught by instructors that meet the requirements of OAR 333-265-0020.

(6) A teaching institution described in section (2) of this rule or a hospital approved by the Authority under section (3) of this rule must submit an application to the Authority on a form prescribed by the Authority that includes all the information necessary to determine whether the course meets the Authority's standards. The form must be received by the Authority at least 30 business days prior to the first day of class.

(7) The Authority will return an application that is incomplete to the applicant.

(8) The Authority will inform an applicant in writing whether the application has been denied or approved.

(9) No teaching institution shall conduct an EMT, AEMT, or Paramedic course until the Authority has approved the course.

(10) The Authority may deny or revoke the approval to conduct an EMT, AEMT, or Paramedic course in accordance with ORS 183.310 through 183.550 for failure to comply with OAR chapter 333, division 265.

Stat. Auth.: ORS 682.017, 682.208
Stats. Implemented: ORS 682.017, 682.208, 682.216
Hist.: HD 63, f. 6-6-74, ef. 6-25-74; HD 1-1981, f. & ef. 1-14-81; Renumbered from 333-023-0630; HD 19-1984, f. & ef. 9-10-84; HD 16-1986, f. & ef. 9-9-86; HD 19-1991, f. & cert. ef. 10-18-91; HD 8-1993, f. 6-22-93, cert. ef. 7-1-93; HD 18-1994, 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0030; HD 8-1995, f. & cert. ef. 11-6-95; OHD 9-2001, f. & cert. ef. 4-24-01; PH 10-2008. f. & cert. ef. 6-16-08; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12; PH 1-2013, f. & cert. ef. 1-25-13

333-265-0011
Applications for Approval of EMT-Intermediate Courses

(1) The Authority is responsible for approving EMT-Intermediate courses.

(2) EMT-Intermediate courses must be offered by an accredited teaching institution or an EMS agency.

(3) Notwithstanding section (2) of this rule, the Authority may allow a hospital to conduct an EMT-Intermediate course if there is no training available at a teaching institution or EMS agency in a rural part of the state. A hospital that wishes to conduct an EMT-Intermediate course in a rural area must send a request to the Authority in writing explaining why there is a need and why there is no training available in its area. The Authority will inform the hospital in writing whether it has permission to conduct the EMT-Intermediate course.

(4) EMT-Intermediate courses must meet the requirements prescribed by the Authority in OAR 333-265-0014.

(5) EMT-Intermediate courses must be taught by instructors that meet the requirements of OAR 333-265-0020.

(6) A teaching institution or EMS agency described in section (2) of this rule or a hospital approved by the Authority under section (3) of this rule must submit an application to the Authority on a form prescribed by the Authority that includes all the information necessary to determine whether the course meets the Authority's standards. The form must be received by the Authority at least 30 business days prior to the first day of class.

(7) The Authority will return an application that is incomplete to the applicant.

(8) The Authority will inform an applicant in writing whether the application has been denied or approved.

(9) No teaching institution, EMS agency, or approved hospital shall conduct an EMT-Intermediate course until the Authority has approved the course.

(10) The Authority may deny or revoke the approval to conduct an EMT-Intermediate course in accordance with ORS 183.310 through 183.550 for failure to comply with OAR chapter 333, division 265.

Stat. Auth.: ORS 682.017, 682.208
Stats. Implemented: ORS 682.017, 682.208, 682.216
Hist.: PH 1-2013, f. & cert. ef. 1-25-13

333-265-0012
Requirements for Conducting Emergency Medical Responder Courses

(1) An ambulance service or any other entity in Oregon may conduct EMR courses that meet the requirements of OAR 333-265-0014.

(2) An entity that wants to conduct an EMR course must submit an application to the Authority on a form prescribed by the Authority that includes all the information necessary to determine whether the course meets the Authority's standards and whether the course director meets the requirements in OAR 333-265-0018. The form must be received by the Authority at least 30 business days prior to the first day of class.

(3) The Authority shall return an application that is incomplete to the applicant.

(4) No entity shall conduct an EMR course until the Authority has approved the course.

(5) The Authority may deny or revoke the approval to conduct an EMR course in accordance with ORS 183.310 through 183.550 for failure to comply with OAR chapter 333, division 265.

Stat. Auth.: ORS 682.017, 682.208
Stats. Implemented: ORS 682.017, 682.208, 682.216
Hist.: PH 10-2008, f. & cert. ef. 6-16-08; PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12

333-265-0014
EMS Provider Course Requirements

(1) All EMS provider courses must have a medical director. The EMS medical director must meet the qualifications of a supervising physician as defined in OAR 847-035-0020.

(2) All EMS provider courses must have a course director as defined in OAR 333-265-0020.

(3) An Oregon teaching institution conducting EMT, advanced EMT, or Paramedic courses must have program faculty consisting of a designated program director, course medical director, course directors, and may have guest instructors. The number of persons carrying out the responsibilities of conducting an EMT, AEMT, or Paramedic course may vary from program to program. One person, if qualified, may serve in multiple roles.

(4) An Oregon teaching institution, EMS agency, or approved hospital conducting EMT- Intermediate courses must have program faculty consisting of a designated program director, course medical director, course directors, and may have guest instructors. The number of persons carrying out the responsibilities of conducting an EMT-Intermediate course may vary from program to program. One person, if qualified, may serve in multiple roles.

(5) An EMR course must include:

(a) A curriculum that meets or exceeds the National Emergency Medical Services Education Standards published by the National Highway Traffic Safety Administration, January 2009 (DOT HS 811 077B);

(b) Didactic and skills instruction; and

(c) A practical and cognitive examination.

(6) An EMT course must include:

(a) A curriculum that meets or exceeds the National Emergency Medical Services Education Standards published by the National Highway Traffic Safety Administration, January 2009 (DOT HS 811 077B);

(b) Didactic and skills instruction;

(c) Clinical education of at least eight hours in a hospital or acute care department or other appropriate clinical or acute care medical facility where the skills within an EMT scope of practice are performed under the supervision of a preceptor; and

(d) Prehospital experience of at least eight hours under the supervision of an EMT or above where the skills within an EMT scope of practice are performed.

(7) An advanced EMT course must include:

(a) A curriculum that meets or exceeds the National Emergency Medical Services Education Standards published by the National Highway Traffic Safety Administration, January 2009 (DOT HS 811 077B);

(b) Didactic and skills instruction; and

(c) A field internship that is described in OAR 333-265-0015.

(8) An EMT-Intermediate course must include:

(a) The EMT-Intermediate curriculum as prescribed by the Authority;; and

(b) Didactic and skills instruction.

(9) A Paramedic course must include:

(a) Paramedic curriculum that meets or exceeds the National Emergency Medical Services Education Standards published by the National Highway Traffic Safety Administration, January 2009 (DOT HS 811 077B);

(b) Didactic and skills instruction;

(c) Clinical experience in hospital clinical areas where the skills within a Paramedic scope of practice are performed under the supervision of a preceptor; and

(d) A field internship that is described in OAR 333-265-0016.

(10) All EMS provider courses must include instructions on Oregon statutes and rules governing the EMS system, medical-legal issues, roles and responsibilities of EMS providers, and EMS professional ethics.

(11) The Authority may deny or revoke course approval in accordance with the provisions of ORS 183.310 through 185.550 for failure to comply with the requirements of this rule.

(12) A person must have a current Oregon EMT license or higher at the time of enrollment in an advanced EMT or Paramedic course.

(13) A person must have a current Oregon advanced EMT license at the time of enrollment in an Oregon EMT-Intermediate course.

(14) A person must maintain a current Oregon EMT license or higher throughout the interval of the advanced EMT or Paramedic cognitive and practical exams.

(15) A person must maintain a current Oregon advanced EMT license throughout the interval of the EMT-Intermediate cognitive and practical exams.

Stat. Auth.: ORS 682.017, 682.208
Stats. Implemented: ORS 682.017, 682.208, 682.216
Hist.: PH 10-2008, f. & cert. ef. 6-16-08; PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12; PH 1-2013, f. & cert. ef. 1-25-13

333-265-0015
Advanced Emergency Medical Technician Field Internships

(1) A field internship is required as part of an advanced EMT course and shall include:

(a) Clinical experience performed under the supervision of a preceptor of at least eight hours and 20 patient contacts in a hospital emergency department or medical clinic where the skills within an AEMT scope of practice are performed under the supervision of a preceptor; and

(b) Prehospital experience of at least eight hours under the supervision of an AEMT or above where the skills within the scope of practice of an AEMT are performed.

(2) A field internship must provide a student the opportunity to demonstrate the integration of didactic, psychomotor skills, and clinical education necessary to perform the duties of an entry-level AEMT.

(3) The student must successfully demonstrate a skill in the classroom lab or hospital clinical setting before that skill is performed and evaluated in a field internship.

(4) During a field internship a student must participate in providing care. All EMS calls shall be under the direct visual supervision of a preceptor. In order for a call to be accepted, the preceptor must document and verify satisfactory student performance, includ-

ing application of specific assessment and treatment skills required of a licensed advanced EMT.

(5) For purposes of this section, "EMS call" means a prehospital emergency medical services response requiring patient care at the advanced life support level and "ambulance call" means an advanced life support prehospital emergency medical services response, which includes dispatch, scene response, patient care while riding in the patient compartment of an ambulance, and participating in specific assessment and treatment skills required of a licensed advanced EMT.

Stat. Auth.: ORS 682.017, 682.208
Stats. Implemented: ORS 682.017, 682.208, 682.216
Hist.: PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12; PH 1-2013, f. & cert. ef. 1-25-13

333-265-0016
Paramedic Field Internships

(1) A field internship is required as part of a Paramedic course.

(2) A field internship must provide a student the opportunity to demonstrate the integration of didactic, psychomotor skills, and clinical education necessary to perform the duties of an entry-level paramedic.

(3) The student must successfully demonstrate a skill in the classroom lab or hospital clinical setting before that skill is performed and evaluated in a field internship.

(4) During a field internship a student must participate in providing care in at least 40 EMS calls with no less than eight each in cardiac, respiratory, general medical, and trauma emergencies, and with at least 30 of the calls being advanced life support ambulance calls. All EMS calls shall be under the direct visual supervision of a preceptor. In order for a call to be accepted, the preceptor must document and verify satisfactory student performance, including application of specific assessment and treatment skills required of a licensed Paramedic.

(5) The intern must not be one of the minimum staff required for an ambulance as described in OAR chapter 333, division 250.

(6) For purposes of this section, "EMS call" means a pre-hospital emergency medical services response requiring patient care at the advanced life support level and "ambulance call" means an advanced life support pre-hospital emergency medical services response, which includes dispatch, scene response, patient care while riding in the patient compartment of an ambulance, and participating in specific assessment and treatment skills required of a licensed Paramedic.

Stat. Auth.: ORS 682.017, 682.208
Stats. Implemented: ORS 682.017, 682.208, 682.216
Hist.: PH 10-2008, f. & cert. ef. 6-16-08; PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12

333-265-0018
Course Director Qualifications for EMR Courses

(1) An ambulance service or entity that has contracted with the Authority to conduct an EMR course must have a qualified Course Director.

(2) An EMR Course Director must:

(a) Have appropriate training and experience to fulfill the role and have the credentials that demonstrate such training and experience;

(b) Be currently licensed in Oregon as an EMT or higher with three years of pre-hospital care experience and in good standing with the Authority, or an EMS medical director;

(c) Have a current healthcare provider CPR instructor card or certificate of course completion that meets or exceeds the 2010 American Heart Association ECC guidelines or equivalent standards approved by the Authority;

(d) Have successfully completed one of the following:

(A) The National Association of EMS Educator Course, developed by the U.S. Department of Transportation, 2002;

(B) The National Fire Protection Association (NFPA) Fire Instructor I or Fire Service Instructor I and II programs developed by the Department of Public Safety Standards and Training (DPSST);

(C) Have at least 40 hours of the Instructor Development Program offered by the DPSST; or

(D) A minimum of three college credits in adult educational theory and practice or vocational educational theory and practice from an accredited institution of higher learning.

(e) Have participated in a course director program offered by the Authority; and

(f) Agree to participate in the course director program updates offered by the Authority.

(3) An EMR Course Director:

(a) Is responsible for course planning and organizing, including scheduling lectures, coordinating, arranging, and conducting the written and practical course completion and licensure examination;

(b) Is the primary instructor, who conducts at least 50 percent of the didactic sessions, unless this requirement is waived by the Authority in advance;

(c) Must ensure, if guest instructors are used, that the guest instructor is qualified to teach the subject matter, meets requirements set forth in OAR 333-265-0020, and presents lessons that address all objectives identified in the course curriculum for the topic being presented. A guest instructor must:

(A) Be qualified and have the expertise in the specific course subject; and

(B) Follow the course curriculum and meet the course objectives for that specific subject.

(d) Must ensure that after completion of the course and successfully passing the written and practical examinations each student completes an application form prescribed by the Authority and that the completed application forms are collected and submitted to the Authority within 30 calendar days of the completion of the course.

(e) Must have written documentation showing whether a student has successfully completed the course as defined in OAR 333-265-0014.

Stat. Auth.: ORS 682.017, 682.208
Stats. Implemented: ORS 682.017, 682.208, 682.216
Hist.: PH 10-2008, f. & cert. ef. 6-16-08; PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12

333-265-0020
Approved EMT, AEMT, EMT-Intermediate, and Paramedic Course Director

(1) A course director for a specific course must:

(a) Be an EMS Medical Director; or

(b) Hold at least the level of Oregon licensure as the course being taught and be in good standing with the Authority, and have at least three years of experience at that licensure level or higher, and:

(A) Have a current healthcare provider CPR instructor card or certificate of course completion that meets or exceeds the 2010 American Heart Association ECC guidelines or equivalent standards approved by the Authority;

(B) Have successfully completed one of the following:

(i) The National Association of EMS Educator Course, developed by the U.S. Department of Transportation, 2002;

(ii) The National Fire Protection Association (NFPA) Fire Instructor I or Fire Service Instructor I and II programs developed by the Department of Public Safety Standards and Training (DPSST);

(iii) At least 40 hours of the Instructor Development Program offered by the DPSST; or

(iv) A minimum of three college credits in adult educational theory and practice or vocational educational theory and practice from an accredited institution of higher learning;

(C) Participated in the Course Director Program offered by the Authority; and

(D) Participated in the Course Director Program updates offered by the Authority.

(2) In addition to the Course Director requirements in section (1) of this rule, a Paramedic Course Director must:

(a) Be an EMS Medical Director and hold a current:

(A) American Board of Emergency Medicine Certificate; or

(B) Advance Cardiac Life Support (ACLS) Instructor certificate and Advance Trauma Life Support certificate or equivalent as approved by the Authority; or

(b) Be a licensed Paramedic in good standing with the Authority with at least three years of experience at the licensure level and:

(A) Possess at least an associate's degree from an accredited institution of higher learning;

(B) Hold an Advance Cardiac Life Support (ACLS) Instructor certificate from the American Heart Association or equivalent that has been approved by the Authority; and

(C) Hold a Basic Trauma Life Support (BTLS) Instructor certificate or equivalent that has been approved by the Authority, or a Pre-hospital Trauma Life Support (PHTLS) Instructor certificate or equivalent that has been approved by the Authority.

(3) A guest instructor must:

(a) Be qualified and have the expertise in the specific course subject; and

(b) Follow the course curriculum and meet the course objectives for that specific subject.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017
Hist.: HD 8-1993, f. 6-22-93, cert. ef. 7-1-93; HD 18-1994, 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0032; HD 8-1995, f. & cert. ef. 11-6-95; OHD 9-2001, f. & cert. ef. 4-24-01; PH 10-2008, f. & cert. ef. 6-16-08; PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12

333-265-0022
Program Administrator and Faculty Responsibilities

(1) A Program Administrator is responsible for course planning, the organizing and administration of courses, periodic review of courses, program evaluation, and continued development and effectiveness of courses.

(2) A course EMS Medical Director shall:

(a) Provide medical direction for the didactic, clinical and field internship portions of an EMS Provider course; and

(b) Act as the ultimate medical authority regarding course content, procedures and protocols.

(3) A Course Director for a specific course:

(a) Is responsible for course planning and organizing, including scheduling lectures, coordinating and arranging clinical rotations, and field internships;

(b) Is the primary instructor, who conducts at least 50 percent of the didactic sessions, unless this requirement is waived by the Authority in advance;

(c) Must ensure, if guest instructors are used, that the guest instructor is qualified to teach the subject matter, meets requirement set forth in OAR 333-265-0020, and presents lessons that address all objectives identified in the course curriculum for the topic being presented;

(d) Must ensure that:

(A) On the first day of class each student completes a registration form prescribed by the Authority;

(B) Each student is informed that failure to complete a registration form will make them ineligible to take the licensure exam; and

(C) The completed registration forms are collected and submitted to the Authority within 21 calendar days of the first day of class.

(e) Must have written documentation showing whether a student has successfully completed the course as defined in OAR 333-265-0014.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017
Hist.: PH 10-2008, f. & cert. ef. 6-16-08; PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12

333-265-0023
EMS Provider Examinations

(1) EMR Exam:

(a) In order to be licensed as an EMR, a candidate shall complete and pass both a cognitive and practical examination.

(b) The EMR cognitive and practical examination must be administered by an entity approved by the Authority to conduct EMR courses and shall use a cognitive and practical exam approved by the Authority.

(2) EMT Exam:

(a) In order to be licensed as an EMT, a candidate shall complete and pass both the cognitive and practical examination designated by the National Registry of Emergency Medical Technicians (NREMT.)

(b) The Authority has adopted the NREMT exam standard: Emergency Medical Technician, Psychomotor Examination User Guide; November 1, 2011, incorporated by reference.

(c) An EMT examination for licensure will be administered by a licensing officer and hosted by a teaching institution that offers EMT courses.

(d) An EMT practical examination must be attended by a licensing officer approved by the Authority who:

(A) Is licensed in Oregon at least at the level of examination they are administering with a minimum of two years field experience at that level or above and is in good standing with the Authority; and

(B) Has completed any training offered by the Authority explaining the role and responsibilities of a licensing officer.

(3) AEMT Exam:

(a) In order to be licensed as an AEMT, a candidate shall complete and pass both the cognitive and practical examination designated by the NREMT.

(b) The Authority has adopted the NREMT exam standard: Advanced Level Examination Coordinator Manual; August 1, 2013, incorporated by reference.

(c) An AEMT practical examination is an NREMT examination offered at various times during the year by the Authority. An AEMT candidate may also take the appropriate practical examination in any state.

(4) EMT-Intermediate Exam: In order to be licensed as an EMT-Intermediate, a candidate shall complete and pass a practical examination in accordance with OAR 333-265-0024.

(5) Paramedic Exam:

(a) In order to be licensed as a Paramedic, a candidate shall complete and pass both the cognitive and practical examination designated by the NREMT.

(b) The Authority has adopted the NREMT exam standard: Advanced Level Examination Coordinator Manual; August 1, 2013, incorporated by reference.

(c) A Paramedic practical examination is an NREMT examination offered at various times during the year by the Authority. A Paramedic candidate may also take the appropriate practical examination in any state.

(6) The Authority shall establish the passing scores for EMR and EMT-Intermediate exams. The NREMT shall establish the passing scores for EMT, AEMT and Paramedic exams.

(7) A candidate seeking accommodation under the American with Disabilities Act shall notify:

(a) The NREMT for the EMT, AEMT or Paramedic exam; or

(b) The Authority for the EMR or EMT-Intermediate exam.

(c) The NREMT or the Authority shall consider and act on the request in accordance with its policies and relevant laws.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available from the National Registry of EMT's website: www.nremt.org.]

Stat. Auth.: ORS 682.017, ORS 682.208, & ORS 682.216
Stats. Implemented: ORS 682.017, 682.208, 682.216
Hist.: PH 10-2008, f. & cert. ef. 6-16-08; PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12; PH 1-2013, f. & cert. ef. 1-25-13; PH 15-2015, f. 8-28-15, cert. ef. 9-3-15

333-265-0024
EMT-Intermediate Provider Examination

(1) The EMT-Intermediate examinations for licensure will be administered by a licensing officer and hosted by a teaching institution, EMS agency, or approved hospital that offers EMT-Intermediate courses.

(2) An EMT-Intermediate candidate who fails:

(a) Three or fewer skill stations of the EMT-Intermediate practical examination may retest those skill stations failed on the same day with no additional charge by the Authority.

(b) One or more skill stations a second time must submit a re-examination fee and be scheduled through the Authority to retest any skill station failed.

(c) More than three skill stations of the EMT-Intermediate practical examination must schedule a retest for a separate day, and submit a re-examination fee to the Authority.

(3) If a candidate fails the practical examination three times, the candidate must submit official documentation of remedial education before becoming eligible to re-enter the licensure examination process. Following successful completion of remedial education, a candidate must re-take and pass the practical examination within three additional attempts.

(4) A candidate must pass the practical examination within 24 months after the completion of the required courses.

(5) A candidate who fails the practical examination six times or does not complete the examination process within 24 months of the completion date of the initial required courses, must successfully complete the entire EMT-Intermediate course and reapply for licensure.

(6) No accommodation shall be provided for a practical licensure examination.

(7) An EMT-Intermediate practical examination must be attended by an Authority-approved licensing officer who:

(a) Is licensed in Oregon at least at an EMT-Intermediate level with at least two years field experience at that level or above and is in good standing with the Authority; and

(b) Has completed training offered by the Authority explaining the role and responsibilities of a licensing officer.

Stat. Auth.: ORS 682.017, 682.208, 682.216
Stats. Implemented: ORS 682.017, 682.208, 682.216
Hist.: PH 1-2013, f. & cert. ef. 1-25-13

333-265-0025
Application Process to Obtain an EMS Provider License

(1) For any person to act as an EMS provider a license must be obtained from the Authority.

(2) An applicant for EMR must:

(a) Be at least 16 years of age;

(b) Submit proof of successfully completing an approved course, including completion of all clinical and internship requirements, if applicable;

(c) Submit proof of passing the required cognitive and practical examinations;

(d) Submit a completed application on a form prescribed by the Authority along with the applicable fee;

(e) Consent to a criminal background check through the Law Enforcement Data System (LEDS), including a nationwide criminal record check by fingerprint identification under the authority of ORS 181.534 and 181.537 if required:

(A) The Authority may use information obtained through FBI criminal history records to determine suitability for licensure.

(B) If the Authority determines the information contained in the criminal history record may result in denial of the application or imposed sanctions on the license the applicant will be afforded reasonable time to complete, challenge, or correct the accuracy of the record before a final disposition or sanction is imposed.

(C) Procedures for obtaining a change, correction, or updating of an FBI identification record are set forth in Title 28, C.F.R., 16.34. Procedures for obtaining a change, correction, or updating of an Oregon criminal history record are set forth in OAR 257-010-0035.

(f) Provide authorization for the release of information, as necessary, from any persons or entities, including but not limited to educational institutions, employers, hospitals, treatment facilities, institutions, organization, governmental or law enforcement agencies.

(3) An individual who wishes to become licensed as an EMT, advanced EMT, EMT-Intermediate, or Paramedic shall:

(a) Be at least 18 years of age;

(b) Submit a completed application on a form prescribed by the Authority along with the applicable fee;

(c) Submit proof of successfully completing an approved course, including all clinical and internship requirements if applicable;

(d) Submit proof of passing the required cognitive and practical examinations;

(e) For an EMT, advanced EMT or EMT-Intermediate applicant, submit proof that the applicant received a high school diploma or equivalent or a degree from an accredited institution of higher learning;

(f) For a Paramedic applicant submit proof that the applicant has received an associate's degree or higher from an accredited institution of higher learning;

(g) Consent to a criminal background check through the Law Enforcement Data System (LEDS), including a nationwide criminal record check by fingerprint identification under the authority of ORS 181.534 and 181.537 if required:

(A) The Authority may use information obtained through FBI criminal history records to determine suitability for licensure.

(B) If the Authority determines the information contained in the criminal history record may result in denial of the application or imposed sanctions on the license the applicant will be afforded reasonable time to complete, challenge, or correct the accuracy of the record before a final disposition or sanction is imposed.

(C) Procedures for obtaining a change, correction, or updating of an FBI identification record are set forth in Title 28, C.F.R., 16.34. Procedures for obtaining a change, correction, or updating of an Oregon criminal history record are set forth in OAR 257-010-0035.

(h) Provide an authorization for the release of information, as necessary, from any persons or entities, including but not limited to educational institutions, employers, hospitals, treatment facilities, institutions, organizations, governmental or law enforcement agencies in order for the Authority to complete the review of the application; and

(4) EMT and EMT-Intermediate applications for licensure must be received by the Authority three weeks prior to the date of the licensing practical examination.

(5) Advanced EMT and Paramedic applications for licensure must be received by the Authority four weeks prior to the date of the practical examinations.

(6) Any fee for a criminal background check through LEDS or a nationwide criminal background check shall be the responsibility of the applicant.

(7) An applicant for an initial license as an EMS provider, who completed training in a program outside Oregon and has never been licensed in another state, must:

(a) Meet all requirements for that level as established in OAR 333-265-0000 through 333-265-0023;

(b) Demonstrate proof of current National Registry certification; and

(c) Make application within 24 months from the date that their training program was completed, unless an applicant has been on active duty in the military within the last four years and in that case, the application may be submitted more than 24 months from the date the training program was completed.

(8) An initial license must not exceed 30 months.

(9) If an applicant has been on active duty in the military within the past four years and the applicant can demonstrate proof of current National Registry certification for the level of license desired, current licensure in another state is not mandatory.

(10) The Authority may return any application that is incomplete or is not accompanied by the appropriate fee.

Stat. Auth.: ORS 682.017, 682.028 & 682.208
Stats. Implemented: ORS 682.017, 682.028 & 682.208
Hist.: OHD 9-2001, f. & cert. ef. 4-24-01; Hist.: PH 10-2008, f. & cert. ef. 6-16-08; PH 11-2008(Temp), f. 6-19-08, cert. ef. 6-20-08 thru 12-12-08; Administrative correction 12-22-08; PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12; PH 1-2013, f. & cert. ef. 1-25-13

333-265-0030
Fees for Licensure and License Renewal of an EMS Provider

(1) Beginning on July 1, 2011 through June 30, 2013 the following fees apply:

(a) Initial application for EMR — $40;

(b) The initial application and same-day practical examination fees for EMTs:

(A) EMT — $100;

(B) Advanced EMT — $110

(C) EMT-Intermediate — $110; and

(D) Paramedic — $275.

(c) Cognitive re-examination fees for EMT-Intermediate — $60.

(d) Practical re-examination fees:

(A) EMT — $50;

(B) Advanced EMT — $75

(C) EMT-Intermediate — $75; and

(D) Paramedic — $95.

(e) Reciprocity licensure fees:

(A) EMR — $40;

(B) EMT — $125;

(C) Advanced EMT — $150

(D) EMT-Intermediate — $150; and

(E) Paramedic — $300.

(f) Provisional licensure fee is an additional $50.

(g) License renewal fees:

(A) EMR — $20;

(B) EMT — $50;

(C) Advanced EMT — $80

(D) EMT-Intermediate — $80; and

(E) Paramedic — $140.

(2) Beginning on July 1, 2013 the following fees apply:

(a) Initial application for EMR — $45;

(b) The initial application and same-day practical examination fees for EMTs:

(A) EMT — $110;

(B) Advanced EMT — $125

(C) EMT-Intermediate — $125; and

(D) Paramedic — $290.

(c) Cognitive re-examination fees for EMT-Intermediate — $60.

(d) Practical re-examination fees:

(A) EMT — $55;

(B) Advanced EMT — $85

(C) EMT-Intermediate — $85; and

(D) Paramedic — $100.

(e) Reciprocity licensure fees:

(A) EMR — $50;

(B) EMT — $140;

(C) Advanced EMT — $165

(D) EMT-Intermediate — $165; and

(E) Paramedic — $300.

(f) Provisional licensure fee is an additional $50.

(g) License renewal fees:

(A) Licensed EMR — $23;

(B) EMT — $55;

(C) Advanced EMT — $85

(D) EMT-Intermediate — $85; and

(E) Paramedic — $150.

(3) As authorized by ORS 682.216, a license renewal application submitted or postmarked after May 1 of the license renewal year must include a $40 late fee in addition to the license renewal fee.

(4) If an EMS Provider has been on active military duty for more than six months of a license renewal period which prevented them from accessing continuing education, the Authority may approve an extension of the current license to permit obtaining the required educational hours.

(5) An ambulance service or rescue service which utilizes volunteers to provide a majority of its services may request that the Authority waive the EMS Provider license renewal fee for its volunteers by applying for a waiver on forms prescribed by the Authority that includes:

(a) A statement certifying that the ambulance or rescue service is unable to maintain an adequate number of volunteer EMS Providers due to the required EMS Provider license renewal fees; and

(b) A copy of a signed agreement between the volunteer service and the volunteer EMS Provider attached to the EMS Provider's application for license renewal specifying that the EMS Provider:

(A) Is not employed as an EMS Provider elsewhere;

(B) Will be affiliated with the volunteer service for the entire upcoming licensure period;

(C) Will be scheduled monthly to staff the ambulance or rescue service; and

(D) Will immediately pay the Authority the required current EMS Provider license renewal fee if the EMS Provider is not scheduled monthly or is no longer affiliated with a volunteer ambulance or rescue service and wants to remain licensed as an EMS Provider.

(6) An Oregon-licensed EMS Provider wishing to obtain a duplicate EMS Provider license must submit a written request to the Authority in the form required by the Authority and pay a fee in the amount of $25.

(7) All fees established in this section are nonrefundable except that the Authority may waive a subsequent examination fee for a person who fails to appear for an examination due to circumstances that are beyond the control of the candidate.

(8) The fees established in sections (1) and (2) of this rule apply to any application submitted on or after the effective date of these rules.

Stat. Auth.: ORS 682.017, 682.212, 682.216
Stats. Implemented: ORS 682.017, 682.212, 682.216
Hist.: HD 19-1984, f. & ef. 9-10-84; HD 16-1986, f. & ef. 9-9-86; HD 19-1991, f. & cert. ef. 10-18-91; HD 18-1994, 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0017; HD 8-1995, f. & cert. ef. 11-6-95; OHD 2-1999, f. & cert. ef. 2-4-99; OHD 9-2001, f. & cert. ef. 4-24-01; PH 10-2008, f. & cert. ef. 6-16-08; PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12

333-265-0040
Licensure as an EMS Provider

(1) The Authority will review an application for licensure as an EMS Provider and will conduct a criminal background check.

(2) If there are no issues that arise during the review of the application and the applicant meets all the requirements of ORS Chapter 682 and these rules, the Authority will grant the applicant a license.

(3) If the applicant does not meet the standards for licensure or there are criminal history or personal history issues that call into question the ability of the applicant to perform the duties of a licensed EMS Provider in accordance with ORS Chapter 682 or these rules, the Authority may deny the applicant on the basis of the information provided in the application, or conduct an additional investigation in accordance with OAR 333-265-0085.

(4) Following an investigation the Authority may:

(a) Deny the application;

(b) Grant the application but place the applicant on probation;

(c) Grant the application but place practice restrictions on the applicant; or

(d) Grant the application if the criminal or personal history issues were resolved through the investigation to the Authority's satisfaction.

(5) Final actions taken by the Authority in denying an applicant, placing an applicant on probation, or by placing restrictions on the applicant's practice shall be done in accordance with ORS Chapter 183.

(6) Nothing in this rule precludes the Authority from taking an action authorized in ORS Chapter 682.

(7) The licenses of EMRs expire on June 30 of even-numbered years.

(8) The licenses of EMTs, Advanced EMTs, EMT-Intermediates and Paramedics expire on June 30 of odd-numbered years.

Stat. Auth.: ORS 682.017, 682.208, 682.216
Stats. Implemented: ORS 682.017, 682.208, 682.216
Hist.: HD 63, f. 6-6-74, ef. 6-25-74; HD 1-1981, f. & ef. 1-14-81; Renumbered from 333-023-0615; HD 19-1984, f. & ef. 9-10-84; HD 16-1986, f. & ef. 9-9-86; HD 19-1991, f. & cert. ef. 10-18-91; HD 18-1994, 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0015; HD 8-1995, f. & cert. ef. 11-6-95; OHD 9-2001, f. & cert. ef. 4-24-01; PH 10-2008, f. & cert. ef. 6-16-08; PH 11-2008(Temp), f. 6-19-08, cert. ef. 6-20-08 thru 12-12-08; Administrative correction 12-22-08; PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12

333-265-0050
EMS Provider Licensure by Reciprocity

(1) A person registered with the National Registry of EMTs as an EMR, first responder, EMT, EMT-Basic, advanced EMT, EMT-Intermediate I-99, EMT-Intermediate I-85, Paramedic, or EMT-Paramedic may apply to the Authority for licensure by reciprocity until January 1, 2015 at which time only National Registry EMR, EMT, advanced EMT, and Paramedic will be accepted for reciprocity.

(a) A National Registry EMT-Intermediate I-99 may apply for an Oregon EMT-Intermediate licensure by reciprocity until January 1, 2015 at which time National Registry EMT-Intermediate I-99 will no longer be accepted for reciprocity.

(b) A National Registry EMT-Intermediate I-85 may apply for an EMT licensure by reciprocity until January 1, 2015 at which time National Registry EMT-Intermediate I-85 will no longer be accepted for reciprocity.

(2) A person applying for Oregon EMS provider licensure by reciprocity shall:

(a) Submit a completed application on a form prescribed by the Authority along with the applicable nonrefundable fee;

(b) Submit documentation of the EMS provider training which meets or exceeds the requirements for Oregon EMS provider licensure at the level of licensure for which the person is applying;

(c) If applying for Paramedic licensure by reciprocity, submit proof of having received an associate's degree or higher from an accredited institution of higher learning or submit proof of having worked for at least three years out of the last five years as a Paramedic in either another state or in the United States military at the National Registry Paramedic level.

(d) Be in good standing with the applicant's current licensing agency and with the National Registry of EMTs; and

(e) Consent to a criminal background check in accordance with OAR 333-265-0025(3).

(3) The Authority shall review an application for licensure by reciprocity and shall conduct a criminal background check.

(4) If there are no issues that arise during the review of the application and the applicant meets all the applicable requirements of ORS Chapter 682 and these rules, the Authority shall grant the applicant a license by reciprocity.

(5) If the applicant does not meet the standards for licensure, or there are criminal history or personal history issues that call into question the ability of the applicant to perform the duties of a licensed EMS provider, in accordance with ORS Chapter 682 or these rules, the Authority may deny the application on the basis of the information provided, or conduct an additional investigation in accordance with OAR 333-265-0085. Following such an investigation the Authority may take any action as specified in OAR 333-265-0040(4).

(6) The Authority shall be the sole agency authorized to determine equivalency of EMS provider course work presented from an out-of-state accredited institution of higher learning.

(7) The Authority shall be the sole agency authorized to determine equivalency of work experience in lieu of the associate degree requirement for Paramedics.

(8) The Authority shall return any application that is incomplete, or cannot be verified.

Stat. Auth.: ORS 682.017, 682.216
Stats. Implemented: ORS 682.017, 682.216
Hist.: HD 63, f. 6-6-74, ef. 6-25-74; HD 1-1981, f. & ef. 1-14-81; Renumbered from 333-023-0620; HD 19-1984, f. & ef. 9-10-84; HD 16-1986, f. & ef. 9-9-86; HD 18-1990(Temp), f. & cert. ef. 6-19-90; HD 19-1991, f. & cert. ef. 10-18-91; HD 8-1993, f. 6-22-93, cert. ef. 7-1-93; HD 18-1994, 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0020; HD 8-1995, f. & cert. ef. 11-6-95; OHD 9-2001, f. & cert. ef. 4-24-01; PH 10-2008, f. & cert. ef. 6-16-08; PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2011, f. & cert. ef. 1-6-11; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12; PH 1-2013, f. & cert. ef. 1-25-13

333-265-0056
Temporary Licensure for Wildland Fire Response

(1) Notwithstanding OAR 333-265-0050, an individual licensed and in good standing as an emergency medical services provider in another state and currently certified by the National Registry of EMTs (NREMT) may apply for a temporary license at the same level the EMS provider is currently certified by the NREMT for the purpose of providing emergency or non-emergency care to other individuals involved in responding to a wildland fire in Oregon.

(2) To apply for temporary licensure an individual must complete a temporary license application and provide any additional information required in the application.

(3) The Authority may conduct a criminal background check on an individual applying for temporary licensure.

(4) If the Authority issues a temporary license that license is only valid:

(a) For 90 calendar days from the date issued;

(b) While the individual is deployed firefighting or otherwise responding to a wildland fire; and

(c) For the purpose of treating individuals engaged in wildland fire response in Oregon.

(5) An individual licensed under this rule must:

(a) Function within the Oregon scopes of practice for EMS providers as described in OAR 847-035-0030;

(b) Practice with written standing orders issued by a supervising physician as defined in OAR 847-035-0001; and

(c) Comply with ORS chapter 682 and all rules adopted under ORS chapter 682.

Stat. Auth.: ORS 682.017, 682.216
Stats. Implemented: ORS 682.017, 682.216
Hist.: PH 12-2016, f. & cert. ef. 4-7-16

333-265-0060
Paramedic Provisional Licensure

(1) As authorized by ORS 682.216, the Authority may issue a provisional Paramedic license to an out-of-state licensed Paramedic who meets the requirements in OAR 333-265-0050, except for the educational requirements in 333-265-0050(3)(a) and is in the process of obtaining an associate's degree or higher from an accredited institution for higher learning.

(2) A provisional license shall only be provided in the event that the associate's degree or higher is obtainable within two years.

(3) An applicant shall comply with the application requirements in OAR 333-265-0050 and shall submit:

(a) A letter of recommendation from the applicant's most recent medical director;

(b) A letter from an Oregon EMS agency specifying that the person shall be immediately employed or has a conditional offer of employment, whether in a paid or volunteer capacity; and

(c) A letter from the applicant's prospective EMS medical director stating that the EMS medical director will serve as his or her EMS medical director while being provisionally licensed.

(4) The Authority may return any application that is incomplete, cannot be verified, or is not accompanied by the appropriate fee.

(5) A Paramedic with a provisional license issued under these rules shall enter into an agreement with the Authority and shall submit quarterly reports to the Authority describing the license holder's progress in obtaining an associate's degree or higher from an accredited institution for higher learning.

(6) A Paramedic provisional license shall be revoked if the person:

(a) Ceases active involvement in emergency medical services;

(b) Fails to meet the conditions set forth in the agreement;

(c) Fails to cooperate or actively participate in a request from the Authority in order to obtain more information or required materials;

(d) Has his or her EMS provider scope of practice revoked or restricted by his or her EMS medical director; or

(e) Does not submit written documentation of the successful completion of any of the educational requirements set out in this rule

Stat. Auth.: ORS 682.017, 682.216
Stats. Implemented: ORS 682.017, 682.216
Hist.: HD 18-1994, 6-30-94, cert. ef. 7-1-94; OHD 9-2001, f. & cert. ef. 4-24-01; PH 10-2008, f. & cert. ef. 6-16-08; PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12; PH 1-2013, f. & cert. ef. 1-25-13

333-265-0070
Licensure as an EMS Provider of Any Person in Another State

(1) Any person who provides pre-hospital emergency or non-emergency care in Oregon must be licensed as an Oregon EMS Provider and function under an Authority-approved EMS Medical Director.

(2) Oregon EMS Provider licensure is not required when:

(a) Specifically exempted by ORS 682.035;

(b) An out-of-state licensed EMS Provider is transporting a patient through the state;

(c) An out-of-state licensed EMS Provider is caring for and transporting a patient from an Oregon medical facility to an out-of-state medical facility or other out-of-state location;

(d) An out-of-state licensed EMS Provider is caring for and transporting a patient originating from outside of Oregon to a medical facility or other location in Oregon; or

(e) A disaster or public health emergency has been declared under ORS Chapter 401 or 433 and licensing provisions have been waived by the Governor.

Stat. Auth.: ORS 682.017, 682.204
Stats. Implemented: ORS 682.017, 682.204
Hist.: HD 63, f. 6-6-74, ef. 6-25-74; HD 1-1981, f. & ef. 1-14-81; Renumbered from 333-023-0625; HD 19-1984, f. & ef. 9-10-84; HD 16-1986, f. & ef. 9-9-86; HD 19-1991, f. & cert. ef. 10-18-91; HD 18-1994, 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0025; OHD 9-2001, f. & cert. ef. 4-24-01; PH 10-2008, f. & cert. ef. 6-16-08; PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12

333-265-0080
Reportable Events; Investigations and Discipline of License Holders

(1) In accordance with ORS 676.150 and using a form prescribed by the Authority, EMS Providers must notify the Authority of the actions or events listed in section (3) of this rule. Failure to comply with the reporting requirements of this rule may result in disciplinary action against the EMS Provider.

(2) An EMS Provider who has reasonable cause to believe another EMS Provider has engaged in prohibited, dishonorable or unprofessional conduct as defined in ORS 676.150, 682.025 and 682.220 shall report that conduct to the Authority without undue delay, within 10 days, after the EMS Provider learns of the conduct unless state or federal laws relating to confidentiality or the protection of health information prohibit such a disclosure.

(3) Within 10 calendar days an EMS Provider shall report to the Authority the following:

(a) Conviction of a misdemeanor or felony;

(b) A felony arrest;

(c) A disciplinary restriction placed on a scope of practice of the license holder by the EMS Medical Director;

(d) A legal action being filed against the license holder alleging medical malpractice or misconduct;

(e) A physical disability that affects the ability of the license holder to meet the Functional Job Analysis, Appendix A of the EMT, National Standard Curriculum, incorporated by reference, and the license holder continues to respond to calls and is providing patient care; or

(f) A change in mental health which may affect a license holder's ability to perform as a licensed EMS Provider.

(4) State or federal laws relating to confidentiality or the protection of health information that might prohibit an EMS Provider from reporting prohibited or unprofessional conduct include but are not limited to:

(a) Public Law 104-191, 42 CFR Parts 160, 162, and 164 (The Health Insurance Portability and Accountability Act, HIPAA);

(b) 42 CFR Part 2 (federal law protecting drug and alcohol treatment information);

(c) ORS 192.518 through 192.529 (state law protecting health information); and

(d) ORS 179.505 (written accounts by health care providers).

Stat. Auth.: ORS 682.017, 682.220, 682.224
Stats. Implemented: ORS 682.017, 682.220, 682.224
Hist.: HD 63, f. 6-6-74, ef. 6-25-74; HD 1-1981, f. & ef. 1-14-81; Renumbered from 333-023-0635; HD 16-1986, f. & ef. 9-9-86; HD 19-1991, f. & cert. ef. 10-18-91; HD 18-1994, 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0035; OHD 9-2001, f. & cert. ef. 4-24-01; PH 10-2008, f. & cert. ef. 6-16-08; PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12

333-265-0083
Conduct or Practice Contrary to Recognized Standards of Ethics

The following list includes, but is not limited to, conduct or practice by an EMS Provider that the Authority considers to be contrary to the recognized standards of ethics of the medical profession:

(1) Knowing or willful violation of patient privacy or confidentiality by releasing information to persons not directly involved in the care or treatment of the patient;

(2) Illegal drug use on or off duty;

(3) Alcohol use within eight hours of going on duty or while on duty or in an on-call status;

(4) Violation of direct verbal orders from a physician who is responsible for the care of a patient;

(5) Violation of orders given by an online medical resource physician, whether delivered by radio or telephone;

(6) Violation of standing orders without cause and documentation;

(7) Use of invasive medical procedures in violation of generally accepted standards of the medical community;

(8) Any action that constitutes a violation of any statute, municipal code, or administrative rule that endangers the public, other public safety officials, other EMS Provider, patients, or the general public (including improper operation of an emergency medical vehicle);

(9) Instructing, causing or contributing to another individual violating a statute or administrative rule, including EMS Provider acting in a supervisory capacity;

(10) Participation in the issuance of false continuing education documents or collaboration therein, including issuing continuing education verification to one who did not legitimately attend an educational event;

(11) Signing-in to an educational event for a person not actually present;

(12) Knowingly assisting or permitting another EMS Provider to exceed his or her lawful scope of practice;

(13) Unlawful use of emergency vehicle lights and sirens;

(14) Providing false or misleading information to the Authority, to the State EMS Committee, to the Subcommittee on EMT Licensure and Discipline, to an EMS teaching institution or clinical/field internship agency;

(15) Responding to scenes in which the EMS Provider is not properly dispatched ("call-jumping"), whether in a private auto, ambulance, or other vehicle, in contravention of local protocols, procedures, or ordinances, or interfering with the safe and effective operation of an EMS system;

(16) Cheating on any examination used to measure EMS related knowledge or skills;

(17) Assisting another person in obtaining an unfair advantage on an EMS Provider examination;

(18) Defrauding the Authority;

(19) Knowingly providing emergency medical care aboard an unlicensed ambulance;

(20) Violation of the terms of a written agreement with the Authority or an order issued by the Authority;

(21) Sexual misconduct that includes but is not limited to:

(a) Sexual harassment; and

(b) Engaging or attempting to engage in a sexual relationship, whether or not the sexual relationship is consensual, with a patient, client, or key party;

(c) Using the EMT-patient, EMT-client, or EMT-key party relationship to exploit the patient, client or key party by gaining sexual favors from the patient, client or key party.

(22) Arriving for duty impaired or in a condition whereby the EMS Provider is likely to become impaired through fatigue, illness, or any other cause, as to make it unsafe for the employee to begin to operate an ambulance or provide patient care;

(23) Failure to cooperate with the Authority in an investigation, including failure to comply with a request for records, or a psychological, physical, psychiatric, alcohol or chemical dependency assessment; and

(24) Any violation of these rules or any law, administrative rule, or regulation governing ambulances, EMS Providers, or emergency medical service systems.

Stat. Auth.: ORS 682.017
Stats. Implemented: ORS 682.017, 682.220, 682.224
Hist.: PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12

333-265-0085
Investigations

(1) The Authority may conduct an investigation of an EMS provider if:

(a) The Authority receives a complaint concerning an EMS provider;

(b) Personal or criminal history questions arise during a review of an application that raise questions about the EMS provider's ability to safely perform the duties of an EMS provider;

(c) A reportable action is received pursuant to OAR 333-265-0080; or

(d) The Authority receives information in any manner that indicates an EMS provider has violated ORS Chapter 682 or these rules, may be medically incompetent, guilty of prohibited, unprofessional or dishonorable conduct or mentally or physically unable to safely function as an EMS provider.

(2) The Authority may investigate the off-duty conduct of an EMS provider to the extent that such conduct may reasonably raise questions about the ability of the EMS provider to perform the duties of an EMS provider in accordance with the standards established by this division.

(3) Upon receipt of a complaint about an EMS provider or applicant, the Authority may conduct an investigation as described under ORS 676.165 and 682.220. Investigations shall be conducted in accordance with ORS 676.175.

(4) The fact that an investigation is conducted by the Authority does not imply that disciplinary action will be taken.

(5) During an investigation the Authority may do any of the following:

(a) Request additional information from the EMS provider;

(b) Conduct a phone or in-person interview; or

(c) Request or order that the EMS provider undergo a psychological, physical, psychiatric, alcohol or chemical dependency assessment.

Stat. Auth.: ORS 676.165, 676.175
Stats. Implemented: ORS 682.017, 682.220, 682.224
Hist.: PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12; PH 1-2013, f. & cert. ef. 1-25-13

333-265-0087
Discipline

(1) Upon completion of an investigation the Authority may do any of the following:

(a) Close the investigation and take no action;

(b) Issue a letter of reprimand or instruction;

(c) Place the EMS Provider on probation;

(d) Place a practice restriction on the EMS Provider;

(e) Suspend the EMS Provider;

(f) Revoke the license of the EMS Provider;

(g) Enter into a stipulated agreement with the EMS Provider to impose discipline; or

(h) Take such other disciplinary action as the Authority, in its discretion, finds proper, including assessment of a civil penalty not to exceed $5,000.

(2) Any disciplinary action taken by the Authority will be done in accordance with ORS Chapter 183.

(3) The Authority may assess the costs of a disciplinary proceeding against an EMS Provider. Costs may include, but are not limited to:

(a) Costs incurred by the Authority in conducting the investigation;

(b) Costs of any evaluation or assessment requested by the Authority; and

(c) Attorney fees.

(4) Voluntary Surrender:

(a) An EMS Provider may voluntarily surrender his or her license if the EMS Provider submits a written request to the Authority specifying the reason for the surrender and the Authority agrees to accept the voluntary surrender.

(b) The Authority may accept a voluntary surrender of the EMS Provider on the condition that the EMS Provider does not reapply for licensure, or agrees not to reapply for a specified period of time.

(5) If an EMS Provider who voluntarily surrendered his or her EMS Provider license applies for reinstatement, the Authority may deny that person's application if the Authority finds that the person has committed an act that would have resulted in discipline being imposed while they were previously licensed.

(6) If an EMS Provider's license is revoked he or she may not reapply for licensure for at least two years from the date of the final order revoking the license.

Stat. Auth.: ORS 682.017, 682.220, 682.224
Stats. Implemented: ORS 682.017, 682.220, 682.224
Hist.: PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12

333-265-0090
Reverting to a Lower Level of EMT Licensure

(1) An EMT, Advanced EMT, EMT-Intermediate, or Paramedic may revert to a lower level of licensure at any time during a license period if the EMT, Advanced EMT, EMT-Intermediate, or Paramedic:

(a) Submits a written request to the Authority specifying the reason for the change in the licensure level;

(b) Submits an application for license renewal for the lower level of licensure sought with the appropriate fee;

(c) Surrenders his or her current EMT, Advanced EMT, EMT-Intermediate, or Paramedic license to the Authority;

(d) Is in good standing with the Authority;

(e) Adequately documents appropriate continuing education hours and courses for the licensure level the individual would revert to; and

(f) Receives written approval from the Authority for a change in licensure level.

(2) If an EMT, Advanced EMT, EMT-Intermediate, or Paramedic requests reinstatement of the higher level of licensure within one year of reverting to a lower level of licensure the EMT, Advanced EMT, EMT-Intermediate, or Paramedic must complete the requirements specified in OAR 333-265-0100(3) and 333-265-0105.

(3) If an EMT, Advanced EMT, EMT-Intermediate, or Paramedic requests reinstatement of the higher level of licensure after one year, but less than two years the EMT, Advanced EMT, EMT-Intermediate, or Paramedic must complete the requirements specified in OAR 333-265-0105.

Stat. Auth.: ORS 682.017, 682.216
Stats. Implemented: ORS 682.017, 682.216
HD 19-1991, f. & cert. ef. 10-18-91; HD 18-1994, 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0037; OHD 9-2001, f. & cert. ef. 4-24-01; PH 10-2008, f. & cert. ef. 6-16-08; PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 16-2010(Temp), f. & cert. ef. 7-16-10 thru 1-1-11; PH 1-2011, f. & cert. ef. 1-6-11; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12

333-265-0100
Expiration and Renewal of EMS Provider License

(1) The licenses of EMRs expire on June 30 of even-numbered years.

(2) The licenses of EMTs, Advanced EMTs, EMT-Intermediates and Paramedics expire on June 30 of odd-numbered years.

(3) An applicant for license renewal must:

(a) Complete and sign an application form prescribed by the Authority certifying that the information in the application is correct and truthful;

(b) Meet the requirements of ORS Chapter 682 and these rules;

(c) Consent to a criminal background check in accordance with OAR 333-265-0025(3);

(d) Provide an authorization for the release of information to the Authority, as necessary, from any persons or entities, including but not limited to employers, educational institutions, hospitals, treatment facilities, institutions, organizations, governmental or law enforcement agencies in order for the Authority to make a complete review of the application.

(e) Complete the continuing education requirements in OAR 333-265-0110; and

(f) Submit a fee set out in OAR 333-265-0030.

Stat. Auth.: ORS 682.017, 682.216
Stats. Implemented: ORS 682.017, 682.216
Hist.: HD 63, f. 6-6-74, ef. 6-25-74; HD 1-1981, f. & ef. 1-14-81; Renumbered from 333-023-0640; HD 19-1984, f. & ef. 9-10-84; HD 16-1986, f. & ef. 9-9-86; HD 19-1991, f. & cert. ef. 10-18-91; HD 18-1994, 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0040; HD 8-1995, f. & cert. ef. 11-6-95; OHD 9-2001, f. & cert. ef. 4-24-01; PH 10-2008, f. & cert. ef. 6-16-08; PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12

333-265-0105
Reinstatement of an EMS Provider License

(1) To reinstate an expired Oregon EMR, EMT, advanced EMT, EMT-Intermediate, or Paramedic license that has been expired for less than one year, an applicant must:

(a) Submit a completed application for license renewal;

(b) Submit the appropriate license renewal fee plus a late fee; and

(c) Provide evidence of completion of continuing education requirements as specified in Appendices 1 through 3, incorporated by reference, and courses completed from the license holder's last successful application through the date of the present application for license renewal, as specified in this rule:

(A) EMR before July 1, 2012 or on or after July 1, 2014 refer to Appendix 1;

(B) EMR on or after July 1, 2012 but before July 1, 2014 refer to Appendix 2;

(C) EMT, AEMT, EMT-Intermediate, and Paramedic before July 1, 2013 or on or after July 1, 2015 refer to Appendix 1;

(D) EMT, AEMT, EMT-Intermediate, and Paramedic on or after July 1, 2013 but before July 1, 2015 refer to Appendix 3;

(2) Reinstatement of an EMR license that has been expired for more than one year will require retaking and passing the course and examinations.

(3) Reinstatement of an EMT-Intermediate license that has been expired for more than one year will require retaking and passing the course and examinations.

(4) To reinstate an Oregon EMT or EMT-Paramedic license that has been expired for more than one year, but less than two years, a license holder must submit a completed application for licensure with the appropriate fee and successfully complete an Authority-approved reinstatement program described in these rules.

(5) Reinstatement program for an EMT:

(a) Obtain an American Heart Association "Health Care Provider," or American Red Cross "Basic Life Support for the Professional Rescuer," or other Authority-approved equivalent CPR course completion document;

(b) Complete the EMT Authority-approved Refresher Training Program;

(c) Pass the EMT cognitive and practical examinations within three attempts, including a same-day re-examination; and

(d) Complete the above listed program requirements within 730 calendar days from expiration date.

(6) Reinstatement program for an advanced EMT:

(a) Obtain an American Heart Association "Health Care Provider," or American Red Cross "Basic Life Support for the Professional Rescuer," or other Authority-approved equivalent CPR course completion document;

(b) Complete a Basic Trauma Life Support (BTLS) course, or Pre-Hospital Trauma Life Support (PHTLS) course, provider or instructor course; and

(c) Complete the above listed program requirements within 730 calendar days from expiration date.

(7) Reinstatement program for a Paramedic:

(a) Complete an Advanced Cardiac Life Support (ACLS) course, provider or instructor course;

(b) Complete a Basic Trauma Life Support (BTLS) course, or Pre-Hospital Trauma Life Support (PHTLS) course, provider or instructor course;

(c) Complete an Advanced Pediatric Life Support (APLS), Pediatric Advanced Life Support (PALS), Pediatric Education for Pre-hospital Professionals (PEPP), or Neonatal Advance Life Support (NALS) course, provider or instructor course;

(d) Complete the U.S. Department of Transportation, National Highway Traffic Safety Administration 2001 Paramedic: National Standard Curriculum Refresher Training Program, incorporated by reference;

(e) Pass the Paramedic cognitive and practical examinations within three attempts, including the same-day re-examination;

(f) Complete the above listed program requirements within two years of applying for reinstatement; and

(g) Document completion of a DOT Paramedic Training Program taken after January 1, 1977.

(h) If the requirements described in OAR 333-265-0105(6) cannot be met prior to 730 calendar days from expiration date an applicant must follow the National Registry's re-entry requirements to obtain a new National Registry certification before applying for a new license as outlined in OAR 333-265-0025.

[ED. NOTE: Appendices referenced are not included in rule text.]
Stat. Auth.: ORS 682.216
Stats. Implemented: ORS 682.017, 682.216
Hist.: PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 16-2010(Temp), f. & cert. ef. 7-16-10 thru 1-1-11; PH 1-2011, f. & cert. ef. 1-6-11; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12; PH 1-2013, f. & cert. ef. 1-25-13

333-265-0110
Licensed EMS Provider Continuing Education Requirements for License Renewal

(1) An EMR is required to:

(a) Complete 12 hours of continuing education as specified in Appendix 1, incorporated by reference;

(b) On or after July 1, 2012 but before July 1, 2014 an EMR must complete 12 hours of continuing education as specified in Appendix 2, incorporated by reference during which period a current National Registry of Emergency Medical Technicians certification will not be accepted in lieu of requirements listed in Appendix 2

(c) On or after July 1, 2014 an EMR must complete 12 hours of continuing education as specified in Appendix 1, incorporated by reference; or

(d) Complete all requirements of the National Registry of Emergency Medical Technicians for EMR re-registration.

(2) An EMT is required to:

(a) Complete 24 hours of continuing education as specified in Appendix 1, incorporated by reference;

(b) On or after July 1, 2013 but before July 1, 2015 an EMT must complete 24 hours of continuing education as specified in Appendix 3, incorporated by reference during which period a current National Registry of Emergency Medical Technicians certification will not be accepted in lieu of requirements listed in Appendix 3;

(c) On or after July 1, 2015 an EMT must complete 24 hours of continuing education as specified in Appendix 1, incorporated by reference; or

(d) Complete all requirements of the National Registry of EMT or Emergency Medical Technician re-registration.

(3) An advanced EMT is required to:

(a) Complete 36 hours of continuing education as specified in Appendix 1, incorporated by reference;

(b) On or after July 1, 2013 but before July 1, 2015 an advanced EMT must complete 36 hours of continuing education as specified in Appendix 3, incorporated by reference during which period a current National Registry of Emergency Medical Technicians certification will not be accepted in lieu of requirements listed in Appendix 3;

(c) On or after July 1, 2015 an advanced EMT must complete 36 hours of continuing education as specified in Appendix 1, incorporated by reference; or

(d) Complete all requirements of the National Registry of EMTs re-registration.

(4) An EMT-Intermediate is required to:

(a) Complete a course with published standards and guidelines for cardiopulmonary resuscitation and emergency cardiac care in which the EMT has demonstrated knowledge and skills in the performance of subcutaneous (SQ) injections, automated external defibrillator (AED) operation, one and two person rescuer cardiopulmonary resuscitation (adult, child, and infant) and relief of foreign body airway obstruction; and

(b) Obtain at least 36 hours of continuing education as specified in Appendix 1, incorporated by reference; or

(c) On or after July 1, 2013 but before July 1, 2015 an EMT-Intermediate must complete 36 hours of continuing education as specified in Appendix 3, incorporated by reference during which period a current National Registry of Emergency Medical Technicians certification will not be accepted in lieu of requirements listed in Appendix 3; or

(d) On or after July 1, 2015 an EMT-Intermediate must complete 36 hours of continuing education as specified in Appendix 1, incorporated by reference.

(5) A Paramedic is required to:

(a) Complete all requirements of the National Registry of EMTs re-registration; or

(b) Obtain at least 48 hours of continuing education as specified in Appendix 1, incorporated by reference; or

(c) On or after July 1, 2013 but before July 1, 2015 a Paramedic must complete 48 hours of continuing education as specified in Appendix 3, incorporated by reference during which period a current National Registry of Emergency Medical Technicians certification will not be accepted in lieu of requirements listed in Appendix 3; or

(d) On or after July 1, 2015 a Paramedic must complete 48 hours of continuing education as specified in Appendix 1, incorporated by reference.

(6) All continuing education credits specified in sections (1) through (5) of this rule shall be completed between the date of the license holder's last successful application to the date of the license holder's current license renewal application.

(7) Continuing education credit shall be granted hour-for-hour for:

(a) Attending training seminars, educational conferences, and continuing education classes within the license holder's scope of practice;

(b) Attending live, webinar, or interactive online courses for the same or higher level of licensure;

(c) Online continuing education that provides a certificate of completion and is approved by the Continuing Education Coordinating Board for Emergency Medical Services (CECBEMS);

(d) Related accredited college courses will count one hour per credit hour received; and

(e) Authority-approved license renewal courses.

(8) Up to 50 percent of the hours of continuing education credits for each subject listed in section 1 of the appropriate appendix as incorporated by reference may be obtained by:

(a) Watching a video, CD-ROM, or other visual media;

(b) Being an EMT practical licensure exam evaluator, if the license holder is qualified as such;

(c) Reading EMS journals or articles; and

(d) Teaching any of the topics listed in the appendices as incorporated by reference, if the license holder is qualified to teach the subject.

(9) In addition to the hours of continuing education required in this rule, any affiliated EMS provider license holder must, as specified in section 2 of the appendices, incorporated by reference, demonstrate skills proficiency through a hands-on competency examination supervised by the EMS medical director or his or her designee. An EMS medical director may require successful performance in a minimum number of clinical skills in these areas on either human subjects or mannequins (e.g. venipunctures, endotracheal intubations, etc.).

(10) An EMS medical director may require additional continuing education requirements and skill competency.

(11) When a license holder obtains an initial license and there is:

(a) Less than six months until license renewal, no continuing education credits are required to obtain license renewal;

(b) More than six months but less than one year until license renewal, the license holder must complete 50 percent of the continuing education credits in each category; or

(c) More than one year until license renewal, the license holder must complete all continuing education credits.

(12) Continuing education credits are granted on an hour-for-hour basis.

(13) It shall be the responsibility of each license holder to ensure the hours obtained meet the Authority's license renewal requirements.

(14) A license holder must submit proof, in a manner prescribed in OAR 333-265-0140 that the continuing education requirements have been met.

(15) Education programs, journals and articles used towards continuing education must be approved by the EMS medical director or the Authority.

[ED. NOTE: Appendices referenced are available from the agency.]

Stat. Auth.: ORS 682.017, 682.216

Stats. Implemented: ORS 682.017, 682.216

Hist.: HD 18-1994, 6-30-94, cert. ef. 7-1-94; HD 63, f. 6-6-74, ef. 6-25-74; HD 1-1981, f. & ef. 1-14-81; Renumbered from 333-023-0645; HD 19-1984, f. & ef. 9-10-84; HD 16-1986, f. & ef. 9-9-86; HD 19-1991, f. & cert. ef. 10-18-91; HD 18-1994, f. 6-30-94, cert. ef. 7-1-94, Renumbered from 333-028-0045; HD 8-1995, f. & cert. ef. 11-6-95; OHD 9-2001, f. & cert. ef. 4-24-01; PH 10-2008, f. & cert. ef. 6-16-08; PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 1-2011, f. & cert. ef. 1-6-11; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12; PH 1-2013, f. & cert. ef. 1-25-13

333-265-0140

Maintaining Licensed EMS Provider Continuing Education Records

(1) A license holder is responsible for retaining records that show successful completion of all required continuing education for the two previous licensure periods.

(2) The Authority will accept as proof of successful completion:

(a) A class roster that contains:

(A) The name of the teaching institution or EMS agency;

(B) The date of the class;

(C) The class topic;

(D) The length of the class;

(E) The full name of the license holder attending the class; and

(F) The full name of the instructor.

(b) A computer-generated printout history of the license holder's continuing education record that contains:

(A) The full name of the license holder;

(B) The name of the teaching institution or EMS agency conducting the classes;

(C) The dates of the classes;

(D) The class topics;

(E) The length of each class; and

(F) The full name of each instructor.

(c) A certificate of course completion for one or more topics that contains:

(A) The name of the teaching institution or EMS agency conducting the course;

(B) The date(s) of the course;

(C) The course topic(s);

(D) The length of the course; and

(E) The full name of the license holder attending the course.

(d) If the certificate does not list each course topic, then a copy of the program listing each course topic and length of each presentation must be attached to the certificate.

Stat. Auth.: ORS 682.017, 682.216

Stats. Implemented: ORS 682.017, 682.216

Hist.: HD 18-1994, 6-30-94, cert. ef. 7-1-94; OHD 9-2001, f. & cert. ef. 4-24-01; PH 10-2008, f. & cert. ef. 6-16-08; PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12

333-265-0150
Licensed EMS Provider Continuing Education Records Audit

(1) The Authority may conduct an audit of a license holder's continuing education records:

(a) The Authority shall notify the license holder by certified mail that he or she is being audited and provide him or her with the necessary audit forms and the date the completed forms are to be returned to the Authority; and

(b) Upon the return of the completed audit forms to the Authority, the Authority shall begin the process of verifying the continuing education records.

(2) If, in the course of an audit of continuing education records, the Authority learns that, contrary to the sworn statement in the application for license renewal or in the official audit form, the license holder has not completed all necessary continuing education requirements, the Authority may:

(a) Discipline the license holder as set out in OAR 333-265-0080;

(b) Assess a monetary penalty in the amount of $10 per each hour of deficient continuing education; or

(c) Require the license holder to demonstrate his or her knowledge and psychomotor skills by taking and passing a cognitive and practical examination conducted by the Authority.

(3) The actions taken by the Authority in section (2) of this rule will be done in accordance with ORS Chapter 183.

Stat. Auth.: ORS 682.017, 682.216, 682.220, 682.224

Stats. Implemented: ORS 682.017, 682.208, 682.220, 682.224

Hist.: HD 18-1994, 6-30-94, cert. ef. 7-1-94; HD 8-1995, f. & cert. ef. 11-6-95; OHD 9-2001, f. & cert. ef. 4-24-01; PH 10-2008, f. & cert. ef. 6-16-08; PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12

333-265-0160
License Holder's Responsibility to Notify the Authority of Changes

(1) A license holder must keep the Authority apprised of and report the following changes within 30 calendar days of a change in:

(a) EMS medical director, unless the license holder is affiliated with an ambulance service that is on file with the Authority;

(b) Legal name;

(c) Mailing address;

(d) Electronic mail address;

(e) Main contact phone number; or

(f) EMS affiliation.

(2) When reporting a new affiliation an EMS provider must supply the Authority with verification of completion of skills competency as referenced in Appendix 1 and it must be signed by his/her medical director or designee unless verification was completed during the most recent license renewal period.

[ED. NOTE: Appendices referenced are not included in rule text.]

Stat. Auth.: ORS 682.017, 682.208, 682.220, 682.224

Stats. Implemented: ORS 682.017, 682.208, 682.220, 682.224

Hist.: HD 18-1994, 6-30-94, cert. ef. 7-1-94; HD 8-1995, f. & cert. ef. 11-6-95; OHD 9-2001, f. & cert. ef. 4-24-01; PH 10-2008, f. & cert. ef. 6-16-08; PH 13-2010, f. 6-30-10, cert. ef. 7-1-10; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12; PH 1-2013, f. & cert. ef. 1-25-13

333-265-0170
Displaying EMS Provider Licensure Level

(1) A licensed EMS Provider providing patient care must display his or her level of licensure on the outmost garment of his or her usual work uniform.

(2) A licensed EMS Provider-licensure level need not be displayed on emergency work apparel not normally worn during the provision of pre-hospital patient care, such as haz-mat suits, anti-contamination or radiation suits, firefighting apparel, etc.

(3) A licensed EMS Provider responding from home or other off-duty locations shall make a reasonable effort to display his or her licensure level. Baseball-type hats, T-shirts, safety vests, etc. are accepted for this purpose.

Stat. Auth.: ORS 682.017, 682.204, 682.220, 682.265

Stats. Implemented: ORS 682.017, 682.204, 682.220, 682.225

Hist.: OHD 9-2001, f. & cert. ef. 4-24-01; PH 10-2008, f. & cert. ef. 6-16-08; PH 15-2011, f. 12-28-11, cert. ef. 1-1-12

DIVISION 270

OREGON POLST (PHYSICIAN ORDERS FOR LIFE-SUSTAINING TREATMENT) REGISTRY

333-270-0010
Purpose

(1) These rules establish a registry (the Oregon POLST Registry) within the Oregon Health Authority for the collection of POLST forms and the dissemination of information from POLSTs to help ensure that medical treatment preferences for individuals nearing the end of the individual's life are honored.

(2) The Registry may be operated and maintained by a contractor of the Authority.

Stat. Auth: ORS 127.666

Stats. Implemented: ORS 127.663-127.684

Hist.: PH 12-2009, f. & cert. ef. 12-3-09

333-270-0020
Scope and Applicability

(1) The requirements for submitting a POLST form or a revocation in OAR 333-270-0040 apply to POLST forms signed on or after December 3, 2009.

(2) The Authority is not responsible for and these rules do not:

(a) Prescribe the content or form of a POLST;

(b) Provide for the dissemination of POLST forms;

(c) Provide POLST teaching resources;

(d) Provide for educating the public about POLST; or

(e) Provide training for health care professionals about POLST.

(3) The Authority and the POLST Registry Advisory Committee may cooperate with organizations and agencies active in POLST issues to help carry out the activities described in section (2) of this rule.

(4) The Registry shall accept POLST forms signed by a physician, nurse practitioner, or physician assistant:

(a) Licensed in Oregon at the time the POLST form information is entered into the Registry; or

(b) Permitted to practice in Oregon under ORS 677.060(1) or 678.031(1).

(5) A person who is the subject of the POLST form (meeting the requirements defined below) need not be a resident of Oregon in order for the form to be included in the Registry.

(6) A more recently executed POLST form automatically voids a previous POLST form.

Stat. Auth: ORS 127.666

Stats. Implemented: ORS 127.663-127.684

Hist.: PH 12-2009, f. & cert. ef. 12-3-09

333-270-0030
Definitions

As used in OAR chapter 333, division 270:

(1) "Ambulance service" has the meaning given that term in ORS 682.025.

(2) "Authority" means the Oregon Health Authority.

(3) "Authorized user" means a person authorized by the Authority to provide information to or receive information from the Registry.

(4) "Hospice program" has the meaning given that term in ORS 443.850.

(5) "Hospital" has the meaning given that term in ORS 442.015.

(6) "Life-sustaining treatment" means any medical procedure, pharmaceutical, medical device or medical intervention that maintains life by sustaining, restoring or supplanting a vital function. "Life-sustaining treatment" does not include routine care necessary to sustain patient cleanliness and comfort.

(7) "Long term care facility" means nursing facilities, assisted living and residential care facilities and adult foster homes licensed under OAR chapter 411, divisions 85, 54, and 50, or facilities federally funded to care for veterans.

(8) "Non-transporting emergency services agency" means any individual, partnership, corporation, association, governmental agency or unit or other entity that uses certified first responders or EMTs to provide emergency care or non-emergency care in the out-of-hospital environment to persons who are ill or injured, but does not transport patients to a hospital.

(9) "Nurse practitioner" has the meaning given that term in ORS 678.010; and means a nurse practitioner permitted to practice in a federal facility pursuant to ORS 678.031(1).

(10) "Patient" means the person who is the subject of the POLST form.

(11) "Personal representative" has the meaning given that term in ORS 192.519.

(12) "Physician" has the meaning given that term in ORS 677.010.

(13) "Physician assistant" has the meaning given that term in ORS 677.495.

(14) "POLST" means a Physician Order for Life-Sustaining Treatment signed by a physician, nurse practitioner or physician assistant.

(15) "POLST form" means a form, prescribed by the Oregon Health & Science University that contains a POLST, and any revision of the POLST.

(16) "Registry" means the Oregon POLST Registry authorized by Oregon Laws 2009, chapter 595, sec. 1184.

(17) "Revocation" means the cancellation of a POLST form in any written form.

Stat. Auth: ORS 127.666
Stats. Implemented: ORS 127.663-127.684
Hist.: PH 12-2009, f. & cert. ef. 12-3-09

333-270-0040
Submission of POLST Forms

(1) Physicians, nurse practitioners, and physician assistants are required to submit or cause to be submitted:

(a) Completed POLST forms they have signed, unless the patient has opted out of the Registry; and

(b) Revocations of which they are aware.

(2) Any person may submit a completed POLST form or revocation to the Registry, regardless of when the POLST form was completed.

(3) In order for a POLST form to be considered complete, the form (and any supporting documentation) shall include, but is not limited to:

(a) The patient's full name;

(b) The patient's date of birth;

(c) Orders related to cardiopulmonary resuscitation;

(d) The legible, printed name and the signature of the physician, nurse practitioner or physician assistant; and

(e) The date the order was signed.

(4) If a POLST form is submitted and determined to be incomplete, the Registry will notify the submitter that the form is incomplete, describe the missing information, and request that the form be resubmitted once it is complete.

(5) A POLST form submitted under this rule may be submitted by fax or mail. If the Registry develops a secure method of accepting POLST forms electronically, POLST forms may be submitted electronically.

(6) The Registry shall record in the Registry records, as soon as reasonably possible after receipt of the POLST form, the following:

(a) The information from a POLST form described in subsections (3)(a) through (e) of this rule; and

(b) Instructions if any, regarding medical interventions, use of antibiotics, and artificially administered nutrition.

(7) If a revocation is submitted to the Registry, that patient's POLST form shall be removed as soon as reasonably possible from the active Registry database. The Registry shall retain the POLST form for documentation, program evaluation and research purposes.

(8)(a) The first time a physician, nurse practitioner, or physician assistant submits a POLST form to the Registry, the Registry shall verify that the physician, nurse practitioner, or physician assistant is licensed, in Oregon, or is otherwise permitted to practice under ORS 677.060(1) or 678.031(1).

(b) Verification of licensure status under this section is not necessary for POLST forms signed before December 3, 2009.

(9) The Registry shall notify, in writing, a patient, or a patient's personal representative if known, and the health care provider who signed the POLST form or revocation when the Registry has received a POLST form or revocation. The notification required by this section only applies if the POLST form or revocation contains contact information for the patient, patient's personal representative, and health care provider. The notification shall inform the person to contact the Registry if any of the information on the POLST form or revocation is incorrect.

(10) Notification under section (9) of this rule shall be documented by the Registry and the documentation shall include the date of notification and who was notified.

(11) A person reporting information to the Registry in good faith is immune from any civil or criminal liability that might otherwise be incurred or imposed with respect to the reporting of information to the Registry.

(12) The Registry or any contractor that operates and maintains the Registry is not responsible for:

(a) Verifying the accuracy of the information on a POLST form or revocation submitted to the Registry, except as specified in section (8) of this rule; or

(b) Actions taken pursuant to information that was fraudulently submitted to the Registry.

NOTE: Practitioners may obtain POLST forms by contacting the Oregon Health and Science University, at: polst@ohsu.edu, or visiting www.POLST.org

Stat. Auth: ORS 127.666
Stats. Implemented: ORS 127.663-127.684
Hist.: PH 12-2009, f. & cert. ef. 12-3-09

333-270-0050
Access to the Registry

(1) Registry staff, including its Emergency Communications Center staff, shall have access to POLST Registry information as needed to perform Registry functions. Registry staff and the Authority shall have access to Registry information as needed to conduct program evaluation.

(2) The following persons are authorized to contact the Registry's Emergency Communication Center and obtain information about a patient currently being treated:

(a) A licensed health care provider working in or for:

(A) A hospital emergency department or acute care unit where a patient is admitted;

(B) A licensed ambulance service; or

(C) A non-transporting emergency services agency.

(b) A staff person calling on behalf of a person described in subsection (a) of this section.

(3) The Registry shall release to a person described in section (1) of this rule, by phone:

(a) Whether the patient being treated has a POLST form recorded in the Registry, and if so;

(b) The POLST orders.

(4) The following persons, facilities, or programs are authorized to contact the Registry's office to determine whether a patient being treated by that person, at that facility, or by that program has a POLST form recorded in the Registry, whether the form is current, and the POLST orders:

(a) A physician, nurse practitioner or physician assistant who signed and submitted a POLST form to the Registry;

(b) Licensed or accredited:

(A) Long term care facilities;

(B) Hospice programs; or

(C) Hospitals.

(c) A patient's health care professional.

(d) A staff person calling on behalf of a person described in subsection (a) or (c) of this section.

(5) A patient or a patient's personal representative may contact the Registry to determine if that patient has a POLST form, whether the form is current, and the POLST order.

(a) The Registry shall request that a patient verify certain information in the Registry to ensure that the patient is who he or she purports to be, prior to the release of any Registry information.

(b) The Registry shall require a patient's personal representative to provide proof of the personal representative's identity and authority to act on behalf of the patient, and if necessary and legally required, provide an Authorization for the Release of Information that meets HIPAA requirements, prior to releasing information.

(6) The Registry may, in its discretion, require that a person described in section (2) or (4) of this rule provide proof of his or her identity, authority, licensing status, or need for the information prior to releasing any information from the Registry

(7) The Registry may provide the information requested under section (4) or (5) of this rule by fax, mail, or electronically, but may not release information over the phone.

(8) A person acting on information obtained from the Registry in good faith is immune from any civil or criminal liability that might otherwise be incurred or imposed with respect to acting on information obtained from the Registry.

(9) A person who requests information from the Registry who does not have the authority to obtain the information, or obtains information from the Registry for fraudulent reasons may be subject to a civil penalty of $500 per violation.

Stat. Auth: ORS 127.666
Stats. Implemented: ORS 127.663-127.684
Hist.: PH 12-2009, f. & cert. ef. 12-3-09

333-270-0060
Confidentiality of Registry Information

(1) Registry information may only be released to:

(a) Persons and facilities described in OAR 333-270-0050 or 333-270-0080; and

(b) Authorized researchers.

(2) Registry information may only be released for the purposes specified in OAR 333-270-0050 or 333-270-0080.

(3) All information collected or developed by the Registry that identifies or could be used to identify a patient, health care provider or facility is confidential and is not subject to civil or administrative subpoena or to discovery in a civil action, including but not limited to a judicial, administrative, arbitration or mediation proceeding.

(4) Only the minimum amount of information needed to accomplish the intended purposes shall be released under this rule.

Stat. Auth: ORS 127.666
Stats. Implemented: ORS 127.663-127.684
Hist.: PH 12-2009, f. & cert. ef. 12-3-09

333-270-0070
POLST Registry Advisory Committee

(1) The POLST Registry Advisory Committee is composed of individuals meeting the requirements in Oregon Laws 2009, chapter 595, section 1186 and committee members are appointed by the director of the Authority.

(2) The Committee shall:

(a) Meet at least four times per year;

(b) Advise the Authority regarding the implementation, operation, and evaluation of the Registry;

(c) Consult with the Authority in drafting rules on the implementation, operation, and evaluation of the Registry; and

(d) Review proposals from researchers to access Registry information and advise the Authority on whether access should be granted.

(3) The Authority shall provide appropriate staff support for the Committee.

Stat. Auth: ORS 127.666
Stats. Implemented: ORS 127.675
Hist.: PH 12-2009, f. & cert. ef. 12-3-09

333-270-0080
Access to Registry Information by Researchers

(1) The Authority may approve the release of Registry information to qualified researchers for appropriate research projects if an institutional review board has approved the research in accordance with 45 CFR Part 46.

(2) A researcher's application shall be reviewed by the POLST Registry Advisory Committee prior to release of information. Such request to the Authority for release of information may be made on a standard POLST Data Request Form or by such other manner approved by the Authority.

(3) If a researcher is permitted access to information in the Registry, the researcher shall agree, in writing, to maintain the confidentiality of the information received from the Registry, provided that this shall not limit aggregation, de-identification and other use and disclosure of such information for appropriate research purposes.

(4) Any Registry information released to a researcher under this rule may be de-identified by the Registry before release if deemed by the Authority as appropriate and reasonable under the circumstances.

Stat. Auth: ORS 127.666
Stats. Implemented: ORS 127.663-127.684
Hist.: PH 12-2009, f. & cert. ef. 12-3-09

DIVISION 275

HEMODIALYSIS TECHNICIANS LICENSING PROCEDURES AND DEFINITIONS

333-275-0001
Purpose

The purpose of OAR 333-275-0001 through 333-275-0180 is to establish standards for the training, testing and certification of hemodialysis technicians. These rules are adopted pursuant to ORS 688.625 through 688.665.

Stat. Auth.: ORS 688.625 - 688.665
Stats. Implemented: ORS 688.625 - 688.665
Hist.: OHD 2-2001, f. & cert. ef. 1-18-01

333-275-0010
Definitions

As used in OAR chapter 333, division 275, unless the context requires otherwise, the following definitions apply:

(1) "Abbreviated training program" means a training program consisting of a minimum of sixteen (16) hours of theory related to hemodialysis and/or supervised clinical learning experiences to train a hemodialysis technician or demonstrate the clinical competencies of an experienced hemodialysis technician.

(2) "Certificate" means a document identifying the legal privilege and authorization to perform specific functions and procedures in the State of Oregon.

(3) "Certified Hemodialysis Technician" (CHDT) has the meaning given the term in ORS 688.625, and includes, but is not limited to, a person who is certified by the Oregon Public Health Division to assist with the direct care of a patient undergoing hemodialysis.

(4) "Competency" means the demonstration of knowledge in a specific area and the ability to perform specific skills and tasks in a safe, efficient manner.

(5) "Contact Hour" means a fifty (50) minute hour of training.

(6) "Continuing Education" is planned learning experiences beyond a basic technician educational program. These experiences are designed to promote the development of knowledge, skills and attitudes for the enhancement of patient care. The Division must determine the appropriateness of all continuing education programs.

(7) "Dialysis" means a process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane. The two types of dialysis that are currently in common use are hemodialysis and peritoneal dialysis.

(8) "Dialysis Facility or Center" means a place awarded conditional or unconditional status by the federal Health Care Financing Administration to provide dialysis services.

(9) "Direct Supervision" means that the registered nurse, nurse practitioner, licensed practical nurse, or licensed physician is physically present and accessible in the immediate patient care area and available to intervene, if necessary."

(10) "Division" means the Public Health Division, Oregon Health Authority.

(11) "Division approved certification" means a process of national certification of hemodialysis technicians currently available or developed in the future, with requirements that, after review and approval by the Health Division, can be substituted wholly or partially for requirements of the Oregon certification of hemodialysis technicians program. Approved national certifications and requirements include, but are not limited to, the Board of Nephrology Examiners for Nursing and Technology (BONENT) certification examination.

(12) "End-Stage Renal Disease" (ESRD) means that stage of renal impairment that appears irreversible and permanent, and requires either the replacement of kidney function through renal transplantation or the permanent assistance of those functions through dialysis.

(13) "Extended training program" means a training program designed for the minimally experienced or inexperienced trainee to gain the skills necessary to become a CHDT.

(14) "Law Enforcement Data System (LEDS)" means a program organized within the Oregon State Police, Law Enforcement Data System Division, which provides a criminal justice telecommunications and information system for the State of Oregonhttp://picture.vzw.com:80/mi/470840425_1647195384_447681338_1260983139999.jpeg?limitsize=345,345&outquality=56&ext=.jpg&border=2,0,0,0, and is the control point for access to similar programs operated by other states and the federal government.

(15) "License" is a document identifying the legal privilege and authorization to practice within a professional category.

(16) "National certification examination" means examinations that have documented validity, reliability, and interrater reliability, are provided on a national level, and are approved by the Oregon Public Health Division. Approved national certification examinations include, but are not limited to, the Board of Nephrology Examiners for Nursing and Technology (BONENT) certification.

(17) A "Preceptor" is an individual with a minimum of one (1) year of clinical hemodialysis experience who supervises and observes students providing direct patient care in a dialysis facility or center.

(18) "Registry" means the listing of Oregon Certified Hemodialysis Technicians maintained by the Division. The Registry contains identifying demographic information on each CHDT, the date of initial and most recent certification. Division sanctions against a CHDT certification are noted on the Registry. Findings of incompetence, unprofessional or dishonorable conduct, or mental or physical inability to perform the functions of a CHDT are noted on the Registry.

(19) "Subject individual" means the applicant for hemodialysis certification.

(20) "Trainee Hemodialysis Technician" means an uncertified hemodialysis technician enrolled in an abbreviated or extended training program, working under the direct clinical supervision of a nurse educator, clinical preceptor, or technician educator.

Stat. Auth.: ORS 688.625 - 688.665
Stats. Implemented: ORS 688.625 - 688.665
Hist.: OHD 2-2001, f. & cert. ef. 1-18-01

333-275-0020
Certification of Hemodialysis Technicians Required

After January 1, 2000 hemodialysis technicians must have a current, valid Oregon CHDT certificate and be listed on the CHDT Registry prior to assuming or continuing hemodialysis technician duties.

(1) A hemodialysis technician hired before January 1, 2000, and who has been employed as a hemodialysis technician for a minimum of 1,000 hours since January 1, 1998, must participate in a Division-approved, abbreviated hemodialysis technician training program and having done so, pass a Division-approved examination prior to certification. Evidence of successful completion of a Division-approved, national certification examination will be accepted as meeting the requirement for an examination.

(2) A hemodialysis technician hired after January 1, 2000, and who has been employed as a hemodialysis technician for a minimum of 1,000 hours within the preceding twenty-four (24) month period, must participate in a Division-approved, abbreviated hemodialysis technician training program and having done so, pass a Division-approved examination prior to certification. Evidence of successful completion of a Division-approved, national certification examination will be accepted as meeting the requirement for an examination.

(3) A hemodialysis technician hired after January 1, 2000, and who has not been employed as a hemodialysis technician for a minimum of 1,000 hours since January 1, 1998, must participate in a Division-approved hemodialysis technician extended training program and having done so, pass a Division-approved examination prior to certification.

Stat. Auth.: ORS 688.625 - 688.665
Stats. Implemented: ORS 688.630(1)
Hist.: OHD 2-2001, f. & cert. ef. 1-18-01

333-275-0030
Application for Certificate and Certification of Hemodialysis Technicians by Exam

(1) In order to meet the prerequisites, the hemodialysis technician applicant must:

(a) Provide evidence that the applicant has received a high school diploma or its equivalent;

(b) Complete a Division-approved hemodialysis technician training program;

(c) Complete an application for certification;

(d) Complete the required examination application within the deadlines and according to all instructions including remittance of required fee to the testing entity; and

(e) Complete a consent for a criminal records check.

(2) Application and fees for the hemodialysis technician certification examination must be submitted to the Division by the application deadline.

(3) Applications containing fraudulent or misrepresented information shall be the basis for denial of certification.

(4) Incomplete applications for certification become null and void one (1) year after date of last activity.

(5) If an applicant fails to appear for the examination, the applicant must resubmit the application and fees.

Stat. Auth.: ORS 688.625 - 688.665
Stats. Implemented: ORS 688.640
Hist.: OHD 2-2001, f. & cert. ef. 1-18-01

333-275-0040
Criminal Conviction History

(1) The Public Health Division shall conduct a criminal records check of all applicants prior to certification.

(2) Failure to provide written consent for a criminal records check or failure to provide completed fingerprint cards for a Federal Bureau of Investigation (FBI) check, where required, shall be grounds for denial of an application.

(3) Criminal offender information will be obtained through the Oregon Law Enforcement Data System (LEDS). Nationwide criminal records checks, if necessary, shall be conducted by the Oregon State Police (OSP) through the FBI. In conducting criminal records checks on subject individuals, the Division shall act in accordance with its obligations under ORS 181.537.

(4) The Division has determined that serious felonies and misdemeanors involving violence or unauthorized sexual conduct with the vulnerable or disabled are fundamentally inconsistent with the responsibility of care for the dialysis patient and thereby related to the fitness of the hemodialysis technician to practice hemodialysis. Conviction of crimes listed in **Table 1** of this rule shall disqualify a CHDT subject individual from receiving certification, unless the subject individual provides sufficient evidence of suitability as described in section (7) of this rule.

(5) The Division has determined that serious felonies and misdemeanors involving theft, fraud, or deception, crimes against the state and public justice, and major traffic violations may substantially jeopardize the safety of the dialysis patient and thereby are related to the fitness of the hemodialysis technician to practice hemodialysis. If any subject individual was convicted of a crime listed in **Table 2** of this rule, [Table not included. See ED. NOTE.] the Division will seek to obtain and review information on all intervening circumstances and other background information related to criminal activity, subject to section (7) of this rule. Based on this information, the Division will make a decision whether to approve certification given the individual subject meets all other requirements for certification.

(6) These rules also apply to:

(a) Any attempts, solicitations or conspiracy to commit a crime listed in **Table 1** or **Table 2**, and;

(b) Conviction of a crime, in another jurisdiction, which is the substantial equivalent of a crime listed in **Table 1** or **Table 2** or any attempts, solicitations or conspiracy to commit a crime, in another jurisdiction, which is the substantial equivalent of a crime listed in **Table 1** or **Table 2**.

(7) Factors in Suitability Determination:

(a) Factors to be considered in determining suitability, based on information available to the Division and information provided by the subject individual, include:

(A) The nature of the crime;

(B) The facts that support the conviction;

(C) The making of a false statement on the consent for criminal records check related to the disqualifying crimes;

(D) The relevancy of the subject individual's criminal conviction history to the fitness of the hemodialysis technician to practice hemodialysis;

(E) Intervening circumstances relevant to the responsibilities and circumstances of the position, services or employment. Such circumstances include but are not limited to:

(i) Passage of time since the commission of the crime;

(ii) The age of the person at the time of the crime;

(iii) The likelihood of a repetition of offenses;

(iv) The commission of other relevant crimes, including the type and number of offenses;

(v) The recommendation of an employer.

(b) Under no circumstances shall a subject individual be barred from certification because of the existence or contents of a juvenile record, which has been expunged pursuant to ORS 419A.260 to 419A.262.

(8) Process for Federal Criminal Records Check:

(a) When conducting a criminal records check on a subject individual, the Division may conduct a federal criminal history check when:

(A) The subject individual has lived outside the state of Oregon any time during the preceding 18 months;

(B) The Oregon record shows "Multi-state Offender" status;

(C) The Division has information about the applicant having crimes in other states.

(b) An applicant subject to the federal criminal records check must submit to the Division:

(A) Properly completed FBI fingerprint cards;

(B) Properly completed consent for criminal records check form;

(C) A description of the crime and conviction if the subject individual acknowledges conviction of a crime; and

(D) The fee for the FBI check.

(9) A subject individual who passes the Oregon criminal records check but is waiting for the FBI criminal records check to be processed may receive a conditional certificate, based upon the Oregon criminal records check and a review of the application, if all other prerequisites are met. This conditional certificate is subject to revocation in the event the FBI criminal records check contains a disqualifying conviction.

(10) Criminal offender information is confidential and shall not be disclosed by the Division. A subject individual may inspect the subject individual's own Oregon record at the Division. The Division may not disclose FBI information to the subject individual or other persons or entities.

(11) If an applicant wishes to challenge the accuracy or completeness of information provided by OSP or the FBI, the subject individual must make a challenge directly to the department, bureau or agency providing that information and not through the contested case hearing process set forth in OAR 333-275-0170.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 688.625 - 688.665

Stats. Implemented: ORS 688.655(1)(e) & 181.537

Hist.: OHD 2-2001, f. & cert. ef. 1-18-01

333-275-0050

Certification Expiration

Each initial certification issued, unless sooner suspended or revoked, shall expire one year after the next June 30 following successful completion of the required examination. Each subsequent certification issued under this section, unless sooner suspended or revoked, shall expire and be renewable after a period of two years.

Stat. Auth.: ORS 688.625 - 688.665

Stats. Implemented: ORS 688.650(5)

Hist.: OHD 2-2001, f. & cert. ef. 1-18-01

333-275-0060

Hemodialysis Technician Certification Renewal

Beginning January 1, 2000, CHDTs are required to renew certification on or before June 30 every second year:

(1) Application for renewal must be postmarked before midnight on May 31 to allow time for a review of the application;

(2) The certificate shall automatically lapse if the certificate holder fails to renew by the appropriate renewal date and an individual who fails to renew by this deadline is considered delinquent;

(3) The Division may renew any lapsed certification upon payment of all past unpaid renewal and delinquent fees;

(4) A CHDT who submits his/her application for renewal greater than ninety (90) days after the June 30 renewal date must retake the extended Division-approved training program, and must retake the Division-approved examination, or show evidence of the successful completion of a Division-approved certification;

(5) Each application must be accompanied by a nonrefundable renewal fee payable to the Division.

Stat. Auth.: ORS 688.625 - 688.665

Stats. Implemented: ORS 688.640(2) - 688.650(5)

Hist.: OHD 2-2001, f. & cert. ef. 1-18-01

333-275-0070
Requirements for Renewal of Certification

(1) A complete application form must be submitted for recertification.

(2) Employment Requirements for Renewal of Certification:

(a) At the time of certification renewal, the applicant must be prepared to provide evidence of a minimum of 1,000 hours worked as a CHDT during the twenty-four (24) month period immediately preceding certification renewal;

(b) An applicant who is unable to provide evidence of the minimum 1,000 hours worked as a CHDT during the twenty-four month period immediately preceding certification renewal or the prorated required hours worked as a CHDT according to the chart under section (4) of this rule, shall satisfy all of the requirements of a new applicant to obtain certification;

(c) Applicable hours worked as a CHDT are not limited to hours spent providing direct patient care but may include a variety of other tasks commensurate with the individual's abilities and job description.

(3) Continuing Education Requirements for Renewal of Certification:

(a) At the time of certification renewal, the applicant must be prepared to provide evidence of a minimum of twenty (20) contact hours of Division-approved continuing education accrued within the twenty-four (24) months immediately preceding renewal. The Oregon Public Health Division shall determine the appropriateness of all continuing education programs. For those CHDTs completing the training program, the training program hours may be applied towards the continuing education requirement as outlined in OAR 333-275-0110;

(b) An applicant who is unable to provide evidence of the minimum 20 hours of Division-approved continuing education during the twenty-four month period immediately preceding certification renewal, or the prorated required hours of Division-approved continuing education hours according to the chart under section (4) of this rule, shall satisfy all of the requirements of a new applicant to obtain certification.

(4) Prorated Requirements Based on Testing Schedule: The following table shall be applied to prorate the required number of hours worked as a CHDT and the required number of continuing education contact hours for those CHDTs receiving a certification less than twenty-four (24) months prior to the June 30 renewal date as per OAR 333-275-0050. See OAR 333-275-0180 Fees for the proration of the certification fee. [Table not included. See ED. NOTE.]

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 688.625 - 688.665
Stats. Implemented: ORS 688.645 & 688.650(3), (4)
Hist.: OHD 2-2001, f. & cert. ef. 1-18-01

333-275-0080
Provisional Certificates

(1) A provisional certificate is issued to:

(a) A hemodialysis technician who was hired prior to January 1, 2000, who has worked a minimum of 1,000 hours prior to January 1, 2000, and who is enrolled in a Division-approved abbreviated training program or has completed a Division-approved abbreviated training program and is waiting for a certification examination or;

(b) A hemodialysis technician hired after January 1, 2000, who has completed an approved training program, and is waiting for a certification examination.

(2) Provisional certificates are valid for a period of six (6) months and are renewable two times from January 1, 2000 until January 1, 2001. After January 1, 2001, provisional certificates are renewable one (1) time only. The technician must apply for the renewal of the certificate three (3) calendar weeks prior to the expiration date of the original provisional certificate.

(3) A provisional certificate will be revoked pursuant to ORS 183.310 to 183.550 when a hemodialysis technician holding a provisional certificate fails a certification examination.

(4) A hemodialysis technician who fails to pass the certification examination can work as a trainee hemodialysis technician until the next scheduled examination. Should a technician fail the examination a second time, that technician cannot practice within a dialysis facility as a technician.

Stat. Auth.: ORS 688.625 - 688.665
Stats. Implemented: ORS 688.650(2)
Hist.: OHD 2-2001, f. & cert. ef. 1-18-01

333-275-0090
Scope of Practice of Hemodialysis Technician

(1) Authorized Functions of Certified Hemodialysis Technicians: CHDTs who hold full or provisional certification by the Oregon Public Health Division may, under the direct supervision of a physician licensed under ORS Chapter 677 or a registered nurse licensed under ORS 678.010 to 678.410:

(a) Perform venipunctures for dialysis access;

(b) Collect data, i.e. pre-weight, complaints, and vital signs, to be utilized by the registered nurse in developing the nursing assessment;

(c) Obtain lidocaine from a stock source and inject intradermal lidocaine in preparation for dialysis access;

(d) Obtain heparin from a stock source and administer a heparin bolus;

(e) Administer a bolus of normal saline;

(f) Connect a dialysis access to normal saline or heparinized normal saline;

(g) Initiate or discontinue dialysis treatment via central lines; and

(h) Administer oxygen on the basis of standing orders, facility protocol, or at the direction of a physician, registered nurse, or licensed practical nurse.

(2) Prohibited functions of the Certified Hemodialysis Technician: CHDTs who have been certified by the Oregon Public Health Division may not:

(a) Administer medications by oral, intramuscular, intravenous, or subcutaneous routes except as addressed in 333-275-0090(1);

(b) Perform arterial punctures outside of dialysis access;

(c) Determine the frequency or duration of dialysis treatments;

(d) Administer blood or blood products;

(e) Accept verbal or telephone orders from a physician or his/her representative;

(f) Perform hemodialysis on a hospitalized intensive care unit patient.

(3) An individual facility may elect to further limit the scope of practice of hemodialysis technicians working in that facility. If so, then the CHDT shall comply with that facility's job description.

Stat. Auth.: ORS 688.625 - 688.665
Stats. Implemented: ORS 688.635
Hist.: OHD 2-2001, f. & cert. ef. 1-18-01

333-275-0100
Trainee Hemodialysis Technicians

(1) A trainee hemodialysis technician may perform the duties of a CHDT when it is an integral part of the training program and the trainee hemodialysis technician is working under the direct clinical supervision of a nurse educator, clinical preceptor, or technician educator. The duties of a CHDT are determined by the scope of practice of the CHDT as defined under OAR 333-275-0090 and the job description of the hemodialysis technicians of the dialysis facility or center in which the clinical training occurs. The job description must not exceed the scope of practice of the CHDT.

(2) Trainees must be selected without discrimination as to age, race, religion, gender, sexual preference, national origin, or marital status.

(3) A person working as a trainee because the person failed to pass the certification examination as provided in OAR 333-275-0080(4) must work under the direct clinical supervision of a nurse educator, clinical preceptor, or technician educator.

Stat. Auth.: ORS 688.625 - 688.665
Stats. Implemented: ORS 688.640
Hist.: OHD 2-2001, f. & cert. ef. 1-18-01

333-275-0110
Approval Guidelines and Minimal Curriculums for Hemodialysis Technician Training Programs to Qualify for Continuing Education Credit

(1) In addition to continuing education programs of varying length of contact hours as defined earlier, there shall be two (2) separate learning programs approved by the Division for training or continuing education credit. These are:

(a) An abbreviated training program to train a hemodialysis technician or demonstrate the clinical competencies of an experienced hemodialysis technician is a training program consisting of a minimum of sixteen (16) hours of theory and/or supervised clinical learning experiences related to hemodialysis as it is performed in a particular facility or facilities or dialysis center;

(b) An extended training program which is designed for the minimally experienced or inexperienced trainee to gain the skills necessary to become a CHDT. There shall be a minimum of eighty (80) hours of classroom study, and a minimum of one hundred sixty (160) hours of supervised clinical experience.

(2) Qualifications and Competencies of Faculty:

(a) The nurse educator shall be a registered nurse and shall hold a current unencumbered license to practice in Oregon.

(b) The nurse educator shall have at least two (2) years of nursing practice experience including at least one (1) year of nursing experience in dialysis. Previous nursing experience in critical care and nursing education is desirable.

(c) The nurse educator shall have a minimum of nine (9) contact hours of continuing education annually in nephrology or be certified by a nationally recognized body.

(d) Clinical preceptors shall have at least one (1) year of clinical dialysis experience. Clinical preceptors shall demonstrate knowledge and skills in clinical dialysis.

(e) Technician educators will be under the supervision of a nurse educator. These technicians shall possess national certification by the Board of Nephrology Examiners for Nursing and Technology (BONENT) and have at least two (2) years experience in hemodialysis and possess current CHDT certification.

(f) A CHDT under direct supervision of the nurse educator and/or approved clinical preceptor may be assigned to assist with the clinical experience\orientation of hemodialysis technician trainees.

(3) Minimum Standards for Approval of Hemodialysis Technician Training Programs for Continuing Education:

(a) Administration and Organization: The hemodialysis technician training program shall employ a nurse educator to administer the training program; he/she shall be responsible for the development, implementation, and evaluation of the training program, arrangements for and supervision of trainees' clinical experiences, and communications with the Health Care Regulation and Quality Improvement (HCRQI) section of the Division.

(b) Objectives: There shall be written objectives for the training program, which serve as the basis for planning, implementing, and evaluating the program. The training program faculty shall develop the objectives. The training program objectives shall describe the knowledge and skills expected of the CHDT, and shall be consistent with the authorized functions of the CHDT and the approved core curriculum.

(c) The training program's nurse educator shall develop a written systematic plan for curriculum and program evaluation.

(d) Training Program Record Retention Requirements: The program shall maintain the orientation checklists and any appropriate certification documentation in employees' personnel files as part of the permanent file.

(e) The nurse educator will submit the objectives of the training program, the names and qualifications of the nurse educator(s) and clinical preceptor(s), the program curriculum, the program schedule, and the program evaluation plan to the Division prior to implementing the program to receive approval for continuing education credit applicable to the CHDT continuing education requirements. If both abbreviated and extended programs are to be offered by the hemodialysis facility or center, the above materials for each program must be submitted for Division approval. The materials must be sent to: Hemodialysis Technician Certification Program, Health Care Regulation and Quality Improvement, Suite #640, Oregon Health Division, PO Box 14450, Portland, OR 97293-0450.

(4) Curriculum:

(a) The curriculum shall extend over a period of time sufficient to provide essential, sequenced learning experiences, which enable the trainee to develop competence and shall show evidence of an organized pattern of instruction consistent with principles of learning and sound educational practices.

(b) Supervised clinical experience shall provide opportunities for the application of theory and for the achievement of stated objectives in a patient care setting and shall include clinical learning experiences to develop the skills required by technicians to provide safe patient care. The nurse educator and/or clinical preceptor must be physically present and accessible to the trainee when the trainee is in the patient care area.

(c) Required core curriculum content for both the abbreviated and extended training programs can be found in Appendix A.

(5) Continuing education credit shall be approved for the actual hours spent in training in an initial abbreviated or an initial extended training program for a single, initial certification period; these hours are not transferrable to subsequent certification periods.

[ED. NOTE: Appendices referenced are available from the agency.]

Stat. Auth.: ORS 688.625 - 688.665

Stats. Implemented: ORS 688.640(2) & 688.650(4)

Hist.: OHD 2-2001, f. & cert. ef. 1-18-01

333-275-0120
Investigation

The Oregon Health Division may investigate any evidence that appears to show that a certified hemodialysis technician is or may be medically incompetent, is or may be guilty of unprofessional or dishonorable conduct, or is or may be mentally or physically unable to safely function as a certified hemodialysis technician (as outlined in ORS 685.655(2)).

Stat. Auth.: ORS 688.625 - 688.665

Stats. Implemented: ORS 685.655(2)

Hist.: OHD 2-2001, f. & cert. ef. 1-18-01

333-275-0130
Dishonorable Conduct Derogatory for a Hemodialysis Technician Defined

A CHDT whose conduct fails to conform to the standards for certified hemodialysis technicians, or who may adversely affect the health, safety, and welfare of the public, may be found to have committed dishonorable conduct for a CHDT. Such conduct shall include, but is not limited to, the following:

(1) Conduct related to the patient's safety and integrity:

(a) Failing to report through proper channels facts known regarding the incompetent, unethical, unsafe, or illegal practice of any health care provider;

(b) Failing to respect the dignity and rights of patients, regardless of social or economic status, age, race, religion, sex, sexual preference, national origin, nature of health problems or disability;

(c) Engaging in sexual contact with a patient.

(2) Conduct related to other federal or state statute/rule violations:

(a) Abusing a patient. The definition of abuse includes, but is not limited to, intentionally causing physical and/or mental harm or discomfort, striking a patient, intimidating, threatening, or harassing a patient;

(b) Neglecting a patient. The definition of neglect includes, but is not limited to, carelessly allowing a patient to be in physical discomfort or be injured;

(c) Failing to report actual or suspected incidents of patient abuse through the proper channels in the work place and to the appropriate state agencies;

(d) Aiding, abetting, or assisting an individual to violate or circumvent any law, rule or regulation intended to guide the conduct of CHDTs or other health care providers.

(3) Conduct related to communication:

(a) Falsifying a patient or agency record; including, but not limited to, filling in another person's omissions, signing another person's name, recording care not given, fabricating data/values;

(b) Altering a patient or agency record: this includes, but is not limited to, changing words/letters/numbers from the original document to mislead the reader of the record, adding to the record after the original time/date without indicating a late entry;

(c) Destroying a patient or agency record;

(d) Directing another person to falsify, alter, or destroy patient or agency records.

(4) Conduct related to clinical practice: Performing acts beyond the authorized scope of practice.

(5) Conduct related to impaired function:

(a) Practicing as a CHDT when unable/unfit to perform procedures and/or make decisions due to physical impairment as evidenced by documented deterioration of functioning in the practice setting and/or by the assessment of a health care provider qualified to diagnose physical condition/status;

(b) Practicing as a CHDT when unable/unfit to perform procedures and/or make decisions due to psychological or mental impairment as evidenced by documented deterioration of functioning in the practice setting and/or by the assessment of a health care provider qualified to diagnose mental condition/status;

(c) Practicing as a CHDT when physical or mental ability to practice is impaired by use of drugs, alcohol, or mind-altering substances.

(6) Conduct related to certification violations:

(a) Allowing another person to use one's CHDT certification for any purpose;

(b) Resorting to fraud, misrepresentation, or deceit during the application process for certification, while taking the certification exam, or while obtaining initial certification or renewal of certification;

(c) CHDT impersonating any applicant or acting as a proxy for the applicant in any certification examination;

(d) Disclosing the contents of the certification examination or soliciting, accepting or compiling information regarding the contents of the examination, before during or after its administration.

Stat. Auth.: ORS 688.625 - 688.665
Stats. Implemented: ORS 688.655(2)
Hist.: OHD 2-2001, f. & cert. ef. 1-18-01

333-275-0140
Duty to Report, Confidential Information, and Liability of Person who Reports

(1) Any dialysis facility or center, any certified hemodialysis technician certified under ORS 688.650, any physician licensed under ORS Chapter 677, or any registered nurse licensed under ORS 678.010 to 678.410 shall report to the Health Care Regulation and Quality Improvement section of the Oregon Health Division any information the person may have that appears to show that a CHDT is or may be medically incompetent or is or may be guilty of unprofessional or dishonorable conduct or is or may be mentally or physically unable to safely function as a hemodialysis technician.

(2) Information provided to the Division pursuant to this section is confidential and shall not be subject to public disclosure, nor shall it be admissible as evidence in any judicial proceeding (as outlined in ORS 685.655(4)).

(3) Any person who reports or provides information to the Division under this section and who provides information in good faith shall not be subject to an action for civil damage as a result thereof (as outlined in ORS 685.655(5)).

Stat. Auth.: ORS 688.625 - 688.665
Stats. Implemented: ORS 688.655(3)
Hist.: OHD 2-2001, f. & cert. ef. 1-18-01

333-275-0150
Grounds for Denying, Suspending or Revoking Certificate

Causes for denial, suspension or revocation of certificate: In the manner prescribed in ORS 183.310 to 183.486 for a contested case, the Division may deny, suspend, or revoke any certificate to perform the duties of a certified hemodialysis technician for the following causes:

(1) Failure to work as a hemodialysis technician 1000 hours over the 24 months preceding recertification or as prorated in OAR 333-275-0070;

(2) Failure to complete the continuing education requirement of 20 contact hours over the 24 months preceding recertification or as prorated in OAR 333-275-0070;

(3) Failure to complete the consent for criminal record check;

(4) Failure to pass the hemodialysis certification examination;

(5) The use of fraud or deception in receiving a certificate;

(6) Use of any controlled substance or intoxicating liquor to an extent or in a manner injurious to the certificate holder or others or to an extent that such impairs the ability to conduct safely the duties of a CHDT;

(7) The presence of a mental disorder that demonstrably affects a technician's performance, as certified by two psychiatrists retained by the Public Health Division, Oregon Health Authority;

(8) Conviction of a CHDT for a criminal offense deemed by the Division to be related to the fitness of the CHDT to practice hemodialysis as in OAR 333-275-0040;

(9) Suspension or revocation of a hemodialysis technician certificate issued by another state;

(10) Gross negligence or repeated negligence in rendering hemodialysis care;

(11) The CHDT has been found to have committed dishonorable conduct for a CHDT as outlined in OAR 333-275-0130.

Stat. Auth.: ORS 688.625 - 688.665
Stats. Implemented: ORS 688.655
Hist.: OHD 2-2001, f. & cert. ef. 1-18-01

333-275-0160
Disciplinary Action and Civil Penalty

(1) When a CHDT has admitted the facts of a complaint alleging the CHDT is in violation of one or more of the grounds for denying, suspending or revoking a certificate as listed in OAR 333-275-0150 or been found to have committed in accordance with ORS 183.310 to 183.550 of one or more of the grounds for denying, suspending or revoking a certificate as listed in OAR 333-275-0150; the Public Health Division may take one or more of the following actions:

(a) Place the CHDT on probation;

(b) Suspend the CHDT's certificate;

(c) Revoke the CHDT's certificate;

(d) Place limitations on the ability of the CHDT to practice hemodialysis in Oregon;

(e) Assess the cost of disciplinary proceedings, not to exceed $1,000, as a civil penalty;

(f) Assess a civil penalty not to exceed $1,000.

(2) The Public Public Health Division may temporarily suspend the CHDT's certificate without a hearing while simultaneously commencing proceedings under ORS 183.310 to 183.550 after receiving evidence that indicates that the continued practice of the CHDT constitutes an immediate danger to the public.

(3) A civil penalty not to exceed $1,000 may be imposed as provided in ORS 183.090, in addition to disciplinary action against the CHDT's certificate. Disciplinary action against the CHDT certificate does not preclude imposing a civil penalty. Criminal conviction does not preclude imposition of a civil penalty for the same conduct.

(4) The civil penalty shall be payable to the Division by cash, cashier's check or money order.

(5) Civil penalties may be imposed pursuant to ORS 183.090 according to the following schedule:

(a) Conviction of a criminal offense as defined in 333-275-0040 that relates to the fitness of the CHDT to practice hemodialysis — $100–$1000.

(b) Gross negligence or repeated negligence in rendering hemodialysis — $500–$1000.

(c) Use of any controlled substance or intoxicating liquor to an extent or in a manner injurious to the certificate holder or others

or to an extent that such impairs the ability to conduct safely the duties of a CHDT — $250–$1000.

(d) The CHDT has been found to have committed dishonorable conduct — $100–$1000.

Stat. Auth.: ORS 688.625 - 688.665
Stats. Implemented: ORS 688.660
Hist.: OHD 2-2001, f. & cert. ef. 1-18-01

333-275-0170
Hearings

An applicant or CHDT shall have an opportunity for a hearing on any decision to deny an application, to suspend or revoke a certificate, or to impose a civil penalty. Hearings are governed by ORS 183.310 to ORS 183.500. Requests for hearings must be in writing and sent to: Section Manager, Health Care Regulation and Quality Improvement, Suite #640, Oregon Public Health Division, PO Box 14450, Portland, OR 97293-0450.

Stat. Auth.: ORS 688.625 - 688.665
Stats. Implemented: ORS 183.310
Hist.: OHD 2-2001, f. & cert. ef. 1-18-01

333-275-0180
Fees

Payment of fees will be accepted in the form of money order, cashier's check, or cash (in exact amount only). Payment should be made out to the Oregon Health Division and sent to Section Manager, Health Care Regulation and Quality Improvement, Suite #640, Oregon Health Division, PO Box 14450, Portland, OR 97293-0450. Fees are non-refundable. Certified Hemodialysis Technician Schedule of Fees. Effective January 1, 2000: [Table not included. See ED. NOTE.]

[ED. NOTE: Tables referenced are available from the agency.]
Stat. Auth.: ORS 688.625 - 688.665
Stats. Implemented: ORS 685.645
Hist.: OHD 2-2001, f. & cert. ef. 1-18-01

HOSPITALS, GENERALLY

DIVISION 500

DEFINITIONS, APPLICATION AND RENEWAL PROCEDURES, FEES, FACILITY CLOSURE

333-500-0005
Applicability

Unless a specific rule provides otherwise, OAR chapter 333, divisions 500 through 535 apply to a hospital classified as general, low occupancy acute care, or psychiatric or mental and do not apply to a hospital classified as a special inpatient care facility.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: PH 11-2009, f. & cert. ef. 10-1-09; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10; PH 17-2012, f. 12-20-12, cert. ef. 1-1-13

333-500-0010
Definitions

As used in OAR chapter 333, divisions 500 through 535, unless the context requires otherwise, the following definitions apply:

(1) "Assessment" means a complete nursing assessment, including:

(a) The systematic and ongoing collection of information to determine an individual's health status and need for intervention;

(b) A comparison with past information; and

(c) Judgment, evaluation, or a conclusion that occurs as a result of subsections (a) and (b) of this definition.

(2) "Authentication" means verification that an entry in the patient medical record is genuine.

(3) "Authority" means the Oregon Health Authority.

(4) "Certified Nursing Assistant" (CNA) means a person who is certified by the Oregon State Board of Nursing (OSBN) to assist licensed nursing personnel in the provision of nursing care.

(5) "Chiropractor" means a person licensed under ORS Chapter 684 to practice chiropractic.

(6) "Conditions of Participation" mean the applicable federal regulations that hospitals are required to comply with in order to participate in the federal Medicare and Medicaid programs.

(7) "Deemed" means a health care facility that has been inspected by an approved accrediting organization and has been approved by the Centers for Medicare and Medicaid Services (CMS) as meeting CMS Conditions of Participation.

(8) "Discharge" means the release of a person who was an inpatient of a hospital and includes:

(a) The release and transfer of a newborn to another facility, but not a transfer between acute care departments of the same facility;

(b) The release of a person from an acute care section of a hospital for admission to a long-term care section of a facility;

(c) Release from a long-term care section of a facility for admission to an acute care section of a facility;

(d) A patient who has died; and

(e) An inpatient who leaves a hospital for purposes of utilizing non-hospital owned or operated diagnostic or treatment equipment, if the person does not return as an inpatient of the same health care facility within a 24-hour period.

(9) "Direct ownership" has the meaning given the term 'ownership interest' in 42 CFR 420.201.

(10) "Division" means the Public Health Division within the Authority.

(11) "Emergency Medical Services" means medical services that are usually and customarily available at the respective hospital in an emergency department and that must be provided immediately to sustain a person's life, to prevent serious permanent disfigurement or loss or impairment of the function of a bodily member or organ, or to provide care to a woman in labor where delivery is imminent if the hospital is so equipped and, if the hospital is not equipped, to provide necessary treatment to allow the woman to travel to a more appropriate facility without undue risk of serious harm.

(12) "Emergency Psychiatric Services" means mental health services that are usually and customarily available in an emergency department at the respective hospital and that must be provided immediately to prevent harm to the patient or others including but not limited to triage and assessment; observation and supervision; crisis stabilization; crisis intervention; and crisis counseling.

(13) "Financial interest" means a five percent or greater direct or indirect ownership interest.

(14) "Full compliance survey" means a survey conducted by the Division following a complaint investigation to determine a hospital's compliance with the CMS Conditions of Participation.

(15) "Governing body" means the body or person legally responsible for the direction and control of the operation of the hospital.

(16) "Governmental unit" has the meaning given that term in ORS 442.015.

(17) "Health care facility" (HCF) has the meaning given the term in ORS 442.015.

(18) "Health Care Facility Licensing Laws" means ORS 441.005 through 441.990 and its implementing rules.

(19) "Hospital" has the meaning given that term in ORS 442.015.

(20) "Indirect ownership" has the meaning given the term 'indirect ownership interest' in 42 CFR 420.201.

(21) "Licensed" means that the person to whom the term is applied is currently licensed, certified or registered by the proper authority to follow his or her profession or vocation within the State of Oregon, and when applied to a hospital means that the facility is currently licensed by the Authority.

(22) "Licensed nurse" means a nurse licensed under ORS Chapter 678 to practice registered or practical nursing.

(23) "Licensed Practical Nurse" means a nurse licensed under ORS Chapter 678 to practice practical nursing.

(24) "Major alteration" means any structural change to the foundation, roof, floor, or exterior or load bearing walls of a building, or the extension of an existing building to increase its floor area. Major alteration also means the extensive alteration of

an existing building such as to change its function and purpose, even if the alteration does not include any structural change to the building.

(25) "Manager" means a person who:

(a) Has authority to direct and control the work performance of nursing staff;

(b) Has authority to take corrective action regarding a violation of law or a rule or a violation of professional standards of practice, about which a nursing staff has complained; or

(c) Has been designated by a hospital to receive the notice described in ORS 441.174(2).

(26) "Minor alteration" means cosmetic upgrades to the interior or exterior of an existing building, such as but not limited to wall finishes, floor coverings and casework.

(27) "Mobile Satellite" means a MRI, CAT Scan, Lithotripsy Unit, Cath Lab, or other such modular outpatient treatment or diagnostic unit that is capable of being moved, is housed in a vehicle with a vehicle identification number (VIN), and does not remain on a hospital campus for more than 180 days in any calendar year.

(28) "NFPA" means National Fire Protection Association.

(29) "Nurse Midwife/Nurse Practitioner" means a registered nurse certified by the OSBN as a nurse midwife/nurse practitioner.

(30) "Nurse Practitioner" has the meaning given that term in ORS 678.010.

(31) "Nursing staff" means a registered nurse, a licensed practical nurse, or other assistive nursing personnel.

(32) "OB Unit" means a dedicated obstetrical unit that meets the requirements of OAR 333-535-0120.

(33) "On-call" means a scheduled state of availability to return to duty, work-ready, within a specified period of time.

(34) "Oregon Sanitary Code" means the Food Sanitation Rules in OAR 333-150-0000.

(35) "Patient audit" means review of the medical record or physical inspection or interview of a patient.

(36) "Person" has the meaning given that term in ORS 442.015.

(37) "Physician" means a person licensed as a doctor of medicine or osteopathy under ORS Chapter 677.

(38) "Physician Assistant" has the meaning given that term in ORS 677.495.

(39) "Plan of correction" means a document executed by a hospital in response to a statement of deficiency issued by the Division that describes with specificity how and when deficiencies of health care licensing laws or conditions of participation shall be corrected.

(40) "Podiatrist" has the same meaning as "podiatric physician and surgeon" in ORS 677.010.

(41) "Podiatry" means the diagnosis or the medical, physical or surgical treatment of ailments of the human foot, except treatment involving the use of a general or spinal anesthetic unless the treatment is performed in a licensed hospital or in a licensed ambulatory surgical center and is under the supervision of or in collaboration with a physician. "Podiatry" does not include the administration of general or spinal anesthetics or the amputation of the foot.

(42) "Public body" has the meaning given that term in ORS 30.260.

(43) "Registered Nurse" means a person licensed under ORS Chapter 678 to practice registered nursing.

(44) "Respite care" means care provided in a temporary, supervised living arrangement for individuals who need a protected environment, but who do not require acute nursing care or acute medical supervision.

(45) "Retaliatory action" means the discharge, suspension, demotion, harassment, denial of employment or promotion, or layoff of a nursing staff person directly employed by the hospital, or other adverse action taken against a nursing staff person directly employed by the hospital in the terms or conditions of employment of the nursing staff person, as a result of filing a complaint.

(46) "Satellite" means a building or part of a building owned or leased by a hospital, and operated by a hospital in a geographically separate location from the hospital, with a separate physical address from the hospital but that is within 35 miles from the hospital, through which the hospital provides:

(a) Outpatient diagnostic, therapeutic, or rehabilitative services;

(b) Psychiatric services in accordance with OAR 333-525-0000 including:

(A) Inpatient psychiatric services; and

(B) Emergency psychiatric services through an emergency department in accordance with OAR 333-520-0070; or

(c) Emergency medical services in accordance with OAR 333-500-0027.

(47) "Special Inpatient Care Facility" means a facility with inpatient beds and any other facility designed and utilized for special health care purposes that may include but is not limited to a rehabilitation center, a facility for the treatment of alcoholism or drug abuse, a freestanding hospice facility, or an inpatient facility meeting the requirements of ORS 441.065, and any other establishment falling within a classification established by the Division, after determination of the need for such classification and the level and kind of health care appropriate for such classification.

(48) "Stable newborn" means a newborn who is four or more hours post-delivery and who is free from abnormal vital signs, color, activity, muscle tone, neurological status, weight, and maternal-child interaction.

(49) "Stable postpartum patient" means a postpartum mother who is four hours or more postpartum and who is free from any abnormal fluctuations in vital signs, has vaginal flow within normal limits, and who can ambulate, be independent in self-care, and provide care to her newborn infant, if one is present.

(50) "Statement of deficiencies" means a document issued by the Division that describes a hospital's deficiencies in complying with health care facility licensing laws or conditions of participation.

(51) "Survey" means an inspection of a hospital to determine the extent to which a hospital is in compliance with health facility licensing laws and conditions of participation

Stat. Auth.: ORS 441.025

Stats. Implemented: ORS 441.025

Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 11, f. 3-16-72, ef. 4-1-72; HD 11-1980, f. & ef. 9-10-80, HD 8-1985, f. & ef. 5-17-85; Renumbered from 333-023-0114; HD 13-1987, f. 9-1-87, ef. 9-15-87; HD 23-1987(Temp), f. 11-27-87, ef. 10-15-87 through 4-15-88; HD 10-1988, f. & cert. ef. 5-27-88; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-070-0000; HD 21-1993, f. & cert. ef. 10-28-93; HD 30-1994, f. & cert. ef. 12-13-94; OHD 2-2000, f. & cert. ef. 2-15-00; OHD 20-2002, f. & cert. ef. 12-10-02; PH 11-2009, f. & cert. ef. 10-1-09; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10; PH 17-2012, f. 12-20-12, cert. ef. 1-1-13; PH 5-2015, f. & cert. ef. 2-6-15; PH 6-2015(Temp), f. & cert. ef. 2-20-15 thru 8-18-15; PH 7-2015(Temp), f. & cert. ef. 3-24-15 thru 9-19-15; PH 11-2015, f. & cert. ef. 8-13-15

333-500-0020
Application for Hospital License

(1) An applicant wishing to apply for a license to operate a hospital shall submit an application on a form prescribed by the Division and pay the applicable fee as specified in OAR 333-500-0030.

(2) A single hospital license may cover more than one building if the applicant meets the requirements in OAR 333-500-0025.

(3) If the applicant is proposing a new hospital the applicant shall also submit evidence of plans review approval as required by OAR chapter 333, division 675.

(4) An applicant that has a certificate of accreditation and deemed status for Medicare certification from the Joint Commission or an accrediting organization approved by the Division shall provide the certificate to the Division with its license application, and shall include:

(a) All Joint Commission or approved accrediting organization survey and inspection reports; and

(b) Written evidence of all corrective actions underway, or completed, in response to Joint Commission or approved accrediting organization recommendations, including all progress reports.

(5) No license shall be issued for any hospital for which a certificate of need is required, unless a certificate of need has first been issued under ORS 442.315.

Stat. Auth.: ORS 441.025

Stats. Implemented: ORS 441.020

Hist.: HB 183, f. & ef. 5-26-66; HB 222, f. 8-26-69, ef. 8-26-69; HD 11, f. 3-16-72, ef. 4-1-72; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0116; HD 21-1985, f. & ef. 10-4-85; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-070-0005; HD 21-1993, f. & cert. ef. 10-28-93; OHD 2-2000, f. & cert. ef. 2-15-00; PH 11-2009, f. & cert. ef. 10-1-09; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-500-0025
Indorsement of Satellite Operations

(1) The Division may indorse, under a hospital's license, a satellite or mobile satellite of a hospital.

(2) In order for a satellite to be indorsed under a hospital's license, the applicant or licensee shall pay the appropriate fee and provide evidence to the Division that:

(a) The satellite meets the requirements in OAR chapter 333, divisions 500 through 535;

(b) The services at the satellite are integrated with the hospital;

(c) The financial operations of the satellite are integrated with the hospital;

(d) The hospital and the satellite have the same governing body;

(e) The satellite is under the ownership and control of the hospital;

(f) Staff at the satellite have privileges at the hospital;

(g) Medical records of the satellite are integrated with the hospital into a unified system;

(h) The facility is not subject to certificate of need requirements in ORS 442.315 to 442.361; and

(i) If the satellite is intended to provide emergency medical services, the satellite can comply with OAR 333-500-0027.

(3) A hospital applying for an emergency medical services satellite indorsement must also submit for its emergency department, the information described in OAR 333-500-0027(1)(e), for the previous six months.

(4) A satellite shall be subject to a plans review and must pass life safety code requirements.

(5) In order for a mobile satellite to be indorsed under a hospital's license, the applicant or licensee shall pay the appropriate fee and provide evidence to the Division that:

(a) The mobile satellite is operated in whole or in part by the hospital through lease, ownership or other arrangement;

(b) The services at the mobile satellite are integrated with the hospital;

(c) The financial operations of the mobile satellite are integrated with the hospital;

(d) The mobile satellite is physically separate from the hospital and other buildings on the hospital campus by at least 20 feet; and

(e) It meets the 2000 NFPA 101 Life Safety Code for mobile units.

(6) A mobile satellite shall keep and provide to the Division and the Fire Marshal upon request, a log that shows where the mobile satellite is located every day of the year, and its use. A copy of the log shall be kept in the mobile satellite at all times.

(7) A hospital that has a satellite that provides inpatient services that is indorsed under its license as of October 1, 2009, may continue to have that satellite indorsed under its license. On or after October 1, 2009, a satellite must meet the definition of satellite in OAR 333-500-0010(46) and comply with all other rules related to satellites in order to have a satellite indorsed under a hospital license.

(8) Nothing in these rules is meant to:

(a) Prevent a satellite as defined in OAR 333-500-0010(46) from providing outpatient medical services; or

(b) Permit the indorsement of satellite under a hospital license as a means to circumvent the certificate of need laws in ORS Chapter 442 and OAR chapter 333, divisions 545 through 670.

(9) The Division may revoke the indorsement of a satellite at any time if it determines a hospital or its satellite:

(a) Is not complying with this rule or OAR 333-500-0027, as applicable; or

(b) Is unable to ensure the safety of patients at the satellite.

Stat. Auth.: ORS 441.025

Stats. Implemented: ORS 441.020

Hist.: PH 11-2009, f. & cert. ef. 10-1-09; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10; PH 5-2015, f. & cert. ef. 2-6-15; PH 6-2015(Temp), f. & cert. ef. 2-20-15 thru 8-18-15; PH 7-2015(Temp), f. & cert. ef. 3-24-15 thru 9-19-15; PH 11-2015, f. & cert. ef. 8-13-15

333-500-0027
Emergency Medical Services Satellites

(1) A facility indorsed as a satellite under a hospital license for the provision of emergency medical services must, in addition to any requirements in OAR 333-500-0025:

(a) Operate 24 hours a day, seven days a week, 365 days a year;

(b) Comply with the hospital emergency department rule in OAR 333-520-0070;

(c) Develop written emergency department policies and procedures for all emergency medical services satellite operations including but not limited to:

(A) The type and scope of emergency medical services provided at the satellite;

(B) Integration of satellite operations with parent hospital surgical, laboratory, radiology, pharmacy, nutrition, and other departments to ensure timely provision of services;

(C) For a patient who cannot be provided the type and level of care needed to complete treatment of the patient's injury or condition within 24 hours of arrival at the satellite:

(i) Transport of the patient to the parent hospital for continuing care using appropriate transportation and personnel; or

(ii) Transfer to another receiving hospital with capability and capacity.

(d) Coordinate with:

(A) Any 9-1-1 jurisdiction within the 9-1-1 service area as those terms are defined in ORS 403.105 to ensure, to the greatest extent possible, that only patients who can receive an appropriate level of care at the satellite are transported to the satellite to limit the need for multiple emergency transports; and

(B) Ambulance services within the ambulance service area as those terms are defined in OAR 333-250-0010 to ensure, to the greatest extent possible, that only patients who can receive an appropriate level of care at the satellite are transported to the satellite to limit the need for multiple emergency transports; and

(e) On a quarterly basis, report to the Division, for each patient evaluated or treated at the satellite, a basic emergency medical services data set including but not limited to:

(A) Unique patient ID;

(B) Gender;

(C) Ethnicity;

(D) Race;

(E) Year of birth;

(F) Date and time of patient presentation to satellite;

(G) Chief complaint;

(H) Diagnosis;

(I) Discharge disposition;

(J) Date and time of patient discharge;

(K) Transport mode to and from the facility, including ambulance service provider, if applicable; and

(L) Facility transferred to, if applicable.

(2) A facility indorsed as a satellite under a hospital license for the provision of emergency medical services may not:

(a) Be located:

(A) In a county with three or more hospitals with an emergency department; or

(B) In a city with a hospital with an emergency department.

(b) Receive a trauma center categorization by the Division;

(c) Keep a patient for more than 24 hours; or

(d) Provide inpatient care.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.020
Hist.: PH 7-2015(Temp), f. & cert. ef. 3-24-15 thru 9-19-15; PH 11-2015, f. & cert. ef. 8-13-15

333-500-0030
Annual License Fee

(1) The annual license fee for a hospital is as specified in ORS 441.020.

(2) If a hospital license covers a satellite or mobile satellite approved by the Division under OAR 333-500-0025, the applicable license fee shall be the sum of the license fees which would be applicable if each location or unit was separately licensed.

(3) The Authority may charge a reduced hospital fee or hospital satellite fee if the Division determines that charging the standard fee constitutes a significant financial burden.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.020
Hist.: HD 11, f. 3-16-72, ef. 4-1-72; HD 143(Temp), f. & ef. 8-4-77; HD 147, f. & ef. 12-2-77; HD 15-1978(Temp), f. 11-17-78, ef. 1-1-79; HD 3-1979 f. & ef. 2-26-79; HD 11-1980, f. & ef. 9-1-80; HD 22-1982(Temp), f. & ef. 11-9-82; HD 4-1984, f. & ef. 2-16-84; Renumbered from 333-023-0117; HD 23-1987 (Temp), f. 11-27-87, ef. 10-15-87 thru 4-15-88; HD 10-1988, f. & cert. ef. 5-27-88; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; Renumbered from 333-070-0010; HD 21-1993, f. & cert. ef. 10-28-93; OHD 2-2000, f. & cert. ef. 2-15-00; OHD 12-2001, f. & cert. ef. 6-12-01; PH 11-2009, f. & cert. ef. 10-1-09; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-500-0031
Fees for Complaint Investigations and Compliance Surveys

(1) In addition to an annual fee, the Division may charge a hospital a fee for:

(a) A complaint investigation, in an amount not to exceed $850;

(b) A full compliance survey, in an amount not to exceed $7,520;

(c) An on-site follow-up survey to verify compliance with a plan of correction, in an amount not to exceed $225; and

(d) An off-site follow-up survey to verify compliance with a plan of correction, in an amount not to exceed $85.

(2) During one calendar year, the Division may charge to all hospitals a total amount not to exceed:

(a) $91,000 for complaint investigations;

(b) $15,000 for full compliance surveys; and

(c) $6,700 for follow-up surveys.

(3)(a) The Division shall apportion the total amount charged under section (2) of this rule among hospitals at the end of each calendar year based on the number of complaint investigations, full compliance surveys and follow-up surveys performed at each hospital during the calendar year.

(b) The Division may not include investigations of employee complaints in a hospital's total number of complaint investigations.

(c) A hospital may not be charged fees in any calendar year under section (2) of this rule for more complaint investigations than the greater of:

(A) The rolling average for the hospital for the previous three years; or

(B) Two complaint investigations for a small hospital and five complaint investigations for a large hospital.

(d) Notwithstanding subsection (3)(c) of this rule, the Division may not charge a hospital for a number of complaint investigations that exceeds the number of complaint investigations actually conducted at the hospital during the calendar year.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.021
Hist.: PH 26-2010, f. 12-14-10, cert. ef. 12-15-10; PH 17-2012, f. 12-20-12, cert. ef. 1-1-13

333-500-0032
Classification

(1) A hospital shall be classified as one of the following:

(a) General Hospital;

(b) Low Occupancy Acute Care Hospital; or

(c) Mental or Psychiatric Hospital.

(2) A hospital's classification shall be determined by the type of services it provides, as described in OAR chapter 333, divisions 520 and 525, and the staffing requirements related to the provision of those services.

(a) A hospital classified as a general hospital shall:

(A) Provide at least general medical, maternity and surgical services;

(B) Have an emergency department;

(C) Have available on-site or through contract, dietary, laboratory, and radiology services;

(D) Have an on-site pharmacy;

(E) Have a pharmacist on call 24 hours a day, 7 days a week (24/7) to staff the pharmacy; and

(F) Have on-site or in-house 24/7 staffing for its laboratory and radiology services.

(b) A low occupancy acute care hospital shall:

(A) Have 25 or fewer inpatient beds;

(B) Provide at least general medical services;

(C) Have an emergency department;

(D) Have available on-site or through contract, dietary, laboratory, and radiology services;

(E) Have an on-site pharmacy or a drug room; and

(F) Have appropriately trained laboratory, radiology, and pharmacy staff on-site or on-call 24/7.

(c) A mental or psychiatric hospital shall:

(A) Be devoted primarily to the care of people suffering from mental illness;

(B) Have available on-site or through contract, dietary, laboratory, and radiology services;

(C) Have an on-site pharmacy or a drug room;

(D) Have appropriately trained laboratory, radiology, and pharmacy staff on-site or on-call 24/7; and

(E) Comply with the requirements in OAR 333-525-0000.

(3) The classification of each hospital shall be included on the license.

(4) A hospital licensed by the Division may not assume a descriptive title or hold itself out under a descriptive title other than the classification title established by the Division and under which the hospital is licensed. This rule applies to the name on the hospital and any stationery, advertising, media, or other representations made by the hospital. A general hospital and a low occupancy acute care hospital may be described as a "hospital" without any modifications. A mental or psychiatric hospital shall use a descriptive title that describes or is reflective of the specialty services it offers.

(5) A hospital may not change its license classification unless it reapplies for licensure on a form prescribed by the Division and submits a fee as required by ORS 441.020. The Division shall conduct an on-site survey prior to granting a hospital a new classification to determine compliance with this rule.

(6) No person shall hold itself out to the public as an emergency department (ED), emergency room (ER), emergency-, emergent- or emergi-care center or use any derivative term in a posted name or advertising that would give the impression that emergency medical services as that is defined in OAR 333-500-0010 is provided by the person at a particular facility unless that facility is a hospital licensed under ORS 441.025 with an emergency department. Use of the words "urgent" or "immediate" shall not be considered derivative terms.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: PH 11-2009, f. & cert. ef. 10-1-09; PH 17-2012, f. 12-20-12, cert. ef. 1-1-13; PH 31-2016, f. 11-14-16, cert. ef. 11-15-16

333-500-0034
Application Review

(1) In reviewing an application for a new hospital the Division shall:

(a) Verify compliance with the applicable sections of ORS Chapters 441 and 476, and OAR 333-500 through 535, 675, and chapter 837;

(b) Determine whether a certificate of need is required and was obtained;

(c) Conduct an on-site licensing survey in coordination with the State Fire Marshal's Office; and

(d) Verify compliance with conditions of participation if the applicant has requested Medicare or Medicaid certification.

(2) In determining whether to license a hospital the Division shall consider factors relating to the health and safety of individuals to be cared for at the hospital and the ability of the operator of the hospital to safely operate the facility, and may not consider whether the hospital is or shall be a governmental, charitable or other nonprofit institution or whether it is or shall be an institution for profit.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.022, 441.025
Hist.: PH 11-2009, f. & cert. ef. 10-1-09; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-500-0036
Approval of License Application

(1) The Division shall notify an applicant in writing if a license application is approved, and shall include the license with the appropriate classification.

(2) A license shall be issued only for the premises and persons or governmental units named in the application and it is not transferable or assignable.

(3) The license shall be conspicuously posted in an area where patients are admitted.

(4) No hospital licensed pursuant to the provisions of ORS Chapter 441 shall in any manner or by any means assert, represent, offer, provide or imply that such person or hospital is or may render care or services other than that which is permitted by or which is within the scope of the license issued to the hospital by the Division nor shall any service be offered or provided which is not authorized within the scope of the license issued to the hospital.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: PH 11-2009, f. & cert. ef. 10-1-09

333-500-0038
Denial of License Application

If the Division intends to deny a license application, it shall issue a Notice of Proposed Denial of License Application in accordance with ORS 183.411 through 183.470.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.037
Hist.: PH 11-2009, f. & cert. ef. 10-1-09; PH 17-2012, f. 12-20-12, cert. ef. 1-1-13

333-500-0040
Expiration and Renewal of License

(1) Each license to operate a hospital shall expire on December 31 following the date of issue, and if a renewal is desired, the licensee shall make application and pay the appropriate fee at least 30 days prior to the expiration date upon a form prescribed by the Division.

(2) For emergency preparedness planning and licensing purposes, a licensee shall provide, in its application for license renewal:

(a) The number of beds currently in use or capable of being used;

(b) The total number of beds that could be used with only minor alterations, taking into consideration existing equipment, the ancillary service capability of the facility, and the physical environment required by OAR 333-500 through 535, as applicable; and

(c) The number of beds to be licensed.

(3) A single hospital license may cover more than one location if the licensee meets the requirements in OAR 333-500-0025.

(4) An applicant that has a certificate of accreditation and deemed status for Medicare certification from the Joint Commission or an accrediting organization approved by the Division shall provide the certificate to the Division with its renewal application, and shall include:

(a) All Joint Commission or approved accrediting organization survey and inspection reports; and

(b) Written evidence of all corrective actions underway, or completed, in response to Joint Commission or approved accrediting organization recommendations, including all progress reports.

(5) If an applicant wishes to renew its license and increase the number of beds licensed from the previous licensing year, the applicant shall include:

(a) Evidence of plans review approval as required by OAR 333-535 and 675 as applicable; and

(b) Evidence that a certificate of need was obtained, or is not required.

(6) The Division may not renew a license for any hospital if a certificate of need is required and has not been obtained pursuant to ORS 442.315.

(7) If the Division intends to deny a license renewal application, it shall issue of Notice of Proposed Denial of License Renewal Application in accordance with ORS 183.411 through 183.470.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: HB 183, f. & ef. 5-26-66; HD 11, f. 3-16-72, ef. 4-1-72; HD 150(Temp), f. & ef. 12-15-77; HD 4-1978, f. & ef. 3-31-78; HD 11-1980, f. & ef. 9-2-80; Renumbered from 333-023-0118; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-070-0015; PH 11-2009, f. & cert. ef. 10-1-09; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-500-0045
Submission of Plans

(1) A hospital proposing to make alterations or additions to an existing facility or to construct a new facility shall, before commencing such alteration, addition or new construction, submit plans and specifications to the Division for preliminary inspection and approval or recommendations with respect to compliance with Division rules and compliance with National Fire Protection Association standards when the facility is also to be Medicare or Medicaid certified.

(2) Submissions shall comply with OAR chapter 333, division 675. Plans should also be submitted to the local building division having authority for review and approval in accordance with state building codes.

Stat. Auth.: ORS 441.025, ORS 441.060
Stats. Implemented: ORS 441.025, ORS 441.060
Hist.: PH 11-2009, f. & cert. ef. 10-1-09; PH 7-2016, f. & cert. ef. 2-24-16

333-500-0055
Discontinuance and Recommencement of Operation of Hospitals

(1) If a hospital wishes to temporarily discontinue operation but retain its license to operate, the hospital shall notify the Division of the fact at least 14 days prior to the temporary discontinuance.

(2) A hospital shall issue a multimedia press release within 24 hours of the temporary discontinuance, notifying the public of hospital closure. Such notice shall include a procedure by which individuals may obtain their medical records.

(3) Before any patient is admitted to a hospital that has temporarily discontinued operation, the hospital shall request that the Division conduct an on-site survey to determine whether the hospital is in compliance with health facility licensing laws and conditions of participation, if applicable.

(4) A hospital may not renew operation until it receives approval, in writing, from the Division.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: HD 20-1988(Temp), f. & cert. ef. 7-29-88; HD 1-1989, f. & cert. ef. 1-10-89; HD 21-1993, f. & cert. ef. 10-28-93; PH 11-2009, f. & cert. ef. 10-1-09

333-500-0060
Return of Hospital License and Hospital Closure

(1) If a hospital's license is suspended, revoked, expires, or if a hospital decides to permanently close, the license certificate in the licensee's possession shall be returned to the Division immediately.

(2) If the hospital is voluntarily permanently closed, the hospital shall issue a multimedia press release within 24 hours, notifying the public of facility closure. Such notice shall include a procedure by which individuals may obtain their medical records.

(3) A hospital shall notify the Division of a hospital's closure under section (2) of this rule at least 14 days prior to the closure and submit a plan for the storage and disposal of medical records. Medical records not claimed that are more than seven years old from the last date of discharge may be destroyed. Medical records not claimed that are less than seven years old from the last date of discharge shall be stored until they are more than seven years old from the last date of discharge. Medical records may be thinned to include only the admission/discharge sheet (face sheet), discharge summary, history and physical, operative report(s), pathology report(s), and X-ray report(s).

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: HB 183, f. & ef. 5-26-66; HD 11, f. 3-16-72, ef. 4-1-72; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0122; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-070-0025; HD 21-1993, f. & cert. ef. 10-28-93; PH 11-2009, f. & cert. ef. 10-1-09

333-500-0065
Waivers

(1) While all hospitals are required to maintain continuous compliance with the Division's rules, these requirements do not prohibit the use of alternative concepts, methods, procedures, techniques, equipment, facilities, personnel qualifications or the conducting of pilot projects or research. A request for a waiver from a rule must be:

(a) Submitted to the Division in writing;

(b) Identify the specific rule for which a waiver is requested;

(c) The special circumstances relied upon to justify the waiver;

(d) What alternatives were considered, if any and why alternatives (including compliance) were not selected;

(e) Demonstrate that the proposed waiver is desirable to maintain or improve the health and safety of the patients, to meet the individual and aggregate needs of patients, and shall not jeopardize patient health and safety; and

(f) The proposed duration of the waiver.

(2) Upon finding that the hospital has satisfied the conditions of this rule, the Division may grant a waiver.

(3) A hospital may not implement a waiver until it has received written approval from the Division.

(4) During an emergency the Division may waive a rule that a hospital is unable to meet, for reasons beyond the hospital's control. If the Division waives a rule under this section it shall issue an order, in writing, specifying which rules are waived, which hospitals are subject to the order, and how long the order shall remain in effect.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: PH 11-2009, f. & cert. ef. 10-1-09; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-500-0090
Adoption by Reference

All rules, standards and publications referred to in OAR 333-500 through 535 are incorporated by reference. Copies are available for inspection in the Division during office hours. Where publications are in conflict with the rules, the rules shall govern.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0119; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-070-0040; HD 21-1993, f. & cert. ef. 10-28-93; PH 11-2009, f. & cert. ef. 10-1-09

DIVISION 501

HOSPITAL MONITORING, SURVEYS, INVESTIGATIONS, DISCIPLINE, AND CIVIL PENALTIES

333-501-0005
Complaints

(1) Any person may make a complaint verbally or in writing to the Division regarding an allegation against a hospital of a violation of any health care facility licensing law or condition of participation.

(2) The identity of a person making a complaint will be kept confidential.

(3) An investigation will be carried out as soon as practicable after the receipt of a complaint in accordance with OAR 333-501-0010.

(4) If the complaint involves an allegation of criminal conduct or an allegation that is within the jurisdiction of another local, state, or federal agency, the Division will refer the matter to that agency.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.057
Hist.: PH 11-2009, f. & cert. ef. 10-1-09

333-501-0010
Investigations

(1) As soon as practicable after receiving a complaint, taking into consideration the nature of the complaint, Division staff will begin an investigation.

(2) A hospital shall permit Division staff access to the facility during an investigation.

(3) An investigation may include but is not limited to:

(a) Interviews of the complainant, patients of the hospital, patient family members, witnesses, hospital management and staff;

(b) On-site observations of patients, staff performance, and the physical environment of the hospital; and

(c) Review of documents and records.

(4) In determining whether a violation has occurred under OAR 333-501-0020(8), the Division will consider the facility name, advertising used, and related content.

(5) Except as otherwise specified in 42 CFR § 401, Subpart B, information obtained by the Division during an investigation of a complaint or reported violation under this section is confidential and not subject to public disclosure under ORS 192.410 to 192.505. Upon the conclusion of the investigation, the Division may publicly release a report of its findings but may not include information in the report that could be used to identify the complainant or any patient at the health care facility. The Division may use any information obtained during an investigation in an administrative or judicial proceeding concerning the licensing of a health care facility, and may report information obtained during an investigation to a health professional regulatory board as defined in ORS 676.160 as that information pertains to a licensee of the board.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.057
Hist.: PH 11-2009, f. & cert. ef. 10-1-09; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10; PH 31-2016, f. 11-14-16, cert. ef. 11-15-16

333-501-0015
Surveys

(1) The Division shall, in addition to any investigations conducted under OAR 333-501-0010, conduct at least one on-site licensing survey of each hospital every three years to determine compliance with health care facility licensing laws and at such other times as the Division deems necessary.

(2) In lieu of an onsite inspection required under section (1) of this rule, the Division may accept:

(a) CMS certification by a federal agency or an approved accrediting organization; or

(b) A survey conducted within the previous three years by an accrediting organization approved by the Division, if:

(A) The certification or accreditation is recognized by the Division as addressing the standards and condition of participation requirements of the CMS and other standards set by the Division. Health care facilities must provide the Division with the letter from CMS indicating its deemed status;

(B) The health care facility notifies the Division to participate in any exit interview conducted by the federal agency or accrediting body; and

(C) The health care facility provides copies of all documentation concerning the certification or accreditation requested by the Division.

(3) A hospital shall permit Division staff access to the facility during a survey.

(4) A survey may include but is not limited to:

(a) Interviews of patients, patient family members, hospital management and staff;

(b) On-site observations of patients, staff performance, and the physical environment of the hospital facility;

(c) Review of documents and records; and

(d) Patient audits.

(5) A hospital shall make all requested documents and records available to the surveyor for review and copying.

(6) Following a survey Division staff may conduct an exit conference with the hospital administrator or his or her designee. During the exit conference Division staff shall:

(a) Inform the hospital representative of the preliminary findings of the inspection; and

(b) Give the person a reasonable opportunity to submit additional facts or other information to the surveyor in response to those findings.

(7) Following the survey, Division staff shall prepare and provide the hospital administrator or his or her designee specific and timely written notice of the findings.

(8) If the findings result in a referral to another regulatory agency, Division staff shall submit the applicable information to that referral agency for its review and determination of appropriate action.

(9) If no deficiencies are found during a survey, the Division shall issue written findings to the hospital administrator indicating that fact.

(10) If deficiencies are found, the Division shall take informal or formal enforcement action in compliance with OAR 333-501-0025 or 333-501-0030.

Stat. Auth.: ORS 441.025 & 441.062
Stats. Implemented: ORS 441.060 & 441.062
Hist.: PH 11-2009, f. & cert. ef. 10-1-09; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-501-0020
Violations

In addition to non-compliance with any health care facility licensing law or condition of participation, it is a violation to:

(1) Refuse to cooperate with an investigation or survey, including but not limited to failure to permit Division staff access to the hospital, its documents or records;

(2) Fail to implement an approved plan of correction;

(3) Fail to comply with all applicable laws, lawful ordinances and rules relating to safety from fire;

(4) Refuse or fail to comply with an order issued by the Division;

(5) Refuse or fail to pay a civil penalty;

(6) Fail to comply with rules governing the storage of medical records following the closure of a hospital;

(7) Establish, conduct, maintain, manage or operate a health care facility or health maintenance organization, without a license; or

(8) Use the terms “emergency,” “emergency department (ED),” “emergency room (ER),” “emergency-,” “emergent-,” or “emergi- care center” or any derivative term in a posted name or advertising that would give the impression that emergency medical services as that is defined in OAR 333-500-0010 is provided by the person at a particular facility unless that facility is a hospital licensed under ORS 441.025 with an emergency department. Use of the words “urgent” or “immediate” shall not be considered derivative terms.

(9) A person not licensed as a hospital under ORS 441.025 with an emergency department using the terms prescribed in section (8) of this rule has 90 days from November 15, 2016 to come into compliance.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.015, 441.025, 441.030 & 441.055
Hist.: PH 11-2009, f. & cert. ef. 10-1-09; PH 31-2016, f. 11-14-16, cert. ef. 11-15-16

333-501-0025
Informal Enforcement

(1) If, during an investigation or survey Division staff document violations of health care facility licensing laws or conditions of participation, the Division may issue a statement of deficiencies that cites the law alleged to have been violated and the facts supporting the allegation.

(2) A signed plan of correction must be received by the Division within 10 business days from the date the statement of deficiencies was mailed to the hospital. A signed plan of correction

will not be used by the Division as an admission of the violations alleged in the statement of deficiencies.

(3) A hospital shall correct all deficiencies within 60 days from the date of the exit conference, unless an extension of time is requested from the Division. A request for such an extension shall be submitted in writing and must accompany the plan of correction.

(4) The Division shall determine if a written plan of correction is acceptable. If the plan of correction is not acceptable to the Division, the Division shall notify the hospital administrator in writing and request that the plan of correction be modified and resubmitted no later than 10 working days from the date the letter of non-acceptance was mailed to the administrator.

(5) If the hospital does not come into compliance by the date of correction reflected on the plan of correction or 60 days from date of the exit conference, whichever is sooner, the Division may propose to deny, suspend, or revoke the hospital license, or impose civil penalties.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.015 & 441.025
Hist.: PH 11-2009, f. & cert. ef. 10-1-09

333-501-0030
Formal Enforcement

(1) If, during an investigation or survey Division staff document substantial failure to comply with health care facility licensing laws, conditions of participation or if a hospital fails to pay a civil penalty imposed under ORS 441.170, the Division may issue a Notice of Proposed Suspension or Notice of Proposed Revocation in accordance with ORS 183.411 through 183.470.

(2) The Division may issue a Notice of Imposition of Civil Penalty for violations of health care facility licensing laws.

(3) At any time the Division may issue a Notice of Emergency License Suspension under ORS 183.430(2).

(4) If the Division revokes a hospital license, the order shall specify when, if ever, the hospital may reapply for a license.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.015, 441.025, 441.030 & 441.037
Hist.: PH 11-2009, f. & cert. ef. 10-1-09

333-501-0035
Nurse Staffing Audit Procedure

(1) The Authority shall conduct an on-site audit of each hospital once every three years to determine compliance with the requirements of ORS 441.152 to 441.177 and 441.192. The Authority shall notify the hospital and both co-chairs of the hospital nurse staffing committee three business days in advance of the audit.

(2) During an audit, the Authority shall review any hospital record and conduct any interview or site visit that is necessary to determine that the hospital is in compliance with the requirements of ORS 441.152 to 441.177 and 441.192.

(3) In conducting an audit, the Authority shall interview:

(a) Both co-chairs of the hospital nurse staffing committee; and

(b) Any additional hospital staff members deemed necessary to determine compliance with applicable nurse staffing laws. Interviews may address, but are not limited to, the following topics:

(A) Implementation and effectiveness of the hospital-wide staffing plan for nursing services;

(B) Input, if any, provided to the hospital nurse staffing committee; or

(C) Any other fact relating to hospital nursing services subject to the Authority's review.

(4) In conducting an audit, the Authority may also interview:

(a) Hospital staff that does not voluntarily come forward for an interview during an audit; and

(b) Hospital patients or family members. Interviews may address, but are not limited to, any concerns or complaints related to nurse staffing in the hospital.

(5) Following an audit, the Authority shall issue a written survey report that communicates the results of the audit no more than 30 business days after the survey closes. This survey report:

(a) Shall be issued to the hospital and both co-chairs of the hospital nurse staffing committee; and

(b) May include a notice of civil penalties that complies with ORS 441.175 and OAR 333-501-0045.

(6) If the survey report identifies any area of noncompliance, the hospital shall submit a written plan to correct each identified deficiency. This plan:

(a) Shall be called the plan of correction;

(b) Shall be submitted no more than 30 business days after receiving the Authority's survey report; and

(c) Shall be evaluated by the Authority for sufficiency.

(7) No more than 30 business days after receipt of the hospital's plan of correction, the Authority shall issue a written determination that communicates whether the plan of correction is sufficient. This determination:

(a) Shall be issued to the hospital and both co-chairs of the hospital nurse staffing committee; and

(b) Shall require the hospital to either:

(A) Revise and resubmit the rejected plan of correction no more than 30 business days after receiving the Authority's determination that the plan is insufficient; or

(B) Implement the approved plan of correction no more than 45 business days after receiving the Authority's determination that the plan is sufficient.

(8) Following the approval of the plan of correction, the Authority shall conduct a second audit of the hospital to verify that the hospital has implemented the approved plan of correction. This audit shall be conducted within 60 business days of the plan of correction approval date.

(9) The identity of an individual providing evidence during an audit will be kept confidential to the extent permitted by law.

Stat. Auth.: ORS 413.042, 441.157 & 441.175
Stats. Implemented: ORS 441.157
Hist.: PH 11-2009, f. & cert. ef. 10-1-09; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10; PH 22-2016, f. & cert. ef. 7-1-16

333-501-0040
Nurse Staffing Complaint Investigation Procedures

(1) The Authority shall conduct an unannounced on-site investigation of a hospital within 60 calendar days after receiving a valid complaint against the hospital for violating a provision of ORS 441.152 to 441.177. A complaint is valid when an allegation, if assumed to be true, would violate a requirement of ORS 441.152 to 441.177.

(2) During an investigation, the Authority shall review any hospital record and conduct any interview or site visit that is necessary to determine whether the hospital has violated a provision of ORS 441.152 to 441.177.

(3) In conducting an investigation, the Authority may:

(a) Review any documentation that may be relevant to the complaint, including patient records; and

(b) Interview any person who may have information relevant to the complaint, including patients and family members.

(4) In reviewing information collected during an investigation, the Authority shall consider:

(a) The amount and strength of objective evidence, if any, that substantiates or refutes the complaint; and

(b) The number and credibility of witnesses, if any, who attest to or refute an alleged violation.

(5) Following an investigation, the Authority shall issue a written investigation report that communicates the results of the investigation no more than 30 business days after the investigation closes. This investigation report:

(a) Shall be issued to the hospital and both co-chairs of the hospital nurse staffing committee; and

(b) May include a notice of civil penalties that complies with ORS 441.175 and OAR 333-501-0045.

(6) If the investigation report identifies any area of noncompliance, the hospital shall submit a written plan to correct each identified deficiency. This plan:

(a) Shall be called the plan of correction;

(b) Shall be submitted no more than 30 business days after receiving the Authority's investigation report; and

(c) Shall be evaluated by the Authority for sufficiency.

(7) No more than 30 business days after receipt of the hospital's plan of correction, the Authority shall issue a written determination that communicates whether the plan of correction is sufficient. This determination:

(a) Shall be issued to the hospital and both co-chairs of the hospital nurse staffing committee; and

(b) Shall require the hospital to either:

(A) Revise and resubmit the rejected plan of correction no more than 30 business days after receiving the Authority's determination that the plan is insufficient; or

(B) Implement the approved plan of correction no more than 45 business days after receiving the Authority's determination that the plan is sufficient.

(8) Following the approval of the plan of correction, the Authority shall conduct a second investigation of the hospital to verify that the hospital has implemented the approved plan of correction. This investigation shall be conducted within 60 business days of the plan of correction approval date.

(9) The identity of an individual providing evidence during an investigation will be kept confidential to the extent permitted by law.

Stat. Auth.: ORS 413.042, 441.025, 441.057, 441.171 & 441.175
Stats. Implemented: ORS 441.057 & 441.171
Hist.: PH 11-2009, f. & cert. ef. 10-1-09; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10; PH 22-2016, f. & cert. ef. 7-1-16

333-501-0045
Civil Penalties for Violations of Nurse Staffing Laws

(1) For the purposes of this rule, "safe patient care" has the meaning given to the term in OAR 333-510-0002.

(2) The Authority may impose civil penalties for a violation of any provision of ORS 441.152 to 441.177 and 441.185 if there is a reasonable belief that safe patient care has been or may be negatively impacted.

(3) Each violation of the written hospital-wide staffing plan shall be considered a separate violation.

(4) If imposed, the Authority will issue civil penalties in accordance with Table 1 of this rule.

(5) In determining whether to issue a civil penalty, the Authority will consider all relevant evidence including, but not limited to, witness testimony, written documents and observations.

(6) A civil penalty imposed under this rule shall comply with ORS 183.745.

(7) The Authority shall maintain for public inspection records of any civil penalties imposed on hospitals penalized under this rule.

[ED. NOTE: Tables referenced are available from the agency.]
Stat. Auth.: ORS 413.042, 441.175 & 441.185
Stats. Implemented: ORS 441.175 & 441.185
Hist.: PH 11-2009, f. & cert. ef. 10-1-09; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10; PH 22-2016, f. & cert. ef. 7-1-16

333-501-0050
Civil Penalties for Violation of Smoking Prohibition

(1) If the Division determines that an administrator or person in charge of a hospital permits a person to smoke tobacco in a hospital or within 10 feet of a doorway, open window or ventilation intake of a hospital, the Division may assess a civil penalty of not more than $500 per day against the administrator or the person in charge of a hospital.

(2) In determining whether an administrator or person in charge of a hospital has permitted a person to smoke tobacco in violation of ORS 441.815, the Division shall consider whether:

(a) A hospital administrator or person in charge of a hospital has taken steps to enforce the smoking prohibitions, including calling law enforcement to report a violation;

(b) The hospital administrator or person in charge of a hospital took affirmative action to address any complaints about smoking in a hospital or within 10 feet of a doorway, open window or ventilation intake of a hospital; and

(c) A hospital administrator or person in charge of a hospital has taken steps to educate the public and staff about the smoking ban.

(3) A civil penalty issued under this rule shall not exceed $2,000 in any 30-day period.

(4) A civil penalty imposed under this rule shall comply with ORS 183.745.

Stat. Auth.: ORS 441.815
Stats. Implemented: ORS 441.815
Hist.: PH 11-2009, f. & cert. ef. 10-1-09

333-501-0055
Civil Penalties, Generally

(1) This rule does not apply to civil penalties for violations of ORS 441.155, 441.166, 441.815, or 435.254 or rules adopted to implement these statutes.

(2) A person that violates a health care facility licensing law, including OAR 333-501-0020 (violations), is subject to the imposition of a civil penalty not to exceed $500 per day per violation.

(3) In addition to the penalties under section (2) of this rule, civil penalties may be imposed for violations of ORS 441.030 or 441.015(1).

(4) In determining the amount of a civil penalty the Division shall consider whether:

(a) The Division made repeated attempts to obtain compliance;

(b) The licensee has a history of noncompliance with health care facility licensing laws;

(c) The violation poses a serious risk to the public's health;

(d) The licensee gained financially from the noncompliance; and

(e) There are mitigating factors, such as a licensee's cooperation with an investigation or actions to come into compliance.

(5) The Division shall document its consideration of the factors in section (4) of this rule.

(6) Each day a violation continues is an additional violation.

(7) A civil penalty imposed under this rule shall comply with ORS 183.745.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.990
Hist.: PH 11-2009, f. & cert. ef. 10-1-09; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10; PH 31-2016, f. 11-14-16, cert. ef. 11-15-16

333-501-0060
Approval of Accrediting Organizations

(1) An accrediting organization may request approval by the Division to ensure that hospitals meet state licensing standards.

(2) An accrediting organization shall request approval in writing and shall provide, at a minimum:

(a) Evidence that it is recognized as a deemed organization by CMS; or

(b) If the accrediting organization is not a deemed organization under CMS, provide:

(A) Documentation of program policies and procedures that its accreditation process meets state licensing standards;

(B) Accreditation history; and

(C) References from a minimum of two facilities currently receiving services from the organization.

(3) If the Division finds that an accrediting organization has the necessary qualifications to certify that state licensing standards have been met, the Division will enter into an agreement with the accrediting organization.

Stat. Auth.: ORS 441.062
Stats. Implemented: ORS 441.062
Hist.: PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

DIVISION 505

HOSPITAL ORGANIZATION AND MANAGEMENT

333-505-0001
Applicability

These rules apply to all hospitals, regardless of classification.

Stat. Auth.: ORS 441.025

Stats. Implemented:ORS 441.025
Hist.: HD 21-1993, f. & cert. ef. 10-28-93; PH 11-2009, f. & cert. ef. 10-1-09; PH 17-2012, f. 12-20-12, cert. ef. 1-1-13

333-505-0005
Governing Body Responsibility

(1) In a multi-hospital system, one governing body may oversee multiple hospitals.

(2) The governing body of a hospital shall be responsible for the operation of the hospital, the selection of the medical staff and the quality of care rendered in the hospital. The governing body shall ensure that:

(a) All health care personnel for whom a state license or registration is required are currently licensed or registered;

(b) Qualified individuals allowed to practice in the hospital are credentialed and granted privileges consistent with their individual training, experience and other qualifications;

(c) Procedures for granting, restricting and terminating privileges exist and that such procedures are regularly reviewed to assure their conformity to applicable law;

(d) It has an organized medical staff responsible for reviewing the professional practices of the hospital for the purpose of reducing morbidity and mortality and for the improvement of patient care;

(e) A physician is not denied medical staff privileges at the facility solely on the basis that the physician holds medical staff membership or privileges at another health care facility;

(f) Licensed podiatric physicians and surgeons are permitted to use the hospital in accordance with ORS 441.063;

(g) All hospital employees and health care practitioners granted hospital privileges have been tested for tuberculosis in compliance with OAR 333-505-0080; and

(h) A notice, in a form specified by the Division, summarizing the provisions of ORS 441.162, 441.166, 441.168, 441.174, 441.176, 441.178, 441.192 is posted in a place where notices to employees and applicants are customarily displayed.

(3) A hospital may grant privileges to nurse practitioners in accordance with ORS 441.064 and subject to hospital rules governing credentialing and staff privileges.

(a) Privileges granted to nurse midwife nurse practitioners, if any, must be consistent with privileges granted to other medical staff and include:

(A) Admitting privileges that do not require a nurse midwife nurse practitioner to co-admit a patient with a physician who is a member of the medical staff; and

(B) Voting rights.

(b) A hospital may refuse to grant privileges to nurse practitioners only upon the same basis that privileges are refused to other licensed health care practitioners.

(4) A hospital shall require that every patient admitted shall be and remain under the care of a member of the medical staff as specified under the medical staff by-laws.

Stat. Auth: ORS 441.025
Stats. Implemented: ORS 441.055, 441.064
Hist.: HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0125; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-070-0050; HD 21-1993, f. & cert. ef. 10-28-93, Renumbered from 333-505-0000; HD 2-2000, f. & cert. ef. 2-15-00; OHD 20-2002, f. & cert. ef. 12-10-02; PH 11-2009, f. & cert. ef. 10-1-09; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10; PH 17-2012, f. 12-20-12, cert. ef. 1-1-13; PH 7-2016, f. & cert. ef. 2-24-16

333-505-0007
Health Care Practitioner Credentialing

Each hospital shall comply with the health care practitioner and telemedicine provider credentialing requirements in accordance with OAR chapter 409, division 045.

Stat. Auth.: ORS 441.056
Stats. Implemented: ORS 441.056 & ORS 441.222
Hist.: OHD 5-2002, f. & cert. ef. 3-4-02; PH 4-2004, f. & cert. ef. 2-6-04; PH 3-2005, f. & cert. ef. 2-4-05; PH 11-2009, f. & cert. ef. 10-1-09; PH 17-2012, f. 12-20-12, cert. ef. 1-1-13; PH 7-2016, f. & cert. ef. 2-24-16

333-505-0010
Administrator

(1) Each hospital shall employ or contract with a chief executive officer (CEO) or administrator who is responsible for the operation of the hospital and hospital based services in a manner commensurate with the authority conferred by the governing body, supports the delivery of high quality hospital care and services and ensures compliance with all hospital policies and applicable state and federal laws and regulations. In determining the appropriate number of facilities for which a CEO or administrator is responsible, the governing body of the hospital or health system should consider distance between hospitals and the size and complexity of each facility.

(2) For hospitals with attached long-term care facilities, the CEO may function as administrator of both the hospital and the long-term care facility.

(3) The hospital shall notify the Division, in writing, of the voluntary or involuntary termination of the CEO or administrator as well as the appointment of a new CEO or administrator.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.055
Hist.: HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; HD 21-1993, f. & cert. ef. 10-28-93; HD 2-2000, f. & cert. ef. 2-15-00; PH 11-2009, f. & cert. ef. 10-1-09; PH 17-2012, f. 12-20-12, cert. ef. 1-1-13

333-505-0020
Medical Staff

(1) The medical staff is responsible for reviewing the professional practices of the hospital for the purpose of reducing morbidity and mortality and for the improvement of patient care, and is accountable to the governing body.

(2) The hospital's medical staff organized pursuant to OAR 333-505-0005(1) shall include Medical Doctors and Doctors of Osteopathy, and may include other licensed health care practitioners as permitted by the governing body.

(3) The medical staff shall adopt and enforce by-laws, medical staff policies, and medical staff rules and regulations to carry out its responsibilities. The by-laws, medical staff policies, and medical staff rules and regulations must be approved by the governing body.

(4) By-laws, medical staff policies, and medical staff rules and regulations shall include but are not limited to:

(a) The organization of the medical staff, including qualifications for serving on the medical staff, nominations, election, appointment or removal of officers, and periodic review of its members;

(b) Criteria for credentialing health care practitioners and the process for applying for credentials;

(c) Criteria for restricting or terminating hospital privileges and the process for restricting or terminating hospital privileges;

(d) A process for periodically reviewing the procedures for granting, restricting, or terminating hospital privileges to ensure that procedures are being followed;

(e) Procedures for insuring that licensed health care practitioners with hospital privileges are acting within their scope of practice and acting consistent with the privileges granted;

(f) Procedures for the acceptance of verbal orders by those individuals authorized by law or their scope of practice to accept verbal orders;

(g) Criteria for tissue specimens and appliances that are subject to a macroscopic or microscopic pathology examination;

(h) Procedures for responding to medical emergencies, including contacting at least one physician in the event of a medical emergency; and

(i) Procedures for notifying patients orally and in writing of any financial interest as required by ORS 441.098.

(5) Amendments to medical staff by-laws shall be accomplished through a cooperative process involving both the medical staff and the governing body. Medical staff by-laws shall be adopted, repealed or amended when approved by the medical staff and the governing body. Approval shall not be unreasonably withheld by either. Neither the medical staff nor the governing body shall with-

hold approval if such appeal, amendment or adoption is mandated by law, statute or regulation or is necessary to obtain or maintain accreditation or to comply with fiduciary responsibilities or if the failure to approve would subvert the stated moral or ethical purposes of this institution.

(6) Physicians and all other health care practitioners with individual admitting privileges are subject to applicable provisions of the medical staff by-laws and rules governing admission and staff privileges.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.055, 441.064 & 441.098
Hist.: HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; HD 21-1993, f. & cert. ef. 10-28-93; HD 30-1994, f. & cert. ef. 12-13-94; PH 11-2009, f. & cert. ef. 10-1-09; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10

333-505-0030
Organization, Hospital Policies

(1) As used in this rule, "lay caregiver" means:

(a) In paragraph (4)(b)(A), an individual who, at the request of a patient, agrees to provide aftercare to the patient in the patient's residence.

(b) In paragraph (4)(b)(B), which applies to patients that are hospitalized for mental health treatment:

(A) For a patient who is younger than 14 years of age, a parent or legal guardian of the patient;

(B) For a patient who is 14 years of age or older, an individual designated by the patient or a parent or legal guardian of the patient to the extent permitted under ORS 109.640 and 109.675.

(2) A hospital's internal organization shall be structured to include appropriate departments and services consistent with the needs of its defined community.

(3) A hospital shall adopt and maintain clearly written definitions of its organization, authority, responsibility and relationships.

(4) A hospital shall adopt, maintain and follow written patient care policies that include but are not limited to:

(a) Admission and transfer policies that address:

(A) Types of clinical conditions not acceptable for admission;

(B) Constraints imposed by limitations of services, physical facilities or staff coverage;

(C) Emergency admissions;

(D) Requirements for informed consent signed by the patient or legal representative of the patient for diagnostic and treatment procedures; such policies and procedures shall address informed consent of minors in accordance with provisions in ORS 109.610, 109.640, 109.670, and 109.675;

(E) Requirements for identifying persons responsible for obtaining informed consent and other appropriate disclosures and ensuring that the information provided is accurate and documented appropriately in accordance with these rules and ORS 441.098; and

(F) A process for the internal transfer of patients from one level or type of care to another.

(b) Discharge and termination of services policies that address:

(A) For patients who identify a lay caregiver to provide aftercare, development of a discharge plan for continuity of patient care including but not limited to:

(i) Assessment of the patient's ability for self-care;

(ii) Opportunity for both the patient and lay caregiver to participate in discharge planning;

(iii) Instructions or training provided to the patient and lay caregiver, prior to discharge, for the lay caregiver to provide assistance with activities of daily living, medical or nursing tasks such as wound care, administering medications, or the operation of medical equipment, or other assistance relating to the patient's condition; and

(iv) Notification of the lay caregiver that patient is being discharged or transferred.

(B) On and after July 1, 2016 for patients hospitalized for mental health treatment, requirements that the hospital:

(i) Encourage the patient to sign an authorization form allowing for the disclosure of information that is necessary for a lay caregiver to participate in the patient's discharge planning and to provide appropriate support measures to the patient;

(ii) Assess the patient's risk of suicide with input from the patient's lay caregiver, if applicable;

(iii) Assess the long-term needs of the patient which include but are not limited to:

(I) Community-based services;

(II) Capacity for self-care; and

(III) Appropriate patient care where patient resided at time of admission;

(iv) Develop a process to coordinate the patient's care and transition the patient to outpatient treatment that may include community-based providers, peer support, lay caregivers or other individuals who can implement the patient's care plan; and

(v) Schedule a follow-up appointment for no later than seven days after discharge. If a follow-up appointment cannot be scheduled within seven days, the hospital must document why.

(c) Patient rights;

(d) Housekeeping;

(e) All patient care services provided by the hospital;

(f) Maintenance of the hospital's physical plant, equipment used in patient care and patient environment;

(g) Treatment or referral of acute sexual assault patients in accordance with ORS 147.403; and

(h) Identification of patients who could benefit from palliative care in order to provide information and facilitate access to appropriate palliative care in accordance with ORS 413.273.

(5) Discharge policies developed in accordance with paragraph (4)(b)(A) of this rule must be publically available and:

(a) Must specify requirements for documenting who is designated by the patient as the lay caregiver and details of the discharge plan;

(b) May incorporate established evidence based practices;

(c) Must ensure that discharge planning is appropriate to the needs and acuity of the patient and the abilities of the lay caregiver;

(d) Must not delay a patient's discharge or transfer to another facility; and

(e) Must not require the disclosure of protected health information without obtaining a patient's consent as required by state and federal laws.

(6) In addition to the policies described in section (3) of this rule, a hospital shall, in accordance with the Patient Self-Determination Act, 42 CFR 489.102, adopt policies and procedures that require (applicable to all capable individuals 18 years of age or older who are receiving health care in the hospital):

(a) Providing to each adult patient, including emancipated minors, not later than five days after an individual is admitted as an inpatient, but in any event before discharge, the following in written form, without recommendation:

(A) Information on the rights of the individual under Oregon law to make health care decisions, including the right to accept or refuse medical or surgical treatment and the right to execute directives and powers of attorney for health care;

(B) Information on the policies of the hospital with respect to the implementation of the rights of the individual under Oregon law to make health care decisions;

(C) A copy of the directive form set forth in ORS 127.531, along with a disclaimer attached to each form in at least 16-point bold type stating "You do not have to fill out and sign this form."; and

(D) The name of a person who can provide additional information concerning the forms for directives.

(b) Documenting in a prominent place in the individual's medical record whether the individual has executed a directive.

(c) Compliance with Oregon law relating to directives for health care.

(d) Educating the staff and the community on issues relating to directives.

(7) A hospital's transfer agreements or contracts shall clearly delineate the responsibilities of parties involved.

(8) Patient care policies shall be evaluated triennially and rewritten as needed, and presented to the governing body or a des-

ignated administrative body for approval triennially. Documentation of the evaluation is required.

(9) A hospital shall have a system, described in writing, for the periodic evaluation of programs and services, including contracted services.

Stat. Auth.: ORS 441.025

Stats. Implemented: ORS 147.025, 413.273, 441.025, 441.196 & 441.198

Hist.: HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; PH 11-2009, f. & cert. ef. 10-1-09; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10; PH 17-2012, f. 12-20-12, cert. ef. 1-1-13; PH 7-2016, f. & cert. ef. 2-24-16

333-505-0033

Patient Rights

A hospital shall comply with the requirements for patients rights as set forth in 42 CFR 482.13.

Stat. Auth.: ORS 441.025

Stats. Implemented: ORS 441.025

Hist.: PH 11-2009, f. & cert. ef. 10-1-09; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10; PH 17-2012, f. 12-20-12, cert. ef. 1-1-13

333-505-0040

Personnel

(1) A hospital shall:

(a) Maintain a sufficient number of qualified personnel to provide effective patient care and all other related services.

(b) Have written personnel policies and procedures that are available to personnel.

(c) Provide orientation for new employees.

(d) Have an annual continuing education plan.

(e) Have a job description for each position that delineates the qualifications, duties, authority and responsibilities inherent in each position.

(f) Provide an annual work performance evaluation for each employee with appropriate records maintained.

(g) Have an employee health screening program for the purpose of protecting patients and employees from communicable diseases, including but not limited to requiring tuberculosis testing for employees in accordance with OAR 333-505-0080.

(2) A hospital shall restrict the work of employees with restrictable diseases in accordance with OAR 333-019-0010.

(3) The actions taken by a hospital under this rule shall be fully documented for each employee and made available to Division representatives upon request.

Stat. Auth.: ORS 441.025

Stats. Implemented: ORS 441.025

Hist.: HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; HD 21-1993, f. & cert. ef. 10-28-93; HD 2-2000, f. & cert. ef. 2-15-00; PH 11-2009, f. & cert. ef. 10-1-09

333-505-0050

Medical Records

(1) A medical record shall be maintained for every patient admitted for care in a hospital.

(2) A legible reproducible medical record shall include, but is not limited to (as applicable):

(a) Admitting identification data including date of admission.

(b) Chief complaint.

(c) Pertinent family and personal history.

(d) Medical history, physical examination report and provisional diagnosis as required by OAR 333-510-0010.

(e) Admission notes outlining information crucial to patient care.

(f) All patient admission, treatment, and discharge orders.

(A) All patient orders shall be initiated, dated, timed and authenticated by a licensed health care practitioner in accordance with section (7) of this rule.

(B) Documentation of verbal orders shall include:

(i) The date and time the order was received;

(ii) The name and title of the health care practitioner who gave the order; and

(iii) Authentication by the authorized individual who accepted the order, including the individual's title.

(C) Verbal orders shall be dated, timed, and authenticated promptly by the ordering health care practitioner or another health care practitioner who is responsible for the care of the patient.

(D) For purposes of this rule, a verbal order includes but is not limited to an order given over the telephone.

(g) Clinical laboratory reports as well as reports on any special examinations. (The original report shall be recorded in the patient's medical record.)

(h) X-ray reports bearing the identification of the originator of the interpretation.

(i) Consultation reports when such services have been obtained.

(j) Records of assessment and intervention, including graphic charts and medication records and appropriate personnel notes.

(k) Discharge planning documentation in accordance with OAR 333-505-0030(5)(a).

(l) Discharge summary including final diagnosis.

(m) Autopsy report if applicable.

(n) Such signed documents as may be required by law.

(o) Informed consent forms that document:

(A) The name of the hospital where the procedure or treatment was undertaken;

(B) The specific procedure or treatment for which consent was given;

(C) The name of the health care practitioner performing the procedure or administering the treatment;

(D) That the procedure or treatment, including the anticipated benefits, material risks, and alternatives was explained to the patient or the patient's representative or why it would have been materially detrimental to the patient to do so, giving due consideration to the appropriate standards of practice of reasonable health care practitioners in the same or a similar community under the same or similar circumstances;

(E) The manner in which care will be provided in the event that complications occur that require health services beyond what the hospital has the capability to provide;

(F) The signature of the patient or the patient's legal representative; and

(G) The date and time the informed consent was signed by the patient or the patient's legal representative.

(p) Documentation of the disclosures required in ORS 441.098.

(3) A medical record of a surgical patient shall include, in addition to other record requirements, but is not limited to:

(a) Preoperative history, physical examination and diagnosis documented prior to operation.

(b) Anesthesia record including preanesthesia assessment and plan for anesthesia, records of anesthesia, analgesia and medications given in the course of the operation and postanesthetic condition.

(c) A record of operation dictated or written immediately following surgery and including a complete description of the operation procedures and findings, postoperative diagnostic impression, and a description of the tissues and appliances, if any, removed. When the dictated operative report is not placed in the medical record immediately after surgery, an operative progress note shall be entered in the medical record after surgery to provide pertinent information for any individual required to provide care to the patient.

(d) Postanesthesia recovery progress notes.

(e) Pathology report on tissues and appliances, if any, removed at the operation.

(4) An obstetrical record for a patient, in addition to the requirements for medical records, shall include but is not limited to:

(a) The prenatal care record containing at least a serologic test result for syphilis, Rh factor determination, and past obstetrical history and physical examination.

(b) The labor and delivery record, including reasons for induction and operative procedures, if any.

(c) Records of anesthesia, analgesia, and medications given in the course of delivery.

(5) A medical record of a newborn or stillborn infant, in addition to the requirement for medical records, shall include but is not limited to:

(a) Date and hour of birth; birth weight and length; period of gestation; sex; and condition of infant on delivery (Apgar rating is recommended).

(b) Mother's name and hospital number.

(c) Record of ophthalmic prophylaxis or refusal of same.

(d) Physical examination at birth and at discharge.

(e) Progress and nurse's notes including temperature; weight and feeding data; number, consistency and color of stools; urinary output; condition of eyes and umbilical cord; condition and color of skin; and motor behavior.

(f) Type of identification placed on infant in delivery room;

(g) Newborn hearing screening tests in accordance with OAR 333-020-0130.

(6) A patient's emergency room, outpatient and clinic records, in addition to the requirements for medical records, shall be maintained and available to the other professional services of the hospital and shall include but are not limited to:

(a) Patient identification.

(b) Admitting diagnosis, chief complaint and brief history of the disease or injury.

(c) Physical findings.

(d) Laboratory and X-ray reports (if performed), as well as reports on any special examinations. The original report shall be authenticated and recorded in the patient's medical record.

(e) Diagnosis.

(f) Record of treatment, including medications.

(g) Disposition of case with instructions to the patient.

(h) Signature or authentication of attending physician.

(i) A record of the pre-hospital report form (when patient is brought in by ambulance) shall be attached to the emergency room record.

(7) All entries in a patient's medical record shall be dated, timed and authenticated.

(a) Authentication of an entry requires the use of a unique identifier, including but not limited to a written signature or initials, code, password, or by other computer or electronic means that allows identification of the individual responsible for the entry.

(b) Systems for authentication of dictated, computer, or electronically generated documents must ensure that the author of the entry has verified the accuracy of the document after it has been transcribed or generated.

(8) The following records shall be maintained in written or computerized form for the time period specified:

(a) Permanent:

(A) Patient's register, containing admissions and discharges;

(B) Patient's master index;

(C) Register of all deliveries, including live births and stillbirths;

(D) Register of all deaths; and

(E) Register of operations.

(b) Seven years:

(A) Register of outpatients; and

(B) Emergency room register.

(c) Blood banking register shall be retained for 20 years.

(9) The completion of the medical record shall be the responsibility of the attending qualified member of the medical staff. Any licensed health care practitioner responsible for providing or evaluating the service provided shall complete and authenticate those portions of the record that pertain to their portion of the patient's care. The appropriate individual shall authenticate the history and physical examination, operative report, progress notes, orders and the summary. In a hospital using interns, such orders must be according to policies and protocols established and approved by the medical staff. An authentication of a licensed health care practitioner on the face sheet of the medical record does not suffice to cover the entire content of the record:

(a) Medical records shall be completed by a licensed health care practitioner and closed within four weeks following the patient's discharge.

(b) If a patient is transferred to another health care facility, transfer information shall accompany the patient. Transfer information shall include but is not limited to:

(A) The name of the hospital from which they were transferred;

(B) The name of physician or other health care practitioner to assume care at the receiving facility;

(C) The date and time of discharge;

(D) The current medical findings;

(E) The current nursing assessment;

(F) Current medical history and physical information;

(G) Current diagnosis;

(H) Orders from a physician or other licensed health care practitioner for immediate care of the patient;

(I) Operative report, if applicable;

(J) TB test, if applicable; and

(K) Other information germane to patient's condition.

(c) If the discharge summary is not available at time of transfer, it shall be transmitted to the new facility as soon as it is available.

(10) Diagnoses and operations shall be expressed in standard terminology. Only abbreviations approved by the medical staff may be used in the medical records.

(11) Medical records shall be filed and indexed. Filing shall consist of an alphabetical master file with a number cross-file. Indexing is to be done according to diagnosis, operation, and qualified member of the medical staff, using a system such as the International or Standard nomenclature systems.

(12) Medical records are the property of the hospital. The medical record, either in original, electronic or microfilm form, shall not be removed from the hospital except where necessary for a judicial or administrative proceeding. Treating and attending physicians shall have access to medical records. When a hospital uses off-site storage for medical records, arrangements must be made for delivery of these records to the hospital when needed for patient care or other hospital activities. Precautions must be taken to protect patient confidentiality.

(13) Authorized personnel of the Division shall be permitted to review medical records and patient registers as necessary to determine compliance with health care facility licensing laws.

(14) Medical records shall be kept for a period of at least 10 years after the date of last discharge. Original medical records may be retained on paper, microfilm, electronic or other media.

(15) Medical records shall be protected against unauthorized access, fire, water and theft.

(16) If a hospital changes ownership, all medical records in original, electronic or microfilm form shall remain in the hospital and it shall be the responsibility of the new owner to protect and maintain these records.

(17) If a hospital closes, its medical records and the registers required under section (8) of this rule may be delivered and turned over to any other hospital in the vicinity willing to accept and retain the same as provided in section (12) of this rule. A hospital which closes permanently shall follow the procedure for Division and public notice regarding disposal of medical records under OAR 333-500-0060.

(18) All original clinical records or photographic or electronic facsimile thereof, not otherwise incorporated in the medical record, such as X-rays, electrocardiograms, electroencephalograms, and radiological isotope scans shall be retained for seven years after a patient's last exam date if professional interpretations of such graphics are included in the medical records. Mammography images shall be retained for 10 years after a patient's last exam date.

(19) If a qualified medical record practitioner, RHIT (Registered Health Information Technician) or RHIA (Registered Health Information Administrator) is not the Director of the Medical Records Department, periodic and at least annual consultation must be provided by a qualified medical records consultant, RHIT/RHIA. The visits of the medical records consultant shall be of sufficient duration and frequency to review medical record systems and assure quality records of the patients. The contract for such services shall be made available to the Division.

(20) A current written policy on the release of medical record information including a patient's access to his or her medical record shall be maintained in the medical records department.

(21) A hospital is not required to keep a medical record in accordance with this rule for a person referred to a hospital ancillary department for a diagnostic procedure or health screening by a private physician, dentist, or other licensed health care practitioner acting within his or her scope of practice.

(22) Pursuant to ORS 441.059, the rules of a hospital that govern patient access to previously performed X-rays or diagnostic laboratory reports shall not discriminate between patients of chiropractic physicians and patients of other licensed health care practitioners permitted access to such X-rays and diagnostic laboratory reports.

(23) Nothing in this rule is meant to prohibit or discourage a hospital from maintaining its records in electronic form.

Stat. Auth: ORS 441.025

Stats. Implemented: ORS 441.025

Hist.: HB 183, f. & ef. 5-26-66; HB 235, f. 2-5-70, ef. 2-25-70; HB 253, f. 7-22-70, ef. 8-25-70; HB 255, f. 9-15-70, ef. 10-11-70; HD 11-1980, f. & ef. 9-10-80; HD 8-1984, f. & ef. 5-7-84; Renumbered from 333-023-0190; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-070-0055; HD 21-1993, f. & cert. ef. 10-28-93; HD 2-2000, f. & cert. ef. 2-15-00; OHD 3-2001, f. & cert. ef. 3-16-01; PH 11-2009, f. & cert. ef. 10-1-09; PH 26-2010, f. 12-14-10, cert. ef. 12-15-10; PH 17-2012, f. 12-20-12, cert. ef. 1-1-13; PH 7-2016, f. & cert. ef. 2-24-16

333-505-0060
Quality Assessment and Performance Improvement

(1) The governing body of a hospital must ensure that there is an effective, written, facility-wide quality assessment and performance improvement program to evaluate and monitor the quality and appropriateness of patient care.

(2) All organized services related to patient care, including services furnished by a contractor, must be evaluated.

(3) Written documentation of quality assessment and performance improvement activities shall be recorded at least quarterly.

(4) Healthcare associated infections, adverse drug reactions, errors in administration of drugs, and blood and blood product transfusions must be evaluated.

(5) All medical and surgical services performed in the hospital must be evaluated as they relate to appropriateness of diagnosis and treatment.

(6) The hospital must have an ongoing plan, consistent with available community and hospital resources, to provide and make available social work, psychological, and educational services to meet the medically-related needs of its patients.

Stat. Auth.: ORS 441.055

Stats. Implemented: ORS 441.025

Hist.: HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; HD 21-1993, f. & cert. ef. 10-28-93; HD 2-2000, f. & cert. ef. 2-15-00; PH 11-2009, f. & cert. ef. 10-1-09; PH 17-2012, f. 12-20-12, cert. ef. 1-1-13

333-505-0070
Infection Control and Prevention

(1) A hospital shall establish and maintain an active facility-wide program for the control and prevention of infection. This program shall, at a minimum, include the following:

(a) Identification of existing or potential infections in patients, employees, medical staff, and health care practitioners with hospital privileges;

(b) Control of factors affecting the transmission of infections and communicable diseases;

(c) Provision for orienting and educating all medical staff, health care practitioners with hospital privileges and employees on the cause, transmission and prevention of infections; and

(d) Collection, analysis and use of data relating to infections in the hospital.

(2) A hospital shall be responsible for the development, implementation and periodic review of policies under section (1) of this rule.

(3) In the hospital, the infection control program shall be managed by a qualified individual and overseen by a multidisciplinary committee with responsibility for investigating, controlling and preventing infections in the facility. The composition of the committee may vary but shall include at least representation from major departments and services and shall provide for consultation both from other departments and services and to them.

(4) A hospital shall comply with all rules of the Division for the control of communicable diseases.

(5) A hospital shall have a system of isolation that prevents the transmission of infections in hospitals.

(a) A system of isolation shall:

(A) Follow the principles of epidemiology and disease transmission;

(B) Include precautions to interrupt the spread of infection by all routes that are likely to be encountered in the hospital; and

(C) Be reviewed and approved by a committee responsible for the oversight of the infection control program.

(b) Guidelines for isolation precautions are published periodically by the Hospital Infection Control Practices Advisory Committee (HICPAC) and may be used by a hospital as a reference in order to maintain up-to-date isolation practices.

(6) The hospital multidisciplinary committee shall oversee all aspects of the infection control program, and will ensure that the

system of isolation implemented addresses the following fundamentals of infection control:

(a) Handwashing and gloving;

(b) Patient placement;

(c) Transport of infected patients;

(d) Protective apparel;

(e) Patient care equipment and articles;

(f) Linen and laundry;

(g) Dishes, glasses, cups, and eating utensils; and

(h) Routine and terminal cleaning.

(7) A hospital shall have policies and procedures related to cleaning, disinfection, sterilization, and disposal of patient care items.

(a) All instruments or equipment used in patient care should be disinfected or sterilized based on whether the item is critical, semi-critical, or non-critical.

(A) Critical items are those patient care items which enter the vascular system. These items must be sterile and should be sterilized by a Federal Drug Administration (FDA) approved method or purchased sterile for use.

(B) Semi-critical items are those patient care items which come into contact with mucous membranes or nonintact skin. These items must be free of all organisms except spores. Semi-critical items require high level disinfection using wet pasteurization or chemical sterilants which are FDA-approved.

(C) Non-critical items are those items that come into contact only with intact skin. Low level disinfectants may be used which have been approved by the Environmental Protection Agency (EPA) as hospital disinfectants.

(b) All patient care items shall be disposed of properly at discharge or processed according to the categorization of the items, i.e. critical, semi-critical, or non-critical. Single patient use equipment must be disposed of or sent home with the patient at discharge.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: HB 183, f. & ef. 5-26-66; HB 212, f. 2-25-69; HB 235, f. 2-5-70, ef. 2-25-70; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0180; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-072-0035; HD 21-1993, f. & cert. ef. 10-28-93; OHD 2-2000, f. & cert. ef. 2-15-00, Renumbered from 333-515-0010; PH 11-2009, f. & cert. ef. 10-1-09

333-505-0080
Tuberculosis Control

(1) As used in this rule, "person" means any:

(a) Hospital employee;

(b) Hospital contractor;

(c) Health care practitioner granted privileges by the hospital; or

(d) Hospital volunteer or student.

(2) A hospital shall comply with the Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005, published in the Morbidity and Mortality Weekly Report by the Centers for Disease Control and Prevention (CDC), December 30, 2005, and incorporated by reference.

(3) A hospital shall obtain documentation that tuberculosis (TB) testing has been conducted in a manner consistent with the CDC guidelines for any person who enters a hospital and who has contact with patients, enters rooms that patients may enter, or who handles clinical specimens or other material from patients or their rooms.

(4) A hospital shall require documentation of baseline TB screening conducted in accordance with the CDC Guidelines, within six weeks of the date of hire, date of executed contract or date of being granted hospital credentials.

(5) A hospital that is classified as "potential ongoing transmission" under CDC Guidelines shall consult with the Oregon TB control program within the Division, for guidance on the extent of TB testing required.

(6) If a hospital learns that a person or a patient at the hospital is diagnosed with communicable TB, the hospital shall notify the local public health authority and conduct an investigation to identify contacts. If the Division or local public health authority conducts its own investigation, a hospital shall cooperate with that investigation and provide the Division or local public health authority with any information necessary for it to conduct its investigation.

(7) A hospital shall notify the local public health administrator of its intent to discharge a patient known to have active TB disease.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: PH 11-2009, f. & cert. ef. 10-1-09; PH 17-2012, f. 12-20-12, cert. ef. 1-1-13

333-505-0090
Request for Tissues and Organs

(1) A hospital administrator or his or her designee shall contact the appropriate organ or tissue procurement organization when a patient dies at the hospital or when a patient's death is imminent.

(2) After consultation with an organ or tissue procurement organization, the hospital administrator or his or her designee shall communicate with the patient or legal next-of-kin and request that the patient's organs and tissue be donated as an anatomical gift, unless:

(a) The medical record shows that the patient has made an anatomical gift;

(b) The appropriate procurement organizations or the medical examiner has ruled out the potential donor based on accepted medical standards;

(c) The legal next-of-kin are not available because:

(A) They cannot be located in a timely manner after reasonable effort by the procurement organizations or the hospital; or

(B) They are mentally incompetent.

(d) In the opinion of the attending physician after consulting with the procurement organization, it is determined that the request would contribute toward the severe emotional distress of the patient or legal next-of-kin.

(3) For purposes of this rule, "legal next-of-kin" is the class of persons described in ORS 97.965 and in addition to spouse, includes Oregon registered domestic partner.

(4) The hospital shall document the request or the absence of a request, in the medical record of the decedent and provide information on the request and its disposition to the person filing the death certificate.

(5) An anatomical gift by a legal next-of-kin or authorized person may be made by a document of gift signed by the donor or made by his or her telegraphic, recorded telephonic or other recorded message.

(6) A hospital or training requestor who acts or omits to act with probable cause in accord with the terms of ORS 97.951 through 97.978 and these rules is not subject to criminal or civil liability.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: PH 11-2009, f. & cert. ef. 10-1-09

333-505-0100
Training for Requestors

(1) All persons making requests for donations of organs, tissues, and eyes shall have received hospital-provided or procurement organization-provided training in accordance with this rule.

(2) Training for requestors shall include but is not limited to:

(a) The legal requirements of ORS 97.951 through 97.978 and these rules, and the necessity for completion of the portion of the death certificate regarding organ, tissue and eye retrieval.

(b) Specifics of organ tissue and eye donation, including: identification of potential donors; medical uses of donated organs, tissues, and eyes; the history and success of transplant programs; reimbursement mechanisms for expenses relating to organ, tissue, and eye retrieval;

(c) A review of the psychological, social, cultural, ethical and religious factors affecting willingness to donate organs, tissues, and eyes, and resistance to organ, tissue, and eye donation, and a review of materials developed to train individuals to request organ, tissue, and eye donation with reasonable discretion and sensitivity;

(d) The family's right to refuse and the need to respect this right;

(e) The effect on funeral arrangements and cost; and

(f) The importance of consulting with the attending physician.

(3) Requestors shall be able to demonstrate knowledge of the training content as defined in this rule.

Stat. Auth.: ORS 441.025

Stats. Implemented: ORS 441.025

Hist.: PH 11-2009, f. & cert. ef. 10-1-09

333-505-0110
Hospital Compliance

(1) A hospital shall demonstrate compliance with OAR 333-505-0090 and 333-505-0100 by maintaining a file, available for Division review, including the following:

(a) Training curriculum;

(b) Hospital policy and procedure regarding request and training for tissues, eyes, and organs;

(c) If not included in policy and procedure, criteria for selection of requestor;

(d) Method by which 24-hour scheduling of requestor(s) is established; and

(e) Policies and procedures for communicating with procurement organizations regarding the availability of donor organs, tissues, and eyes.

(2) Hospitals may provide appropriate procurement organization personnel access to medical records of decedents on a periodic basis. The timing of this review will be mutually agreed to by both the hospital and procurement organizations. Procurement organizations will provide appropriate staff to conduct the review in the hospital. The purpose of this review will be to provide information to the hospital to assist in compliance with state and federal regulations related to organ, tissue and eye donation. If the hospital agrees to the review, all findings will remain strictly confidential.

(3) In the case of a hospital in which organ transplants are performed, the hospital must be a member of the Organ Procurement and Transplantation network established under Section 372 of the Public Health Service Act and abide by its rules and requirements.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 441.025
Hist.: PH 11-2009, f. & cert. ef. 10-1-09

333-505-0120
Emergency Contraception

(1) A hospital providing care to a female victim of sexual assault shall:

(a) Promptly provide the victim with unbiased, medically and factually accurate written and oral information about emergency contraception;

(b) Promptly orally inform the victim of her option to be provided emergency contraception at the hospital; and

(c) If requested by the victim and not medically contraindicated, provide the victim of any child bearing age with emergency contraception immediately at the hospital, notwithstanding ORS 147.397 (defining the availability of the Sexual Assault Victims' Emergency Medical Response fund "SAVE Fund").

(d) For purposes of this rule, "emergency contraception" means the use of a drug or device that is approved by the United States Food and Drug Administration to prevent pregnancy after sexual intercourse.

(2) A hospital shall post a written notice, approved by the Division, to inform victims of their right to be provided emergency contraception at the hospital.

(3) Pursuant to ORS 109.640, anyone under the age of 18 has the right to consent to birth control information and services, including emergency contraception.

(4) A hospital shall document in writing that the information required to be given to a female victim of sexual assault in section (1) of this rule, was provided. Failure to have such documentation may result in the issuance of a civil penalty.

(5) A hospital may only provide the victim informational materials about emergency contraception that has been approved by the Division.

(6) The Division shall investigate complaints of violations of sections (1) or (2) of this rule in accordance with ORS 441.057.

(7) In addition to investigating complaints, the Division shall monitor compliance with ORS 435.254 and this rule during scheduled visits to hospitals.

(8) The Division may impose a civil penalty, not to exceed $1000, against a hospital for each violation of ORS 435.254 or these rules. In addition to the assessment of a civil penalty, the Ore-

gon Health Authority will require corrective actions from the hospital.

(a) For the first violation the civil penalty shall be $250;

(b) For the second violation the civil penalty shall be $500;

(c) For the third and any subsequent violations, the civil penalty shall be $1000.

Stat. Auth.: ORS 441.025
Stats. Implemented: ORS 183.745, 441.025, 435.254, 435.256 & 441.057
Hist.: PH 11-2009, f. & cert. ef. 10-1-09

DIVISION 510

PATIENT CARE AND NURSING SERVICES IN HOSPITALS

333-510-0001
Applicability

These rules apply to all hospitals, regardless of classification.

Stat. Auth.: ORS 413.042, 441.055
Stats. Implemented: ORS 441.055 & 442.015
Hist.: HD 21-1993, f. & cert. ef. 10-28-93; PH 11-2009, f. & cert. ef. 10-1-09

333-510-0002
Definitions

As used in OAR chapter 333, division 510, the following definitions apply:

(1) "Direct Care Registered Nurse" means a nurse who is routinely assigned to a patient care unit, who is replaced for scheduled and unscheduled absences and includes charge nurses if the charge nurse is not management services.

(2) "Direct Care Staff" means registered nurses, licensed practical nurses and certified nursing assistants that are routinely assigned to patient care units and are replaced for scheduled or unscheduled absences.

(3) "Direct Care Staff Member" means an individual who is a direct care registered nurse, licensed practical nurse or certified nursing assistant who is routinely assigned to a patient care unit and is replaced for a scheduled or unscheduled absences.

(4) "Epidemic" means the occurrence of a group of similar conditions of public health importance in a community or region that are in excess of normal expectancy and that are from a common or propagated source.

(5) "Evidence Based Standards" means standards that have been scientifically developed, are based on current literature, and are driven by consensus.

(6) "Hospital" means a hospital as described in ORS 442.015 and an acute inpatient care facility as defined in ORS 442.470.

(7) "Mandatory Overtime" is any time that exceeds those time limits specified in ORS 441.166 unless the nursing staff member voluntarily chooses to work overtime.

(8) "Nurse Manager" means a registered nurse who has administrative responsibility 24 hours a day, 7 days a week for a patient care unit, units or hospital and who is not replaced for short-term scheduled or unscheduled absences.

(9) "Nursing care intensity" means the level of patient need for nursing care as determined by the nursing assessment.

(10) "Nursing staff" means registered nurses, licensed practical nurses and certified nursing assistants.

(11) "Nursing staff member" means an individual who is a registered nurse, licensed practical nurse or a certified nursing assistant.

(12) "On Call" means a scheduled state of availability to return to duty, work-ready, within a specified period of time.

(13) "On Call Nursing Staff" means individual nursing staff members or nursing service agencies maintained by a hospital that are available and willing to cover nursing staff shortages due to unexpected nursing staff absences or unanticipated increased nursing service needs.

(14) "Patient acuity" means the complexity of patient care needs requiring the skill and care of nursing staff.

(15) "Potential Harm" or "At Risk of Harm" means that an unstable patient will be left without adequate care for an unacceptable period of time if the assigned nursing staff member leaves the assignment or transfers care to another nursing staff member.

(16) "Quorum" means that a majority, or one-half plus one, of the staffing committee members are present during a staffing committee meeting.

(17) "Safe Patient Care" means nursing care that is provided appropriately, in a timely manner, and meets the patient's health care needs. The following factors may be, but are not in all circumstances, evidence of unsafe patient care:

(a) A failure to implement the written nurse staffing plan;

(b) A failure to comply with the patient care plan;

(c) An error that has a negative impact on the patient;

(d) A patient report that his or her nursing care needs have not been met;

(e) A medication not given as scheduled;

(f) The nursing preparation for a procedure that was not accomplished on time;

(g) A nursing staff member who was practicing outside his or her authorized scope of practice;

(h) Daily unit-level staffing that does not include coverage for all known patients, taking into account the turnover of patients;

(i) The skill mix of employees and the relationship of the skill mix to patient acuity and nursing care intensity of the workload is insufficient to meet patient needs; or

(j) An unreasonable delay in responding to a request for nursing care made by a patient or made on behalf of a patient by his or her family member.

(18) "Staffing Committee" means the hospital nurse staffing committee.

(19) "Staffing Plan" means the written hospital-wide staffing plan for nursing services developed by the hospital nurse staffing committee.

(20) "Standby" means a scheduled state of availability to return to duty, work-ready within a specified period of time.

(21) "Waiver" means a variance to the hospital-wide staffing plan requirements as described in ORS 441.164.

Stat. Auth.: ORS 413.042 & 441.151 – 441.177
Stats. Implemented: ORS 441.165, 441.166 & 441.179
Hist.: PH 21-2006, f. & cert. ef. 10-6-06; PH 11-2009, f. & cert. ef. 10-1-09; PH 22-2016, f. & cert. ef. 7-1-16

333-510-0010
Patient Admission and Treatment Orders

(1) No patient, including patients admitted for observation status, shall be admitted to a hospital except on the order of an individual who has admitting privileges. The admitting physician or nurse practitioner shall provide sufficient information at the time of admission to establish that care can be provided to meet the needs of the patient. Admission medical information shall include a statement concerning the admitting diagnosis and general condition of the patient. Other pertinent medical information, orders for medication, diet, and treatments shall also be provided, as well as a medical history and physical.

(2) Within 24 hours of a patient's admission, a hospital shall ensure that:

(a) The patient's medical history is taken and a physical examination performed, unless:

(A) A medical history and physical examination has been completed within 30 days prior to admission, as provided in the medical staff rules and regulations; or

(B) The patient is readmitted within a month's time for the same or related condition, as long as an interval note is completed.

(b) The patient is given a provisional diagnosis.

(3) Even if a medical history or physical examination at the time of admission is not required under section (2) of this rule, a hospital shall ensure that any changes crucial to patient care are noted in an admission note.

(4) Visits from licensed health care providers shall be according to patient's needs. Initial and ongoing assessments shall be performed for each patient and the results and observations recorded in the medical record.

(5) A Doctor of Medicine (MD) or Doctor of Osteopathy (DO) or nurse practitioner with admitting privileges shall be responsible, as permitted by the individual's scope of practice for the care of any medical problem that may be present on admission or that may arise during an inpatient stay.

(6) No medication or treatment shall be given except on the order of a licensed healthcare professional authorized to give such orders within the State of Oregon.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055 & 442.015
Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 11-1980, f. & ef. 9-10-80; HD 5-1981, f. & ef. 3-30-81; Renumbered from 333-023-0172; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-072-0015(1); HD 2-1993, f. & cert. ef. 3-11-93; HD 21-1993, f. & cert. ef. 10-28-93, HD 30-1994, f. & cert. ef. 12-13-94; HD 2-2000, f. & cert. ef. 2-15-00; PH 11-2009, f. & cert. ef. 10-1-09

333-510-0020
Nursing Care Management

(1) The nursing care of each patient, including patients admitted for observation status, in a hospital shall be the responsibility of a registered nurse (RN).

(2) The RN will only provide services to the patients for which the RN is educationally and experientially prepared and for which competency has been maintained.

(3) The RN shall be responsible and accountable for managing the nursing care of the RN's assigned patients. The RN shall only assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available. The responsible RN shall ensure that the following activities are completed:

(a) Document the admission assessment of the patient within four hours following admission and initiate a written plan of care. This shall be reviewed and updated whenever the patient's status changes.

(b) Develop and document within eight hours following admission a plan of care for nursing services for the patient, based on the patient assessment and realistic, understandable, achievable patient goals consistent with the applicable rules in OAR chapter 851, division 045.

(c) Observe and report to the nurse manager and the patient's physician or other responsible health care provider authorized by law, when appropriate, any significant changes in the patient's condition that warrant interventions that have not been previously prescribed or planned for:

(A) When the RN questions the efficacy, need or safety of continuation of medications being administered to a patient, the RN shall report that question to the physician or other responsible health care provider authorized by law authorizing the medication and shall seek further instructions concerning the continuation of the medication.

(4)(a) A hospital shall maintain documentation of certification of certified nursing assistants (CNAs), which shall be available on request to Division personnel.

(b) A nursing assistant who works in a hospital must be certified prior to assuming nursing assistant duties in accordance with OAR chapter 851, division 062.

(c) A hospital shall maintain documentation that CNAs whose functions include administration of non-injectable medications, are qualified. This documentation shall be available on request to Division personnel.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055 & 442.015
Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 11-1980, f. & ef. 9-10-80; HD 5-1981, f. & ef. 3-30-81; Renumbered from 333-023-0172; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-072-0015(7); HD 21-1993, f. & cert. ef. 10-28-93; HD 2-2000, f. & cert. ef. 2-15-00; PH 11-2009, f. & cert. ef. 10-1-09; PH 17-2012, f. 12-20-12, cert. ef. 1-1-13

333-510-0030
Nursing Services

(1) The hospital shall provide a nursing service department, which provides 24-hour onsite registered nursing care, 7 days per week.

(2) The nursing services department shall be under the direction of a nurse executive who is a registered nurse, licensed to practice in Oregon.

(3) All nursing personnel shall maintain current certification in cardiopulmonary resuscitation.

Stat. Auth.: ORS 413.042, 441.055
Stats. Implemented: ORS 441.160 - 441.192
Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 11-1980, f. & ef. 9-10-80; HD 5-1981, f. & ef. 3-30-81; Renumbered from 333-023-0172; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-072-0015(2); HD 21-1993, f. & cert. ef. 10-28-93; HD 2-2000, f. & cert. ef. 2-15-00; PH 21-2006, f. & cert. ef. 10-6-06; PH 11-2009, f. & cert. ef. 10-1-09; PH 7-2016, f. & cert. ef. 2-24-16

333-510-0040
Nurse Executive

(1) The nurse executive position shall be full-time (40 hours per week). Time spent in professional association workshops, seminars and continuing education may be counted as duties in considering whether or not the nurse executive is full-time. If the nurse executive has responsibility for direct patient care activities, sufficient time must be available to devote to administrative duties. For hospitals with attached long-term care facilities, the nurse executive may function as the nurse executive for both the hospital and the long-term care facility.

(2) The nurse executive shall have had progressive responsibility in managing in a health care setting. The nurse executive shall be a registered nurse licensed in Oregon. In addition, the nurse executive must have a baccalaureate degree, other advanced degree, or appropriate equivalent experience, with emphasis in management preferred.

(3) The nurse executive shall have written administrative authority, responsibility, and accountability for assuring functions and activities of the nursing services department and shall participate in the development of any policies that affect the nursing services department. This includes budget formation, implementation and evaluation. The nurse executive shall ensure the:

(a) Development and maintenance of a nursing service philosophy, objective, standards of practice, policy and procedure manuals, and job descriptions for each level of nursing service personnel;

(b) Development and maintenance of personnel policies of recruitment, orientation, in-service education, supervision, evaluation, and termination of nursing service staff or ensure it is done by another department;

(c) Development and maintenance of policies and procedures for determination of nursing staff's capacity for providing nursing care for any patient seeking admission to the facility;

(d) Development and maintenance of a quality assessment and performance improvement program for nursing service;

(e) Coordination of nursing service departmental function and activities with the function and activities of other departments; and

(f) Ensure participation with the administrator and other department directors in development and maintenance of practices and procedures that promote infection control, fire safety, and hazard reduction.

(4) Whenever the nurse executive is not available in person or by phone, the nurse executive shall designate in writing a specific registered nurse or nurses, licensed to practice in Oregon, to be available in person or by phone to direct the functions and activities of the nursing services department.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055 & 442.015
Hist.: HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; HD 21-1993, f. & cert. ef. 10-28-93; HD 2-2000, f. & cert. ef. 2-15-00; PH 11-2009, f. & cert. ef. 10-1-09; PH 17-2012, f. 12-20-12, cert. ef. 1-1-13

333-510-0045
Nurse Staffing Posting and Record Requirements

(1) On each hospital unit, a hospital shall post a complaint notice that:

(a) Summarizes the provisions of ORS 441.152 to 441.177;

(b) Is clearly visible to the public; and

(c) Includes the Authority's complaint reporting phone number, electronic mail address and website address.

(2) A hospital shall also post an anti-retaliation notice on the premises that:

(a) Summarizes the provisions of ORS 441.181, 441.183, 441.184 and 441.192;

(b) Is clearly visible; and

(c) Is posted where notices to employees and applicants for employment are customarily displayed.

(3) A hospital shall keep and maintain all records necessary to demonstrate compliance with ORS 441.152 to 441.177. These records shall:

(a) Be maintained for no fewer than three years;

(b) Be promptly provided to the Authority upon request; and

(c) Include, at minimum:

(A) The staffing plan;

(B) The hospital nurse staffing committee charter;

(C) Staffing committee meeting minutes;

(D) Documentation showing how all members of the staffing committee were selected;

(E) All complaints filed with the staffing committee;

(F) Personnel files for all nursing staff positions that include, at minimum, job descriptions, required licensure and specialized qualifications and competencies required for the individual's assigned nurse specialty or unit;

(G) Documentation showing work schedules for nursing staff in each hospital nurse specialty or unit;

(H) Documentation showing actual hours worked by all nursing staff;

(I) Documentation showing all work schedule variances that resulted in the use of replacement nursing staff;

(J) Documentation showing how many on-call hours, if any, required nursing staff to be on the hospital premises;

(K) Documentation showing how many required meeting, education and training hours, if any, were required of nursing staff;

(L) The hospital's mandatory overtime policy and procedure;

(M) Documentation showing how many, if any, overtime hours were worked by nursing staff;

(N) Documentation of all waiver requests, if any, submitted to the Authority;

(O) Documentation showing how many, if any, additional hours were worked due to emergency circumstances and the nature of those circumstances;

(P) The list of on-call nursing staff used to obtain replacement nursing staff;

(Q) Documentation showing how and when the hospital updates its list of on-call staff used to obtain replacement nursing staff and how the hospital determines eligibility to remain on the list;

(R) Documentation showing the hospital's procedures for obtaining replacement nursing staff, including efforts made to obtain replacement staff;

(S) Documentation showing the hospital's actual efforts to seek replacement staff when needed;

(T) Documentation showing each actual instance in which the hospital implemented the policy described in OAR 333-510-0110(2)(g) to initiate limitations on admission or diversion of patients to another hospital; and

(U) All staffing committee reports filed with the hospital administration following a review of the staffing plan.

Stat. Auth.: ORS 413.042, 441.155, 441.169, 441.173 & 441.185
Stats. Implemented: ORS 441.155, 441.169, 441.173 & 441.185
Hist.: OHD 2-2000, f. & cert. ef. 2-15-00; OHD 3-2001, f. & cert. ef. 3-16-01; OHD 20-2002, f. & cert. ef. 12-10-02; PH 22-2005(Temp), f. 12-30-05, cert. ef. 1-1-06 thru 6-29-06; PH 21-2006, f. & cert. ef. 10-6-06; PH 11-2009, f. & cert. ef. 10-1-09; PH 22-2016, f. & cert. ef. 7-1-16

333-510-0050
Inservice Training Requirements for Nursing

(1) The nurse executive or her or his designee shall coordinate all inservice training for nursing. Each year the inservice training agenda shall include at least the following:

(a) Infection control measures;

(b) Emergency procedures including, but not limited to, procedures for fire and other disaster;

(c) Application of physical restraints (if the facility population includes any patient with orders for restraints); and

(d) Other special needs of the facility population.

(2) Training for procedures for life-threatening situations, including cardiopulmonary resuscitation shall be provided every two years.

(3) The facility, through the nurse executive, shall assure that each licensed or certified employee is knowledgeable of the laws and rules governing his or her performance and that employees function within those performance standards.

(4) Documentation of such training shall include the date, content and names of attendees.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055 & 442.015
Hist.: HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; HD 21-1993, f. & cert. ef. 10-28-93; OHD 2-2000, f. & cert. ef. 2-15-00; PH 11-2009, f. & cert. ef. 10-1-09

333-510-0060
Patient Environment

(1) A hospital shall provide for each patient:

(a) A good bed, mattress, pillow with protective coverage, and necessary bed coverings;

(b) Items needed for personal care; and

(c) Separate storage space for clothing, toilet articles, and other personal belongings.

(2) In multiple-bed rooms, opportunity for patient privacy shall be provided by flame retardant curtains or screens. In hospitals caring for pediatric patients, cubicle curtains or screens are not required for beds assigned these patients.

(3) No patient shall be admitted to a bed in any room, other than one regularly designated as a bedroom or ward. The placing of a patient's bed in a diagnostic room, treatment room, operating room or delivery room is expressly prohibited, except under emergency circumstances.

(4) No towels, wash cloths, bath blankets, or other linen which comes directly in contact with the patient shall be interchangeable from one patient to another unless it is first laundered.

(5) Temperature-controlled pads shall be so covered that the patient cannot be harmed by excessive heat or cold and carefully checked as to temperature and leakage. Electrical heating pads, blankets, or sheets shall be used only on the written order of the physician or other health care practitioner authorized by law.

(6) The use of torn or unclean bed linen is prohibited.

(7) In facilities caring for pediatric patients, an emergency signaling system for use by attendants summoning assistance and a two-way voice intercommunication system between the nurses' station and rooms or wards housing pediatric patients shall be provided.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055 & 442.015
Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0170; HD 5-1981, f. & ef. 3-30-81; Renumbered from 333-023-0172; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-072-0010 & 333-072-0015(3) thru (6); HD 21-1993, f. & cert. ef. 10-28-93; HD 2-2000, f. & cert. ef. 2-15-00; PH 11-2009, f. & cert. ef. 10-1-09

333-510-0105
Nurse Staffing Committee Requirement

(1) Each hospital shall establish and maintain a hospital nurse staffing committee. The staffing committee shall develop a written hospital-wide staffing plan for nursing services in accordance with ORS 441.155 and OAR chapter 333, division 510 rules. In developing the staffing plan, the staffing committee's primary goal shall be to ensure that the hospital is adequately staffed to meet the health care needs of its patients.

(2) The staffing committee shall meet:

(a) At least once every three months; and

(b) At any time and place specified by either co-chair of the staffing committee.

(3) The hospital shall release a member of the staffing committee from his or her assignment to attend committee meetings and provide paid time for this purpose.

(4) The staffing committee shall be comprised of an equal number of hospital nurse managers and direct care staff. Direct care staff members shall be selected as follows:

(a) The staffing committee shall include at least one direct care registered nurse from each hospital nurse specialty or unit as t h e specialty or unit is defined by the hospital to represent that specialty or unit;

(b) In addition to the direct care registered nurses described in subsection (a) of this section there must be one position on the staffing committee that is filled by a direct care staff member who is not a registered nurse and whose services are covered by the staffing plan;

(c) If the direct care registered nurses working at the hospital are represented under a collective bargaining agreement, the bargaining unit shall coordinate voting to allow the direct care registered nurses who work at the hospital to select each direct care registered nurse on the staffing committee;

(d) If the direct care registered nurses working at the hospital are not represented under a collective bargaining agreement, the direct care registered nurses belonging to each hospital nurse specialty or unit shall select the direct care registered nurse to represent it on the staffing committee; and

(e) If the position that must be filled by a direct care staff member who is not a registered nurse and whose services are covered by the staffing plan is represented under a collective bargaining agreement, the bargaining unit shall coordinate voting to allow the direct care staff members who are not registered nurses to select the direct care staff member who is not a registered nurse to represent them on the staffing committee.

(f) If the position that must be filled by a direct care staff member who is not a registered nurse and whose services are covered by the staffing plan is not represented under a collective bargaining agreement, the direct care staff members who are not registered nurses shall select the direct care staff member who is not a registered nurse to represent them on the staffing committee.

(5) The staffing committee shall have two co-chairs. One co-chair must be a hospital nurse manager elected by a majority of the staffing committee members who are hospital nurse managers. The other co-chair must be a direct care registered nurse elected by a majority of the staffing committee members who are direct care staff.

(6) The staffing committee must develop a written charter that documents the policies and procedures of the staffing committee. At minimum, the charter must include:

(a) How meetings are scheduled;

(b) How members are notified of meetings;

(c) How agendas are determined;

(d) How input from hospital nurse specialty or unit staff is submitted;

(e) Who may participate in decision-making;

(f) How decisions are made; and

(g) How the staffing committee shall monitor, evaluate and modify the staffing plan over time.

(7) Staffing committee meetings must be conducted as follows:

(a) A meeting may not be conducted unless a quorum of staffing committee members is present;

(b) Except as set forth in subsection (c) of this section, a meeting must be open to all hospital nursing staff as observers and to any other individual as either observer or presenter by invitation of either co-chair of the staffing committee;

(c) Either co-chair of the staffing committee may temporarily exclude all non-members from a meeting during staffing committee deliberations and voting; and

(d) Each staffing committee decision must be made by majority vote; however, if a quorum consists of an unequal number of hospital nurse managers and direct care staff, only an equal number of hospital nurse managers and direct care staff may vote.

(8) The staffing committee must document meeting proceedings by keeping written meeting minutes that include, but are not limited to, the following information:

(a) The name and position of each staffing committee member in attendance;

(b) The name and position of each observer or presenter in attendance;

(c) Motions made;

(d) Outcomes of votes taken;

(e) A summary of staffing committee discussions; and

(f) Instances in which non-members have been excluded from staffing committee meetings.

(9) The staffing committee shall approve meeting minutes prior to or during the next staffing committee meeting.

(10) The staffing committee shall provide meeting minutes to hospital nursing staff and other hospital staff upon request no more than 30 calendar days after the meeting minutes are approved by the staffing committee.

Stat. Auth.: ORS 413.042, 441.151 & 441.154
Stats. Implemented: ORS 441.154
Hist.: PH 22-2016, f. & cert. ef. 7-1-16

333-510-0110
Nurse Staffing Plan Requirements

(1) Each hospital shall implement a written hospital-wide staffing plan for nursing services that is developed and approved by the hospital nurse staffing committee established in accordance with ORS 441.154 and OAR chapter 333 division 510 rules.

(2) The staffing plan:

(a) Must be based on the specialized qualifications and competencies of the nursing staff and provide for the skill mix and level of competency necessary to ensure that the hospital is staffed to meet the health care needs of patients;

(b) Must be based on a measurement of hospital unit activity that quantifies the rate of admissions, discharges and transfers for each hospital unit and the time required for a direct care registered nurse belonging to a hospital unit to complete admissions, discharges and transfers for that hospital unit;

(c) Must be based on total diagnoses for each hospital unit and the nursing staff required to manage that set of diagnoses;

(d) Must be consistent with nationally recognized evidence-based standards and guidelines established by professional nursing specialty organizations such as, but not limited to: The American Association of Critical Care Nurses, American Operating Room Nurses (AORN), or American Society of Peri-Anesthesia Nurses (ASPAN);

(e) Must recognize differences in patient acuity and nursing care intensity;

(f) Must establish minimum numbers of nursing staff, including licensed practical nurses and certified nursing assistants, required on specified shifts, provided that no fewer than one registered nurse and one other nursing staff member is on duty in a unit when a patient is present;

(g) Must include a formal process for evaluating and initiating limitations on admission or diversion of patients to another hospital when, in the judgment of a direct care registered nurse or a nurse manager, there is an inability to meet patient care needs or a risk of harm to patients;

(h) Must consider tasks not related to providing direct care, including meal breaks and rest breaks;

(i) May not base nursing staff requirements solely on external benchmarking data;

(j) May not be used by a hospital to impose upon unionized nursing staff any changes in wages, hours or other terms and conditions of employment unless the hospital first provides notice to and, upon request, bargains with the union; and

(k) May not create, preempt or modify a collective bargaining agreement or require parties to an agreement to bargain over the staffing plan while a collective bargaining agreement is in effect.

Stat. Auth.: ORS 413.042 & 441.155
Stats. Implemented: ORS 441.155
Hist.: PH 22-2016, f. & cert. ef. 7-1-16

333-510-0115
Nurse Staffing Plan Review Requirement

(1) The staffing committee shall:

(a) Review the staffing plan at least once per year; and

(b) At any other time specified by either co-chair of the staffing committee.

(2) In reviewing the staffing plan, the staffing committee shall consider:

(a) Patient outcomes;

(b) Complaints regarding staffing, including complaints about a delay in direct care nursing or an absence of direct care nursing;

(c) The number of hours of nursing care provided through a hospital unit compared with the number of patients served by the hospital unit during a 24-hour period;

(d) The aggregate hours of mandatory overtime worked by nursing staff;

(e) The aggregate hours of voluntary overtime worked by nursing staff;

(f) The percentage of shifts for each hospital unit for which staffing differed from what is required by the staffing plan;

(g) Any other matter determined by the committee to be necessary to ensure that the hospital is staffed to meet the health care needs of patients; and

(h) Any report filed by a nursing staff member stating the nursing staff member's belief that the hospital unit engaged in a pattern of requiring direct care nursing staff to work overtime for nonemergency care.

(3) Following its review of the staffing plan, the staffing committee shall issue a written report to the hospital that indicates whether the staffing plan ensures that the hospital is adequately staffed and meets the health care needs of patients. If the report indicates that it does not, the staffing committee shall modify the staffing plan as necessary to accomplish this goal.

Stat. Auth.: ORS 413.042 & 441.156
Stats. Implemented: ORS 441.156
Hist.: PH 22-2016, f. & cert. ef. 7-1-16

333-510-0120
Nurse Staffing Plan Mediation

(1) If the staffing committee is unable to reach an agreement on the staffing plan, either co-chair of the staffing committee may invoke a waiting period of 30 business days.

(a) During the 30-day waiting period, the staffing committee shall continue to develop the staffing plan; and

(b) The hospital shall promptly respond to any reasonable requests for data that is related to the impasse and is submitted by either co-chair of the staffing committee.

(2) If at the end of the 30-day waiting period, the staffing committee remains unable to reach an agreement on the staffing plan, one of the staffing committee co-chairs shall notify the Authority of the impasse. This notification shall include:

(a) Documentation that the staffing committee voted on the provision or provisions in question and a deadlock resulted;

(b) Documentation that either co-chair of the staffing committee formally invoked a 30-day waiting period;

(c) Documentation that during the 30-day waiting period, the staffing committee continued to develop the staffing plan including documentation of options the staffing committee considered after invoking the 30-day waiting period;

(d) Documentation of any reasonable requests for data submitted to the hospital by either staffing committee co-chair and the hospital's response, if any; and

(e) Documentation that the staffing committee voted on the provision or provisions in question again after the 30-day waiting period formally ended and another deadlock resulted.

(3) No more than 15 business days after receiving notice of an impasse, the Authority shall assign the staffing committee a mediator to assist the staffing committee in reaching an agreement on the staffing plan.

(a) Mediation shall be consistent with requirements for implementing and reviewing staffing plans set forth in ORS 441.155 and 441.156 and OAR chapter 333 division 510 rules; and

(b) Mediation shall be provided for no more than 90 calendar days.

(4) The Authority may impose civil monetary penalties against a hospital, if the staffing committee is unable to reach an agreement on the staffing plan after 90 days of mediation.

Stat. Auth.: ORS 413.042, 441.154 & 441.175
Stats. Implemented: ORS 441.154
Hist.: PH 22-2016, f. & cert. ef. 7-1-16

333-510-0125
Replacement Nurse Staffing Requirements

(1) A hospital must maintain and post or publish a list of on-call nursing staff that may be contacted to provide qualified replacement or additional nursing staff in the event of a vacancy or unexpected shortage. This list must:

(a) Provide for sufficient replacement nursing staff on a regular basis; and

(b) Be available to the individual who is responsible for obtaining replacement staff during each shift.

(2) When developing and maintaining the on-call list, the hospital must explore all reasonable options for identifying local replacement staff and these efforts must be documented.

(3) When a hospital learns about the need for replacement nursing staff, the hospital must make every reasonable effort to obtain adequate voluntary replacement nursing staff for unfilled hours or shifts before requiring a nursing staff member to work overtime and these efforts must be documented. Reasonable efforts include, but are not limited to:

(a) The hospital seeking replacement nursing staff at the time the vacancy is known; and

(b) The hospital contacting all available resources on its list of on-call nursing staff as described in this rule.

Stat. Auth.: ORS 413.042, 441.155 & 441.166
Stats. Implemented: ORS 441.155 & 441.166
Hist.: PH 22-2016, f. & cert. ef. 7-1-16

333-510-0130
Nursing Staff Member Overtime

(1) For purposes of this rule "require" means to make compulsory as a condition of employment whether as a result of a previously scheduled shift or hours actually worked during time spent on call or on standby.

(2) A hospital may not require a nursing staff member to work:

(a) Beyond the agreed-upon and prearranged shift, regardless of the length of the shift;

(b) More than 48 hours in any hospital-defined work week;

(c) More than 12 hours in a 24-hour period;

(d) During the 10-hour period immediately following the 12th hour worked during a 24-hour period. This work period begins when the nursing staff member begins a shift; or

(e) During the 10-hour period immediately following any agreed-upon and prearranged shift in which the nurse worked more than 12 hours in a 24-hour period.

(3) Time spent by the nursing staff member in required meetings or receiving education or training shall be included as hours worked for the purpose of section (2) of this rule.

(4) Time spent on call or on standby when the nursing staff member is required to be at the hospital shall be included as hours worked for the purpose of section (2) of this rule.

(5) Time spent on call or on standby when the nursing staff member is not required to be at the hospital may not be included as hours worked for the purpose of section (2) of this rule.

(6) Nothing in this rule precludes a nursing staff member from volunteering to work overtime.

(7) A hospital may require an additional hour of work beyond the hours authorized in section (2) of this rule if:

(a) A staff vacancy for the next shift becomes known at the end of the current shift; or

(b) There is a potential harm to an assigned patient if the nursing staff member leaves the assignment or transfers care to another nursing staff member.

(8) Each hospital must have a policy and procedure in place to ensure, at minimum, that:

(a) Mandatory overtime, when required, is documented in writing; and

(b) Mandatory overtime policies and procedures are clearly written, provided to all new nursing staff and readily available to all nursing staff.

(9) If a nursing staff member believes that a hospital unit is engaging in a pattern of requiring direct care nursing staff to work overtime for nonemergency care, the nursing staff member may report that information to the staffing committee. The staffing committee shall consider the information when reviewing the staffing plan as described in OAR 333-510-0115.

(10) The provisions of sections (2) through (8) of this rule do not apply to nursing staff needs:

(a) In the event of a national or state emergency or circumstances requiring the implementation of a facility disaster plan; or

(b) In emergency circumstances that include:

(A) Sudden and unforeseen adverse weather conditions;

(B) An infectious disease epidemic suffered by hospital staff;

(C) Any unforeseen event preventing replacement staff from approaching or entering the premises; or

(D) Unplanned direct care staff vacancies of 20 percent or more of the nursing staff for the next shift hospital-wide at the Oregon State Hospital if, based on the patient census, the Oregon State Hospital determines the number of direct care staff available hospital-wide cannot ensure patient safety.

(11) Nothing in section (10) of this rule relieves the Oregon State Hospital from contacting voluntary replacement staff as described in OAR 333-510-0125 and documenting these contacts.

(12) A registered nurse at a hospital may not place a patient at risk of harm by leaving a patient care assignment during an agreed upon scheduled shift or an agreed-upon extended shift without authorization from the appropriate supervisory personnel as required by the Oregon State Board of Nursing OAR, chapter 851.

(13) Until the Authority defines "other nursing staff" as that term is described in ORS 441.166(1), this rule applies only to "nursing staff member" as that term is defined in these rules.

Stat. Auth.: ORS 413.042, 441.166 & 441.168
Stats. Implemented: ORS 441.155 & 441.165
Hist.: PH 22-2016, f. & cert. ef. 7-1-16; PH 29-2016(Temp), f. & cert. ef. 10-25-16 thru 4-21-17

333-510-0135
Nurse Staffing Plan Waiver

(1) At a hospital's request, the Authority may waive any staffing plan requirement set forth in ORS 441.155 provided that a waiver is necessary to ensure that the hospital is staffed to meet the health care needs of its patients.

(2) All requests for a waiver must:

(a) Be submitted to the Authority in writing;

(b) State the reason or reasons for which the hospital is seeking the waiver;

(c) Explain how the waiver is necessary for the hospital to meet patient health care needs; and

(d) Include verification that the hospital notified the staffing committee of the request for a waiver prior to its submission.

Stat. Auth.: ORS 413.042 & 441.165
Stats. Implemented: ORS 441.155 & 441.165
Hist.: PH 22-2016, f. & cert. ef. 7-1-16

333-510-0140
Nurse Staffing Plan During an Emergency

(1) A hospital is not required to follow the staffing plan developed and approved by the staffing committee in the event of:

(a) A national or state emergency requiring the implementation of a facility disaster plan;

(b) Sudden and unforeseen adverse weather conditions; or

(c) An infectious disease epidemic suffered by hospital staff.

(2) In the event of an emergency circumstance not described in section (1) of this rule, either co-chair of the staffing committee may specify a time and place to meet to review and potentially modify the staffing plan in response to the emergency circumstance.

Stat. Auth.: ORS 413.042 & 441.165
Stats. Implemented: ORS 441.155 & 441.165
Hist.: PH 22-2016, f. & cert. ef. 7-1-16

DIVISION 515

HOSPITAL ENVIRONMENTAL AND MAINTENANCE SERVICES

333-515-0001
Applicability

These rules apply to all hospitals, regardless of classification.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055 & 442.015
Hist.: HD 21-1993, f. & cert. ef. 10-28-93; PH 11-2009, f. & cert. ef. 10-1-09

333-515-0005
Sterilization of Instruments, Equipment and Supplies

(1) After the discharge of any patient, the bed, bed furnishings, bedside furniture, bed pans, urinals, wash basins, denture cups, drinking glasses, or any similar utensil or piece of equipment used by a patient shall be thoroughly cleaned and disinfected prior to reuse, or disposed of properly. Mattresses shall be professionally renovated when necessary.

(2) Single patient use equipment must be labeled with patient name and room number when the equipment is used in a multi-bed room.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055 & 442.015
Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0174; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-072-0020; HD 21-1993, f. & cert. ef. 10-28-93, Renumbered from 333-515-0000; HD 2-2000, f. & cert. ef. 2-15-00; PH 11-2009, f. & cert. ef. 10-1-09

333-515-0020
Sanitary Precautions

(1) Provision shall be made for the proper cleaning of linen and other washable goods and proper disposal of all refuse.

(2) All garbage and refuse shall be stored and disposed of in a manner that will not create a nuisance or a public health hazard. Infectious waste shall be stored and disposed of in accordance with OAR chapter 333, division 56.

(3) Measures shall be taken to prevent the entry of rodents, flies, mosquitoes, and other insects. Adequate measures shall include but are not limited to preventing their entry through doors, windows, or other outside openings.

(4) The walls and floors shall be of a durable and cleanable composition necessary to maintain a sanitary environment appropriate to the use of the area. The building shall be kept clean and in good repair.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055 & 442.015
Hist.: HB 183, f. & ef. 5-26-66; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0182; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-072-0040; HD 21-1993, f. & cert. ef. 10-28-93; HD 2-2000, f. & cert. ef. 2-15-00; PH 11-2009, f. & cert. ef. 10-1-09

333-515-0030
Safety and Emergency Precautions

(1) A hospital shall:

(a) Have a physical plant and overall hospital environment that is developed and maintained in such a manner that the safety and well-being of patients are provided for.

(b) Have telephone or another communication method to summon help in case of fire or other emergency.

(c) Comply with ORS chapter 479, its implementing rules, and all other requirements of the State Fire Marshal.

(d) Have emergency power facilities that are tested monthly and are in readiness at all times for use in the delivery, operating and emergency rooms, nurseries and other areas as required in NFPA 99 and the National Electrical Code.

(2) In collaboration with local emergency medical services, a hospital shall develop, maintain, update, train, and exercise an emergency plan for the protection of all individuals in the event of an emergency, in accordance with OAR chapter 837, division 040.

(a) A hospital shall conduct at least two drills every year to demonstrate that employees have practiced their specific duties and assignments, as outlined in the emergency preparedness plan. A hospital shall document the drills.

(b) An emergency plan shall:

(A) Include the contact information for the hospital's local emergency management.

(B) Address all applicable hazards that may include, but are not limited to, the following:

(i) Chemical emergencies;

(ii) Dam failure;

(iii) Earthquakes;

(iv) Fire;

(v) Flood;

(vi) Hazardous material;

(vii) Heat;

(viii) Hurricane;

(ix) Landslide;

(x) Nuclear power plant emergency;

(xi) Pandemic;

(xii) Terrorism; or

(xiii) Thunderstorms.

(C) Address the provision of sufficient supplies for patients and staff to shelter in place for a minimum of four days under the following conditions:

(i) Extended power outage;

(ii) No running water;

(iii) Replacement of food or supplies is unavailable; and

(iv) Staff members do not report to work as scheduled.

(D) Address evacuation, including:

(i) Identification of individual positions' duties while vacating the building, transporting, and housing residents;

(ii) Method and source of transportation;

(iii) Planned relocation sites;

(iv) Method by which each patient will be identified by name and facility of origin by people unknown to them;

(v) Method for tracking and reporting the physical location of specific patients until a different entity resumes responsibility for the resident; and

(vi) Notification to the Division about the status of the evacuation.

(E) Address the clinical and medical needs of the patients, including provisions to provide:

(i) Storage of and continued access to medical records necessary to obtain care and treatment of patients, and the use of paper forms to be used for the transfer of care or to maintain care on-site when electronic systems are not available;

(ii) Continued access to pharmaceuticals, medical supplies and equipment, even during and after an evacuation; and

(iii) Alternative staffing plans to meet the needs of the patients when scheduled staff members are unavailable. Alternative staffing plans may include, but are not limited to, on-call staff, the use of travelers, the use of management staff, or the use of other emergency personnel.

(c) A hospital shall ensure that its emergency plan is available to Division staff during licensing and certification surveys.

(d) A hospital shall re-evaluate and revise its emergency plan as necessary or when there is a significant change in the facility or population of the hospital.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 441.025

Stats. Implemented: ORS 441.025

Hist. HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0186; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-072-0045; HD 21-1993, f. & cert. ef. 10-28-93; PH 13-2008, f. & cert. ef. 8-15-08; PH 11-2009, f. & cert. ef. 10-1-09; PH 7-2016, f. & cert. ef. 2-24-16

333-515-0040
Smoking Prohibition

(1) The administrator or person in charge of the hospital may not permit a person to smoke tobacco:

(a) In the hospital; or

(b) Within 10 feet of a doorway, open window or ventilation intake of the hospital.

(2) A hospital shall comply with ORS 433.835 through 433.875 and its implementing rules, OAR 333-015.

Stat. Auth.: ORS 441.815

Stats. Implemented: ORS 441.815

Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HB 252, f. 7-22-70, ef. 8-25-70; HD 25, f. 10-20-72, ef. 11-1-72; HD 72, f. 11-7-74, ef. 12-11-74; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0126; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-072-0005(5); PH 11-2009, f. & cert. ef. 10-1-09

DIVISION 520

HOSPITALS, GENERALLY

Hospital Services

333-520-0000
Applicability

Whether a hospital is required to provide a service listed in this division depends on a hospital's classification, as those classifications are described in OAR 333-500-0032. If a hospital chooses to provide a service that is not required it shall comply with the applicable rule in this division.

Stat. Auth.: ORS 441.055 & 442.015

Stats. Implemented: ORS 441.055 & 442.015

Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HB 252, f. 7-22-70, ef. 8-25-70; HD 25, f. 10-20-72, ef. 11-1-72; HD 72, f. 11-7-74, ef. 12-11-74; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0126; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-072-0005(1) & (2); HD 21-1993, f. & cert. ef. 10-28-93; PH 11-2009, f. & cert. ef. 10-1-09

333-520-0020
Dietary Services

(1) All hospitals, regardless of classification, shall comply with this rule.

(2) A hospital shall:

(a) Have an organized dietary department, directed by qualified personnel, that conforms to the requirements in OAR 333-150-0000, the Food Sanitation Rules.

(b) Employ supportive personnel competent to carry out the functions of the dietary service, including a full-time director with overall supervisory responsibility for the dietary service and who is:

(A) A qualified dietitian who is registered by the Commission on Dietetic Registration of the Academy of Nutrition and Dietetics;

(B) A person who has received a baccalaureate or higher degree with major studies in food, nutrition, diet therapy or food service management and has at least one year of supervisory experience in a health care dietetic service, and participates in continuing education related to the dietetic profession;

(C) A graduate of a dietetic technician or dietetic assistant training program, corresponding or classroom, approved by the Academy of Nutrition and Dietetics;

(D) A graduate of a state approved course that provides 90 or more hours of classroom instruction in food service supervision and has one year's experience as a supervisor in a health care institution; or

(E) Has training and experience in food service supervision and management in a military service equivalent in content to one of the above criteria for qualifying.

(c) Contract with a dietician with the qualifications listed in paragraph (2)(b)(A) of this rule, if the Director is not a qualified dietitian under paragraph (2)(b)(A) of this rule, and:

(A) Consult at least quarterly with the contractor;

(B) Have on file a contract signed by the consultant and the hospital administrator stating the relationship of the consultant to

the hospital, services to be provided, length of contract, terms and hours; and

(C) Require the contractor to submit quarterly reports to the hospital administrator and the committee, council or other reviewing body designated by the hospital as having responsibility for dietary services that include:

(i) The date(s) of visit(s) and length of time spent on premises;

(ii) Staff members seen;

(iii) Services performed;

(iv) Action taken on previous reports;

(v) Problems identified; and

(vi) Recommended action and distribution of the report.

(d) Require the on-site visits of the Consulting Dietitian to be of sufficient duration and frequency to review dietetic systems and assure quality food to the patient.

(e) Provide dietetic services to patients in accordance with a written order by the responsible physician, or other health care practitioner authorized within the scope of his or her professional license, and record appropriate dietetic information in the patient's medical record including the following:

(A) Timely and periodic assessments of the patient's nutrient intake and tolerance to the prescribed diet modification, including the effect of the patient's appetite and food habits on food intake;

(B) A description of the diet instructions given to the patient or family and assessment of their diet knowledge;

(C) A description or copy of the diet information forwarded to another institution upon patient discharge; and

(D) Nutritional care follow-up with the patient's health care practitioner or a health care agency.

(f) Regularly review and evaluate the quality and appropriateness of nutritional care provided by the dietetic service including the nutritional adequacy of all menus.

(g) Ensure that the Dietetic Service is represented on hospital committees concerned with nutritional care.

(h) Serve food that has an appetizing appearance, is palatable, is served at proper temperature and is cooked and served in such a way as to retain the nutrient value of food.

(i) Restrict admittance to the kitchen area to those who must enter to perform assigned duties.

(j) Develop written procedures for cleaning equipment and work areas and enforce those procedures.

Stat. Auth.: ORS 441.02

Stats. Implemented: ORS 441.025

Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HB 252, f. 7-22-70, ef. 8-25-70; HD 25, f. 10-20-72, ef. 11-1-72; HD 72, f. 11-7-74, ef. 12-11-74; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0126; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-072-0005(7); HD 21-1993, f. & cert. ef. 10-28-93; HD 2-2000, f. & cert. ef. 2-15-00; PH 11-2009, f. & cert. ef. 10-1-09; PH 7-2016, f. & cert. ef. 2-24-16

333-520-0030
Laboratory Services

(1) All hospitals, regardless of classification, are required to comply with this rule.

(2) A hospital shall:

(a) Have on-site or use a licensed clinical laboratory that meets the requirements of ORS 438.010 through 438.510 and OAR 333-024; or has been issued a valid certificate from the federal government under the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88), and that provides timely laboratory services to support a hospital's medical, surgical and other services.

(b) Have on staff or under contract a clinical pathologist to oversee clinical laboratory testing including pathology services.

(c) Have appropriately trained laboratory staff on-site or on-call 24 hours a day, 7 days a week (24/7).

(3) If a hospital performs clinical laboratory testing at point of care, the requirements of subsection (2)(a) of this rule shall be met and the hospital shall:

(a) Have a written policy for point of care testing that is reviewed by a committee, council or other reviewing body designated by the hospital as having responsibility for laboratory services;

(b) Designate a person responsible for the direction and supervision of this testing;

(c) Assure that in addition to manufacturers instructions there are procedures to cover specimen collection and preservation;

(d) Maintain documentation of staff specific orientation, training, and ongoing competency for two years; and

(e) Maintain documentation of instrument calibration, quality control records and preventative maintenance for two years.

(4) Blood banking transfusion records shall be maintained and kept for 20 years.

Stat. Auth.: ORS 441.055

Stats. Implemented: ORS 441.055 & 442.015

Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HB 252, f. 7-22-70, ef. 8-25-70; HD 25, f. 10-20-72, ef. 11-1-72; HD 72, f. 11-7-74, ef. 12-11-74; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0126; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-072-0005(8); HD 21-1993, f. & cert. ef. 10-28-93; PH 11-2009, f. & cert. ef. 10-1-09

333-520-0035
Pharmacy Services

(1) A general hospital is required to have an on site pharmacy and a pharmacist on call 24/7 to staff the pharmacy.

(2) Low occupancy acute care hospitals and mental or psychiatric hospitals may have an on-site pharmacy or a drug room.

(3) Low occupancy acute care hospitals and mental or psychiatric hospitals shall have appropriately trained pharmacy staff on-site or on-call 24/7.

(4) A pharmacy in a hospital shall comply with the applicable requirements in ORS Chapter 689 and OAR chapter 855, including 855-041-0120 through 855-041-0132.

(5) A drug room in a hospital shall comply with the applicable requirements in ORS Chapter 689 and OAR 855-041-0135 through 855-041-0140.

(6) All hospitals, regardless of classification shall dispose of old medications, including special prescriptions for patients who have left the hospital, by incineration or another equally effective method, except narcotics and other drugs under the drug abuse law, which shall be handled in the manner prescribed by the Drug Enforcement Administration of the U.S. Department of Justice.

Stat. Auth.: ORS 441.055

Stats Implemented: ORS 441.055 & 442.015

Hist.: PH 11-2009, f. & cert. ef. 10-1-09; PH 17-2012, f. 12-20-12, cert. ef. 1-1-13

333-520-0040
Radiology Services

(1) All hospitals, regardless of classification shall have on-site or contract radiology services that:

(a) Comply with ORS Chapter 453 and its applicable implementing rules;

(b) Support the hospital's medical, surgical and other services; and

(c) Are available on a timely basis.

(2) All hospitals, regardless of classification, shall:

(a) Employ or contract with a radiologist to certify the quality and adequacy of all radiology; and

(b) Have on-site or in-house radiology staff available 24/7.

Stat. Auth.: ORS 441.055 & 442.015

Stats. Implemented: ORS 441.055 & 442.015

Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HB 252, f. 7-22-70, ef. 8-25-70; HD 25, f. 10-20-72, ef. 11-1-72; HD 72, f. 11-7-74, ef. 12-11-74; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0126; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-072-0005(9); HD 21-1993, f. & cert. ef. 10-28-93; PH 11-2009, f. & cert. ef. 10-1-09

333-520-0050
Surgery Services

(1) For purposes of this rule:

(a) "Circulating nurse" means a registered nurse who is responsible for coordinating the nursing care and safety needs of the patient in the operating room and who also meets the needs of the operating room team members during surgery.

(b) "Rural or medically underserved community" means a geographic area of Oregon that is 10 or more miles from the geographic center of a population center of 40,000 or more individuals.

(c) "Surgical technology" means intraoperative surgical patient care that involves:

(A) Preparing an operating room for surgical procedures by ensuring that surgical equipment is functioning properly and safely;

(B) Preparing an operating room and the sterile field for surgical procedures by preparing sterile supplies, instruments and equipment using sterile techniques;

(C) Anticipating the needs of a surgical team based on knowledge of human anatomy and pathophysiology and how those fields relate to the surgical patient and the patient's surgical procedure; and

(D) Performing tasks as directed in an operating room, including:

(i) Passing instruments, equipment or supplies;

(ii) Sponging or suctioning of an operative site;

(iii) Preparing and cutting suture material;

(iv) Transferring fluids or drugs;

(v) Handling specimens;

(vi) Holding retractors and other equipment;

(vii) Applying electrocautery to clamps on bleeders;

(viii) Connecting drains to suction apparatus;

(ix) Applying dressings to closed wounds; and

(x) Assisting in counting supplies and instruments, including sponges and needles.

(2) General hospitals are required to comply with this rule. A low occupancy acute care or mental or psychiatric hospital shall comply with this rule if it offers surgery services.

(3) A hospital that provides surgical services shall have operating rooms that conform to the applicable requirements in OAR chapter 333, division 535.

(4) A hospital's operating rooms must be supervised by an experienced registered nurse or doctor of medicine or osteopathy.

(5) The duties of a circulating nurse performed in an operating room of a hospital shall be performed by a registered nurse licensed under ORS 678.010 through 678.410. In all cases requiring anesthesia or conscious sedation, a circulating nurse shall be assigned to, and present in, an operating room for the duration of the surgical procedure unless it becomes necessary for the circulating nurse to leave the operating room as part of the surgical procedure. While assigned to a surgical procedure, a circulating nurse may not be assigned to any other patient or procedure.

(6) Nothing in section (5) precludes a circulating nurse from being relieved during a surgical procedure by another circulating nurse assigned to continue the surgical procedure.

(7) In order for a person to practice surgical technology at a hospital, the hospital's governing body shall ensure that the following provisions are met by the individual:

(a) Documentation showing that the person has completed a training program for surgical technologists in a branch of the armed forces of the United States or in the United States Public Health Service Commissioned Corp and completes 16 hours of continuing education as described in section (11) of this rule every two years; or

(b) Completion of a surgical technology education program accredited by the Commission on Accreditation of Allied Health Education Program (CAAHEP) or the Accrediting Bureau of Health Education Schools (ABHES) and certification as a surgical technologist issued by the National Board of Surgical Technology and Surgical Assisting (NBSTSA); or

(c) Documentation that a person has practiced surgical technology at least two years between January 1, 2014 and January 1, 2017 in a hospital, ambulatory surgical center or as an employee of a federal government agency or institution and completes 16 hours of continuing education as described in section (11) of this rule every two years.

(8) Notwithstanding subsection (7)(b), a hospital may allow a person who is not certified by the NBSTSA to practice surgical technology at the hospital for 12 months after the person completes an educational program accredited by the CAAHEP or ABHES.

(9) A hospital located in a rural or medically underserved community may allow a person to practice surgical technology at the hospital who does not meet the requirements specified in section (7) of this rule until July 1, 2017. After July 1, 2017 a person not meeting the requirements specified in section (7) of this rule may work at a hospital in a rural or medically underserved community while the person is attending an educational program accredited by the CAAHEP or ABHES. Such persons are exempt from these educational requirements for three years from the date on which the person began practicing at the hospital.

(10) These rules do not prohibit a licensed practitioner from performing surgical technology if the practitioner is acting within the scope of the practitioner's license and a hospital allows the practitioner to perform such duties.

(11)(a) The continuing education requirements described in subsections (7)(a) and (7)(c) shall:

(A) Consist of 16 hours every two years;

(B) Be tracked by the surgical technologist and is subject to audit by the hospital in which the person is practicing; and

(C) Be relevant to the medical-surgical practice of surgical technology.

(b) Continuing education may include but is not limited to:

(A) Continuing education credits approved by the Association for Surgical Technologist;

(B) Healthcare sponsored conferences, forums, seminars, symposiums or workshops;

(C) Online distance learning courses;

(D) Live lectures at national conferences; or

(E) College courses.

(12) A hospital shall conduct a random audit of a representative sample of the surgical technologists employed by the hospital every two years to verify compliance with educational requirements.

(13) The requirements identified in section (7), (8) and (10) through (12) of this rule become effective on July 1, 2016.

Stat. Auth.: ORS 441.025 & ORS 676.890

Stats. Implemented: ORS 441.025, 676.870 – 676.890 & 678.362

Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HB 252, f. 7-22-70, ef. 8-25-70; HD 25, f. 10-20-72, ef. 11-1-72; HD 72, f. 11-7-74, ef. 12-11-74; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0126; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-072-0005(10) & (11); HD 21-1993, f. & cert. ef. 10-28-93; PH 11-2009, f. & cert. ef. 10-1-09; PH 17-2012, f. 12-20-12, cert. ef. 1-1-13; PH 7-2016, f. & cert. ef. 2-24-16

333-520-0060
Maternity Services

(1) General hospitals are required to comply with this rule. A low occupancy acute care hospital shall comply with this rule if it offers maternity services.

(2) A hospital that provides maternity services shall have separate maternity facilities and a maternity care department that:

(a) Has labor, delivery, recovery, postpartum, and nursery rooms that conform to the applicable requirements of OAR chapter 333, division 535;

(b) Requires every person in the delivery room during a delivery to be appropriately attired according to the hospital's Infection Control Policy;

(c) Has appropriate resuscitation equipment immediately available to rooms where deliveries are planned and where newborn infants are kept;

(d) Has a warmed blanket or incubator for newborns to prevent thermal loss;

(e) Has incubators for premature infants equipped with a governor to control the flow of oxygen at 40 percent or under, and an oxygen analyzer;

(f) Has an accurate scale for weighing of infants; and

(g) Includes a nursery and a separate bassinet for each infant with a clean mattress covered with suitable sheeting, washable pads, and bed linen that is kept clean at all times.

(3) A health care practitioner attending the birth of a newborn shall evaluate and treat a newborn at risk for chlamydial or gonococcal ophthalmia neonatorum in accordance with OAR 333-019-0036.

(4) A parent or legal representative that refuses to allow prophylaxis for an infant shall be informed by the attending health care practitioner of the risks of the refusal and must sign a witnessed affidavit that attests they have been so informed and nonetheless refuse to allow prophylaxis.

(5) A hospital shall ensure that all newborns are given Vitamin K at birth as required by ORS 433.303 through 433.314.

(a) A physician or midwife attending the mother at the birth of the child shall be responsible for ensuring that the newborn infant receives Vitamin K within 24 hours of birth to protect the infant against hemorrhagic disease of the newborn.

(b) The Vitamin K forms suitable for use are:

(A) Vitamin K 1 (Phytonadione) for oral or injectable use;

(B) Mephyton for oral use; or

(C) Aquamephyton or konakion for injectable use.

(c) A parent may, after being provided a full and clear explanation, decline to permit the administration of Vitamin K based on religious tenets and practices. If a parent or legal representative declines Vitamin K, the parent shall sign a form acknowledging his or her understanding of the reason for administration of Vitamin K and possible adverse consequences in the presence of a person who witnessed the instruction of the parent, who shall also sign the form. The form shall become a part of the medical record of the newborn infant.

(6) A hospital shall ensure that every newborn infant born in the hospital is tested for Metabolic Diseases as required by OAR 333-024-0210 through 333-024-0235 and instructions to the parents or legal representative regarding the testing that be documented in the medical record.

(7) A hospital shall ensure that every newborn infant born in the hospital receives a Newborn Hearing Screening Test as required by ORS 433.321 and OAR chapter 333, division 20.

(8) A hospital must perform pulse oximetry screening on every newborn infant delivered at the hospital before discharging the newborn infant in conformance with the following requirements:

(a) The pulse oximetry screening must be performed using evidence-based guidelines such as those recommended by Strategies for Implementing Screening for Critical Congenital Heart Disease, AR Kemper et al., Pediatrics 2011;128(5): e1259–1267.

(b) The hospital must have policies and procedures based on the guidelines required by subsection (a) of this section for:

(A) Determining what is considered a positive screening result; and

(B) Determining what follow-up services, treatment, or referrals must be provided if a newborn infant has a positive screening result.

(c) A Federal Drug Administration (FDA) approved motion tolerant pulse oximeter must be used.

(d) The pulse oximetry screening must be performed no sooner than 24 hours after birth or as close to discharge of the newborn infant as possible.

(e) If a newborn infant is admitted to a hospital as the result of a transfer from another hospital or Birthing Center before a pulse oximetry screening is performed, the hospital from which the newborn infant is discharged to home is responsible for performing the screening.

(f) The hospital must provide the following notifications and document them in the newborn infant's medical record:

(A) Prior to the pulse oximetry screening, notify a parent or legal representative of the newborn about the reasons for the screening and the risks and consequences of not screening.

(B) Following the pulse oximetry screening, notify the health care provider responsible for the newborn infant and the infant's primary care provider of the results of the screening.

(C) Following the pulse oximetry screening and prior to discharge, notify a parent or legal representative of the newborn infant of the screening result, an explanation of its meaning and, if it is a positive screening result, provide information about the importance of timely diagnosis and intervention.

(g) A parent or legal representative of a newborn infant may decline pulse oximetry screening and, if screening is declined, the hospital must document the declination in the newborn infant's medical record.

(h) Following the pulse oximetry screening, the hospital, in accordance with the applicable standard of care, must provide any appropriate follow-up services or treatment for the newborn infant if necessary or provide a referral to a parent or legal representative of the newborn for follow-up services or treatment if necessary.

(i) The hospital must document in the newborn infant's medical record that the screening was performed, the screening result, the names of the health care providers who were notified of the screening result, and any follow-up services or treatment or referral for services or treatment.

(j) No newborn infant may be refused screening because of the inability of a parent or legal representative to pay for the screening.

(9) Every infant born in a hospital shall be marked for identification before the infant is removed from the place of delivery and such identification shall not be removed from the infant until the infant is discharged.

(10) A hospital shall not admit visitors to a delivery room, maternity rooms, wards, units, or the nursery except in accordance with the hospital's visiting policy.

(11) A hospital shall ensure that persons entering the nursery are attired according to the hospital infection control policy and that hands are washed before touching an infant.

(12) A hospital shall follow its infection control policy when handling and storing linens.

(13) Formula feedings and any other feedings shall be given only as prescribed in writing by the physician or certified nurse midwife.

(14) A hospital shall maintain and preserve a log of births giving date of birth, name of newborn, and mother's name and chart number, in addition to complying with the requirements of the Authority's Center for Health Statistics.

(15) A hospital may use a part of the maternity department for selected, non-communicable non-obstetrical patients as defined by hospital policy and approved by the hospital's infection control program under the following conditions:

(a) Patients admitted or transferred to the maternity department shall be instructed by appropriate maternity service personnel as to their responsibilities regarding use of the facility.

(b) Patients admitted to the maternity department shall be limited to obstetrical patients admitted for delivery, patients with obstetric complications, and selected non-communicable, non-obstetrical patients.

(c) Obstetrical patients and medical/surgical patients shall not occupy the same room.

(d) If necessary, one or more medical/surgical patients shall be transferred to another service in order to admit obstetrical patients.

(16) A hospital shall adhere strictly to the guidelines for standard precautions developed by the Hospital Infection Control Practices Advisory Committee (HICPAC) when caring for obstetrical patients with infectious conditions. Patients with infectious conditions requiring strict isolation according to the above guidelines shall be transferred out of the maternity department following delivery, and given care in an area of the hospital where that isolation can be provided. If a maternity patient is found to have an infectious condition during surgery or delivery, the patient shall be returned to the maternity department and isolated according to hospital infection control policy.

(17) A delivery room suite may be used for surgical procedures on non-obstetrical patients if approved by the Chief of Obstetrics in accordance with medical staff rules and regulations.

(18) A hospital with maternity services may place stable postpartum patients and stable newborns, as those terms are defined in

OAR 333-500-0010, on another acute care unit on a periodic basis under the following conditions:

(a) When a postpartum patient or newborn to be transferred out of the OB unit meet the hospital's criteria for care on another unit as described in this rule;

(b) Where the decision to place a postpartum patient or newborn on another unit is based on currently accepted postpartum and newborn care standards and the ability of that unit to meet the needs of the patient; and

(c) When nursing staff on the non-OB unit have received training required by this rule and have demonstrated continuing competence.

(19) A hospital that provides care to postpartum patients and newborns on non-OB units shall:

(a) Develop and implement policies and procedures that include but are not limited to:

(A) The transfer of postpartum patients and newborns to non-OB units including a delineation of the authority for medical, clinical and administrative nursing staff, and, when applicable, nurse practitioner staff to make the decision;

(B) Staffing guidelines for the nursing care of postpartum patients and newborns on the non-OB unit;

(C) Provision of information to maternity patients of possible or intended placement on a non-OB unit;

(D) Provision of consumer information related to the availability and location of specialty maternity services;

(E) Infection control practices including the use of standard precautions;

(F) Procedures for patient placement, privacy, and safety that prohibit postpartum patients and newborns from occupying the same room as non-obstetrical patients;

(G) Protocols for the placement of newborns without mothers;

(H) Procedures to assure the inclusion of the care of postpartum patients and newborns on non-OB units in the hospital's quality assurance program; and

(I) Delineation of hospital protocols for the return of postpartum patients and newborns to the OB unit, including addressing situations when safe care can no longer be provided on the non-OB unit.

(b) Develop and implement staff training, continuing education, and continuing competency program that includes but is not limited to:

(A) Postpartum nursing care;

(B) Nursing care of the newborn;

(C) Newborn resuscitation;

(D) Newborn feeding;

(E) Maternal and family education;

(F) Infection control practices including the use of standard precautions; and

(G) Maternity services policies and procedures including those required in subsection (19)(a) of this rule.

Stat. Auth.: ORS 441.055

Stats. Implemented: ORS 441.055 & 442.015

Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HB 252, f. 7-22-70, ef. 8-25-70; HD 25, f. 10-20-72, ef. 11-1-72; HD 72, f. 11-7-74, ef. 12-11-74; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0126; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-072-0005(12), (13), & (14); HD 21-1993, f. & cert. ef. 10-28-93; HD 30-1994, f. & cert. ef. 12-13-94; HD 2-2000, f. & cert. ef. 2-15-00; OHD 3-2001, f. & cert. ef. 3-16-01; PH 11-2009, f. & cert. ef. 10-1-09; PH 17-2012, f. 12-20-12, cert. ef. 1-1-13; PH 18-2013(Temp), f. 12-31-13, cert. ef. 1-1-14 thru 6-29-14; PH 18-2014, f. & cert. ef. 6-17-14

333-520-0070
Emergency Department and Emergency Services

(1) Hospitals classified as general and low occupancy acute care shall have an emergency department that provides emergency services.

(2) A hospital with an emergency department shall:

(a) Provide emergency services 24 hours a day including providing immediate life saving intervention, resuscitation, and stabilization;

(b) Have a licensed health care practitioner with admitting privileges on-call, 24 hours a day;

(c) Have at least one registered nurse, appropriately trained to provide emergency care within the emergency service area;

(d) Have adequate medical staff and other ancillary personnel necessary to provide emergency care either present in the emergency service area or available 24 hours a day in adequate numbers to respond promptly;

(e) Ensure that when surgical, laboratory, and X-ray procedures are indicated and ordered, due regard is given to promptness in carrying them out;

(f) Ensure that it has items for resuscitation, stabilization, and basic emergency medical care, including airway equipment and cardiac resuscitation medications and supplies for adults, children and infants;

(g) Have a communication system and personnel available 24 hours a day to ensure rapid communication with ambulances and departments of the hospital including, but not limited to, X-ray, laboratory, and surgery;

(h) Have a plan for emergency care based on community needs and on hospital capabilities which sets forth policies, procedures and protocols for prompt assessment, treatment and transfer of ill or injured persons, including specifying the response time permissible for medical staff and other ancillary personnel;

(i) Provide for the prompt transfer of patients, as necessary, to an appropriate facility in accordance with transfer agreements, approved trauma system plans, consideration of patient choice, and consent of the receiving facility;

(j) Have written transfer agreements for the care of injured or ill persons if the hospital does not provide the type of care needed;

(k) Ensure that personnel are able to provide prompt and appropriate instruction to ambulance personnel regarding triage, treatment and transportation;

(l) Develop, maintain, and implement current written policies and procedure that include clearly-defined roles, responsibilities, and reporting lines for emergency service personnel;

(m) Maintain emergency records in accordance with OAR 333-505-0050;

(n) Establish a committee of the emergency department staff who shall at least quarterly, review emergency services by evaluating the quality of emergency medical care given, and engage in ongoing development, implementation, and follow-up on corrective action plans; and

(o) Ensure it provides appropriate training programs for hospital emergency service personnel.

(3) If a hospital is also designated or categorized as a trauma hospital under ORS 431.607 through 431.671, the hospital shall:

(a) Comply with the applicable provisions in OAR chapter 333, division 200 through 205;

(b) Report trauma data to the State Trauma Registry in accordance with the requirements of the Division; and

(c) Fully cooperate with the approved area trauma system plan.

(4) An officer or employee of a general or low occupancy acute care hospital licensed by the Division may not deny a person an appropriate medical screening examination needed to determine whether the person is in need of emergency medical services if the screening is within the capability of the hospital, including ancillary services routinely available to the emergency department.

(5) An officer or employee of any hospital licensed by the Division may not deny services to a person diagnosed by a physician as being in need of emergency medical services because the person is unable to establish the ability to pay for the services if those emergency medical services are customarily provided at the hospital.

(6) A mental or psychiatric hospital shall assess and provide initial treatment to a person that presents to the hospital with an emergency medical condition, as that term is defined in 42 CFR 489.24. The hospital shall admit the person if the emergency medical condition falls within the specialty services provided by the hospital under OAR chapter 333, division 525.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055 & 442.015
Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HB 252, f. 7-22-70, ef. 8-25-70; HD 25, f. 10-20-72, ef. 11-1-72; HD 72, f. 11-7-74, ef. 12-11-74; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0126; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-072-0005(15) & (16); HD 21-1993, f. & cert. ef. 10-28-93; HD 2-2000, f. & cert. ef. 2-15-00; PH 11-2009, f. & cert. ef. 10-1-09; PH 17-2012, f. 12-20-12, cert. ef. 1-1-13

333-520-0075
Respite Care

(1) A general hospital or low occupancy acute care hospital may provide respite services.

(2) Application for permission to accept respite care guests shall be made to the Division on a form provided by the Division.

(3) The Division may grant permission for a hospital to accept respite care guests if:

(a) Admittance of a respite care patient will not interfere with the care to be provided to other patients.

(b) The hospital has written policies that address respite care services that are evaluated annually, and are implemented and followed by hospital staff. These policies shall address:

(A) Type(s) of guests who may be admitted;

(B) Scope of services provided;

(C) Length of stay (which shall not exceed 30 consecutive days);

(D) Emergency care provisions;

(E) Written criteria delineating situations which necessitate physician contact;

(F) Written criteria delineating situations which necessitate family or personal representative contact; and

(G) Written criteria for administration and storage of medications.

(4) Sufficient physical space shall be provided for respite care guests for dining and activities. Space shall allow for mobility and exercise. Respite care areas shall provide for bathing and toileting facilities. Each respite care guest shall have an assigned licensed bed and storage area for personal belongings. Regular acute care licensed beds may be utilized for respite care guests; however, respite care guests shall not share a room with acute care patients. Activities which are suitable to the needs of respite care guests shall be provided.

(5) Respite care guest records:

(a) There shall be available for each respite care guest an admission summary form containing the guest's name, address, telephone number, and other demographic data including the name, address, and telephone number of attending qualified member of the medical staff and nearest relative or personal representative.

(b) The guest record shall include admission evaluation, medication administration record, flow sheets, assessments, and progress notes as required by paragraph (7)(d)(C) of this rule.

(6) Medical supervision:

(a) The name and telephone number of the guest's physician or other qualified member of the medical staff shall be readily available to respite care staff members.

(b) A qualified health care practitioner order shall not be required for admission to respite care.

(c) An order from a qualified health care practitioner authorized by law shall be required for any new medications or treatments.

(7) Registered nurse (RN) supervision:

(a) Respite care services shall be supervised by an RN.

(b) The RN shall review the guest's medications and usual diet and verify information within four hours of admission. Documented intake information shall include, but not be limited to, current medications, dietary needs, level of ability for assisted or self-care, and any other information germane to the guest's condition. The RN shall document an evaluation of the guest's need on admission.

(c) If the respite care guest stays seven days or more, a nursing assessment shall be performed and documented by the RN on the eighth day and weekly thereafter. If the respite care guest is initially planning to stay for seven or more days, a nursing assessment shall be performed and documented by an RN on admission and weekly thereafter.

(d) In addition to the documentation required in subsections (7)(b) and (c) of this rule, the hospital shall maintain:

(A) Activities of daily living (ADL) sheet by shift;

(B) Medication administration record; and

(C) Weekly progress notes by caregivers.

(8) Medication administration:

(a) Respite care guests taking medication prescribed by their physicians or other qualified health care practitioners may bring such medications in the original containers to the facility. All prescription medications brought in by guests shall be verified by a pharmacist prior to administration.

(b) All medications shall be clearly labeled with the name of the medication, strength/dose, directions for administration, expiration date, and guest's name.

(c) No outdated medication shall be administered.

(d) Any change or alteration in medication shall require an order from a health care practitioner authorized by law.

(e) Medications may be independently self-administered, self-administered under supervision of an RN/LPN, or administered by an RN, LPN, or certified medication aide, depending on the guest's ability. The type of administration shall be determined by the RN. This determination shall be in writing. Medications administered and the type of administration shall be documented on medication administration records.

(9) Quality assurance:

(a) Respite care services shall be included in the hospital-wide quality assurance program.

(b) A mechanism for quality assurance activities shall be defined and implemented.

(c) There shall be documentation of ongoing quality assurance activities.

(d) Quality assurance activities shall be reported to the hospital committee, council, or other reviewing body designated by the hospital as having responsibility for quality assurance.

(10) Nothing in this rule shall be interpreted for creating any obligations for third party payors to reimburse hospital respite care.

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055 & 442.015
Hist.: HD 21-1993, f. & cert. ef. 10-28-93; HD 2-2000, f. & cert. ef. 2-15-00; PH 11-2009, f. & cert. ef. 10-1-09

333-520-0120
Psychiatric Services

A hospital classified as mental or psychiatric or a general or low occupancy acute care hospital that provides inpatient psychiatric services and has an inpatient psychiatric unit shall comply with OAR 333-525-0000(2) through (10).

Stat. Auth.: ORS 441.055
Stats. Implemented: ORS 441.055 & 442.015
Hist.: PH 11-2009, f. & cert. ef. 10-1-09

DIVISION 525

SPECIALTY HOSPITALS

333-525-0000
Mental or Psychiatric Hospital

A hospital classified as mental or psychiatric shall:

(1) Be devoted primarily to the diagnosis and treatment of mentally ill persons.

(2) Have adequate numbers of qualified professional and supportive staff to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures, and engage in discharge planning, including:

(a) A clinical director, service chief, or equivalent who:

(A) Is qualified to provide the leadership required for an intensive treatment program;

(B) Meets the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry;

(C) Monitors and evaluates the quality and appropriateness of services and treatment provided by the medical staff; and

(D) Supervises inpatient psychiatric services.

(b) Doctors of medicine or osteopathy and other appropriate professional personnel available to provide necessary medical and surgical diagnostic and treatment services. If medical and surgical diagnostic and treatment services are not available within the hospital, the hospital must have an agreement with an outside source of these services to ensure that they are immediately available or a satisfactory agreement must be established for transferring patients to a licensed hospital.

(c) A director of psychiatric nursing services who:

(A) Is a registered nurse with a master's degree in psychiatric or mental health nursing, or its equivalent from a school of nursing accredited by the National League for Nursing Accrediting Commission, or the Commission on Collegiate Nursing Education, or is qualified by education and experience in the care of the mentally ill; and

(B) Demonstrates competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.

(d) Registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each patient's active treatment program and to maintain progress notes on each patient.

(e) The availability of a registered professional nurse 24 hours each day.

(f) The availability of staff to provide other psychological services to meet the needs of the patients.

(g) A director of social services who:

(A) Has a master's degree from an accredited school of social work or is qualified by education and experience in the social services needs of the mentally ill; and

(B) Monitors and evaluates the quality and appropriateness of social services furnished.

(h) At least one staff member with a master's degree in social work if the director of social services does not have such a degree.

(i) Social service staff with responsibilities that include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital.

(j) Qualified therapists, support personnel, and consultants adequate to provide comprehensive therapeutic activities consistent with each patient's active treatment program.

(k) In a satellite as defined in OAR 333-500-0010(46)(b), the prompt availability of at least one psychiatrist to provide emergency psychiatric services or other psychiatric services to meet the needs of the patients 24 hours each day in person or using telemedicine technology.

(3) Have a therapeutic activities program that is appropriate to the needs and interests of patients and directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

(4) Maintain medical records in a manner that permits determination of the degree and intensity of the treatment provided to individuals who are furnished services in the institution. Medical records shall stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized. A patient's medical record shall include:

(a) The patient's legal status;

(b) The provisional or admitting diagnosis, including the diagnoses of intercurrent diseases as well as the psychiatric diagnoses;

(c) The reasons for admission as stated by the patient or others significantly involved;

(d) The social service records, including reports of interviews with patients, family members, and others, including an assessment of home plans and family attitudes, and community resource contacts as well as a social history;

(e) When indicated, a complete neurological examination recorded at the time of the admission physical examination;

(f) Documentation of all active therapeutic efforts; and

(g) A discharge summary that includes a recapitulation of the patient's hospitalization and recommendations from appropriate services concerning follow-up or aftercare, as well as a brief summary of the patient's condition on discharge.

(5) Have a psychiatrist perform a psychiatric evaluation of each patient that:

(a) Is completed within 60 hours of admission;

(b) Includes a medical history;

(c) Contains a record of mental status;

(d) Notes the onset of illness and the circumstances leading to admission;

(e) Describes attitudes and behavior;

(f) Estimates intellectual functioning, memory functioning, and orientation; and

(g) Includes an inventory of the patient's assets in descriptive, not interpretative, fashion.

(6) Develop a written individual comprehensive treatment plan that is based on an inventory of the patient's strengths and disabilities that includes:

(a) A substantiated diagnosis;

(b) Short-term and long-range goals;

(c) The specific treatment modalities utilized;

(d) The responsibilities of each member of the treatment team; and

(e) Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.

(7) Ensure that progress notes are recorded by:

(a) The doctor of medicine or osteopathy responsible for the care of the patient; and

(b) Nurses, social workers and, when appropriate, others significantly involved in active treatment modalities.

(8) The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first two months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan.

(9) Provide discharge planning in accordance with OAR 333-505-0030.

(10) Comply with the applicable rules of the Authority's Health Systems Division, Mental Health Services, OAR chapter 309, divisions 31 and 33.

Stat. Auth.: ORS 441.025

Stats. Implemented: ORS 441.025

Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 17(Temp), f. & ef. 6-19-72; HD 18, f. 7-31-72, ef. 8-15-72; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0138; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-073-0000; HD 21-1993, f. & cert. ef. 10-28-93; PH 11-2009, f. & cert. ef. 10-1-09; PH 5-2015, f. & cert. ef. 2-6-15; PH 7-2016, f. & cert. ef. 2-24-16

DIVISION 535

NEW CONSTRUCTION AND ALTERATIONS OF EXISTING HOSPITALS

Building Requirements for General Hospitals

333-535-0000
Applicability

OAR 333-535-0000 through 333-535-0310 shall apply to all hospitals not licensed or for which plans have not been approved on the effective date of these rules for major alterations and new construction. Major alteration has the meaning given that term in OAR 333-500-0010.

Stat. Auth.: ORS 441.060

Stats. Implemented: ORS 441.060

Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 7-1979, f. & ef. 7-017-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200; HD

29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-074-0200; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0001
Referenced Codes and Standards

(1) The codes and standards referenced in these rules shall be considered part of the requirements of these rules to the prescribed extent of each such reference. Where differences occur between provisions of these rules and referenced codes and standards, the provisions of the most restrictive code shall apply.

(a) 2007 Oregon Structural Specialty Code.

(b) 2007 Oregon Mechanical Specialty Code.

(c) 2008 Oregon Electrical Specialty Code.

(d) 2008 Oregon Plumbing Specialty Code.

(e) 2007 Oregon Fire Code.

(f) National Fire Protection Association, NFPA 101 Life Safety Code, 2000 Edition.

(g) National Fire Protection Association, NFPA 99 Standard for Healthcare Facilities, 1999 Edition.

(h) National Fire Protection Association, NFPA 110 Standard for Emergency and Standby Power Systems, 2002 Edition.

(i) National Fire Protection Association, NFPA 90A Standard for Installation of Air-Conditioning and Ventilating Systems, 1996 Edition.

(j) National Fire Protection Association, NFPA 96 Standard for Ventilation Control and Fire Protection of Commercial Cooking, 2008 Edition.

(k) National Fire Protection Association, NFPA 255 Standard Method of Test of Surface Burning Characteristics of Building Materials, 2000 Edition.

(l) National Fire Protection Association, NFPA 801 Standard for Fire Protection for Facilities Handling Radioactive Materials, 1998 Edition OSHA and radiology.

(m) Illuminating Engineering Society, IES RP 28, 2007 Edition.

(n) Illuminating Engineering Society, IES RP 29, 2006 Edition with Errata.

(o) American National Standards Institute/ American Society of Sanitary Engineering, ANSI/ASSE 6000, 2004 edition.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: PH 10-2009, f. & cert. ef. 10-1-09

333-535-0010
General Rules

(1) When conditions make certain changes to existing institutions impractical to accomplish, minor variations from these requirements (other than fire and life safety requirements) may be permitted if the intent of the requirement is met, the care and safety of patients will not be jeopardized, and with written approval of the Oregon Health Authority, Public Health Division (Division). (Refer to OAR 333-500-0065.)

(2) Sizes: The sizes of various departments will depend upon program requirements and organization of services within the hospital. Some functions requiring separate spaces or rooms in these minimum requirements may be combined, provided that the resulting plans will not compromise the best standards of safety and of medical and nursing practices, and with written approval of the Division.

(3) Conflicts of requirements: Certain projects may be subject to the regulations of several different federal, state and local agencies. Should a difference in requirements occur, the more stringent requirement shall be applied. In cases of conflicting or opposing regulations, the problem shall be directed to the responsible programs for resolution.

(4) All departmental requirements included in these rules are not necessarily applicable to all institutions. Each service element provided in the hospital must, however, comply with requirements found herein.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68: HD 7-1979, f. & ef. 7-17-79: HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(1); HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-074-0205; HD 2-2000, f. & cert. ef. 2-15-00; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0025
Medical/Surgical Patient Care Unit

Except as permitted under OAR 333-535-0010(1) or 333-500-0065, each patient care unit shall include the following:

(1) Patient rooms. Each patient room shall meet the following requirements:

(a) For new construction projects, maximum room capacity shall be two patients. For major alteration projects, the maximum room capacity shall be the present capacity or four patients, whichever is less.

(b) For new construction, patient rooms shall be constructed to meet the needs of the Functional Program and shall have a minimum of 100 square feet of clear floor area per bed in multiple bedrooms and 120 square feet of clear floor area in single patient rooms, exclusive of toilet rooms, closets, lockers, wardrobes, alcoves, or vestibules. The dimensions and arrangements of rooms shall be such that there is a minimum clearance of 3 feet around the perimeter of the bed and any wall or any other fixed obstruction. In multiple bedrooms, a clearance of 4 feet shall be available at the foot of each bed to permit the passage of equipment and beds, and 4 feet shall be provided between beds. Minor encroachments, including columns and hand washing stations, that do not interfere with function may be ignored when calculating required space. For renovation projects, every effort shall be made to meet the requirement set out in this subsection for new construction. However, if full compliance is not practical for a renovation project, the Division may permit deviations from these requirements as long as patient rooms include at least 80 net square feet of clear floor area per bed in a multiple bedroom and 100 net square feet of clear floor area in a single patient room.

(c) Patient room windows:

(A) Operable windows are not required in patient rooms. If operable windows are provided, operable sections shall be designed to inhibit possible escape or suicide attempt.

(B) A minimum window area of 16 square feet shall be provided for each patient room. The maximum sill height shall be 3 feet above the finished floor. A minimum of 8 square feet of window shall be viewable by the patient from the bed. Walls and other non-moveable items shall not block the view of the window.

(C) Windows located in outside walls shall be 20 feet or more from another building or opposite wall and 10 feet or more from the property line except when the window faces on a street or public right of way of greater than 20 feet in width.

(D) For renovation projects where the exterior wall is being retained, windows shall be permitted to vary from the requirements of this subsection if approved by the Division.

(d) Hand-washing stations: A hand-washing station shall be provided serving each patient room. A hand-washing station shall also be located in each patient toilet room. For new construction, the patient room hand-washing station shall be located within the room and shall be situated for convenient access by staff and to prevent splash on patients. For renovation projects involving single patient rooms that have a private toilet room, a hand-washing station shall be located in either the toilet room or the patient room. Hand-washing stations shall comply with the requirements of OAR 333-535-0260.

(e) Patient toilet rooms: Each patient shall have access to a toilet room without having to enter the corridor. One toilet room shall serve no more than four beds and no more than two patient rooms. The toilet room shall contain a toilet, hand-washing station, and bathing facilities. Patient toilet rooms and central bathing facilities shall comply with the requirements of OAR 333-535-0260.

(f) Each patient shall have a separate wardrobe, locker, or closet suitable for hanging full-length garments and for storing personal effects within the room.

(g) Visual privacy from casual observation by other patients and visitors shall be provided for each patient. The design for privacy shall not restrict patient access to the entrance, hand-washing station, toilet, or nurse call system.

(2) Service areas. Provision for the services listed below shall be in or readily available to each patient care unit. The size and location of each service area will depend upon the numbers and types of beds served. Identifiable spaces are required for each of the indicated functions. Each service area may be arranged and located to serve more than one patient care unit but, unless noted otherwise, at least one such service area shall be provided on each nursing floor. Where the words "room" or "office" are used, a separate, enclosed space for the one named function is intended; otherwise, the described area may be a specific space in another room or common area.

(a) Administrative center(s) or nurses' station(s): This area shall include a desk, storage and work counters and shall have convenient access to a hand-washing station within 20 feet and not through a door, to meet infection control standards. It may be combined with or include facilities for reception and communication systems;

(b) Private consultation/administrative office;

(c) Charting facilities: Charting facilities shall have sufficient surface space to provide for charting by staff and physicians to meet the functional needs of the unit;

(d) Toilet room(s) conveniently located for staff use (may be unisex);

(e) Staff facilities: In addition to lounge facilities, securable closets or cabinet compartments shall be provided for the personal articles of nursing personnel. At a minimum, these shall be large enough for purses and billfolds. Coats may be stored in closets or cabinets on each floor or in a central staff locker area;

(f) Multi-purpose room(s) for staff, patients, patients' families for patient conferences, reports, education, training sessions, and consultation. These rooms shall be accessible to each patient care unit but may be located on other floors if convenient for regular use;

(g) Clean and soiled utility rooms shall be provided in accordance with OAR 333-535-0260(5);

(h) Medication station: Provision shall be made for convenient and prompt 24hour distribution of medicine to patients. This shall be from a medicine preparation room, a self-contained medicine dispensing unit, or by another system approved by the Division. A medicine preparation room or unit shall be under the visual control of the nursing or pharmacy staff. It shall contain a work counter, hand-washing station, and an electrical receptacle for a lockable refrigerator and locked storage for biologicals and drugs. A secured medicine dispensing unit may be located at the nurses' station, in the clean utility room or area, or in an alcove or other space under the direct control of the nursing or pharmacy staff. This area shall have adequate lighting to easily identify drugs;

(i) Clean linen storage: Each patient care unit shall contain a designated area for clean linen storage. This may be within the clean utility room or area, a separate closet, or a distribution system approved by the Division on each floor. If a closed cart system is used, storage may be in an alcove;

(j) Nourishment area: There shall be a nourishment area with sink, work counter, refrigerator, storage cabinets, and equipment for hot and cold nourishments between scheduled meals. The nourishment area shall include space for trays and dishes used for non-scheduled meal service. Provisions and space shall be included for separate temporary storage of unused and soiled dietary trays not picked up at mealtime. A hand-washing station shall be in or immediately accessible from the nourishment area;

(k) Ice machine: Each nursing unit shall have direct access to equipment to provide ice for treatments and nourishment. Ice-making equipment may be in the clean utility room or area or at the nourishment station. Ice intended for human consumption shall be from self-dispensing icemakers;

(l) Equipment storage room(s) or alcove(s): Appropriate room(s) or alcove(s) shall be provided for storage of equipment necessary for patient care as required by the Functional Program, the location of which shall not interfere with the flow of traffic. Each patient care unit shall provide sufficient storage area(s) located on the patient floor to keep the required corridor width free of all equipment and supplies, but at least 10 square feet per patient bed shall be provided. If stretchers and wheelchairs are stored on the patient care unit, additional storage space shall be provided;

(m) In remodel projects that do not include bathing facilities in all existing patient rooms, common use showers and bathtubs shall be provided in accordance with OAR 333-535-0260(6);

(n) Emergency equipment storage: Space for emergency equipment such as cardiopulmonary resuscitation (CPR) carts shall be provided. This space shall be out of traffic, under the direct control of the nursing staff and proximate to the nurses' station;

(o) Housekeeping room: One housekeeping room shall be provided for each patient care unit or nursing floor. It shall be directly accessible from the patient care unit or floor and may serve more than one patient care unit on a floor. At least one housekeeping room per floor shall contain a service sink or floor receptor and space for the storage of supplies and housekeeping equipment and cart. A minimum of 35 square feet shall be provided for each housekeeping room. This housekeeping room shall not be used for other departments and patient care units that are specifically required by rule to have separate housekeeping rooms; and

(p) Low voltage room/closet(s), electrical room/closet(s) and other technical support spaces shall be provided as required to meet the service needs of the patient care unit.

(3) Patient care units shall comply with the requirements of OAR 333-535-0260, 333-535-0270, 333-535-0280, 333-535-0300 and 333-535-0310. Additional rule requirements may apply to specialty patient care units.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: OHD 1-2002, f. & cert. ef. 2-28-02; PH 14-2005, f. 8-10-05, cert. ef. 8-15-05; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0035
Infection Control Physical Requirements

(1) An Infection Control Risk Assessment (ICRA) shall be provided for all projects that include Airborne Infection Isolation Rooms, Protective Environment Rooms, surgical facilities, emergency departments, hospital immediate care and minor emergency facilities, and any other identified areas of special risk related to infection. As used in division 535, an Infection Control Risk Assessment is documentation focusing on reduction of risk from infection. The assessment shall have input from the hospital's infection control personnel, and be based on current Centers for Disease Control guidelines or other applicable rules and guidelines. Each subject health care facility shall also comply with the requirements of OAR 333-505-0070. The Infection Control Risk Assessment shall include at least the following elements:

(a) A statement explaining the needs and risks of the patient population to be served that includes:

(A) The number, location, and type of airborne infection isolation and protective environment rooms;

(B) Location(s) of special ventilation and filtration such as emergency department waiting and intake areas; and

(C) Air-handling and ventilation needs in surgical services, airborne infection isolation and protective environment rooms, laboratories, local exhaust systems for hazardous agents, and other special areas.

(b) Statements regarding infection control risk mitigation recommendations including:

(A) Patient placement and relocation;

(B) Standards for barriers and other protective measures required to protect adjacent areas and susceptible patients from airborne contaminants;

(C) Temporary provisions or phasing for construction or modification of heating, ventilating, air conditioning, and water supply systems; and

(D) Measures to be taken to train hospital staff, visitors, and construction personnel.

(c) Management of potentially infectious patients that includes:

(A) Location of patients by susceptibility to infection and definition of risks to each; and

(B) Infection control risk mitigation recommendations that describe the specific methods by which transmission of air and waterborne biological contaminants will be avoided during the course of the construction project.

(d) Infection control risks during construction and plan for containment that includes:

(A) The impact of disrupting essential services to patients and employees;

(B) Location of known hazards;

(C) Determination of the specific hazards and protection levels for each;

(D) Assessment of external as well as internal construction activities; and

(E) Impact of potential outages or emergencies and protection of patients during planned or unplanned outages, movement of debris, traffic flow, cleanup, and testing and certification.

(2) Airborne Infection Isolation Room(s): Airborne Infection Isolation Rooms are single occupancy patient care rooms where environmental factors are controlled in an effort to minimize the transmission of those infectious agents usually spread from person to person by droplet nuclei associated with coughing and inhalation. Airborne Infection Isolation Room requirements shall be predicated on the Infection Control Risk Assessment (ICRA) and the needs of specific community and patient populations served, and shall include the following:

(a) Each facility shall have at least one Airborne Infection Isolation Room. These rooms may be located within individual patient care units and used for normal acute care when not required for isolation cases, or they may be grouped as a separate isolation unit. The number of airborne infection isolation rooms for individual patient units shall be increased based upon an ICRA or by a multidisciplinary group designated for that purpose. Each room shall contain only one bed and shall comply with the requirements of OAR 333-535-0025, and ventilation requirements of OAR 333-535-0300.

(b) Each Airborne Infection Isolation Room shall have an area for hand-washing, gowning, and storage of clean and soiled materials located directly outside or immediately inside the entry door to the room.

(c) Airborne infection isolation room perimeter walls, ceilings, and floors, including penetrations, shall be sealed tightly so that air does not infiltrate the environment from the outside or from other spaces.

(d) Each Airborne Infection Isolation Room shall have a self-closing device on all room exit doors, or doors shall be signed "Door shall be closed at all times."

(e) A separate toilet, bathtub (or shower), and hand-washing station shall be required for each Airborne Infection Isolation Room and shall be accessible without having to enter the corridor.

(f) Each Airborne Infection Isolation Room shall have a permanently installed visual mechanism to constantly monitor the pressure status of the room when occupied by a patient with airborne infectious disease. The mechanism shall continuously monitor the direction of the airflow.

(3) Protective Environment Room(s): Protective Environment Rooms are patient care rooms where severely immuno-suppressed patients are cared for (e.g. bone marrow transplant units). Protective Environment Rooms shall meet all rules for Airborne Infection Isolation Rooms as required by subsection (2)(a) through (f) of this rule but shall provide positive air pressure relative to adjoining spaces, with all supply air passing through filters in compliance with OAR 333-535-0300. When determined necessary by an ICRA, special design considerations and air ventilation to ensure the protection of patients shall be required. The appropriate number and location of Protective Environment Rooms shall be determined by the ICRA. Each Protective Environment Room shall contain only one bed.

(4) Surgical facilities, emergency departments, immediate care and minor emergency facilities and other identified areas of special risk related to infection: Requirements shall be predicated on the ICRA in addition to the rules applicable to each type of area.

(5) Infectious waste:

(a) Soiled utility or soiled holding room(s) shall include segregated infectious waste storage and recycle storage if part of hospital operations unless a separate designated room for waste storage is provided.

(b) The infectious waste storage spaces shall have a floor drain, cleanable floor and wall surfaces, lighting and exhaust ventilation, and safe from weather, animals and unauthorized entry.

(c) Infectious waste management shall be in accordance with the requirements of OAR 333-056-0010 through 333-056-0050.

(d) Refrigeration requirements for such storage facilities shall also comply with OAR 333-535-0300 and the Oregon Mechanical Specialty Code.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: OHD 1-2002, f. & cert. ef. 2-28-02; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0041
Critical Care Units

(1) Critical Care Units: Generally, Critical Care Units require special space and equipment considerations for effective staff functions. In addition, space must be arranged to include provisions for immediate access for emergency medical equipment from other departments. Critical Care Units shall comply in size, number and type with the requirements of this rule and with the hospital's Functional Program. This rule is intended for the more common types of critical care services. Where specialized services are required, the Division may allow such additions and modifications as are necessary for efficient, safe and effective patient care. (See also OAR 333-535-0300 for mechanical requirements and 333-535-0310 for electrical requirements.)

(2) Adult Critical Care Units: Each Adult Critical Care Unit shall comply with the following requirements:

(a) The location shall be convenient for access from emergency, respiratory, laboratory, radiology, surgery, and other essential departments and services, and be located so that medical emergency resuscitation teams may respond promptly to emergency calls;

(b) The location shall be arranged to eliminate the need for through traffic;

(c) For new construction, a private room shall be provided for each patient. A minimum of 200 square feet of clear floor area shall be provided exclusive of anterooms, vestibules, toilet rooms, closets, lockers, wardrobes, and alcoves. A combined total of at least 7 feet of clear space shall be available at the head and foot of the bed. Minimum head wall width shall be 13 feet;

(d) Renovation projects shall comply with subsection (2)(c) of this rule except when existing structural conditions make full compliance impractical. In such cases, the Division may allow the following deviations: Private patient room size may be reduced to 160 square feet with a minimum headwall width of 11 feet 6 inches. The combined total of clear space available at the head and foot of the bed may be reduced to a minimum of 6 feet. Multiple bed rooms may be provided with cubicle curtains for patient privacy. The minimum patient cubicle size shall be 130 square feet with a minimum headwall width of 11 feet for each bed. Three of the 7 feet of combined total clear space required at the head and foot of the bed may be outside the curtained cubicle area;

(e) In private rooms or curtained cubicles, visual access to the corridor shall be provided. In multiple bed rooms, cubicle curtains or other alternative methods approved by the Division shall be provided for visual privacy from casual observation by other patients and visitors;

(f) Where only one door is provided to a bed space, it shall be at least 3 feet 8 inches in clear width and arranged to minimize interference with the movement of beds and large equipment. Sliding doors shall not have floor tracks and shall have hardware that minimizes jamming. When a secondary door is desired for staff use, it may be of a smaller width;

(g) For the purpose of allowing day from night orientation, newly constructed patient rooms shall include at least one window meeting the requirements of OAR 333-535-0025(1)(c), arranged to allow direct visual access by the patient to the outside. Patient

rooms and cubicles in renovation projects shall also meet this requirement except when the Division determines that existing structural conditions make it impractical to do so. In these instances, patients must have direct visual access to an outside window, but it may be a clerestory type and the distance from the patient bed to the outside window may be up to 50 feet;

(h) A nurse call device shall be provided at each bed for patient use. A staff use emergency call station shall also be provided in each patient room to summon assistance. In multiple bed rooms, at least one such emergency call station shall be provided for each eight patient beds;

(i) Hand-washing stations shall be convenient to nurses' stations and patient bed areas. One hand-washing station shall be provided in each patient room. The hand-washing station shall be located near the entrance of the patient room, designed to minimize splashing water onto the floor, and shall be equipped with hands-free operable controls. In multiple bed rooms allowed under paragraph (2)(b)(D) of this rule, if the Division determines that existing structural conditions make it impractical to comply with this requirement, there shall be at least one hand-washing station provided for every two beds in multiple bed rooms. The hand-washing station shall be located near the entrances to patient cubicles;

(j) A toilet shall be provided within each patient room or in a separate private toilet room entered directly from the patient room. Space shall be provided adjacent to toilets to allow for staff assistance. An exception to this requirement may be granted by the Division when the project is within an Oregon Health Authority designated Level 1 Trauma Center Hospital and patients typically are unable to utilize toilets. In renovation projects if the Division determines that existing structural conditions make it impractical to comply with this paragraph, a minimum of one enclosed toilet room and hand-washing station shall be provided for each eight patient beds. In these instances, portable toilets are permitted in place of fixed toilets within each patient room or cubicle. If portable toilets are used, facilities for cleaning and storing them shall be conveniently located within or adjacent to the Critical Care Unit;

(k) The nurses' station or a substation with space for charting, monitoring and a hand-washing station within 20 feet not through a door, shall be located so that nurses will have direct visual observation of each patient. In larger Critical Care Units, more than one nurses' station may be needed to provide for observation of all patients;

(l) Individual patient closets or lockers shall be provided for the secure storage of clothing and personal effects. This storage may be within patient rooms or in a central location convenient to the Critical Care Unit; and

(m) Each Critical Care Unit shall provide space for equipment used for continuous physiological monitoring, including a bedside and remote visual display for each patient.

(3) Airborne Infection Isolation Room: At least one Airborne Infection Isolation Room shall be provided for use by Critical Care Unit patients. The number and location of Airborne Infection Isolation Rooms shall be determined based upon an Infection Control Risk Assessment conducted in accordance with OAR 333-535-0035(1). Each Airborne Infection Isolation Room shall comply with the requirements of OAR 333-535-0035(2) with the following exceptions:

(a) The requirement for the bathtub or shower may be eliminated;

(b) Compact, modular toilet/sink combination units may replace the requirement for a toilet room if discussed and allowed through the ICRA; and

(c) Toilets may be eliminated entirely from patient rooms of Oregon Health Authority designated Level 1 Trauma Center Hospitals when patients typically are unable to utilize a toilet.

(4) Service areas: One service area may serve two or more adjacent Critical Care Units. The size and location of each service area will depend upon the number of beds to be served. The following service areas shall be located in, or readily available to, each Critical Care Unit:

(a) Charting facilities. Documentation and information review spaces shall be provided within the unit to accommodate the recording of patient information. The documentation space shall be located within or adjacent to the patient bed space. It shall include a countertop that will provide for a large flow sheet typical of critical care units and a computer monitor and keyboard. There shall be one documentation space with seating for each patient bed. There shall be a specifically designated area within the unit for information review located to facilitate concentration;

(b) Staff lounges and toilet(s). The following may be located outside the unit if conveniently accessible:

(A) Staff lounge(s) and toilet(s) shall be located so that staff may be recalled quickly to the patient area in emergencies;

(B) The lounge shall have telephone or intercom and emergency code alarm connections to the critical care unit it serves;

(C) Lounge facilities shall be sized in accordance with the Functional Program but shall not be less than 100 square feet; and

(D) Staff personal effects storage. Space located at or near the nurses' work area for the secure storage of the personal effects of nursing personnel. If not provided elsewhere, provisions for the storage of coats, etc., shall be made in this area.

(c) Sleeping and personal care accommodations shall be provided for staff on 24-hour call work schedules;

(d) Clean utility or clean storage room. This room shall be provided in accordance with OAR 333-535-0260(4), for the storage and distribution of all clean medical and surgical supplies kept in the Critical Care Unit;

(A) This room shall be immediately available in each critical care suite.

(B) More than one critical care unit shall be permitted to share a clean utility or clean storage room provided direct access is available from each.

(C) Such rooms shall be separate from and have no direct connection with soiled utility or soiled holding rooms.

(D) If the clean utility room is used to prepare patient care items, it shall contain a work counter, a hand-washing station, and storage facilities for clean and sterile supplies.

(E) If the room is used only for storage and holding as part of a system for distribution of clean and sterile materials, omission of the work counter and hand-washing station shall be permitted.

(e) Clean linen storage. Location of the designated area within the clean utility room, a separate closet, or an approved distribution system on each floor shall be permitted. If a closed cart system is used, storage of clean linen carts in an alcove shall be permitted. The cart storage must be out of the path of normal traffic and under staff control;

(f) Appropriate room(s) or alcove(s) shall be provided for storage of equipment necessary for patient care and as required by the Functional Program. Each unit shall provide sufficient storage area(s) located on the patient floor to keep its required corridor width free of all equipment and supplies, but not less than 10 square feet per patient bed shall be provided;

(A) Equipment storage room or alcove. Appropriate room(s) or alcove(s) shall be provided for storage of large items of equipment necessary for patient care and as required by the Functional Program. Each Critical Care Unit shall provide sufficient storage area(s) in addition to subsection (4)(f) of this rule, located on the patient floor to keep its required corridor width free of all equipment and supplies, but not less than 20 square feet per patient bed shall be provided. Additional space shall be provided for stretcher or bed storage if stored on the floor.

(B) Emergency equipment storage. Space shall be provided for emergency equipment that is under direct control of the nursing staff, such as a cardiopulmonary resuscitation (CPR) cart. This space shall be located in an area appropriate to the Functional Program but out of normal traffic.

(g) Soiled utility room. Each patient Critical Care Unit shall include at least one soiled utility room that meets the requirements of OAR 333-535-0260(5);

(h) Medication station. Medication stations shall be in accordance with the requirements of OAR 333-535-0025(2)(h). The

medication station shall be designed to allow for secure, convenient, and prompt 24-hour distribution of medicine to patients;

(i) Nourishment station. A nourishment station with sink, work counter, refrigerator, storage cabinets, and equipment for hot and cold nourishments between scheduled meals shall be provided. The nourishment station shall include space for trays and dishes used for non-scheduled meal service. Provision and space shall be included for separate temporary storage of unused and soiled dietary trays not picked up at meal time. Nourishment stations shall not share storage, counters, sinks or refrigerator space with medical supplies or pharmaceuticals;

(j) Ice machine. Equipment to provide ice for treatments and nourishment shall be provided. Ice-making equipment may be in the clean work room or at the nourishment station. Ice intended for human consumption shall be from self-dispensing icemakers;

(k) Visitors' waiting room. A visitors' waiting room shall be provided that is designed to accommodate the long stays and stressful conditions common to such spaces, including provisions for privacy, means to facilitate communications, and access to toilets. The waiting room may be located outside the unit if conveniently accessible. The locations and size shall be appropriate for the number of patients and units served, with a seating capacity of not less than one family member per patient bed;

(l) Multipurpose room(s). Multipurpose room(s) shall be provided for staff, patients, and patient's families for patient conferences, reports, education, training sessions, and consultation. These rooms shall be accessible to each nursing unit; and

(m) Housekeeping room. A housekeeping room shall be provided within or immediately adjacent to the critical care unit. This room shall not be shared with other nursing units or departments. It shall contain a service sink or floor receptor and provisions for storage of supplies and housekeeping equipment.

(5) Pediatric Critical Care Unit:

(a) If a facility has a distinct Pediatric Critical Care Unit, the Functional Program must include consideration for staffing, control, and the safe transportation of critically ill pediatric patients with life support and environmental systems from other areas of the facility. The Pediatric Critical Care Unit may be an open ward plan or may have private or semi-private patient rooms. Private rooms at the rate of at least one per 10 beds shall be provided. In addition, at least one private room for each Pediatric Critical Care Unit shall be provided for seclusion and airborne infection isolation. The room(s) provided for seclusion and airborne infection isolation shall comply with the requirements for Airborne Infection Isolation Rooms set forth in OAR 333-535-0035(2). (See also OAR 333-535-0300 for mechanical requirements and 333-535-0310 for electrical requirements.)

(b) In addition to complying with the requirements of sections (1), (2), (3) and (4) of this rule, each Pediatric Critical Care Unit shall also include the following features:

(A) Space in the patient room for family and visitors. Sleeping space for parents who may be required to spend long hours with the patient. This sleeping space may be provided at the patients' bedside. If the sleeping area is separate from the patient area, a system for communication with Pediatric Critical Care Staff must be provided. Storage for associated bedding shall be provided;

(B) If an examination and treatment room is required by the Functional Program, it shall be located in or directly accessible from the Pediatric Critical Care Unit. Examination and treatment rooms shall have a floor area of at least 80 square feet and shall include a hand-washing station, storage facilities and a surface for charting;

(C) Provisions shall be made for the storage of formula or breast milk. Formula/breast milk storage may be outside the unit but should be available for use at all times. The Functional Program should determine the location and size of formula/breast milk storage;

(D) Consultation/demonstration room within, or convenient to, the Pediatric Critical Care Unit for private discussions; and

(E) Separate storage cabinets or closets for toys and games.

(6) Newborn Intensive Care Units (NICU): Each Newborn Intensive Care Unit shall include or comply with the following requirements:

(a) The NICU shall have a clearly identified entrance and reception area with a counter for charting and enclosed storage for supplies. The area shall permit visual observation of, and contact with, all traffic entering the NICU. A hand-washing station shall be provided for visitors entering the NICU.

(b) The NICU shall be designed as part of an overall safety program to protect the physical security of infants, parents, and staff and to minimize the risk of infant abduction. There shall be controlled physical access and controlled egress to and from the NICU.

(c) In a multiple-bed room, every bed position shall be within 20 feet of a hands-free hand-washing station. Where an individual room concept is used, a hands-free hand-washing station shall be provided within each infant care room. All hand-washing stations shall be large enough to contain splashing.

(d) At least one door to each patient room in the NICU must be large enough in both width and height to accommodate portable X-ray and ultrasound equipment.

(e) The NICU shall be located proximate to Labor and Delivery Departments when that service is also provided at the facility.

(f) When viewing windows are provided, provisions shall be made to control casual viewing of infants. Each patient care space shall be designed to allow privacy for the infant and family.

(g) Noise control:

(A) Infant bed areas and the spaces opening onto them shall be designed to produce minimal background noise and to contain and absorb much of the transient noise that arises within the NICU;

(B) The combination of continuous background sound and transient sound in any patient care area shall not exceed an hourly Leq of 50dB and an hourly L10 of 55dB, both A-weighted slow response. The Lmax (transient sounds) shall not exceed 70dB, A-weighted slow response;

(C) Ceilings shall have a noise reduction coefficient (NRC) of at least 0.90; and

(D) The ceiling construction shall limit passage of particles from above the ceiling plane into the clinical environment. If a t-bar acoustic tile ceiling system is used, the tiles shall be clipped down, weighted or gasketed to limit passage of particles and be easily cleanable and non-friable.

(h) Lighting:

(A) Provisions shall be made for indirect lighting and high-intensity lighting in the NICU;

(B) Controls shall be provided to enable lighting to be adjusted over individual patient care spaces from one to 60 foot-candles at 3 feet above the floor level;

(C) Darkening sufficient for trans-illumination shall be available when necessary;

(D) No direct ambient lighting shall be permitted in the infant care space, and any direct ambient lighting used outside the infant care area shall be located or framed to avoid a direct line of sight from any infant to the fixture. This does not exclude the use of direct procedure lighting; and

(E) Lighting fixtures shall be easy to clean.

(i) Space requirements: Each infant care space shall contain a minimum of 150 square feet per bassinet, excluding sinks and aisles. Each bassinet shall have a minimum clearance of 4 feet to walls or any permanent obstruction. When single infant rooms or fixed cubicle partitions are used, there shall be an adjacent aisle of not less than 8 feet in clear unobstructed width to permit passage of equipment and personnel. In multiple bed rooms, there shall be a minimum of 8 feet between infant care beds. Each infant care space shall be designed to allow privacy for the baby and family.

(j) A medication station meeting subsection (4)(h) of this rule.

(k) At least one Airborne Infection Isolation Room is required within the NICU. The room shall be enclosed and separated from other areas of the nursery with provisions for visual observation of the infant from adjacent nurseries or control area(s). All Airborne

Infection Isolation Rooms shall comply with the requirements of OAR 333-535-0035(2), except that a separate toilet, bathtub, or shower are not required.

(l) Rooms at the rate of at least one per 15 infant isolettes shall be provided within the NICU to allow parents and infants to spend extended private time together.

(A) These room(s) shall have direct, private access to a hand-washing station and toilet facilities;

(B) Communication linkage with the NICU staff;

(C) Electrical and medical gas outlets as specified for other NICU beds;

(D) Sleeping facilities for at least one parent; and

(E) Sufficient space for the infant's bed and equipment.

(m) Lactation support space. Dedicated space shall be provided for lactation support and consultation in or immediately adjacent to the NICU. Provision shall be made, either within the room or conveniently located nearby, for a hand-washing station, counter, refrigerator and freezer, storage for pump and attachments, and educational materials.

(n) Charting facilities shall have adequate linear surface space to ensure that staff and physicians may chart and have simultaneous access to information and communication systems.

(o) A clean utility room or clean supply room shall be provided in accordance with the requirements of subsection (4)(d)of this rule.

(p) A soiled utility room or soiled holding room shall be provided in accordance with the requirements of subsection (4)(g) of this rule.

(q) A lounge, locker room, and staff toilet shall be provided within or adjacent to the NICU for staff use in accordance with the requirements of subsection (4)(b) of this rule.

(r) Space for storage of emergency equipment shall be provided in accordance with the requirements of paragraph (4)(f)(B) of this rule.

(s) A housekeeping closet directly accessible from the unit and dedicated for the exclusive use of the NICU shall be provided in accordance with the requirements of subsection (4)(m) of this rule.

(t) A visitors' waiting room shall be provided in accordance with the requirements of subsection (4)(k) of this rule.

(u) A nurses'/supervisors' office or station shall be provided in accordance with the requirements of subsection (2)(k) of this rule.

(v) Multipurpose room(s) for staff, patients, and patients' families for patient conferences, reports, education, training sessions, and consultation. These rooms must be accessible to each NICU. They may be located on other floors if convenient for regular use. One such room may serve several nursing units or departments.

(w) Equipment storage or alcove shall be provided in accordance with paragraph (4)(f)(a) of this rule.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: PH 1-2003, f. & cert. ef. 2-20-03; PH 8-2004(Temp), f. & cert. ef. 3-17-04 thru 7-30-04; PH 19-2004, f. & cert. ef. 5-26-04; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0050
Pediatric Patient Care Unit

Young children and adolescents shall be housed in a patient care unit separate from adults or in a separate pediatrics room of a general nursing unit. This unit shall meet the following requirements:

(1) Patient rooms. The requirements noted in OAR 333-535-0025 shall be applied to a pediatric and adolescent care unit containing hospital beds or cribs, except that patient rooms used for cribs shall contain at least 60 square feet of clearance for each crib with no more than six cribs in a room.

(2) Nursery. Each nursery serving pediatric patients shall contain no more than eight bassinets. The minimum clear floor area per bassinet shall be 40 square feet. Each room shall contain a lavatory equipped for hand-washing, nurses' emergency calling system, and glazed viewing windows for observing infants from public areas and workroom.

(3) Nursery workrooms. Each nursery shall be served by a connecting workroom that shall contain:

(a) Gowning facilities at the entrance for staff;

(b) Work counter;

(c) Refrigerator;

(d) Storage facilities; and

(e) A hand-washing station.

(f) One workroom may serve more than one nursery provided that required services are convenient to each.

(g) The workroom serving the full-term and continuing care nurseries may be omitted if equivalent work and storage areas and facilities, including those for scrubbing and gowning, are provided within that nursery. Space required for work areas located within the nursery is in addition to the area required for infant care.

(h) Provision shall be made for storage of emergency cart(s) and equipment out of traffic.

(i) Provision shall be made for the sanitary storage and disposal of soiled waste.

(j) Visual control shall be provided via borrowed lights or view panels between the staff work area and each nursery.

(4) Examination/Treatment Rooms. An examination/ treatment room shall be provided for pediatric and adolescent patients. A separate area for infant examination and treatment shall be permitted within the pediatric nursery workroom. It shall contain a work counter, storage facilities, and a hand-washing station. Examination/treatment rooms shall have a minimum floor area of 120 square feet.

(5) Service areas. The service areas in the pediatric and adolescent nursing unit shall conform to the conditions listed in OAR 333-535-0025 and shall meet the following additional conditions:

(a) Multipurpose or individual room(s) shall be provided within or adjacent to areas serving pediatric and adolescent patrons for dining, educational and developmentally appropriate play and recreation, with access and equipment for patients with physical restrictions. Insulation, isolation, and structural provisions shall be made to minimize the transmission of impact noise through the floor, walls, or ceiling of the multipurpose room(s).

(b) Space for preparation and storage of infant formula or breast milk shall be provided in the unit or other convenient location. The Functional Program should determine the location and size of formula/breast milk storage. Provisions shall be made for continuation of special formula that may have been prescribed for the infant prior to admission or readmission.

(c) Patients' toilet room(s) with hand-washing stations in each room, in addition to those serving bed areas, shall be convenient to multipurpose room(s) and to each central bathing facility.

(d) Storage closets or cabinets shall be provided for toys, and educational and recreational equipment.

(e) Storage space shall be provided to permit exchange of cribs and adult beds.

(f) Storage space shall be provided for equipment and supplies (including cots, recliners, extra linen, etc.) for parents who stay with the patient overnight.

(g) Separate clean and soiled utility or holding rooms shall be provided in accordance with OAR 333-535-0260(4) and (5).

(h) Housekeeping closet shall be provided for each nursery per OAR 333-535-0260(8).

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(5); HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-074-0225; HD 21-1993, f. & cert. ef. 10-28-93; HD 2-2000, f. & cert. ef. 2-15-00; OHD 1-2002, f. & cert. ef. 2-28-02; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0061
Psychiatric Patient Care Units and Rooms

(1) The design of inpatient psychiatric patient care units shall be supportive of the types of psychiatric therapies provided for patients and their psychiatric care needs. Interior finishes, lighting and furnishings shall, to the extent practicable, reflect a residential

rather than an institutional setting with an emphasis on natural light and exterior views while not compromising patient privacy and safety design. Inpatient psychiatric patient care units shall include patient rooms meeting the requirements of section (4) of this rule and service areas meeting the requirements of section (5) of this rule.

(2) Patient and Staff Safety Assessment. The hospital psychiatric care staff and the hospital administration, in consultation with the project architects, shall develop a Patient and Staff Safety Assessment that addresses security and safety design features and devices. A copy of this Assessment shall accompany construction documents submitted to the Licensing Plans Review Program. The Patient and Staff Safety Assessment shall include at least the following elements:

(a) A statement explaining the psychiatric population groups served;

(b) A discussion of the capability for staff visual supervision of patient ancillary areas and corridors;

(c) A discussion of the risks to patients, including self-injury, and the project solutions employed to minimize such risks;

(d) A discussion of building features and equipment, including items which may be used as weapons, that is intended to minimize risks to patients, staff and visitors;

(e) A statement explaining how potentially infectious patients will be managed; and

(f) A discussion of outdoor areas used by patients. Discussion must include, but is not limited to, the number of patients each outdoor area will serve at one time, staffing, security and shifts.

(3) Except as permitted under OAR 333-500-0065, every hospital classified as mental or psychiatric and other hospitals, regardless of classification, that provide psychiatric services, shall have at least one psychiatric seclusion room which meets the requirements of section (7) of this rule and OAR 309-033-0727.

(4) Psychiatric patient care rooms shall comply with the requirements of OAR 333-535-0025, except as follows:

(a) A nurse call system is not required. If included, provisions shall be made for easy removal or covering of call buttons;

(b) Patient toilets shall not have bed pan flushing devices;

(c) Hand-washing stations are not required in patient rooms;

(d) Visual privacy in multi-bed rooms (for example, cubicle curtains) is not required;

(e) Each patient room shall be provided a private toilet room and hand-washing station. Grab bars are only required in rooms required to be accessible to the disabled;

(f) All hardware shall have tamper-resistant fasteners; and

(g) Patient rooms shall comply with the requirements of section (6) of this rule.

(5) Psychiatric patient care unit service areas shall comply with the requirements of OAR 333-535-0025, except as follows:

(a) A secured storage area shall be provided for patients' belongings that are determined to be potentially harmful;

(b) A secured storage station will be provided for storing law enforcement weapons prior to officers entering the patient care unit;

(c) The medication station shall include provision against unauthorized access;

(d) Between meal nourishment(s) facilities within the unit shall be one, or a combination of the following:

(A) A nourishment station;

(B) A kitchenette, designed for patient use, with a sink and a keyed switch or other acceptable method for staff control of any heating and cooking devices; or

(C) A kitchen service within the unit that includes a hand washing station, storage space, refrigerator and facilities for full meal preparation. A keyed switch or other acceptable method for staff control of any heating and cooking devices is required.

(e) All storage spaces within the psychiatric patient care unit shall be secured from patient access;

(f) A bathtub or shower shall be provided for every six beds not otherwise served by bathing facilities within the patient rooms. Bathing facilities shall be designed and located for patient safety, convenience, privacy and shall comply with section (6) of this rule;

(g) A separate charting area shall be provided with provisions for visual and acoustical privacy. Viewing windows to permit observation of patient areas by the charting nurse or physician may be used if the arrangement is such that patient files cannot be read from outside the charting area. Viewing windows shall meet the requirements of subsection (6)(g) of this rule;

(h) At least two separate social spaces, one appropriate for noisy activities and one for quiet activities shall be provided. The combined area shall be at least 40 square feet per patient with each space being at least 120 square feet in size. These spaces may be shared by dining activities;

(i) Space for group therapy shall be provided. This space may be combined with the quiet space required by subsection (5)(h) of this rule when the unit accommodates 12 or fewer patients and when at least 225 square feet of closed private space is available for group therapy activities;

(j) Securable patient laundry facilities with an automatic washer and dryer and secured space for chemicals shall be provided;

(k) Each psychiatric patient care unit shall include, or have close access to, a soiled utility room that meets the requirements of OAR 333-535-0260(5) or a soiled holding room. A soiled holding room shall meet all the requirements of a soiled utility room except that a clinical sink may be omitted;

(l) The following elements shall also be provided, but shall be permitted to serve several nursing units and may be on a different floor if conveniently located to the unit for routine use:

(A) Space requirements. Examination rooms shall have a minimum floor area of 120 square feet, excluding space for vestibule, toilets, and closets. The room shall contain a hand-washing station, storage facilities and a surface for charting. In existing psychiatric facilities exam rooms may continue to be 80 square feet excluding space for vestibules, toilets and closets;

(B) Separate consultation room(s), lockable from the outside. Each consultation room shall have a minimum floor space of 100 square feet and shall be provided at a room-to-bed ratio of one consultation room for every 12 psychiatric beds. The room(s) shall be designed for acoustical and visual privacy and be constructed to achieve a level of voice privacy of 50 STC;

(C) Separate space for patient therapy/multipurpose use. The greater of at least 300 square feet or at least 15 square feet per patient shall be provided. The space shall include a hand-washing station, work counter(s), storage and space for displays and may serve more than one psychiatric patient care unit. However, when a psychiatric patient care unit contains less than 12 beds, the therapy and other functions may be performed within the noisy activities area required by subsection (5)(h) of this rule if at least an additional 10 square feet per patient is provided; and

(D) A conference and treatment planning room, for use by psychiatric patient care unit staff, constructed to achieve a level of voice privacy of 50 STC.

(m) Outside area shall be provided for all patients. The area shall be discussed as part of the Functional Program per subsection (2)(f) of this rule.

(6) Patient and staff safety features, security and safety devices shall not, to the extent practicable, be presented in a manner to attract or invite tampering by patients. Design, finishes and furnishings shall be designed and installed to minimize the opportunity for patients to cause injury to themselves or others. Special design considerations for prevention of self injury and injury to staff and others shall include:

(a) Visual control of nursing unit corridors, passive activity areas and outdoor areas shall be provided;

(b) Hidden alcoves are prohibited;

(c) Non-patient areas, including staff support rooms, mechanical and electrical spaces shall be secured from patients;

(d) Door closers and door and cabinet hardware, including hinges in patient areas, shall be designed to prevent attachment of other articles and to limit possible patient or staff injury;

(e) Doors to patient toilet and shower rooms shall not swing into the room. These doors shall either not be lockable from within the room or shall be provided with privacy locks that can be opened by staff with a key or tool. Hardware shall be designed to preclude patients from tying the door closed;

(f) Furnishings, movable equipment and accessories shall be addressed by the Patient and Staff Safety Assessment required by section (2) of this rule;

(g) Windows, including interior and exterior glazing, shall be non-operable and shall be of break-resistant material and will not shatter. Window sills, curtains and blinds shall be constructed to prevent attachment of other articles;

(h) Curtains and blinds shall be constructed to break-away with a vertical load of greater than 40 pounds;

(i) Ceilings in patient bedrooms, toilet and shower rooms shall be of continuous bonded construction. T-bar ceilings with lay-in tiles are not allowed;

(j) The ceiling and air distribution devices, lighting fixtures, sprinkler heads, smoke detectors, and other appurtenances shall be designed and installed to be tamper resistant, non-breakable, prevent the attachment of other articles and to limit possible patient or staff injury in patient rooms, toilet and shower rooms;

(k) Flooring base in patient rooms, toilet and shower rooms shall be installed to preclude removal by patients;

(l) Shower, bath, toilet and sink plumbing fixture hardware and accessories, including grab bars and toilet paper holders, shall prevent attachment of other articles and removal by patients. Shut-offs under patient sinks shall be covered and secured to prevent patient access;

(m) Grab bars, if provided, shall be contiguous to the wall so that nothing can pass between the edge of the rail and the wall;

(n) Toilet flush valves shall be recessed or of the push button type;

(o) Hand-washing station faucet hardware shall be recessed or of the push button type to preclude patient or staff injury;

(p) Shower curtains, if provided, shall have a breakaway maximum of 40 pounds and be supported on curtain tracks attached or flush to the ceiling. Shower curtains shall not be permitted where facilities accommodate children whose weight is close to, or within the breakaway weight limits;

(q) Shower heads shall be sloped or otherwise designed to prevent attachment of other articles;

(r) Fire extinguisher cabinets and fire alarm pull stations shall be located or installed to prevent inappropriate use;

(s) Electrical outlets in patient areas shall be of a ground fault interrupter type ("GFI") or shall be protected by GFI breakers at electrical panels;

(t) Patient mirrors shall be non-breakable and shatterproof;

(u) Medical gas outlets, if provided, shall be located or installed to prevent patient access;

(v) All devices attached to walls, ceilings and floors and all door and window hardware shall be tamper resistant and be securely fastened with tamper proof screws;

(w) All exit door hardware shall have concealed rods, if any are used, and they shall not be removable by patients. Door closure and panic bars, if provided, shall not allow attachment of other articles;

(x) Time delay closers shall not be used on locked doors; and

(y) Outdoor areas shall be secured in accordance with the Patient and Staff Safety Assessment required by section (2) of this rule.

(7) Psychiatric Seclusion Rooms. Psychiatric seclusion rooms shall comply with the following requirements:

(a) As required by section (3) of this rule, and except as permitted by OAR 333-500-0065, each hospital classified as general or psychiatric shall have at least one psychiatric seclusion room. A minimum of one psychiatric seclusion room is required for every 24 psychiatric beds or fraction thereof. The rooms shall be proximate to a nurses' station. Each room shall be for only one patient and shall be at least 80 square feet in size. The design of the room shall prevent patient hiding and minimize the potential for escape and self injury;

(b) Psychiatric seclusion rooms shall meet the requirements of section (6) of this rule;

(c) Outside room corners, door hardware protrusions and other projections shall be avoided to minimize points for possible patient injury;

(d) No items shall be attached to the walls and there shall be no exposed curtains, drapes, rods or furniture, except a portable bed which can be removed if necessary. Beds that are securely fastened to the floor are allowable but must have no sharp protrusions, such as bed posts or corners;

(e) Wall and other room finish materials shall be securely constructed to resist attempts at intentional damage;

(f) Exposed pipes or electrical wiring is prohibited. Electrical outlets, if provided, shall be permanently capped or covered with a metal shield that opens with a key and shall be circuited and controllable from outside the room. Ceiling lights shall be unbreakable and shall be either recessed or surface mounted;

(g) Room construction shall contain no readily combustible materials (for example, wood or vinyl wall covering surfaces). If the room interior is padded with combustible materials, such materials shall meet the requirements of the National Fire Protection Association (NFPA) 101 Code as enforced by the State Fire Marshal;

(h) Sprinkler heads shall be of a recessed pop-down type and shall have a breakaway strength of under 80 pounds;

(i) A toilet and hand-washing station that meets the requirements of section (6) of this rule shall be available for patient use but shall not be located within the room;

(j) The door to the room shall open outward and shall include a viewing window of shatterproof glass or plastic through which the entire room may be viewed from the outside before entering; and

(k) The door to the room shall be lockable from the outside and shall include tamper-proof hardware. The lock must release with initiation of the fire alarm, sprinkler flow or power failure as required for controlled egress in accordance with the Oregon Structural Specialty Code and NFPA 101 Code as enforced by the appropriate building codes agency and fire marshal.

(8) Child and Adolescent Psychiatric Units. The requirements of sections (1) through (6) of this rule, and of section (7) of this rule if a psychiatric seclusion room is provided, shall apply to child and adolescent psychiatric units, except as follows:

(a) The environment of the unit shall reflect the age, social and developmental needs of children and adolescents, including space to accommodate family and other caregivers;

(b) At least one single occupancy timeout room shall be provided;

(c) An outdoor activity area shall be provided with a minimum of 50 square feet per patient but not less than 400 total square feet;

(d) Child and adolescent care units shall be physically and visually separate from one another and from adult care units; and

(e) Showers. Shower curtains shall not be permitted in child adolescent care units.

(9) Geriatric, Alzheimer and Other Dementia Units. The requirements of sections (1) through (6) of this rule, and of section (7) of this rule if a psychiatric seclusion room is provided, shall apply to geriatric, Alzheimer and other dementia units, except as follows:

(a) Single patient rooms shall be at least 120 square feet in size. Multiple patient rooms shall provide at least 80 square feet per patient exclusive of closets, vestibules and bathroom facilities and allow for a minimum of 3 feet between beds;

(b) A nurse call system meeting the requirements of section (6) of this rule shall be provided. Provisions shall be made for the removal or covering of call button outlets as required by the Patient Safety Assessment. Call cords or strings in excess of six inches shall not be permitted;

(c) Handrails shall be provided on both sides of corridors used by patients. These handrails shall be contiguous with the wall so that nothing may pass between the rail and wall;

(d) Doors to patient rooms and patient ancillary use areas shall be a minimum of 3 feet 8 inches in clear width;

(e) Slip resistant flooring surfaces shall be provided in all bathing rooms; and

(f) Secure storage for wheelchairs shall be provided in a location readily accessible to the unit.

(10) Forensic Psychiatric Units. The requirements of sections (1) through (6) of this rule shall apply to forensic psychiatric units, except as follows:

(a) Security vestibules or sally ports are required at the unit entrance;

(b) Additional treatment areas, police and courtroom space, and special security considerations shall be provided in accordance with the Patient and Staff Safety Assessment; and

(c) Children and adolescents shall be separated from one another as defined by the Functional Program. Children and adolescents shall also be physically and visually separate from adult care units.

Stat. Auth.: ORS 441.025 & 441.060
Stats. Implemented: ORS 441.025 & 441.06
Hist.: OHD 13-2002, f. & cert. ef. 9-27-02; PH 18-2003(Temp), f. & cert. ef. 10-31-03 thru 4-26-04; PH 7-2004, f. & cert. ef. 3-17-04; PH 14-2005, f. 8-10-05, cert. ef. 8-15-05; PH 10-2009, f. & cert. ef. 10-1-09; PH 7-2016, f. & cert. ef. 2-24-16

333-535-0065
Detoxification Rooms

(1) In hospitals that provide drug or alcohol detoxification services, a minimum of one patient room for detoxification, located to allow direct observation by nursing staff, shall be provided.

(a) Windows in detoxification rooms shall be of a security type that can only be opened by keys or tools that are under the control of the staff.

(b) An adjoining or closely available toilet room and a hand-washing station serving detoxification patients only is also required.

(2) All secured portions of the detoxification facility must comply with the Group I, Division 2 occupancy classification requirements in accordance with the Oregon Structural Specialty Code.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: HD 21-1993, f. & cert. ef. 10-28-93; HD 2-2000, f. & cert. ef. 2-15-00; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0070
Newborn Nursery Units

(1) General. Newborn infants not cared for in a "rooming in" program in post-partum or LDR rooms, shall be housed in nurseries that comply with the standards below. Location shall allow for transfer of infants to post partum and birthing and LDR rooms without going through unrelated departmental or public corridors and spaces. The nursery shall be located and arranged to preclude the need for non-related pedestrian traffic. No nursery shall open directly into another nursery. See OAR 333-535-0050(2) for pediatric nurseries. See OAR 333-535-0041(4) for neonatal intensive care nurseries. Refer to mechanical and electrical sections for ventilation, oxygen, suction, medical air and electrical standards. All nurseries shall contain the following:

(a) At least one hand-washing station for each eight infant beds equipped with controls that can be operated without use of hands.

(b) Nurses' emergency calling system to summon assistance without leaving the patient area. Alternate technologies shall be permitted for emergency or nurse call systems. If radio frequency systems are utilized, consideration shall be given to electromagnetic compatibility between internal and external sources. Refer to OAR 333-535-0310, Electrical Requirements.

(c) Glazed observation windows to permit viewing infants from public areas, from workrooms, and from adjacent nurseries.

(d) Provisions shall be included for storage and convenient access at each nursery room for linens and infant supplies.

(2) Full-Term Nursery. Each full-term nursery shall contain no more than 16 standard infant stations. The minimum floor area shall be 24 square feet for each infant station exclusive of auxiliary work areas. When a "rooming-in" program is used, the total number of bassinets provided in these units may be appropriately reduced, but the full-term nursery may not be omitted in its entirety from any facility that includes obstetrical services. (When facilities use a "rooming-in" program in which all infants are returned to the nursery at night, a reduction in nursery size may not be practical.)

(3) Continuing Care Nursery. Hospitals having 25 or more maternity beds shall have a separate nursery that provides continuing care for infants who need close observation. The minimum floor area per infant shall be 50 square feet, exclusive of auxiliary work areas, with provisions for at least 4 feet between and at all sides of bassinets. The Division, however, may waive this requirement for low-risk obstetrical services in service areas where a second, full service nursery exists, and a safe method for transfer is in place and discussed in the Functional Program.

(4) Charting Facilities. Charting facilities shall have linear surface space to ensure that staff and physicians may chart and have simultaneous access to information and communication systems.

(5) Nursery workrooms. Each nursery shall be served by a connecting workroom that shall contain:

(a) Gowning facilities at the entrance for staff;

(b) Work counter;

(c) Refrigerator;

(d) Storage facilities; and

(e) A hand-washing station.

(f) One workroom may serve more than one nursery provided that required services are convenient to each.

(g) The workroom serving the full-term and continuing care nurseries may be omitted if equivalent work and storage areas and facilities, including those for scrubbing and gowning, are provided within that nursery. Space required for work areas located within the nursery is in addition to the area required for infant care.

(h) Provision shall be made for storage of emergency cart(s) and equipment out of traffic.

(i) Provision shall be made for the sanitary storage and disposal of soiled waste.

(j) Visual control shall be provided via borrowed lights or view panels between the staff work area and each nursery.

(6) Examination and Treatment Room or Space for Infants. Such areas, when required by the Functional Program shall contain a work counter, storage, and a hands-free hand-washing station. Exam and Treatment space may be located within the nursery workroom.

(7) Isolation Nursery. A separate isolation nursery is required unless other provision for the isolation of infants who are suspected of being infectious is made and included in the hospital's infection control policy.

(8) Infant Formula Facilities. Where infant formula is prepared on site, direct access from formula preparation room to any nursery room is prohibited. The room must include clean-up washing and sterilization facilities, separate facilities for formula preparation, and refrigerated storage and warming facilities. If commercial infant formula is used, storage and handling may be done in the nursery workroom or other appropriate room in the hospital that is accessible at all hours. The preparation area shall have a work counter, a hand-washing station, and storage facilities.

(9) Housekeeping Closet. In hospitals with continuing care nurseries, a housekeeping closet directly accessible from the unit and dedicated for the exclusive use of the Newborn Nursery, containing a floor receptor or sink and storage space for housekeeping equipment and supplies, shall be provided.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(7); HD 21-1987, f. & ef. 11-13-87; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered

from 333-074-0235; HD 21-1993, f. & cert. ef. 10-28-93; HD 2-2000, f. & cert. ef. 2-15-00; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0080
Emergency Department

(1) Hospitals offering emergency patient care services shall include facilities required under section (2) of this rule. If outpatient clinical services are to be included as a part of the Emergency Department, elements under OAR 333-535-0085 shall also be provided.

(a) Except as permitted under OAR 333-500-0065, every hospital classified as mental or psychiatric and any other hospital, regardless of classification, that provides psychiatric services shall have at least one psychiatric seclusion room that meets the requirements of section (7) of OAR 333-535-0061 and 309-033-0727.

(2) Hospitals providing emergency services shall include the following:

(a) Entrance located on the same level and proximate to the emergency department, sheltered from the weather, and with provision for ambulance and disabled pedestrian access. Emergency entrance location shall be marked by a lighted sign. The emergency access shall be paved to permit discharge of patients from automobiles and ambulances. Temporary parking convenient to the entrance shall be provided;

(b) A reception, triage and control area conveniently located near the entrance, waiting area(s), and treatment room(s). The control station(s) shall be located to permit staff observation and control of access to treatment areas, pedestrian and ambulance entrances and public waiting area;

(c) Public waiting space with toilet facilities, public telephone, and drinking fountain;

(d) Examination and Treatment room(s):

(A) Space requirements. Each examination room shall have a minimum clear floor area of 120 square feet exclusive of toilets, waiting area and casework.

(B) Each examination room shall contain an examination light, medication storage, work counter, a hand-washing station, medical gas outlets per Table 5 (OAR 333-535-0300), electrical outlets above floor level to accommodate required equipment, suction, and space for storage of emergency equipment such as emergency treatment trays, defibrillator, cardiac monitor, and resuscitator.

(C) Treatment cubicles:

(i) Where treatment cubicles are in open multiple-bed areas, each cubicle shall have a minimum of 80 square feet of clear floor space with a minimum of 5 feet between beds and shall be separated from adjoining cubicles by curtains.

(ii) Hand-washing stations shall be provided at a rate of one per four treatment cubicles.

(e) Trauma/cardiac rooms for emergency procedures, including emergency surgery shall have:

(A) At least 250 square feet of clear floor space.

(B) Additional square footage and cubicle curtains for privacy shall be provided to accommodate more than one patient at a time in the trauma room.

(C) Cabinets and emergency supply shelves, image readers, examination lights, and counter space for writing in each room.

(D) Provisions in each room for monitoring equipment.

(E) Storage provided for immediate access to protective attire for infection control.

(F) Doorways leading from the ambulance entrance to the cardiac trauma room shall be a minimum of 5 feet wide to simultaneously accommodate stretchers, equipment, and personnel.

(G) Medical gas outlets shall equal that required of an operating room in Table 5, OAR 333-535-0300;

(f) Provisions for orthopedic and cast work. There shall be storage for orthopedic supplies including but not limited to: splints, traction hooks, portable image readers or exam lights. These provisions may be in a separate room(s) or in a treatment room. If a sink is used for the disposal of plaster of paris, a plaster trap shall be provided. The amount of clear floor space for this area shall be dependent on the Functional Program, procedures planned and the equipment needed;

(g) Scrub stations or hand-washing stations located in or adjacent to each trauma or orthopedic room;

(h) Provisions for infection control and for the handling of a patient requiring isolation in accordance with the hospital's ICRA. If so determined by the hospital's ICRA, the emergency department waiting area and triage areas shall require special measures to reduce the risk of airborne infection transmission. These measures may include enhanced general ventilation and air disinfection similar to inpatient requirements for airborne infection isolation rooms;

(i) Communication center with related equipment shall be convenient to the control station(s), nursing station and have radio, telephone, and intercommunication systems;

(j) Access to radiology and laboratory services;

(k) Storage area out of line of traffic for stretchers and wheelchairs with access from emergency entrances;

(l) Staff work and charting area(s). This may be combined with reception and control area or located within the treatment room;

(m) Storage out of traffic and under staff control for general medical/surgical emergency supplies, medications and equipment such as a ventilator, defibrillator, pumps, patient monitoring, portable image readers and splints;

(n) Soiled utility room or area per OAR 333-535-0260(5) containing clinical sink, work counter, a hand-washing station, waste receptacle, and linen receptacle;

(o) Patients' toilet room convenient to treatment room(s) that shall include a nurse call device or other approved alternative to summon staff; and

(p) Security station. Where dictated by the Functional Program, a security station system shall be located near the emergency entrances and triage/reception area.

(A) Accommodation for hospital security staff, police officers and monitoring equipment, for example, silent alarms, panic buttons, intercom systems or visual monitoring devices.

(B) Located near emergency entrance and triage/reception area.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 441.060

Stats. Implemented: ORS 441.060

Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HB 213, f. 3-25-69 ; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(8); HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-074-0240; HD 21-1993, f. & cert. ef. 10-28-93; HD 2-2000, f. & cert. ef. 2-15-00; OHD 1-2002, f. & cert. ef. 2-28-02; PH 14-2005, f. 8-10-05, cert. ef. 8-15-05; PH 10-2009, f. & cert. ef. 10-1-09; PH 7-2016, f. & cert. ef. 2-24-16

333-535-0085
Hospital Licensed Urgent Care Facilities

This section applies to immediate care and minor emergency facilities that are physically separate from the Emergency Department and do not possess a trauma level designation as defined by OAR 333-200-0080. Such services may be located within an inpatient facility or in a satellite location as defined by 333-500-0025, that is under direct control of a general hospital and is licensed as a part of the general hospital. The following elements shall be provided:

(1) Administration and public areas:

(a) Entrance. Located at grade level or accessible by ramp, sheltered from weather, and disabled accessible.

(b) Lobby and waiting areas. These shall include access to:

(A) Wheelchair storage space(s);

(B) Reception and information counter or desk;

(C) Waiting space(s);

(D) Public toilet facilities;

(E) Public telephone(s). Access to a telephone shall be provided to public, patients and patient's family regardless of the installation of a public pay telephone installed by the telephone company; and

(F) Provisions for drinking water. Conveniently accessible provisions for drinking water shall be provided. This may be outside the patient area, in shared facilities.

(c) Interview space(s) for private interviews relating to social service, credit, and admissions. Multipurpose rooms for conferences, meetings, and health education shall be provided. In small facilities, the room may also serve for consultation and other purposes.

(d) An office area for business transactions, records, and other administrative functions, separate from public and patient areas for confidentiality, shall be provided.

(e) Secure storage for employees' personal property. Locked storage (cabinets or secure drawers) convenient to workstations shall be provided for staff valuables.

(f) General storage facilities for office supplies, equipment, sterile supplies, and pharmaceutical supplies shall be provided within or convenient to administrative areas.

(g) Housekeeping requirements. At least one housekeeping room per floor shall be provided. Each housekeeping room shall contain a floor sink or service sink and storage for housekeeping supplies and equipment.

(2) Clinical Areas:

(a) Examination room(s) for medical, obstetrical, and similar examinations shall have a net minimum floor area of 80 square feet, excluding such spaces as vestibule, toilet, closet, and work counter (whether fixed or movable). Arrangement shall permit at least 2 feet 8 inches clearance at each side and at the foot of the examination table. A hand-washing station and a counter or shelf space for writing shall be provided.

(b) Treatment room(s) for minor surgical procedures and cast procedures shall have a minimum floor area of 120 square feet, excluding such spaces as vestibule, toilet, closet, and work counter (whether fixed or movable). The minimum room dimension shall be 10 feet. A minimum clearance of 3 feet around the perimeter of the treatment table shall be provided. Work counters, storage cabinets, and a hand-washing station shall be provided.

(c) Documentation space for charting and writing clinical records shall be provided. Work counter, communication system, and space for supplies shall be provided. A separate space may be omitted if these functions are accommodated in each examination room and each treatment room.

(d) A Cardiac Pulmonary Recitation emergency cart shall have a dedicated storage space away from traffic but immediately available to all areas including entrance and receiving areas. (See OAR 333-535-0310, Electrical Requirements)

(e) Medication storage meeting Board of Pharmacy administrative rules OAR 855, division 41.

(f) Clean storage. A separate room or enclosed closet(s) for storing clean and sterile supplies shall be provided. This storage shall be in addition to cabinets and shelves in treatment rooms. Sterile items shall be protected from dust.

(g) Soiled holding area. Provisions shall be made for separate collection and disposal of soiled materials. A hand-washing station shall be provided.

(h) Sterilizing facilities. A system for sterilizing equipment and supplies shall be provided. Sterilizing procedures may be done on or off-site. Disposable items may also be used to satisfy functional needs.

(i) Laboratory facilities, meeting laboratory licensing rules under OAR 333-024 and 333-535-0090 shall be readily available either within the department or through an effective contract with nearby hospitals or laboratory services.

(j) Staff lounge and toilet facilities shall be readily available to the unit.

(k) Patient toilets. Provide patient toilet(s) readily available or within the clinic space.

(l) If radiographic equipment is provided, the installation shall meet rules of the Oregon Health Authority, Public Health Division, Radiation Protection Services under OAR 333-100 through 120.

(m) Medical records storage requirements. Filing cabinets and storage shall be provided for the safe and secure storage of patient records with provisions for ready retrieval.

(n) A toilet room containing a hand-washing station shall be accessible from all examination and treatment rooms. Where a facility contains no more than three examination or treatment rooms, the patient toilet shall be permitted to serve waiting areas.

(o) Basic diagnostic procedures (these may be part of the outpatient service, off-site, shared, by contract, or by referral) shall be provided and shall include the following for imaging facilities:

(A) Support areas for imaging facilities:

(i) Viewing and administrative areas;

(ii) Film and media processing facilities in accordance with the Functional Program; and

(iii) Storage facilities for exposed film as required by the Functional Program.

(B) Support areas for patients that include dressing rooms or booths with convenient toilet access. Toilet rooms with hand-washing stations shall be accessible to procedure room(s) where the procedure may result in the immediate need for toilet facilities.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: OHD 2-2000, f. & cert. ef. 2-15-00; PH 14-2005, f. 8-10-05, cert. ef. 8-15-05; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0086
Hospital Licensed Physician's Offices and Outpatient Clinics

This rule applies to Physician Outpatient Clinics that are under the license of a general hospital and either physically connected or in freestanding, satellite locations, as defined by OAR 333-500-0025(1)(a).

(1) OAR 333-535-0085 shall apply except as follows:

(a) Subsection (1)(a) shall not apply except the entry shall be disabled accessible;

(b) Subsection (2)(d) shall not apply;

(c) Subsection (2)(j) shall not apply; and

(d) Subsection (2)(n) shall apply except in existing conditions where public toilet rooms do not exist, then patient toilets may be used for public when addressed by the hospital's Functional Program.

(2) The ventilation requirements of OAR 333-535-0300 and electrical requirements of 333-535-0310 shall not apply, but spaces shall conform to the requirements of the Oregon Mechanical Specialty Code, the Oregon Electrical Specialty Code, and the Oregon Structural Specialty Code as they are enforced by the Oregon Building Codes Division and Authorities having Jurisdiction.

(3) For Outpatient Clinics where only counseling or non-clinical services are provided, wheelchair storage space(s), examination room(s), treatment room(s), drug distribution station, clean workroom or clean holding room, and soiled workroom or soiled holding room may be omitted.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: OHD 2-2000, f. & cert. ef. 2-15-00; OHD 1-2002, f. & cert. ef. 2-28-02; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0090
Laboratory Suite

(1) Inpatient hospital laboratory facilities shall be provided for hematology, clinical chemistry and urinalysis, and may include cytology, pathology, immunohematology, microbiology, serology, and immunology to meet requirements for services as stated in General Rules (OAR 333-535-0010). These may be provided within the hospital or through an effective contract arrangement with a nearby laboratory service. Hospital laboratories located in freestanding clinics shall conform to rules under section (2) of this rule. The following shall be provided:

(a) Laboratory work counter(s) with space for microscopes, appropriate chemical analyzer(s), incubator(s), and centrifuge(s). Work areas shall include sinks with water and access to electrical services as needed;

(b) Refrigerated blood storage facilities for transfusions shall be provided. Blood storage refrigerator shall be equipped with temperature-monitoring and alarm signals located for 24-hour response. Blood banks must be provided emergency power for continued cooling during an interruption of the normal power supply;

(c) Dedicated hand-washing stations shall be located within 20 feet of each workstation and within each room with a workstation;

(d) Appropriate storage facilities, including refrigeration shall be provided for reagents, patient specimens, controls, and supplies;

(e) Urine and feces collection rooms shall be equipped with a toilet and hand-washing station. This may be outside the laboratory suite;

(f) Blood collection facilities shall include a work counter, conveniently located hand-washing station, space for patient seating and sharps container(s);

(g) Chemical safety provisions, which may include emergency shower, eye flushing devices, and appropriate storage for flammable liquids shall be provided in accordance with Oregon State Public Health Laboratory Licensing rules, OAR 333-024-0005 through 333-024-0055, and Oregon OSHA Administrative Rules;

(h) Facilities and equipment for sterilization of contaminated specimens before transport to incineration facilities in accordance with Oregon State Public Health Laboratory Licensure Rules and Oregon OSHA Administrative Rules;

(i) If radioactive materials are used or stored, facilities shall be available for their safe storage and disposal;

(j) Administrative areas including offices as well as space for clerical work, filing, and record maintenance shall be provided apart from testing or storage areas;

(k) Lounge, locker, and toilet facilities shall be conveniently located for laboratory staff. These may be outside the laboratory area and shared with other departments; and

(l) The Functional Program shall describe the type and location(s) for all special laboratory equipment that is to be wired, plumbed, or plugged in, and the building utility systems required to operate each.

(2) Laboratory services serving hospital outpatient clinics may be onsite or through an effective contractual arrangement with a laboratory service or through the primary hospital laboratory. Services may include hematology, clinical chemistry, urinalysis, cytology, pathology, microbiology, serology, immunology, and immunohematology. When these services are not effectively provided elsewhere, the following shall be available within the clinic:

(a) Laboratory work counter(s), with sink;

(b) Designated sink equipped for hand-washing station in addition to process sink(s);

(c) Storage cabinet(s) or closet(s);

(d) Specimen collection room with a toilet, hand-washing station, and an area for handling and storing specimens;

(e) Blood collection facilities including secure seating, a work counter, and access to a hand-washing station. Collection facilities may be within the laboratory or in satellite location(s); and

(f) Refrigeration for storage of reagents, controls and patient specimens as necessary. Separate refrigeration must be provided for injectibles and food or drink that is to be consumed by patients or staff.

(3) Laboratory units shall conform to OAR 333-024-0000 and the rules there under regarding laboratory requirements. Standards contained in NFPA 99 regarding laboratories and health related institutions are also required.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 441.060

Stats. Implemented: ORS 441.060

Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(9); HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-074-0245; HD 21-1993, f. & cert. ef. 10-28-93; HD 2-2000, f. & cert. ef. 2-15-00; PH 14-2005, f. 8-10-05, cert. ef. 8-15-05; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0100
Imaging Facilities

(1) General: Imaging facilities are those which provide fluoroscopy, radiography, mammography, tomography, computerized tomography scanning, ultrasound, magnetic resonance, angiography, and other similar techniques. Room layouts, including clearances, must meet equipment manufacturers' minimum recommendations.

(2) Radiation Protection: All imaging facilities and radiation producing equipment installations must comply with Oregon Health Authority, Public Health Division, Regulations for Control of Radiation, OAR 333-100 through 123, and be licensed by Radiation Protection Services of the Division.

(a) Where protected alcoves with view windows are required, a minimum of 1 foot 6 inches between the view window and the outside partition edge shall be provided.

(3) Angiography. The following shall be provided:

(a) Procedure rooms shall be a minimum of 400 square feet in size exclusive of fixed cabinets and built-in shelves;

(b) A control room shall be provided to house associated staff and equipment. A view window shall be provided to permit full view of the patient;

(c) Area for image reading;

(d) A scrub sink, as referenced in OAR 333-535-0260, located outside the staff entry to the procedure room shall be provided for staff use;

(e) Facilities shall be available for patients waiting on stretchers that are out of the line of traffic;

(f) Storage for equipment; and

(g) Facilities shall be available within the facility for extended post-procedure observation of outpatients.

(4) Cardiac Catheterization Lab. Facilities for cardiac catheterization may be combined with the imaging department or be part of the surgery suite. If provided, cardiac catheterization lab facilities shall meet the rules for angiography rooms under section (3) above. The following additional requirements shall be provided:

(a) A separate scheduling and staff work space, cardiologist's office and staff toilet shall be provided when the facilities are located outside the imaging suite; and

(b) There shall be access to a clean assembly/workroom with Hi-vacuum or gravity steam sterilizers and sterilization equipment to accommodate heat sensitive equipment.

(c) Electrophysiology labs. If electrophysiology labs are also provided in accordance with the approved Functional Program, these labs may be located within the catheterization suite or located in a separate functional area proximate to the cardiac care unit.

(d) For Cardiac Catheterization Lab combined with Surgery refer to OAR 333-535-0110 to be used in conjunction with this section.

(5) Computerized Tomography (CT) Scanning. The following shall be provided:

(a) Procedure rooms shall be configured to accommodate equipment in accordance with the equipment manufacturers' recommendations;

(b) When required by the Functional Program, control room(s) shall be located to allow for film processing and designed to accommodate the computer and other controls for the equipment. When viewing of patients is required, a window shall be provided to permit full view of the patient; and

(c) A conveniently available patient toilet.

(6) Diagnostic X-ray (Radiography). The following shall be provided:

(a) Radiography room(s), sized to accommodate the Functional Program;

(b) Each X-ray room shall include a shielded control alcove designed to provide a full view of the patient when the table is in the tilt position or the chest X-ray is being utilized. For mammography machines with built-in shielding for the operator, the alcove may be omitted when approved by the Oregon Health Authority, Public Health Division, Radiation Protection Services; and

(c) Rooms primarily utilized for fluoroscopy shall have direct access to a toilet room.

(7) Magnetic Resonance Imaging (MRI). The following shall be provided:

(a) MRI procedure room(s) to accommodate the Functional Program and meet equipment manufacturers' recommendations;

(b) Secure storage for patient belongings;

(c) A control room with full view of the MRI;

(d) A computer room as needed to support the specific equipment installation;

(e) Cryogen storage when service to replenish supplies is not otherwise available;

(f) Power conditioning and voltage regulation equipment as well as direct current (DC) when required by the equipment manufacturer;

(g) Magnetic shielding and radio frequency shielding when required by the equipment manufacturer;

(h) Patient holding area convenient to the MRI unit and large enough to accommodate stretchers;

(i) Venting of cryogen exhaust to the outside; and

(j) Signage shall be provided for the purpose of limiting ferrous material.

(8) Ultrasound. The following shall be provided:

(a) Procedure room(s) meeting equipment manufacturers' minimum room size and configuration recommendations; and

(b) A patient toilet room shall be accessible to every three procedure rooms without traveling through public areas.

(9) Nuclear medicine. The nuclear medicine area shall include the following: (See also, OAR 333-535-0105(3))

(a) Space requirements. Space shall be adequate to permit entry of stretchers and beds and able to accommodate imaging equipment, electronic consoles, and if present, computer terminals;

(b) Hand-washing stations provided within each procedure room;

(c) Dose administration area(s) as specified by the Functional Program shall be provided near the preparation area. The area shall provide for visual privacy from other areas due to long periods for dose effects, as well as features for comfortable seating, varied lighting, and entertainment; and

(d) Positron Emission Tomography (PET). When provided, in addition to the nuclear medicine requirements, PET facilities shall be in accordance with the Functional Program, including the following:

(A) Laboratory and equipment space shall be provided as follows:

(i) Scanner room should be not less than 300 square feet and space for the cyclotron room should be not less than 225 square feet with 16 square feet of space safe for storage of parts that may require cool-down periods of one year or more;

(ii) Both hot (radioactive) labs and cold labs, each requiring a minimum of 250 square feet. Blood labs having a minimum of 80 square feet;

(iii) Patient holding areas capable of accommodating a minimum of two stretchers; and

(iv) Gas storage areas large enough to accommodate sufficient bottles of gas piped individually to the cyclotron or the lab.

(B) Construction requirements capable of providing protection from the high radiation generated from the cyclotron shall be provided.

(C) Ventilation adequate for the occupancy shall be provided as follows:

(i) Compressed air, or equivalent, shall be provided to pressurize a water circulation system;

(ii) Special ventilation systems together with monitors, sensors, and alarm systems shall be provided to vent gases and chemicals; and

(iii) Regarding heating, ventilating, and air-conditioning systems, the highest pressure shall be in the coldest (radiation) areas and the exhaust shall be in the hottest (radiation) areas. (Redundancy may be important.)

(D) A redundant plumbing system connected to a holding tank shall be required to prevent accidental leakage of contaminated water into the regular plumbing system.

(10) Support Spaces. The following spaces shall be common to the imaging department and shall be minimum requirements unless stated otherwise:

(a) Patient waiting areas shall provide seating capacity in accordance with the Functional Program;

(b) Control desk and reception area;

(c) Patient holding area under staff control, designed to accommodate inpatients on stretchers or beds and outpatients, that is not in the path of traffic. This area may be shared with the dose administration area and patient waiting areas provided there is visual privacy between the areas;

(d) Patient toilet room with hand-washing station shall be provided and reserved for nuclear medicine patients convenient to waiting and procedure rooms and directly accessible from each fluoroscopy room;

(e) Patient dressing rooms. Dressing rooms with convenient access to waiting areas and procedure rooms shall include a seat or bench, a mirror, and provisions for hanging patient's clothing and securing valuables;

(f) Access to staff toilet, lounge and locker facilities which shall be within or closely available to the department;

(g) Film storage facilities for active and inactive files under departmental administrative control shall be provided to properly secure and protect film against loss or damage. This storage is permitted to be off site;

(h) Storage for unexposed film;

(i) Contrast media preparation area with sink, counter and storage to allow mixing of contrast media. Where prepared media is used, this area may be omitted and storage shall be provided for the prepared media;

(j) A darkroom shall be provided for film processing unless the processing equipment does not require a darkroom for loading and transfer;

(k) If automatic film processors are used, a receptacle of adequate size with hot and cold water for cleaning processor racks shall be provided;

(l) Quality control room. An area or room for immediate viewing of film after processing shall be provided unless other viewing facilities are immediately available;

(m) Housekeeping facilities, including a service sink or floor receptacle and storage for cleaning equipment and supplies;

(n) A hand-washing station shall be provided in each procedure room unless it is used only for routine diagnostic screening such as for chest X-rays and where the patient is not physically handled by the staff. A hand-washing station shall be provided convenient to MRI, CT and ultrasound rooms, but it need not be within the room;

(o) Clean storage area. Provisions shall be made for storage of clean supplies and linens (See OAR 333-535-0260 for clean storage details and definitions);

(p) Soiled holding area. Provisions shall be made for a separated holding area for soiled materials, linens and trash. Handwashing facilities shall be closely available. If cleaning and disinfecting of equipment occurs within the imaging department, a counter, sink, hand-wash station and exhaust ventilation shall be provided (See OAR 333-535-0260 for clean storage details and definitions);

(q) Provisions shall be made for locked storage of medications and drugs when the program includes their use; and

(r) When the Functional Program requires a centralized computer area, it shall be a separate room with access terminals available within the imaging rooms.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(10); HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-074-0250; HD 21-1993, f. & cert. ef. 10-28-93; HD 2-2000, f. & cert. ef. 2-15-00; PH 14-2005, f. 8-10-05, cert. ef. 8-15-05; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0105
Radiation Oncology Facility or Department

All radiation oncology installations must comply with provisions of the Oregon Health Authority, Public Health Division, Regulations for Control of Radiation, OAR 333-100 through 123 and be licensed by Radiation Protection Services of the Division.

(1) Treatment Rooms:

(a) Rooms and control areas shall be provided as necessary to accommodate the radiation oncology Functional Program. Equipment manufacturers' recommendations should be sought and fol-

lowed. Any radiotherapeutic (i.e. cobalt, linear accelerators, high dose rate after loading, etc.) treatment room shall be sized in accordance with manufacturers' recommended standards and shall accommodate a stretcher;

(b) Control areas shall have visual and audio contact with the patient in the treatment room as appropriate to the radiation protection needs of the equipment;

(c) If invasive procedures take place in the treatment room, the room must also meet the rules for surgery facilities, OAR 333-535-0110; and

(d) Hyperthermia room, when provided, shall be of adequate size to accommodate equipment, stretcher, and a hand-washing station. This may be combined with an examination room.

(2) Treatment Support Areas:

(a) Simulator room and control area shall be sized to accommodate equipment and stretcher per the manufacturers' recommendations. A hand-washing station shall be provided within the room.

(b) The control area shall have visual and audio contact with the simulator room.

(c) Darkroom or film processing area shall be convenient to the treatment room(s) and simulator area, and shall include a utility sink in or convenient to this area. Film storage for unprocessed film shall be provided.

(d) Block fabrication, when provided, shall have seamless flooring and integral coved base. Non-porous counter tops shall have backsplash, and a hand-washing station shall be provided. Exhaust hoods shall be provided.

(e) Treatment planning, if provided, shall be sized to accommodate manufacturers' dosimetry system requirements.

(3) Hot lab, if provided, shall include the following features:

(a) Seamless flooring and integral coved base.

(b) Non-porous counter tops with backsplash.

(c) Adequate storage and work area for multiple types of radioactive material, with adequate shielding and security including additional support areas for cobalt room for hot lab storage.

(d) A hand-washing station shall be accessible. If located in the hot lab, the sink must have a filtration trap. Refer to OAR 333-535-0300(5)(e)(G) for mechanical requirements.

(e) If radiopharmaceutical preparation is performed on site, an area adequate to house a radiopharmacy shall be provided with appropriate shielding.

(A) Space requirements shall include the following:

(i) Adequate space for storage of radionuclides, chemicals for preparation, dose calibrators, a film file area, and record-keeping;

(ii) If pre-prepared materials are used, storage and calculation area may be considerably smaller than that for on site preparation; and

(iii) Space shall be adequately provided for dose calibration, quality assurance, and record-keeping.

(B) Radiation protection requirements. The area may still require shielding from other portions of the facility.

(C) Construction requirements shall include the following:

(i) Floors and walls constructed of materials that are easy to decontaminate;

(ii) Vents and traps for radioactive gases shall be provided if such are used; and

(iii) Hoods for pharmaceutical preparation shall be in accordance with mechanical requirements of OAR 333-535-0300 and other applicable standards.

(f) Nuclear Waste Disposal. See Code of Federal Regulations (CFR), Title X, parts 20 and 35, concerning the handling and disposal of nuclear materials in health care facilities.

(4) Patient Support Areas: These areas shall include, but not be limited to:

(a) Examination rooms equipped with a hand-washing station. At least one examination room shall accommodate stretcher patients;

(b) Patient reception and waiting area. The waiting area shall be out of traffic, under staff control, and both shall have seating capacity in accordance with anticipated needs. If the suite is routinely used for outpatients and inpatients at the same time, separate waiting areas shall be provided with screening for visual privacy between the waiting areas;

(c) Patient toilet rooms. Toilet rooms shall be provided accessible to the waiting rooms and shall be equipped with an emergency call station; and

(d) Patient dressing rooms. Dressing rooms shall be provided in accordance with the anticipated needs, shall be accessible to the waiting areas with the provision for safe storage of valuables and clothing. At least one space shall be large enough for staff-assisted dressing.

(5) General Support Areas: These areas shall include, but not be limited to:

(a) Clean storage. Provisions shall be made for the storage of clean supplies and linens, in or closely available to the department;

(b) Soiled holding area. Provisions shall be made for handling and separately holding contaminated items. If toxic chemicals are used, exhaust shall be provided. Whenever soiled items are handled, a hand-washing station shall be provided;

(c) Housekeeping closet shall be equipped with service sink or floor receptor. The closet shall be large enough for equipment or supplies storage;

(d) Staff facilities. Toilets shall be convenient for staff use. Staff lounge with lockers is required if not available elsewhere; and

(e) Film and radiation oncology patient record file area.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: OHD 2-2000, f. & cert. ef. 2-15-00; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0110
Surgical Facilities

A surgical unit shall consist of but not be limited to facilities as follows for exclusive use of the surgery department, unless otherwise noted:

(1) The number of operating rooms and recovery beds and the sizes of the service areas shall be based on the expected surgical workload. The surgical suite shall be located and arranged to prevent non-related traffic through the suite. Also see OAR 333-535-0300 for mechanical rules and 333-535-0310 for electrical rules which apply;

(2) Certain rules of this section differ dependent upon the type of surgical procedures performed. These are classified as one of the following three categories:

(a) Unrestricted areas for Minor Surgical and Diagnostic Procedures: Unrestricted areas include a central control point established to monitor the entrance of patients, personnel, and materials. Street clothes are permitted in this area and traffic is not limited. Minor procedures are those that conform to the criteria listed in paragraphs (2)(a)(A) through (D) of this rule based on an assessment of the patient. These procedures are non-invasive and require no general anesthetic.

(A) Anesthesia is limited to local anesthesia or conscious sedation;

(B) Procedure time (duration) is less than two hours;

(C) Procedure is non-invasive with low risk for infection; and

(D) Patient assessment indicates no special risks for cardiorespiratory complications.

(b) Semi-restricted areas include the following:

(A) The peripheral support areas of the surgical suite, and storage areas for clean and sterile supplies, work areas for storage and processing of instruments, and corridors leading to the restricted areas of the surgical suites; and

(B) Traffic in this area is limited to authorized personnel and patients. Personnel are required to wear surgical attire and cover all head and facial hair.

(c) Restricted areas for Major Surgical and Diagnostic Procedures are those which exceed the criteria described for Minor Surgical and Diagnostic Procedures in OAR 333-535-0110(2)(a). Restricted areas include the following:

(A) The operating and procedure rooms, the clean core, and scrub sink areas.

(B) Where surgical attire, hair coverings, and masks are required due to the presence of open sterile supplies, scrubbed people or similar circumstances.

(3) Operating Rooms:

(a) One or more operating rooms shall be provided. Each operating room shall provide a system for emergency communication with the surgical control station which can be operated without use of the hands, but which is not foot operated. No plumbing fixtures or open drains shall be provided in operating rooms except as stipulated in subsection (3)(d). Each operating room shall have a minimum clear area as follows:

(A) Existing operating rooms shall have not less than 360 square feet exclusive of fixed cabinets and built-in shelves. The minimum dimension shall be 18 feet between fixed cabinets and built-in shelves. At least one image reader shall also be provided.

(B) In new construction, operating rooms shall have a minimum clear area of 400 square feet exclusive of fixed or wall-mounted cabinets and built-in shelves, with a minimum of 20 feet clear dimension between fixed cabinets and built-in shelves. At least one image reader shall also be provided.

(b) Operating room(s) for orthopedic surgery, when provided, shall in addition to meeting subsection (a) of this section, have enclosed storage space for splints and traction equipment. Storage may be outside the operating room but must be located for convenient access. If plaster of paris is used for cast work, also provide a plaster sink outside the operating room, but within the operating suite.

(c) Operating rooms for cardiovascular surgery, when provided, shall provide appropriate plumbing connections in both the cardiovascular operating room and pump room and shall in addition to meeting subsection (a) of this section, provide a minimum clear area as follows:

(A) Existing facilities shall have not less than 400 square feet exclusive of fixed cabinets and built-in shelves with a minimum of 20 feet clear dimension between fixed cabinets and built-in shelves; and

(B) In new construction, rooms for cardiovascular, orthopedic, neurological, and other special procedures or combination of procedures such as cardiac catheterization lab and surgery that require additional personnel or large equipment shall have, in addition to the above requirements for general operating rooms, a minimum clear area of 600 square feet with a minimum room dimension of 20 feet clear dimension exclusive of fixed or wall-mounted cabinets and built-in shelves.

(d) Operating rooms for surgical cystoscopic and surgical endoscopic procedures and operating rooms dedicated to eye surgery, when provided, shall meet requirements of subsection (a) of this section, but clear area of the room shall be as follows:

(A) Existing facilities shall have not less than a minimum of 250 square feet exclusive of fixed cabinets and built-in shelves.

(B) In new construction, rooms for surgical cystoscopic and other endourologic procedures shall have a minimum clear area of 350 square feet exclusive of fixed or wall-mounted cabinets and built-in shelves, with a minimum of 15 feet clear dimension between fixed cabinets and built-in shelves. If cystoscopy rooms are used for procedures other than cystoscopy, provisions must be made to allow cleaning and sealing of any floor drains, and such procedures must be included in the hospital's written infection control policy.

(e) Operating rooms for minor surgical procedures, as defined in section (2) of this rule, shall meet requirements of subsection (a) of this section, except that clear area of the room shall be a minimum of 200 square feet exclusive of fixed cabinets and built-in shelves and minimum dimensions do not apply. Film illuminators are required only if procedures involve the use of X-rays.

(f) Despite requirements under subsections (a) through (e) of this section, needs for some procedures may require additional clear operating room space, and special plumbing and mechanical features. Such specialized operating rooms are not addressed by subsections (a) through (e) of this section, and are the responsibility of the hospital and their design consultants.

(4) Service areas: Services, except the enclosed soiled utility room mentioned in subsection (f) of this section and the housekeeping closet in subsection (q) of this section, may be shared with obstetrical facilities if the Functional Program and project design reflect this concept. Service areas, when shared with delivery rooms, shall be arranged to avoid the need for patients or staff to pass between the operating room and the delivery room areas. (See also obstetrical rules under OAR 333-535-0120.) The following services shall be provided:

(a) Control station located to permit visual observation of all traffic into and within the suite;

(b) Administrative and administrative support space in accord with the hospital's program needs;

(c) Sterilizing facility(ies) with high speed autoclave(s) for emergency use. Other facilities for processing and sterilizing reusable instruments may be located in another hospital department such as Central Services. Immediate access to sterilizing facilities is not required where only disposable supplies, instruments and equipment are used. Sterilization equipment shall conform to the Oregon Boiler and Pressure Vessel Specialty Code, ORS 480.525(1)(e);

(d) Medication storage and distribution facilities. Provisions shall be made for storage and preparation of medications administered to patients. A refrigerator and storage system meeting the requirements of Oregon Board of Pharmacy rules, OAR chapter 855, division 41 shall be provided. A hand-washing station shall be provided in or accessible to each area or room;

(e) Scrub facilities. For major surgical procedures, two scrub facilities shall be provided near the entrance to each operating room. Two scrub positions may serve two operating rooms if both are located adjacent to the entrance of each operating room. For minor surgical procedures, a scrub sink or a hand-washing station shall be provided in or accessible to each room. This sink shall be equipped with fittings usable without the use of hands;

(f) Soiled utility room. An enclosed soiled utility room for the exclusive use of the surgical suite staff or soiled holding room that is part of a system within the building for the collection and disposal of soiled material shall be provided. The soiled utility room shall contain a clinical sink or equivalent flushing type fixture, work counter, sink equipped for hand-washing, waste receptacle, and linen receptacle. When a soiled holding room is used, the clinical sink and work counter may be omitted from that room. (Also see subsection (g) of this section for fluid waste disposal facilities.) Soiled utility or holding areas shall not have direct connection with operating rooms or other sterile activities. The maximum travel distance to soiled utility or holding rooms shall be not more than six rooms or 180 feet;

(g) Fluid waste disposal facilities. These shall be located convenient to, but not connected with, the operating rooms. A clinical sink or equivalent equipment in a soiled utility room or in a soiled holding room would meet this standard if convenient for use. When the surgical program does not include procedures with substantial liquid or solid wastes (for example, minor eye surgery), a clinical sink is not required;

(h) Clean utility room or a clean supply room. A clean utility room is required when clean materials are assembled within the surgical suite prior to use. A clean utility room shall contain work counter, a hand-washing station, and space for clean and sterile supplies. If the Functional Program defines a system for the storage and distribution of clean and sterile supplies in a clean supply room, the counter and sink may be omitted. The clean workroom or supply room may be shared with the delivery suite when provisions for joint use are included in the hospital's infection control policy and arrangement allows for direct access from both surgery and delivery suites. (See also obstetrical rules under OAR 333-535-0120.);

(i) Medical gas storage facilities. Storage of bulk medical gases shall be provided outside or inside the facility. Provisions shall be made for additional separate storage of reserve gas cylinders to complete at least one day's procedures. Storage

facilities shall be in compliance with National Fire Protection Association (NFPA) 99;

(j) Anesthesia workroom. Inhalation anesthesia workroom for cleaning, testing, and storing anesthesia equipment shall contain a work counter and sink. Provisions shall be made for separated storage of clean and holding of soiled items. When facilities for cleaning and testing are available elsewhere in the building or the surgical program does not involve substantial anesthesia, a separate utility room is not required;

(k) Anesthesia storage. Anesthesia storage facilities shall be provided for anesthesia-related materials stored within the surgery suite;

(l) Equipment storage room(s) for equipment and supplies used in surgical suite. Ten percent of the surgical suite shall be devoted to equipment storage space. See OAR 333-535-0270 for storage requirements;

(m) Staff clothing change areas. Appropriate areas shall be provided for male and female personnel including orderlies, technicians, nurses and doctors working within the surgical suite. Each area shall contain lockers, showers, toilets, hand-washing stations, and space for donning scrub attire. In surgical suites providing general anesthesia and invasive surgical procedures, these areas shall be arranged to encourage a traffic pattern so that personnel entering from outside the surgical suite can change and move directly into the surgical suite. Showers are not required in suites limited to minor procedures;

(n) Pre-surgical waiting area. In facilities with two or more operating rooms, a room or separate area shall be provided to accommodate stretcher patients waiting for surgery. This may be adjoining the post anesthesia recovery area and be serviced by the same staff nurse when feasible. The area shall be located to allow for nursing supervision and emergency communications;

(o) Storage areas for portable equipment used in surgery, such as portable X-ray unit, stretchers, fracture tables, warming devices or auxiliary lamps. These areas shall not infringe on the width of exit corridors;

(p) Lounge, toilet facilities, and dictation and report preparation space for surgical staff. These facilities shall be provided in hospitals having three or more operating rooms and shall be located to permit use without leaving the surgical suite. A toilet room shall be provided near the recovery room(s);

(q) Housekeeping closet. A closet containing a floor receptor or service sink and storage space for housekeeping supplies and equipment shall be provided exclusively for the surgical suite;

(r) For major procedures, an area for preparation and examination of frozen sections. This may be part of the general laboratory if the system and procedures provide immediate results that will not unnecessarily delay the completion of surgery;

(s) Ice machine to supply ice for patient use and treatments;

(t) Provisions for refrigerated blood bank storage when major procedures are included; and

(u) Post anesthesia care unit for major surgical procedures. Each recovery unit shall be designed to provide:

(A) A medication distribution station, hand-washing stations (at a rate of one sink per four beds), nurses' station with charting facilities and clinical sink. Provisions for bedpan cleaning, storage space for stretchers, supplies and equipment shall be closely available.

(B) Clearance space of at least 5 feet between patient beds and 4 feet between sides of beds and adjacent walls.

(C) Patient privacy such as cubicle curtains.

(D) Provisions shall be made for isolation of infectious patients, although a separate isolation room is not mandated. At least one door to a recovery unit shall access directly from the surgical suite without crossing uncontrolled common hospital corridors. Separate and additional recovery space may be necessary to accommodate surgical outpatients, where applicable but is not required.

(5) Separate Hospital Licensed Outpatient Surgical Facilities. The following additional features shall be provided when an outpatient surgical facility is outside the inpatient hospital building or remote from the inpatient suite:

(a) Visual privacy shall be provided for registration, preparation, examination and recovery. Audible privacy shall be provided during registration;

(b) Provisions shall be made for patient examination, interview, testing and preparation prior to surgery;

(c) Outpatient surgical facilities not part of an inpatient hospital structure shall meet the requirements of the Oregon Structural Specialty Code and the NFPA 101 and 99; and

(d) Outpatient surgery change areas. If the Functional Program defines an outpatient surgery component as part of the inpatient surgical suite, facilities shall be provided where outpatients may change from street clothing into hospital gowns and be prepared for surgery. This would include facilities for waiting, storage of clothing, toilets, and space for gowning. Separate clothes changing areas are not required when sufficient pre-operative holding cubicles are available;

(e) Phase 1 recovery. If the facility provides outpatient surgery, rooms or cubicles for postanesthesia care and recovery shall be provided. At least 3 feet shall be provided at each side of each bed or recovery lounge chair and at the foot of each bed as needed for circulation of staff and gurneys and wheelchairs. Recovery spaces shall be observable from a nursing station. Provide hand wash stations at a rate of one sink per six recovery beds; and

(f) Phase 2 recovery spaces. Dedicated recovery spaces or a dedicated recovery lounge shall be provided in facilities where the surgical program includes patients who do not require postanesthesia recovery or who have completed postanesthesia recovery, but need additional time for observation by staff prior to leaving the facility. Access to toilet facilities shall be provided.

(g) Administrative and public areas. The following shall be provided:

(A) A patient and visitor waiting room or area and information and reception desk or counter;

(B) Public telephone or other phone(s) usable by patients and visitors;

(C) Space(s) for private interviews relating to social services, credit and admission;

(D) Office space(s) for business transactions, records, and administrative and professional staff, and space and equipment for medical records dictating, recording and retrieving. These shall be separate from public and patient areas with provisions for confidentiality of records;

(E) Secure storage for staff clothing and personal effects; and

(F) General storage for administrative supplies.

(6) Dental operations: Dental surgery facilities not part of a multi-specialty surgical unit shall meet the requirements of sections (1) through (4) of this rule. Operating rooms dedicated to dental surgery shall also conform to the following:

(a) Operating rooms used for invasive maxillofacial and reconstructive dental procedures with general anesthesia shall meet the rules of an operating room for major surgical procedures, except that room size shall be a minimum of 250 square feet; and

(b) Operating rooms for extractions and minor operative procedures within limited anesthesia or conscious sedation shall provide a minimum of 132 square feet of clear space and include the following features:

(A) Four feet or more of clear space at one side of the dental chair and a clear access route for a stretcher or gurney; and

(B) Mechanical and electrical features of a minor surgical procedure room according to OAR 333-535-0300 and 333-535-0310.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 441.025 & 441.060

Stats. Implemented: ORS 441.025 & 441.060

Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(11); HD 21-1987, f. & ef. 11-13-87; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89, Renumbered from 333-074-0255; HD 21-1993, f. & cert. ef. 10-28-93; HD 2-2000, f. & cert. ef. 2-15-00; PH 14-2005, f. 8-10-05, cert. ef. 8-15-05; PH 10-2009, f. & cert. ef. 10-1-09; PH 7-2016, f. & cert. ef. 2-24-16

333-535-0115
Endoscopy Facilities

If diagnostic endoscopy procedures are performed, the following shall apply:

(1) Diagnostic Procedure Room(s):

(a) Each diagnostic procedure room shall have a minimum clear area of 200 square feet exclusive of fixed cabinets and built-in shelves. If portable equipment is used for vacuum and oxygen, room size shall be increased to 225 square feet.

(b) A hand-washing station with hands-free controls shall be available in each procedure room.

(c) Station outlets for oxygen, vacuum (suction), and medical air shall be provided in accordance with Table 5, OAR 333-535-0300. Use of portable equipment is allowable when a piped-in central system is not available.

(d) Mechanical ventilation shall comply with OAR 333-535-0300, including Tables 2 and 3 of the same rule. If endoscopy rooms also serve for bronchoscopy services, these systems must meet ventilation requirements for this service in Table 2, OAR 333-535-0300.

(2) Instrument Processing Facilities. There shall be dedicated processing room(s) for cleaning and disinfecting instrumentation. Cleaning spaces shall allow for flow of instrumentation from the contaminated area to the clean area and, then to clean storage cabinets which may be in enclosed cabinets in the procedure rooms. Clean equipment spaces, including storage, must protect equipment from contamination. The following space and equipment shall also be included:

(a) If scopes are cleaned by hand, two separate utility sinks, arranged to prevent splash from one to the other, one for clean and one for soiled equipment processing;

(b) A separate hand washing sink;

(c) Space and facilities for the disposal of waste materials;

(d) When automatic endoscope cleaners and sonic processors are used, space and plumbing fixtures for this equipment shall be provided;

(e) Ventilation system: Negative air pressure and exhaust air from the room per Table 2, OAR 333-535-0300, shall be maintained. A hood is recommended for off-gassing and sterilants that cause respiratory irritation; and

(f) Outlets for vacuum and/or compressed air shall be provided in accordance with the Functional Program.

(3) Patient Holding and Recovery Area (if not shared with surgical recovery). The following shall be provided:

(a) Each patient cubicle shall allow a minimum 3 feet between stretchers or recovery chairs;

(b) Each patient cubicle shall be equipped with oxygen and vacuum outlets in accordance with Table 5, OAR 333-535-0300;

(c) Provisions for respiratory isolation shall be provided if bronchoscopy patients are also served in patient cubicles. When procedures are to be performed on persons who are known to have or suspected of having airborne infectious diseases, these procedures shall be performed only in a room meeting airborne infection isolation ventilation requirements or in a space using local exhaust ventilation. See also the CDC "Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Healthcare Facilities";

(d) Medication preparation and storage with a hand-washing station;

(e) Toilet facilities;

(f) Change areas and secure storage for patients' personal property. Patient recovery cubicles may be used when scheduling and capacity allows;

(g) Nurses' reception and charting area that allows for visual observation of patients;

(h) Storage provisions for clean supplies;

(i) A dedicated housekeeping closet;

(j) A nurse call system or other workable system that allows for summoning staff assistance; and

(k) A soiled utility or soiled holding room as referenced in OAR 333-535-0260(5) shall be located to serve the endoscopy facility.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 441.060

Stats. Implemented: ORS 441.060

Hist.: OHD 2-2000, f. & cert. ef. 2-15-00; PH 14-2005, f. 8-10-05, cert. ef. 8-15-05; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0120
Obstetrical Facilities

The maternity unit shall consist of, but not be limited to, facilities as follows for exclusive use of the maternity department, unless otherwise noted:

(1) General:

(a) The maternity unit shall be located in one area of the hospital and include delivery rooms, labor rooms, recovery rooms, postpartum rooms, labor, delivery, recovery (LDR) and/or labor, delivery, recovery, postpartum (LDRP) rooms, and the support features described in this section to support the estimated obstetrical workload;

(b) The obstetrical care unit shall be located and arranged to prohibit non-related traffic through the unit;

(c) When delivery and non-obstetrical operating rooms are part of the same suite, access and service arrangements shall be such that neither staff nor patients need to travel through one area to reach the other;

(d) At least one delivery room shall be provided within the obstetrical unit for performing Caesarean sections (C-sections) and complex deliveries except for hospital-based obstetrical centers limited to less than 300 low-risk deliveries per year. In such centers, mothers requiring emergency C-sections and complex deliveries may be transferred to surgery, provided a clean operating room can normally be made available, and infants can be transported back to the obstetrical unit in a controlled transport environment such as an isolette;

(e) When the program indicates wide usage of LDR and/or LDRP rooms in place of separate labor, delivery, recovery and postpartum rooms, the number of labor and postpartum rooms may be reduced or eliminated in accord with the hospital's obstetrical program and workload. Delivery rooms shall be provided per subsection (d) of this section; and

(f) Service areas may be arranged to serve LDR rooms, LDRP rooms and delivery rooms. However, gowning facilities, clean supply, soiled utility rooms, and anesthesia facilities must be arranged to conveniently serve delivery rooms used for C-sections and allow for a sterile operating suite environment. When such support areas are not immediately adjacent, the program and infection control policy must be submitted for Oregon Health Authority, Public Health Division approval and shall account for such arrangement.

(2) The following patient care facilities shall be provided in accord with section (1) of this rule for exclusive use of the maternity department, unless otherwise noted:

(a) Postpartum patient rooms must meet the same rules as medical and surgical patient rooms under OAR 333-535-0025(1);

(b) Each delivery room shall have a minimum clear area of 300 square feet exclusive of fixed cabinets and built-in shelves and shall be not less than 16 feet wide. Delivery rooms that are routinely used for C-sections shall have not less than 360 square feet of clear area. An emergency communications system that can be activated without use of hands shall be connected with the obstetrical suite control station. Resuscitation facilities (electrical outlets, oxygen, suction, and compressed air) shall be provided for newborn infants within each delivery room in addition to the facilities required for the mother;

(c) LDR and LDRP rooms, when provided, shall be entered from a corridor within the maternity department where public access is under direct control of maternity staff and include the following features:

(A) Each room shall be for single occupancy and provide for a minimum of 5 feet of clear space at the sides and foot of the bed during delivery procedures. Additional space shall be provided for relatives and significant others, a chair for mothers who are breastfeeding, and an infant cribbette;

(B) Mechanical and electrical services for LDR and LDRP rooms shall meet applicable requirements stated in OAR 333-535-0300 and 333-535-0310; and

(C) Each room shall contain or be closely served by each of the following:

(i) Enclosed storage cabinets or space for a covered cart for supplies used in normal spontaneous vaginal delivery and the immediate care of a normal newborn, unless the program indicates centralized storage and distribution from a nearby clean supply room;

(ii) Storage space for equipment utilized in medical emergencies for mother and infant;

(iii) A hand-washing station or scrub sink equipped with a wrist blade fitting or equivalent fitting allowing operation without use of the hands;

(iv) Toilet facility and shower;

(v) A window is required in each patient room as noted in OAR 333-535-0025;

(vi) Storage space for clothing, toilet articles, and other personal belongings of the patient;

(vii) An electrically operated nurses' calling system as specified under electrical requirements of this division; and

(viii) Examination lighting shall be provided but may be built-in or portable.

(d) Labor rooms. When provided, these rooms shall be single bed or two-bed rooms with a minimum clear area of 100 square feet per bed. In facilities having only one delivery room, two or more labor rooms or LDRP rooms shall also be provided. When two labor rooms only are utilized in connection with a single delivery room, one labor room shall be large enough to function as an emergency delivery room with a minimum of 160 square feet and have at least two oxygen and two suction outlets. Each labor room shall contain a hand-washing station and shall have direct access to a toilet room. One toilet room may serve two labor rooms. Labor rooms shall be closely served by facilities for medication, charting, and storage for supplies and equipment. At least one shower for use of labor room patients shall be provided. A water closet shall be accessible to shower facility. Windows, if provided, shall be located, draped or otherwise arranged, to preserve patient privacy from observation from outside.

(e) Recovery room. It shall contain not less than two beds, charting facilities located to permit staff to have visual control of all beds, facilities for medicine dispensing, hand-washing stations at a rate of one per four beds or a minimum of one, clinical sink with bedpan flushing device, and storage for supplies and equipment. The recovery room may be omitted in hospitals with fewer than 300 annual births.

(3) Service Areas. Individual rooms shall be provided as indicated in the following standards. Otherwise, alcoves or other open spaces that do not interfere with traffic may be used. Services, except the father's waiting room mentioned in subsection (c) of this section, soiled workroom in subsection (g) of this section, and the housekeeping closet in subsection (p) of this section, may be shared with the surgical facilities if the Functional Program reflects this concept. Where shared, areas shall be arranged to avoid direct traffic between the delivery and operating rooms. The following services shall be provided:

(a) Control station located to permit visual surveillance of all traffic that enters the obstetrical suite.

(b) Supervisor's office or station.

(c) Fathers' waiting room located convenient to the labor room area with provisions for personal communication between fathers and staff. Toilets, telephones, and drinking fountains shall be convenient to the waiting room. In hospitals with less than 300 deliveries per year, a separate fathers' waiting room is not required when a general purpose waiting area can be made available.

(d) Sterilizing facility(ies) with high speed autoclave(s) conveniently located to serve all delivery rooms. When a written program indicates that adequate provisions have been made for replacement of sterile instruments during a delivery, sterilizing facilities in the obstetrical suite will not be required.

(e) Drug distribution station. Provision shall be made for storage, preparation, and dispensing of medication.

(f) Scrub facilities. Two scrub stations shall be provided near the entrance to each delivery room; however, two scrub stations may serve two delivery rooms if the scrub stations are located adjacent to the entrance of each delivery room. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel or supply carts.

(g) An enclosed soiled utility room for the exclusive use of the obstetrical suite staff or a soiled holding room that is part of a system for the collection and disposal of soiled materials. The soiled utility room shall contain a clinical sink or equivalent flushing type fixture, work counter, a hand-washing station, waste receptacle, and linen receptacle. If a soiled holding room is used, the hand-washing station and work counter may be omitted. Soiled utility and/or holding areas shall not have a direct connection with delivery rooms or other sterile activities.

(h) Fluid waste disposal facilities shall be provided in a location convenient to but not connected with the delivery rooms. (The clinical sink or equivalent equipment in a soiled utility room or soiled holding room would meet this standard.) See OAR 333-535-0260(5) for sanitary references.

(i) Clean utility room(s) or clean supply room(s). A clean utility room is required when clean materials are assembled within the obstetrical suite prior to use. A clean utility room shall contain a work counter, a hand-washing station, and space for clean and sterile supplies. A clean supply room shall be provided when the program defines a system for the storage and distribution of clean and sterile supplies that would not require the use of a clean utility room. When clean supplies and equipment used in LDR and LDRP rooms are kept in a central location, the room shall be sized to reflect this concept. (A clean utility room or supply room may be shared with surgery department when provisions for joint use are included in the hospital's infection control policy and arrangement allows direct access to both delivery and surgery suites.).

(j) Anesthesia storage facilities. Unless the narrative program and official hospital board action in writing prohibit use of flammable anesthetics, a separate room shall be provided for storage of flammable gases in accordance with the requirements detailed under the mechanical section of these rules (OAR 333-535-0300). (Anesthesia storage facilities may also serve the surgery suite when provision is made for direct access from both surgery and delivery suites.).

(k) Anesthesia utility room or space for cleaning, testing, and storing anesthesia equipment. It shall contain a work counter, sink, and provisions for separation of clean and soiled items. This may occur at a location outside the suite, provided that sufficient clean equipment and supplies are available at all times. The anesthesia utility room may be omitted when a narrative statement and hospital board policy are submitted stating that no anesthetics are utilized.

(l) Equipment storage room(s) for equipment and supplies used in obstetrical suite.

(m) Staff's clothing change areas. Appropriate areas shall be provided for male and female personnel (technicians, nurses, aides, and doctors) working within the obstetrical suite. The areas shall contain lockers, showers, toilets, hand-washing stations, and space for donning scrub apparel. A receptacle for discarding soiled surgical gowns and boots shall be located to minimize contact with clean personnel. (The same clothes change areas may serve the surgery suite when provision for joint use is included in the hospital's infection control policy and arrangement allows for direct access from both surgery and delivery suites.).

(n) Lounge and toilet facilities for obstetrical staff convenient to delivery, labor, recovery, LDR and LDRP rooms. A separate lounge may be omitted, however, in hospitals with less than 300 deliveries per year.

(o) Facilities for physician waiting, charting, and sleeping are recommended where the obstetrical staffing program and workload indicate need for such, but are not required.

(p) Housekeeping closet. A dedicated closet containing a floor receptor or service sink, in accordance with OAR 333-535-

0260(7), and storage space for housekeeping supplies and equipment shall be provided exclusively for the obstetrical suite.

(q) Stretcher storage area. This area shall be out of direct line of traffic.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(12); HD 21-1987, f. & ef. 11-13-87; HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; Renumbered from 333-074-0260; HD 21-1993, f. & cert. ef. 10-28-93; OHD 1-2002, f. & cert. ef. 2-28-02; PH 14-2005, f. 8-10-05, cert. ef. 8-15-05; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0130
Rehabilitation Therapy Department

(1) If a formal rehabilitation therapy service is provided, facilities and equipment shall be required for the effective function of the program. Where two or more rehabilitative services are included, items may be shared between service elements, in accordance with the Functional Program.

(2) The rehabilitative therapy department shall include the following, which may be shared or provided as separate units for each service, in accordance with the Functional Program:

(a) Office space with provision for filing and retrieval of patient records;

(b) Patient waiting space with provisions for wheelchairs out of traffic;

(c) Treatment area(s) as programmed for thermo-therapy, diathermy, ultrasonic and hydrotherapy. Cubicle curtains shall be provided around each individual treatment area. Hand-washing stations shall be provided at a rate of one per four treatment spaces. Facilities for collection of wet and soiled linen and other materials shall be provided;

(d) Exercise area;

(e) Storage for clean linen, supplies, and equipment;

(f) Patient dressing areas and toilet rooms with hand-washing stations accessible to wheelchair patients;

(g) A conveniently accessible housekeeping closet and service sink;

(h) Wheelchair and stretcher storage shall be provided out of traffic and treatment space areas, but shall be conveniently located;

(i) Secure storage shall be available to the department for staff personal property;

(j) Convenient access to toilets shall be provided.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(13); HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; Renumbered from 333-074-0265; HD 21-1993, f. & cert. ef. 10-28-93; HD 2-2000, f. & cert. ef. 2-15-00; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0140
Occupational Therapy Suite

The occupational therapy suite shall include the following elements:

(1) Office space.

(2) Activities area. A hand-washing station shall be provided. Facilities for collection of waste products prior to disposal shall be provided, in accordance with the Functional Program.

(3) Storage for supplies and equipment.

(4) Ready access to patient toilet facilities.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(14); HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; Renumbered from 333-074-0270; HD 21-1993, f. & cert. ef. 10-28-93; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0150
Respiratory Therapy Unit

The respiratory therapy unit shall include space to accommodate program needs and shall contain the following additional elements:

(1) Office space including records file.

(2) Storage for supplies and equipment.

(3) Equipment servicing area.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(15); HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; Renumbered from 333-074-0275; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0160
Morgue and Autopsy

(1) These facilities shall be directly accessible to an outside entrance and shall be located to avoid transfer of cadavers through public areas.

(2) The following elements shall be provided when autopsies are performed within the hospital:

(a) Refrigerated facilities for body-holding equipped with temperature monitoring and alarms.

(b) Autopsy room. This room shall contain:

(A) Work counter with a hand-washing station;

(B) Storage space for supplies, equipment, and specimens;

(C) Autopsy table;

(D) Clothing change area with shower, toilet, and lockers, within the area; and

(E) Housekeeping service sink or receptacle.

(3) If autopsies are performed outside the facility, only a well-ventilated body-holding room need be provided within the hospital.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(16); HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; Renumbered from 333-074-0280; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0170
Pharmacy Suite

(1) The size and type of services to be provided in the pharmacy will depend upon the type of drug distribution system to be used in the hospital and whether the hospital proposes to provide, purchase, or share pharmacy services with other hospitals or other medical facilities.

(2) Provision shall be made for the following functional areas:

(a) Hand-washing stations shall be provided within each separate room where open medication is prepared for administration;

(b) Dispensing area;

(c) Editing or order review area;

(d) Sterile products area. (For the compounding of IV admixtures and other sterile products. May also be used for extemporaneous compounding). If intravenous (IV) solutions are prepared in the pharmacy, a sterile work area with a laminar-flow workstation designed for product protection shall be provided. See OAR 333-535-0300;

(e) Administrative areas. (Office area for the chief pharmacist and any other offices required for the proper maintenance of records and reports and also for purchasing, accounting, and personnel activities.);

(f) Storage areas (bulk, active, refrigeration, vault, volatile liquids);

(g) Drug information area;

(h) Packaging area. (Provide only if required by program.);

(i) Bulk compounding area. (Provide only if required by program.); and

(j) Quality control area. (Required only if either packaging or bulk compounding areas are provided)

(3) The pharmacy suite shall be in conformance with statutes and administrative rules pertaining to the State Board of Pharmacy.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(17); HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; Renumbered from 333-074-0285; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0180
Dietary Facilities

(1) Food service facilities may consist of an on-site conventional food preparing system, a convenience food service system, or an appropriate combination of the two, and shall meet the requirements of the Oregon Food Sanitation Rules OAR 333-150-0000.

(2) Functional elements. The following facilities shall be provided in the size required to implement the type of food service selected:

(a) Control station for receiving food supplies.

(b) Storage space for four days' supply including food requiring cold storage.

(c) Food preparation facilities. Conventional food preparation systems require space and equipment for preparing, cooking, and baking. Convenience food service systems such as frozen prepared meals, bulk packaged entrees, and individual packaged portions, or systems using contractual commissary services require space and equipment for thawing, portioning, cooking, and/or baking.

(d) Hand-washing stations located in the food preparation area.

(e) Patients' meal service facilities. Examples are those required for tray assembly and distribution.

(f) Dining space for ambulatory patients, staff, and visitors.

(g) Ware-washing space located in a room or an alcove separate from food preparation and serving area. Commercial-type dishwashing equipment shall be provided. Space shall also be provided for receiving, scraping, sorting, and stacking soiled tableware and for transferring clean tableware to the using areas. A hand-washing station shall be conveniently available.

(h) Pot-washing facilities.

(i) Storage areas and sanitizing facilities for cans, carts, and mobile tray conveyors.

(j) Waste storage facilities located in a separate room easily accessible to the outside for direct pickup and disposal.

(k) Office(s) or desk spaces for dietitian(s) or the dietary service manager.

(l) Toilets for dietary staff. A hand-washing station shall be immediately available.

(m) Housekeeping closet. Located within the dietary department and shall contain a floor receptor or service sink and storage space for housekeeping, equipment and supplies.

(n) Self-dispensing ice-making facilities. May be in area or room separate from food preparation area but must be easily cleanable and convenient to dietary facilities.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(18); HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; Renumbered from 333-074-0290; HD 21-1993, f. & cert. ef. 10-28-93; HD 2-2000, f. & cert. ef. 2-15-00; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0190
Administration and Public Areas

The following areas shall be provided:

(1) Entrance at grade level, sheltered from the weather, and able to accommodate wheelchairs.

(2) Lobby. It shall include:

(a) Storage space for wheelchairs;

(b) Reception and information counter or desk;

(c) Waiting space(s);

(d) Public toilet facilities;

(e) Public telephones; and

(f) Drinking fountain(s).

(3) Interview space(s) for private interviews relating to social service, credit, and admissions.

(4) General or individual office(s) for business transactions, medical and financial records, and administrative and professional staffs.

(5) Multipurpose room(s) for conferences, meetings, and health education purposes including provisions for showing visual aids.

(6) Library facilities.

(7) Storage for office equipment and supplies.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(19); HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; Renumbered from 333-074-0295; HD 21-1993, f. & cert. ef. 10-28-93; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0200
Medical Records Unit

The following rooms and areas shall be provided:

(1) Medical records administrator/technician office or space.

(2) Review and dictating room(s) or spaces.

(3) Work area for sorting, recording, or archiving records.

(4) Storage area for records.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(20); HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; Renumbered from 333-074-0300; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0205
Central Services Supply

The following shall be provided:

(1) Soiled utility room. This room shall be physically separated from all other areas of the department. The work space shall be provided to handle the cleaning and initial sterilization/disinfection of all medical/surgical instruments and equipment. Work tables, sinks, flush-type devices, and washer/sterilizer decontaminators shall be provided. Hand-washing stations shall be provided. Lockers, showers, and toilets shall be provided for staff employed in this area if these facilities are not available in adjacent employee facilities servicing other soiled areas.

(2) Clean assembly/utility room. The utility room shall contain work space and equipment for terminal sterilizing medical and surgical equipment and supplies and hand-washing stations.

(a) A sterilization room shall be provided that is used exclusively for the inspection, assembly, and packaging of medical/surgical supplies and equipment for sterilization.

(A) Access to the sterilization room shall be restricted.

(B) This room shall contain Hi-Vacuum or gravity steam sterilizers and sterilization equipment to accommodate heat-sensitive equipment (ETO sterilizers) and ETO aerators.

(C) This room shall contain work tables, counters, a hand-washing station, ultrasonic storage facilities for backup supplies and instrumentation, and a drying cabinet or equipment.

(D) The area shall be designed to accommodate sterilizer carts for loading of prepared supplies for sterilization.

(3) Storage areas for clean supplies and for sterile supplies. A room for breakdown shall be provided for manufacturers' clean/sterile supplies. The clean processing area shall not be in this area but in an adjacent space.

(4) Equipment storage room. Storage for packs, etc., shall include provisions for ventilation, humidity, and temperature control.

(5) Cart storage. This area shall be adjacent and easily available to clean and sterile storage and close to the main distribution point to keep traffic to a minimum and ease workflow.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68: HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(21); HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; Renumbered from 333-074-0305; HD 21-1993, f. & cert. ef. 10-28-93; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0210
General Stores

The following shall be provided:

(1) Off street unloading facilities.

(2) Receiving area. Adequate receiving areas shall be provided to accommodate delivery trucks and other vehicles.

(a) The location of the receiving area shall be located to promote safe, secure, and efficient movement of arriving materials without compromising patient areas.

(A) Dock areas shall be segregated from other occupied building areas and located so that noise and odors from operation will not adversely affect building occupants.

(B) The receiving area shall be convenient to service elevators and other internal corridor systems.

(C) Receiving areas shall be segregated from waste staging and other outgoing materials-handling functions.

(b) Space requirements shall be adequate to enable breakdown, sorting, and staging of incoming materials and supplies.

(A) Balers and other devices shall be located to capture packaging for recycling or return to manufacturer or deliverer.

(B) In facilities with centralized warehousing, adequate space shall be provided at receiving points to permit the staging of reusable transport containers for supplies moving from central warehouses to individual receiving sites.

(3) General storage rooms or storage system shall be provided to meet hospital needs. They shall generally be concentrated in one area, but, in a multiple building complex, they may be in separate concentrated areas in one or more individual buildings on site. Off-site locations for a portion of this storage shall be permitted. The following shall be provided:

(a) Provisions for protection against inclement weather during transfer of supplies.

(b) General storage room(s) with a total area of not less than 20 square feet per inpatient bed shall be provided.

(c) Additional storage areas for outpatient facilities in combination with and in addition to the general stores, or in a central area within the outpatient department shall be permitted. Off-site location(s) for a portion of this storage shall also be permitted.

(d) Additional storage areas for outpatient facilities shall be provided in an amount not less than five percent of the total area of those facilities.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(22); HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; Renumbered from 333-074-0310; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0220
Linen Services

(1) On-site processing. If linen is to be processed on the hospital site, the following shall be provided:

(a) Laundry processing room with commercial-type equipment that can process seven days' needs within a regularly scheduled workweek. A hand-washing station shall be provided;

(b) Soiled linen utility, room with a hand-washing station and holding rooms. Lockers, showers, and toilets shall be provided for staff employed in this area if these facilities are not available in adjacent employee facilities servicing other soiled areas;

(c) Storage for laundry supplies;

(d) Clean linen inspection and mending room or area;

(e) Clean linen storage, issuing, and holding room or area;

(f) Housekeeping closet containing a floor receptor or service sink and storage space for housekeeping equipment and supplies;

(g) Cart storage area(s). These shall be provided for separate parking of clean- and soiled-linen carts out of traffic;

(h) Arrangement of equipment and procedures shall be in a manner to permit orderly work flow with a minimum of cross-traffic that might mix clean and soiled operations.

(2) Off-site processing. If linen is processed off the hospital site, the following shall be provided:

(a) Soiled linen holding room. A separate room shall be provided for holding soiled linen until ready for pickup or processing;

(b) Clean linen receiving, holding, inspection, and storage room(s). A central clean linen storage and issuing room(s) shall be provided in addition to the linen storage required at individual patient units;

(c) Cart storage area(s). These shall be provided for separate parking of clean- and soiled-linen carts out of traffic.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(23); HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; Renumbered from 333-074-0315; HD 21-1993, f. & cert. ef. 10-28-93; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0230
Employees' Facilities

In addition to the employees' facilities such as locker rooms, lounges, toilets, or shower facilities called for in certain departments, a sufficient number of such facilities, as required to accommodate the needs of all personnel and volunteers, shall be provided in accordance with the Functional Program.

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 7-1979, f. & ef. 7-17-79; HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(24); HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; Renumbered from 333-074-0320; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0250
Waste Processing Services

(1) Storage and disposal. Space and facilities shall be provided for the sanitary storage and disposal of waste by incineration, mechanical destruction, compaction, containerization, removal, or by a combination of these techniques.

(2) Incinerator:

(a) Design and construction of incinerators and trash chutes shall be in accordance with NFPA 82 and State Structural and Mechanical Codes.

(b) Incinerators shall be designed and equipped to conform to requirements prescribed by the Oregon Department of Environmental Quality for emission levels and equipment.

(c) Other technologies for non-incineration. Waste treatment technologies shall be determined by the facility in conjunction with environmental, economic, and regulatory considerations. The Functional Program shall describe waste treatment technology components that include the following:

(A) Safe locations, transfer routes, distances from waste sources, temporary storage and spacing requirements shall be provided that will not cause traffic problems, and limits odor, noise, and visual impact to patients, visitors and the public;

(B) Space shall be determined by the equipment requirements, including associated area for opening waste entry doors, access to control panels, space for hydraulic lifts, conveyors, and operational clearances. The method of waste treatment or disposal is subject to the local regulatory approvals;

(C) Ventilation. Exhaust vents, if any, from the treatment technology shall be located a minimum of 25 feet from inlets to HVAC systems. If technology involves heat dissipation, sufficient cooling and ventilation shall be provided; and

(D) Nuclear Waste Disposal. See Code of Federal Regulations (CFR), Title X, parts 20 and 35, concerning the handling and disposal of nuclear materials in health care facilities.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(26); HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; Renumbered from 333-074-0330; HD 21-1993, f. & cert. ef. 10-28-93; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0260
Sanitary Environment

(1) A hand-washing station is an area providing a sink for hand-washing with hot and cold water supply and a faucet that facilitates easy on and off mixing capabilities without use of the hands. The station shall include provision of cleansing agents and drying capability. In addition to hand-washing stations required for individual departments, adequate hand-washing stations shall be provided for the total hospital population. Hand-washing stations shall be available in all toilet rooms. For the purpose of providing

accuracy and consistency within these rules, these terms are defined as follows:

(a) Hand-washing sink. Hand-washing sinks are a general component of hand-washing stations that are available in all toilet rooms and provided for the total hospital population.

(b) Scrub sink. Scrub sinks are provided for the exclusive use of staff in restricted and semi-restricted locations within operating and surgical suites and rooms.

(2) Toilet and hand-washing stations shall be available to patient care units as follows, with the exception of intensive patient care units and special locked psychiatric units where provision of these fixtures within the room may pose undue risks or problems:

(a) In newly constructed single patient rooms having a private toilet room, a hand-washing station in both the toilet room and the patient room shall be provided. For renovation projects involving single patient rooms that have a private toilet room, a hand-washing station shall be located in either the toilet room or the patient room;

(b) In single patient rooms having a toilet room connecting two rooms, a hand-washing station shall be provided in the toilet room and in each of the two patient rooms;

(c) All wards of two or more beds, having a separate or connecting toilet rooms shall have a hand-washing station in the toilet room as well as in the ward;

(d) A toilet room shall be directly accessible from each patient room without going through the general corridor;

(e) One toilet room shall serve not more than four patients or two patient rooms; and

(f) In general psychiatric units, the hand-washing station may be omitted from the patient room when a hand-washing station is located in an adjoining toilet room. Toilet and hand-washing stations in special-care, locked psychiatric units may be provided based on patients' needs and the Patient and Staff Safety Assessment.

(3) Toilet rooms, conveniently located and separate from those used by patients, shall be provided for all hospital personnel. No toilet room shall open directly into any room in which food, drink, or utensils are handled or stored.

(4) Clean utility or clean storage: Each patient care unit shall include or have direct access to a clean utility room or area open to the corridor containing a work counter, hand-washing station and facilities for storage and distribution of clean and sterile supply materials. If the room is used for clean storage only, the hand-washing sink may be omitted. If the utility area is open to the corridor, all supply cabinets shall be fully enclosed.

(5) Soiled utility or soiled holding: Each patient care unit shall include or have direct access to a soiled utility room or a soiled holding room as required in other related sections.

(a) Soiled utility rooms shall contain a clinical sink or equivalent flushing rim sink. Where a bed pan flushing device is provided in patient toilet rooms, a utility sink may be provided in the soiled utility room instead of a clinical sink. The utility sink shall be at least 10 inches deep and measure at least 22 inches by 21 inches. Each soiled utility room shall also provide a hand-washing station, work counter, waste receptacle and linen receptacle for collection and disposal of soiled materials, including separate infectious waste storage if not provided elsewhere, and recycle storage if part of hospital operations.

(b) Soiled holding rooms. Soiled holding rooms are intended for temporary holding of soiled material. Clinical sinks and work counters are not required in rooms used only for temporary holding of soiled material. If the flushing-rim clinical sink is not provided, facilities for cleaning bedpans shall be provided elsewhere.

(6) Patients' bathing facilities for medical, surgical, obstetrical, and pediatric patient care units: at least one shower or tub for each 12 beds shall be provided, except that in postpartum units, a minimum of one shower per 12 beds shall be provided. Each tub or shower shall be in an individual room or enclosure that provides space for the private use of the bathing fixture and for drying and dressing. At least one bathing fixture on each patient floor shall have space for a wheelchair with an assisting attendant. In new construction, at least one toilet for each 12 beds shall be provided in the bathing room. Patient/public toilets shall be provided conveniently near multi-purpose rooms.

(7) Housekeeping closets. In addition to closets noted in other sections of these rules, sufficient housekeeping closets, with a floor sink or service sink and storage space for janitorial equipment, cart and supplies, located in each, shall be provided to serve all areas of the hospital and shall also include the following:

(a) A minimum of 35 square feet shall be provided for each housekeeping room;

(b) A minimum of one housekeeping closet shall be provided for each floor; and

(c) If practical, a hand-washing station shall be provided proximate to the housekeeping closet.

(8) Overhead drainage piping. Refer to OAR 333-535-0300(5)(d)(B).

Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: HB 183, f. & ef. 5-26-66; HB 209, f. 12-18-68; HD 7-1979, f. & ef. 7-17-79: HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(27); HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; Renumbered from 333-074-0335; HD 21-1993, f. & cert. ef. 10-28-93; OHD 1-2002, f. & cert. ef. 2-28-02; PH 14-2005, f. 8-10-05, cert. ef. 8-15-05; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0270
Details and Finishes

(1) The nonconforming portions of existing facilities that are not being totally modernized shall comply with the safety requirements dealing with interior finishes as listed in chapters 18, 19, 20 and 21 of the National Fire Protection Association (NFPA) 101, when the facility is also to be Medicare or Medicaid certified.

(2) Details and finishes in new construction projects, including additions and major alterations, shall comply with the following:

(a) Details:

(A) Compartmentation, exits, fire alarms, automatic extinguishing system, and other details relating to fire prevention and fire protection shall comply with requirements listed in chapters 18, 19, 20 and 21 of the NFPA101, when the facility is also to be Medicare or Medicaid certified.

(B) Items such as drinking fountains, telephone booths, vending machines, and portable equipment shall be located so as not to restrict corridor traffic or reduce the corridor width below the required minimum.

(C) Rooms containing any of the following: bathtubs, sitz baths, showers, or water closets, subject to occupancy by patients, shall be equipped with doors and hardware that will permit access from the outside in any emergency. When such rooms have only one opening, the door shall be capable of opening outward or be otherwise designed to be opened without need to push against a patient who may have collapsed within the room.

(D) If psychiatric care units are required by the program, suitable hardware shall be provided on doors to patient toilet rooms so that access to these rooms can be controlled by staff.

(E) If required by the program, doors to patient rooms in psychiatric care units shall not be lockable from inside the room.

(F) Windows and other doors that may be frequently left in an open position shall be provided with insect screens.

(G) Patient rooms intended for occupancy of 24 hours or more shall have windows with sills not more than 3 feet above the floor (windows in Intensive Care Unit and Critical Care Unit may be 5 feet above the floor).

(H) Linen and refuse chutes shall meet requirements of NFPA101, and have a minimum cross sectional dimension of not less than 2 feet.

(I) Thresholds and expansion joint covers shall be made flush with the floor surface to facilitate use of wheelchairs and carts. Expansion joints shall be constructed to restrict passage of smoke and fire.

(J) Grab bars shall be provided at all patients' toilets, showers, tubs, and sitz baths, except in psychiatric patient care units. The bars shall have one and one-half inch clearance to walls and shall have sufficient strength and anchorage to sustain a concentrated load of 250 pounds.

(K) Anchoring. Sinks in hand-washing stations shall be securely anchored to withstand an applied vertical load of not less than 250 pounds on the fixture front.

(L) Mirrors shall not be installed at hand-washing stations in food preparation areas or in sensitive areas such as nurseries, clean and sterile utility, storage rooms and scrub sinks.

(M) Hand drying devices. Provision for hand drying shall be included at all hand-washing stations except scrub sinks. Hospital policy shall determine hand drying procedures at scrub sink locations. These shall be single use separate individual paper or cloth units enclosed in such a way as to provide protection against dust or soil and insure single unit dispensing. Hot air dryers are permitted provided that installation is such to preclude possible contamination by recirculation of air.

(N) Radiation protection requirements for Radiographic Imaging and gamma ray installations shall be in accordance with National Council of Radiation Protection Reports Numbers 33 and 49. Provision shall be made for testing the completed installation before use and all defects must be corrected before acceptance. Prior to their use, all installations shall be approved and licensed by the Radiation Control Section of the Oregon Health Authority, Public Health Division.

(O) The minimum ceiling height shall be 7 feet 10 inches with the following exceptions:

(i) Boiler rooms shall have ceiling clearances not less than 2 feet 6 inches above the main boiler header and connecting piping.

(ii) Radiographic, operating and delivery rooms, and other rooms containing ceiling-mounted equipment or ceiling-mounted surgical light fixtures shall have height required to accommodate the equipment or fixtures.

(iii) Ceilings in corridors, storage, toilet rooms, and other minor rooms shall be not less than 7 feet 6 inches.

(iv) Soffits, signage, lights, mechanical items and other suspended items located in the path of normal traffic shall not be less than 7 feet above the floor. Cubicle curtain tracks and television suspensions in individual rooms shall not be less than 6 feet 8 inches above the floor.

(P) Recreation rooms, exercise rooms and similar space where impact noises may be generated shall not be located directly over patient bed area, delivery or operating suites, unless special provisions are made to minimize such noise.

(Q) Rooms containing heat-producing equipment (such as boiler or heater rooms and laundries) shall be insulated and ventilated to prevent any floor surface above from exceeding a temperature of 10°F above the ambient room temperature of the room producing the heat generation.

(R) Sound transmission criteria shown in Table 1 (OAR 333-535-0270) shall apply to partition, floor and ceiling construction in patient areas.

(S) Mechanical equipment located on the same floor or above patient rooms, offices, nurse stations, and similar occupied spaces shall be effectively sound isolated from the floor and structure.

(T) Equipment and supply storage shall be provided for each hospital department in accordance with the Functional Program; however, a minimum of 10 square feet per bed shall be provided in patient care areas. In all other departments, the amount required shall be based on either a study of supply and equipment needs which shall be submitted with construction plans for review or a minimum of 10 percent of gross departmental area. All rooms and corridors within a department shall be included when calculating gross departmental area.

(b) Finishes:

(A) Cubicle curtains and draperies shall be noncombustible or rendered flame retardant and shall pass both the large and small scale tests of NFPA Standard 701.

(B) Flame spread and smoke developed ratings of finishes are covered under the State of Oregon Building Code. Whenever possible, the use of materials known to produce large amounts of noxious gases shall be avoided.

(C) Floor materials shall be easily cleanable and have wear resistance appropriate for the location involved. Floors in areas used for food preparation or food assembly shall be water-resistant and grease-proof. Joints in tile and similar material in such areas shall be resistant to food acids. In all areas frequently subject to wet cleaning methods, floor materials shall not be physically affected by germicidal and cleaning solutions. Floors that are subject to traffic while wet (such as shower and bath areas, kitchens, operating and C-section rooms, clean core areas, recovery areas except step-down recovery and similar work areas) shall have a non-slip surface as recommended by Americans with Disabilities Act, Architectural and Transportation Barriers Compliance Board (Access Board).

(D) Wall bases in kitchens, operating and C-section rooms, clean core areas, surgical scrub corridors, soiled workrooms, endoscopy rooms, housekeeping closets and other areas that are frequently subject to wet cleaning methods shall be made integral and coved with the floor, tightly sealed to the wall, and constructed without voids that can harbor insects.

(E) Wall finishes shall be washable and, in the immediate area of plumbing fixtures, shall be smooth and moisture resistant (orange peel not allowed). Finish, trim, and floor and wall construction in dietary and food preparation areas shall be free from spaces that can harbor rodents and insects.

(F) Floor and wall penetrations by pipes, ducts, and conduits shall be tightly sealed to minimize entry of rodents and insects. Joints of structural elements shall be similarly sealed.

(G) Ceilings in restricted areas such as: surgery rooms, delivery rooms, clean core areas and specialized radiographic rooms shall be constructed with material that are monolithic, scrubbable, and capable of withstanding chemicals, such as gypsum board, and be without crevices that can contain dirt particles.

(H) Ceilings in semi-restricted areas such as: airborne infection isolation rooms, protective environment rooms and central sterile supply spaces shall be smooth, scrubbable, nonabsorptive, nonperforated, capable of withstanding cleaning with chemicals, and without crevices that can harbor mold and bacterial growth.

(I) If lay-in ceiling is provided in semi-restricted areas, it shall be gasketed or clipped down to prevent the passage of particles from the cavity above the ceiling plane into the semi-restricted environment. Perforated, tegular, serrated cut, or highly textured tiles are not acceptable.

(J) Dietary and food preparation areas shall have a finished ceiling covering all overhead duct work and piping.

(K) Finished ceilings may be omitted in general storage areas, and similar spaces, unless required for fire-resistive purposes.

(L) Acoustical ceilings shall be provided for corridors in patient areas, nurses' stations, labor rooms, day rooms, recreation rooms, dining areas, and waiting areas.

(M) In dietary areas and in other areas where dust fallout may present a problem, suspended ceilings shall be provided.

(N) Ceilings of patient rooms in psychiatric care units shall be of monolithic or bonded construction.

(O) Top-set rubber or vinyl wall base, where used, shall be sealed tightly to the floor as well as to the wall.

[ED. NOTE: Tables & Publications referenced are available from the agency.]

Stat. Auth.: ORS 441.060

Stats. Implemented: ORS 441.060

Hist.: HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(28); HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; Renumbered from 333-074-0340; HD 21-1993, f. & cert. ef. 10-28-93; OHD 2-2000, f. & cert. ef. 2-15-00; OHD 1-2002, f. & cert. ef. 2-28-02; PH 14-2005, f. 8-10-05, cert. ef. 8-15-05; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0280
Construction, Including Fire-Resistive Requirements

Construction shall be in accordance with the requirements of *NFPA 99* and *NFPA 101*, the *Oregon Structural Specialty Code*, and *Oregon Fire Code*, and the minimum requirements contained herein.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 441.060

Stats. Implemented: ORS 441.060

Hist.: HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(29) HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; Renumbered from 333-074-0345; HD 21-1993, f. & cert. ef. 10-28-93; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0290
Elevators

(1) General. All hospitals having patients' facilities (such as bedrooms, dining rooms, or recreation areas) or critical services (such as operating, delivery, diagnostic, or therapy) located on floors other than the main entrance floor shall have electric or electro-hydraulic elevators. Installation and testing of elevators shall comply with the Oregon Elevator Code.

(2) Number of Elevators:

(a) At least one hospital-type elevator shall be installed where 1 to 59 patient beds are located on any floor other than the main entrance floor.

(b) At least two hospital-type elevators shall be installed where 60 to 200 patient beds are located on floors other than the main entrance floor, or where the major inpatient services are located on a floor other than those containing patient beds. (Elevator service may be reduced for those floors that provide only partial inpatient services.).

(c) At least three hospital-type elevators shall be installed where 201 to 350 patient beds are located on floors other than the main entrance floor, or where the major inpatient services are located on a floor other than those containing patient beds. (Elevator service may be reduced for those floors that provide only partial inpatient services.).

(d) For hospitals with more than 350 beds, the number of elevators shall be determined from a study of the hospital plan and the estimated vertical transportation requirements.

(3) Cars and platforms. Cars of hospital-type elevators shall have inside dimensions that will accommodate all patient beds to be utilized and attendants. The car door shall have a clear opening of not less than 4 feet.

(4) Operation. Elevators, except freight elevators, shall be equipped with a two-way special service switch to permit cars to bypass all landing button calls and be dispatched directly to any floor.

(5) Elevator controls, alarm buttons, and telephone shall be accessible to wheelchair occupants.

(6) Elevator call buttons, controls, and door safety stops shall be of a type that will not be activated by heat or smoke.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 441.060
Stats. Implemented: ORS 441.060
Hist.: HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(30) HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; Renumbered from 333-074-0350; HD 21-1993, f. & cert. ef. 10-28-93; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0300
Mechanical Requirements

(1) General standards:

(a) In addition to requirements of this rule, the mechanical system serving hospitals and hospital outpatient facilities may be subject to general review for overall efficiency and life cycle cost, although no requirements will be enforced beyond those included in this rule. Recognized engineering procedures are recommended to achieve specific requirements and performance for the most economical and effective results. Different geographic areas may have climate variations and use conditions that would favor one system over another in terms of overall cost and efficiency. In no case shall patient care or safety be sacrificed for conservation. Construction shall comply with the Oregon Structural Specialty Code (OSSC), the Oregon Mechanical Specialty Code (OMSC), the Oregon Plumbing Specialty Code (OPSC), Oregon Fire Code (OFC), NFPA 90A, and NFPA 99 Health Care Facilities as enforced by the State Building Codes Division and Authorities having Jurisdiction. Responsibility for enforcement remains with these authorities.

(b) The facility shall include provisions for recovery of waste cooling and heating energy (ventilation, exhaust, water and steam discharge, cooling towers, incinerators, etc.) in compliance with local codes.

(c) Recirculating room units (such as induction units and unit ventilators) may be used in individual rooms for heating and cooling purposes. Outdoor air requirements shall be met by separate air handling systems with proper filtration, as noted in Table 3.

(d) To reduce utility costs, facility design shall include consideration of recognized procedures such as variable air volume systems, energy recovery devices, load shedding, programmed controls for unoccupied periods including nights and weekends, and use of natural ventilation where site and climatic conditions permit. Systems with excessive operational or maintenance costs that would negate long-range energy savings should be avoided.

(e) To the extent possible, this rule has been written to permit maximum use of simplified systems including that for variable air volume (VAV). However, care must be taken in design to avoid possibility of large temperature differentials, high velocity supply, excessive noise, and stagnation. Air supply, return, and exhaust in rooms may vary in response to room load provided the total and outside air change rates stay within the limits of Table 2, Note 4. Construction drawing submissions shall include information listing the actual supply air and outside air change rates provided to the areas listed in Table 2 at maximum and minimum terminal unit settings.

(f) To maintain asepsis control, air supply, return, and exhaust quantities should generally be controlled to ensure movement from "clean" to "less clean" areas and maintain directional air movement within the limits of Table 2, Note 2. Special considerations shall be given to sterile areas such as Operating Rooms, Delivery Rooms, and Central Supply.

(g) Variable air volume systems serving inpatient facilities or surgical outpatient facilities shall include controls or equipment necessary to ensure that minimum outside air quantities in cubic feet per minute and the resulting space pressure relationships are maintained over the range of fan operation. Examples of methods to ensure the delivery of minimum quantities of outside air include the installation of airflow monitoring stations or dedicated supply fans.

(h) Prior to acceptance of the facility, all mechanical systems shall be tested, balanced and operated to demonstrate to the design engineer or his or her representative that the installation and performance of these systems conform to the design intent and requirements herein. Test results shall be documented for maintenance files and be available for inspection by Division's surveyors or Authorities having Jurisdiction.

(i) Functional performance tests shall be provided for projects that include the addition or modification of major equipment and systems. These tests shall ensure that mechanical systems operate in accordance with the design intent and in compliance with requirements herein. Description of procedures and test results for each functional performance test shall be documented to demonstrate to the design engineer, or his or her representative, that systems operate in accordance with the design intent. Documentation shall be included in the maintenance files and be available for inspection by the Division's surveyors or Authorities having Jurisdiction. Functional performance tests shall be developed and performed for the following systems and system functions in hospital inpatient facilities where applicable:

(A) Outdoor air ventilation system components and control modes.

(B) Humidity control components and control modes.

(C) Maintenance of space pressure relationships through all modes of air handling system operation.

(D) Airborne infectious isolation and protective environment room ventilation and pressurization monitoring systems.

(E) Smoke evacuation systems serving anesthetizing areas.

(F) Fire/smoke damper controls.

(G) Boiler and generator fuel oil supply transfer systems including alarms.

(H) Laboratory hood systems.

(j) Upon completion of the contract, the facility shall be furnished and retain on file a complete set of building drawings, man-

ufacturers' operating, maintenance and preventive maintenance instructions, parts lists and procurement information with model numbers, and a description of the operation of each piece of equipment. Responsible operating staff persons shall also be provided with instructions in the proper operational use of systems, equipment, and controls. This information shall be available for inspection by the Division's surveyors or Authorities having Jurisdiction.

(k) If inpatient facility system modifications affect greater than 25 percent of the system capacity, designers shall obtain and utilize pre-renovation water/air flow rate measurements to verify that sufficient capacity is available and that renovations have not adversely affected flow rates in non-renovated areas.

(l) Psychiatric patient room fixtures and equipment shall be tamper resistant and shall be selected to meet the requirements of the Patient and Staff Safety Assessment. Equipment shall be selected to minimize the need for maintenance within the room. Refer to OAR 333-535-0061 for additional requirements.

(m) Identification. All piping, including heating ventilation, gas, vacuum and air conditioning (HVAC) except control line tubing, shall be color coded or otherwise marked for easy identification. Major equipment shall be labeled. All valves shall be tagged. Identification and valve schedules shall be provided to the facility for permanent record and reference.

(2) Insulation:

(a) Insulation shall be provided within the building to conserve energy, protect personnel, prevent vapor condensation, and reduce noise.

(b) Insulation on cold surfaces shall include an exterior vapor barrier. (Materials which will not absorb or transmit moisture will not require a separate vapor barrier.)

(c) Insulation, including finishes and adhesives on the exterior surfaces of ducts, piping, and equipment, shall have a flame spread rating of 25 or less and a smoke developed rating not to exceed 50 when tested in accordance with NFPA 255.

(d) If duct lining is used, it shall be coated and sealed and shall meet ASTM C1071. These linings, including coatings, adhesives, and insulation on pipes and ducts in building spaces, shall have a flame spread rating of 25 or less and a smoke developed rating of 50 or less when tested in accordance with NFPA 255.

(e) No duct linings exposed to air movement shall be used in ducts, terminal boxes or other systems downstream of final filters supplying operating rooms, invasive special procedure rooms, C-section delivery rooms, post anesthesia recovery rooms, critical care, nurseries, protective environment rooms, intensive care, and central supply areas. Fully encapsulated lining may be used in terminal boxes serving these areas. Sound traps or duct silencers downstream of final filters shall be all metal with no fill or shall have special coatings over such linings per ASTM C1071.

(f) If existing lined ductwork is reworked in a renovation project, the liner seams and punctures shall be resealed, repaired or replaced.

(3) Steam and hot water systems:

(a) Boilers and domestic water heaters. Boilers shall have the capacity, based upon the net ratings published by the Hydronics Institute, to supply the normal requirements of all systems and equipment. Their number and arrangement shall accommodate facility need during time of breakdown or routine maintenance of any one boiler. The capacity of the remaining boiler(s) shall be sufficient to provide domestic hot water service for clinical, dietary, and patient use; steam for sterilization and dietary purposes; and heating for operating, delivery, labor, recovery, intensive care, nursery, emergency departments, and general patient rooms. If the domestic water heating system is independent of the building heating boilers, the domestic water heating system shall be capable of providing a back-up source of domestic hot water for clinical, dietary, and sterilizer use when the primary domestic water heating system is not operable. These requirements do not apply to outpatient facilities except outpatient surgical facilities providing invasive or anesthetizing procedures shall provide backup equipment for hot water and sterilizer needs only.

(b) Boiler system accessories. Boiler feed pumps, heating circulating pumps, condensate return pumps, heat exchangers, and fuel oil pumps shall be connected and installed to provide normal and standby service where back-up or standby service is required.

(c) Valves. Supply and return mains and risers of cooling, heating and steam systems shall be valved to isolate the various sections of each system. Each piece of equipment shall be valved at the supply and return ends.

(d) Fuel supplies. Fuel used for boiler systems serving hospital inpatient facilities that provide building heating to the areas listed in subsection (3)(a) shall include a backup on-site fuel system if the primary fuel system fuel is not stored on site. The on-site fuel storage system shall have sufficient fuel/power to operate the boiler systems for a minimum of 48 hours, or for a time period consistent with the facility emergency management plan. The on-site fuel system shall include a low level fuel sensor alarmed at a staffed location. On-site fuel systems may be combined with the emergency generator fuel systems per the requirements of NFPA 110.

(4) Air conditioning, heating, and ventilating systems:

(a) The ventilation system shall be designed and balanced to provide ventilation rates and directional flow as shown in Table 2. (See notes 2 and 4 for reduction and shutdown of ventilation systems when room is unoccupied.) The ventilation rates shown in Table 2 shall be used only as model standards; they do not preclude the use of higher rates that may be appropriate. All occupiable rooms and areas in the facility shall have provision for mechanical ventilation. Natural ventilation systems and operable windows shall be permitted to supplement mechanical ventilation where they will not adversely affect required pressure relationships, air change rates, and room temperatures. Freestanding immediate care clinics, physician's clinics, imaging facilities, outpatient physical therapy, dialysis facilities, and occupational therapy facilities that are not part of an inpatient facility are not required to meet the ventilation requirements of Table 2, except endoscopy, isolation, and bronchoscopy areas.

(b) Outside air ventilation intakes shall be located at least 25 feet from exhaust outlets of ventilating systems, combustion equipment stacks, medical-surgical vacuum systems, plumbing vents, cooling towers, or from areas that may collect vehicular exhaust or other noxious fumes in all inpatient areas and in outpatient areas providing invasive or anesthetizing procedures. In non-anesthetizing hospital outpatient facilities, this distance may be reduced to 10 feet. Plumbing vents that terminate above the level of the top of the air intake may be located as close as 10 feet. Outside air ventilation intakes shall be located a minimum of 25 feet from the combustion vents of rooftop air handling units, except that the clearance may be reduced to 10 feet when the vent is above the level of the intake. Outside air ventilation intakes shall be located a minimum of 6 feet from relief/economizer air outlets that do not include required building exhaust. The bottom of outside ventilation air intakes in inpatient facilities shall be located as high as practical but at least 15 feet above ground level or 3 feet above the roof level.

(c) Fans serving exhaust systems shall be located at the discharge end of the system to limit positively pressurized ductwork within the building and shall be conveniently accessible for service. Where existing conditions prohibit fans from being located at the discharge end of the system, alternate systems may be considered provided discharge ductwork is sealed and tested per medium pressure duct requirements. Hospital outpatient facilities are not required to have exhaust fans at the discharge end of the system except endoscopy, isolation, and bronchoscopy area. Exhaust systems may be combined as necessary for efficient use of recovery devices required for energy conservation.

(d) Exhaust systems from areas that may be contaminated shall not be combined with other exhaust systems, shall include fans located outside the building with outlets discharging vertically a minimum of 6 feet above the roof level, and shall be arranged to minimize recirculation of exhaust air into the building. Consideration shall be given to redundant fan systems. Contaminated exhaust ducts and discharge points shall be labeled. Contaminated areas

include infectious isolation, decontamination, ETO sterilizer, non-refrigerated body holding, and bronchoscopy. Contaminated exhaust shall not be served by exhaust systems that may allow cross contamination, such as heat wheels. Where existing conditions prohibit fans from being located outside the building, alternate systems that are designed to limit cross contamination and exposure to workers and patients may be considered. (Refer to OMSC for additional requirements.)

(e) Operating and C-section delivery room air supply shall be from ceiling outlets near the center of the work area to effectively control air movement. Laminar flow design diffusers shall be used in operating rooms. Each operating and C-section delivery room shall have at least two return/exhaust air inlets located near the floor level in opposite corners of the room. (Design should consider turbulence and other factors of air movement to minimize fall of particles into wound site.) Where extraordinary procedures, such as organ transplants, may justify other special designs, the installation shall be as required to properly meet the performance needs. Special designs shall be reviewed on a case by case basis. Installation of equipment requiring service shall be kept to a minimum above operating rooms and sterile core areas. Temperature shall be individually controlled for each operating and C-section delivery room. The air handling systems for operating and C-section delivery rooms shall operate at all times.

(f) Humidity control and smoke vent systems in inpatient facility anesthetizing areas shall be provided as required by NFPA 99, Environmental Systems Chapter. Smoke vent systems shall prevent smoke within individual anesthetizing rooms from affecting adjacent anesthetizing rooms. Adjacent rooms shall remain at a positive pressure in relationship to the areas with detected smoke. Smoke dampers shall not affect the operation of the smoke vent system.

(g) Air supply for intensive care nurseries, airborne infectious isolation rooms, bronchoscopy treatment rooms, and rooms used for invasive procedures shall be at or near the ceiling. Return/exhaust air inlets shall be near the floor level. Special designs shall be reviewed on a case by case basis.

(h) Each airborne infectious isolation room and protective environment room shall have a permanently installed and labeled visual mechanism to constantly monitor the pressure status to the room when occupied by a patient requiring isolation or protection. The mechanism shall continuously monitor the direction of the air flow. Audible alarms, if provided, shall include a silencing switch. Rooms with reversible airflow provisions for the purpose of switching between airborne infectious and protective environment isolation rooms are not acceptable. Rooms used for sputum induction, aerosolized pentamadine treatments, or other cough inducing treatments shall meet the requirements of Table 2 for airborne infectious isolation rooms. Protective environment rooms shall be provided with HEPA filters at 99.97 percent efficiency (MERV 17) per Table 3. Recirculating HEPA filter units may be used in protective environment rooms, but shall not be used to meet the minimum filtering requirements of Table 3.

(i) The bottoms of ventilation (supply/return/exhaust) openings shall be at least 6 inches above the floor.

(j) Emergency waiting rooms and other waiting rooms where airborne infection is a concern, as defined by the Infection Control Risk Assessment, shall have low wall return/exhaust and shall conform to the requirements of Table 2. Special designs shall be reviewed on a case by case basis.

(k) Air handling systems in inpatient facilities shall be fully ducted except when serving non-patient care areas.

(l) All ventilation or air conditioning systems, except individual room units serving non-critical care areas, shall be equipped with filters having efficiencies equal to, or greater than, those specified in Table 3. Where two filter beds are required, filter bed No. 1 shall be located upstream of the air conditioning equipment, and filter bed No. 2 shall be downstream of any cooling coils and blowers. Non-central air handling systems (individual room units) shall be equipped with filters with minimum 60 percent efficiency (MERV 11).

(A) Where only one filter bed is required, it shall be located upstream of the air conditioning coils unless an additional pre-filter is employed.

(B) Filter efficiencies shall be average ratings tested in accordance with American Society of Heating, Refrigeration, & Air Conditioning Engineering Standard 52-1 and MERVs rating shall be based on ASHRAE Standard 52-2, except as noted otherwise.

(C) Filter frames shall be manufactured housings designed for maximum 500 FPM velocity and shall provide an airtight fit with the enclosing ductwork. All joints between filter segments and the enclosing ductwork shall be gasketed or sealed to provide a positive seal against air leakage. Filter housing blank off panels shall be permanently attached to the frame, constructed of rigid materials, and have sealing surfaces equal to or greater than the filter media installed in the filter frame.

(D) Magnahelics or manometers shall be installed across all filter beds having a required efficiency of 75 percent (MERV 12) or more. When these filters are located remote from the air handling unit, monitoring of filter condition shall be provided in a staffed area or through the building control system.

(m) Steam humidifiers shall be used for humidification. Central steam shall be used only if chemical treatment is food grade. Humidifiers shall be located to prevent moisture on filters or lined ductwork. Ductwork with duct mounted humidifiers shall be stainless steel or aluminum construction and shall have a means for water removal. An adjustable high limit humidistat shall be located downstream of the humidifier to reduce the potential for condensation inside the duct. Humidifiers shall be connected to airflow proving switches that prevent humidification unless the required volume of airflow is present. All duct takeoffs shall be sufficiently downstream of the humidifier to ensure complete moisture absorption.

(n) Ducts and piping which penetrate construction intended for X-ray, MRI, RF, or other radiation protection shall not impair the effectiveness of the protection.

(o) Fire and smoke dampers shall be constructed, located, activated, and installed in accordance with the requirements of NFPA 90A, NFPA 101, and OSSC. Fans, smoke dampers, and detectors shall be interconnected so that activation of dampers will not damage the ducts. Access for maintenance shall be provided at all dampers. All damper locations must be shown on drawings. When smoke partitions are required, zones for air handling systems shall be coordinated with compartmentation insofar as practical to minimize the need to penetrate fire and smoke partitions.

(p) Systems shall be provided to exhaust chemicals and fumes that cause respiratory irritation or other hazards to workers, including laboratory processes, instrument processing rooms, radioactive processes, chemo hoods, and pharmacies. If the minimum air change standards in Table 2 do not provide sufficient air for use by hoods and safety cabinets, makeup air shall be provided to maintain the required air flow direction and to avoid depending upon infiltration from outdoors or from contaminated areas.

(q) All laboratory and pharmacy hood systems shall meet OMSC and shall meet the following general standards. (Laminar flow hoods used in clean applications are exempt from these requirements.)

(A) Have an average face velocity of 75 to 125 feet per minute or as required by the hood manufacturer, whichever is greater;

(B) Be connected to an exhaust system to the outside that is separate from the building exhaust system;

(C) Have a labeled exhaust fan located at the discharge end of the system outside the building with the outlet discharging vertically a minimum of 6 feet above the roof;

(D) Have an exhaust duct system of noncombustible corrosion-resistant materials as needed to meet the planned usage of the hood; and

(E) Be equipped with devices and alarms to alert staff of fan shutdown or loss of airflow.

(F) If equipped with HEPA filters, have a means to alert staff when filter change is required.

(G) Each hood that processes highly infectious or radioactive materials shall have a minimum face velocity of 90 to 110 feet per minute or as required by the hood manufacturer; shall be connected to an independent exhaust system; shall have filters with a 99.97 percent efficiency (MERV 17); and shall be designed and equipped to permit the safe removal, disposal and replacement of contaminated filters. Filters shall be as close to the hood as practical to minimize duct contamination.

(H) Hoods that process radioactive materials shall meet requirements of the Nuclear Regulatory Commission and NFPA 801 Facilities for Handling Radioactive Materials, and discharge vertically a minimum of 10 feet above the roof of the building. Radioactive isotopes used for injections, etc., without probability of airborne particulate or gases may be processed in a "clean work bench" type hood where acceptable to the Nuclear Regulatory Commission.

(I) Duct systems serving hoods in which strong oxidizing agents (e.g., perchloric acid) are used shall be equipped with washdown facilities. Provisions shall be made for safe removal of filters during washdown operations.

(r) Exhaust hoods in food preparation centers shall comply with NFPA 96. Dedicated kitchen hood make-up air system intakes may be a minimum of 10 feet from kitchen hood exhaust outlets. The food preparation area may have air movement "in" during cooking and hood operation for odor control. Makeup systems for hoods shall be arranged to minimize "short circuit" of air movement and to avoid reduction in air velocity at the point of contaminant capture.

(s) The ventilation system for medical gas storage rooms shall conform to the requirements of NFPA 99.

(t) The space that houses ethylene oxide (ETO) sterilizers and cylinder storage shall be provided with a dedicated local exhaust system with adequate capture velocity (i.e., with a minimum capture velocity of 200 fpm) to exhaust over sterilizer door, exhaust at sterilizer drain, and exhaust at the aerator and multiple load station. The exhaust shall discharge vertically a minimum of 10 feet above the roof and shall be labeled. An audible and visual alarm shall activate in the sterilizer work area and in a continuously staffed location upon loss of airflow in the exhaust system. Relief vents for safety valves shall be provided and shall terminate outside the building. Installation shall also conform to applicable standards of the sterilizer manufacturer. Testing of installations to standards of the Department of Consumer and Business Services, Oregon Occupational Safety and Health Division shall be made before routine use occurs. Such standards are provided in OAR chapter 437, division 2.

(u) Boiler rooms shall be provided with sufficient outdoor air to maintain combustion rates and to limit workstation temperatures.

(v) Gravity exhaust may be used, where conditions permit, for non-patient areas such as boiler rooms, central storage, etc.

(5) Plumbing and other piping systems:

(a) Plumbing fixtures:

(A) All fixtures used by medical and nursing staff and all lavatories used by patients and food handlers shall be trimmed with valves that can be operated without the use of hands (single lever devices, wrist blades, sensor operated, foot pedal operated, or similar). Blade handles used for this purpose shall not exceed 4.5 inches in length. Standard fittings are allowable on lavatories in patient toilet rooms when a second lavatory is provided in the adjacent patient room(s). In patient care areas, faucet and water closet sensors requiring electrical energy to operate shall be connected to emergency power.

(B) Clinical sinks shall be trimmed with valves that can be operated without hands. Single lever or wrist blade devices shall be permitted. Handles on clinical sink faucets shall be a minimum of 6 inches long.

(b) Potable water supply systems:

(A) Bedpan flushing devices (may be cold water) shall be provided in each inpatient toilet room, except that installation is optional in psychiatric, alcohol abuse, and other units where patients are ambulatory.

(B) Water distribution systems in inpatient facilities and in outpatient surgical facilities shall be arranged to provide for continuous hot water at each hot water outlet. Piping branches from recirculating hot water system mains to individual outlets shall not exceed 30 feet for standard faucets and 10 feet for sensor operated and low flow faucets. Hot water for showers and bathing facilities shall be at appropriate temperatures for comfortable use but shall not exceed 49°C or 120°F (see Table 4).

(c) Hot water systems: The system for heating domestic water shall have sufficient capacity to supply water at the temperatures and amounts indicated in Table 4.

(d) Drainage systems:

(A) Drain lines from fixtures in which acid wastes may be poured shall be fabricated from acid-resistant material.

(B) Sanitary and storm drainage piping shall not be installed overhead whether within the ceiling or exposed, in operating and C-section rooms, pharmacy IV admixture clean rooms, intensive care nurseries, food storage areas, central sterile supply areas, and other sensitive areas. Where overhead drain piping is unavoidable in these areas as may occur in existing facilities special provisions, such as the use of drain pans or FM 1680 approved couplings, shall be made to protect the space below from possible leakage, condensation or dust particles. If drain pans are installed for protection, the pans shall be drained to an open site, air-gap drain and shall be labeled.

(C) Floor drains and cleanouts shall not be installed in operating and C-section delivery rooms. Flushing rim type drains may be used in cystoscopic rooms, except as prohibited by rules for surgical facilities under OAR 333-535-0110(3)(d). Flushing rim valves shall not be located within the cystoscopic room, but the means of actuation may be in the cystoscopic room.

(D) Building sewers shall discharge into a community sewage system. Where such a system is not available, the facility must treat its sewage in accordance with standards of the Oregon Department of Environmental Quality and local governmental agencies having jurisdiction.

(E) Grease interceptors for kitchens shall comply with requirements of OPSC.

(F) Where plaster traps are used, they shall meet standards of OPSC.

(G) Provide traps at hot lab sinks where radioactive materials are processed.

(H) All domestic water service mains, risers, and branch mains shall have shut off valves.

(I) Drain systems for autopsy rooms shall be designed to prevent splatter or overflow onto floors, to prevent back siphonage, and for easy cleaning and trap flushing.

(J) Where decontamination shower areas are provided, waste containment tanks shall be provided and sized in accordance with the Hospital's Emergency Management Plan. Provisions shall be made to divert or pump the waste from the tank for appropriate disposal.

(K) Jetted tubs shall provide for removal of jets for cleaning and for the discharge of all water within piping between uses.

(e) Nonflammable medical gas and vacuum systems: The installation of non-flammable medical gas and vacuum systems shall comply with the requirements of NFPA 99. See Table 5 for rooms that require station outlets and inlets. Installers of medical gas systems shall meet the requirements of ANSI/ASSE Standard 6010 and verification testing agencies shall meet the requirements of ANSI/ASSE Standard 6030.

(A) Medical gas systems verification test results certifying the medical gas and vacuum system testing required in NFPA 99 shall be documented for maintenance files and be available for inspection by Division surveyors or Authorities having Jurisdiction.

(B) When any existing medical gas or vacuum system is altered or augmented, all the new and existing components in the immediate zone or area located upstream for vacuum systems and downstream for medical gas systems of the altered section shall be tested and certified per NFPA 99 requirements.

(C) Each space with piped anesthetic gas and any space routinely used for administering inhalation anesthesia shall be provided with a scavenging system to vent waste gases. Gases from the scavenging system shall be exhausted directly to the outside. If the medical vacuum system is used, the gas collecting system shall be arranged so that it does not interfere with the patient's respiratory system. The anesthesia evacuation system may be a dedicated exhaust fan system with monitoring and alarming through an airflow switch or other means. Separate scavenging systems are not required for areas where gases are used only occasionally such as the emergency room, offices for routine dental work, labor, delivery and recovery rooms, etc. Cautionary comments of NFPA 99 may be especially applicable when vacuum system is being considered for scavenging of anesthetic gases.

(D) Medical vacuum system discharge shall be located a minimum of 25 feet from all doors, windows and other openings into the building, a minimum of 25 feet above grade, a minimum of 25 feet from medical air systems intakes, and a minimum of 10 feet from designated mechanical areas and walkways.

[ED. NOTE: Tables and Publications referenced are available from the agency.]

Stat. Auth.: ORS 441.060

Stats. Implemented: ORS 441.060

Hist.: HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(31); HD 21-1987, f. & ef. 11-13-87 HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; Renumbered from 333-074-0355; HD 21-1993, f. & cert. ef. 10-28-93; OHD 2-2000, f. & cert. ef. 2-15-00; OHD 1-2002, f. & cert. ef. 2-28-02; PH 14-2005, f. 8-10-05, cert. ef. 8-15-05; PH 10-2009, f. & cert. ef. 10-1-09

333-535-0310
Electrical Requirements

(1) General:

(a) All material including equipment, conductors, controls, and signaling devices shall be installed in compliance with Oregon Structural Specialty Code (OSSC), the Oregon Electrical Specialty Code (OESC), and NFPA 99 Health Care Facilities. All materials shall be listed as complying with state approved standards;

(b) The electrical installations including, but not limited to, alarm, nurses' call, communication, and emergency generator systems shall be tested to demonstrate that equipment installation and operation is as intended and appropriate. A written record of performance tests of special electrical systems and equipment shall show compliance with applicable codes and standards. Grounding continuity, receptacles and isolated power systems shall be tested as described in NFPA 99;

(c) Functional performance tests shall be provided for projects that include the addition or modification of major equipment and systems. These tests shall be performed to ensure electrical systems operate in accordance with the design intent and in compliance with requirements herein. Description of procedures and test results for each functional performance test shall be documented to demonstrate to the design engineer, or his or her representative, that systems operate in accordance with the design intent. Documentation shall be included in the maintenance files and be available for inspection by the Division's surveyors or Authorities having Jurisdiction. Functional performance tests shall be developed and performed for the following systems and system functions in inpatient facilities where applicable:

(A) Emergency power systems;

(B) Generator fuel oil supply transfer systems including alarms;

(C) Fire alarm systems;

(D) Nurse call systems;

(E) Communication systems;

(F) Grounding systems;

(G) Isolated power systems;

(H) Receptacle continuity and grounding system tests; and

(I) Emergency power system load shedding controls.

(d) When remodels occur in hospitals in which emergency electrical services branches are not divided in accordance with NFPA 99 and OESC, and less than 50 percent of an individual system is affected, the entire system is not required to be made to conform to these codes. Modifications, however, shall be done in a manner to minimize required work should the full system later be brought into conformance;

(e) Upon completion of the electrical contract, the owner shall be furnished, and shall retain on file, a complete set of building drawings, a complete set of operating, maintenance, and preventative maintenance instructions, parts lists, and procurement information for all major electrical equipment and systems, including electrical distribution equipment, generators, nurse call equipment, smoke detection equipment, alarm systems, and arc flash labeling. Responsible operating staff shall be provided with instructions in the proper operational use of system, equipment, and controls. This information shall be available for inspection by the Division's surveyors or Authorities having Jurisdiction.

(f) Psychiatric patient room fixtures and equipment shall be tamper resistant and shall be selected to meet the requirements of the Patient and Staff Safety Assessment. Refer to OAR 333-535-0061 for additional requirements. Equipment shall be selected to minimize the need for maintenance within the room.

(2) Switchboards, power panels, equipment and their installation shall comply with OESC. The normal power main switchboard shall be located in an area separate from the essential electrical system equipment; in an area separate from plumbing and mechanical equipment, except equipment required to support electrical equipment; and in an area accessible only to authorized persons.

(3) Panelboards. Panelboards serving normal lighting and appliance and all critical care circuits shall be located on the same floor as the circuits they serve. Panelboards for life safety circuits may serve no more than one floor above and/or below, and the floor on which they are located. Provide labeling at fixed, major electrical equipment served by the equipment branch indicating the panel designation. New panelboards, serving patient care areas, shall not be located in corridors accessible to the general public.

(4) Lighting:

(a) Lighting shall conform to the recommended lighting standards for public buildings contained in the OSSC (Means of Egress Illumination), Illuminating Engineering Society (IES) RP-28 and RP-29. Approaches to buildings and parking lots, and all occupied spaces within buildings shall have illuminated fixtures as necessary.

(b) Approaches to buildings and parking lots shall have lighting at a minimum of 1 foot-candle to allow for the safe passage of pedestrians.

(c) Inpatients' rooms shall have general illumination, night illumination, reading illumination and exam illumination.

(A) General illumination fixtures shall be provided in each inpatient room. At least one fixture shall be connected to the emergency power system, critical branch.

(B) Night illumination fixtures shall be provided in each inpatient room to light the pathway from the room entrance to the bed and from the bed to the toilet. The night illumination fixture(s) shall be permanently installed low-intensity luminaires mounted at or below the patient bed level. Night luminaires shall be controlled at the room entrance.

(C) Reading illumination fixtures shall be provided for each patient. The patient shall be able to control the reading light without getting out of bed. Flexible light arms, if provided, shall be mechanically controlled to prevent the bulb from coming in contact with bed linen.

(D) Exam illumination fixtures and all lights positioned over the patient bed shall be designed or positioned to prevent damage from intravenous (IV) poles and traction devices when the head of the bed is raised.

(d) All light controls in patient areas shall be of the quiet operating type.

(e) Lighting for intensive care, critical care, and newborn nursery bed and crib areas shall be designed or arranged to permit staff observation of patients, but minimize glare, i.e., no downlights over patient bed areas. Provisions shall be made to allow staff to lower the light levels through switching of alternate lamps or by dimming the lighting. Refer to OAR 333-535-0041(6)(h) for lighting controls required at NICU beds.

(f) Operating and C-section delivery rooms shall have general lighting in addition to that provided by special luminaires at the surgical and obstetrical tables. Each fixed special luminaire at the table shall be connected to an independent circuit. Portable units may share circuits.

(g) Patient care unit corridors shall have general illumination with provisions for reduction of light level at night.

(h) Non-lensed fixtures shall not be allowed in patient care areas.

(i) Adaptable or universal rooms shall be in accordance with the most restrictive use.

(5) Receptacles (Convenience Outlets): See Table 6 for receptacle requirements in specific areas.

(a) In pediatric units, psychiatric units, emergency department waiting areas, and outpatient waiting areas receptacles shall be tamper resistant, hospital grade, safety grounding type;

(b) Anesthetizing locations. Each operating and C-section delivery room shall have a minimum of six independent circuits serving receptacles. Where mobile X-ray equipment requiring special electrical considerations is used, additional receptacles distinctively marked for X-ray use shall be provided. (See OESC for receptacle requirements when capacitive discharge or battery operated mobile X-ray units are used.);

(c) Patient areas. Each patient room shall have duplex grounding type receptacles located as follows: One on each side of the head of each bed, at least one of which shall be connected to the emergency electrical system critical branch; one for the motorized bed; and one on each other wall. A separate receptacle shall be provided for television, if used. Receptacles may be omitted from exterior walls where construction would make installation impractical. Adaptable or universal rooms shall be in accordance with the most restrictive use.

(d) All critical care areas, as defined in OESC and NFPA 99, including pediatric intensive care, trauma, and resuscitation, shall have at least four duplex outlets within 6 feet of the head of each bed, crib, or bassinet, all of which shall be connected to the emergency electrical system critical branch. Additional outlets (which may be shared) shall be available at the head of each bed;

(e) Resuscitation, LDRP, and LDR rooms shall have receptacles at the bed as required for patient rooms and shall have additional receptacles at the crib/bassinet as required for normal newborn nurseries.

(f) Patient areas with renal dialysis water and waste connections shall be provided with GFI protection.

(g) Corridors. Duplex grounded receptacles for general use shall be installed approximately 50 feet apart in all corridors and within 25 feet of the ends of corridors. Receptacles in pediatric unit corridors shall be hospital grade, tamper resistant, safety grounding type. At least one single polarized receptacle marked for use of X-ray only shall be installed in corridors of inpatient areas. Where capacitive discharge or battery-powered X-ray units are used in lieu of the portable electrically powered type, separate polarized receptacles are not required.

(h) Provide duplex outlets for emergency resuscitation carts, connected to the critical branch of the emergency system.

(6) Equipment Installation in Special Areas:

(a) Anesthetizing locations. All electrical equipment and devices, receptacles and wiring shall comply with applicable sections of NFPA 99 and OESC.

(b) X-ray installation. Fixed and mobile X-ray equipment installations shall conform to OESC.

(c) Ground fault protection for personnel shall be provided as follows:

(A) Individual 125 volt ground fault circuit interrupter receptacles shall be provided when located adjacent to any sink or within 6 feet of any shower or tub;

(B) Ground fault circuit interrupter protection shall be provided for all 15 or 20 amp, 125 volt receptacles located within 6 feet of kitchen or other food preparation area sinks; and

(C) When ground fault circuit interrupters are used in critical care areas, provisions shall be made to ensure that other essential equipment is not affected by activation of an interrupter.

(d) In inpatient care areas, electronic faucets and water closets requiring electricity to operate shall be connected to the critical or equipment branch of the emergency system.

(e) Domestic hot water systems in inpatient facilities shall be served by the equipment branch of the emergency system and a minimum of one kitchen refrigerator and one kitchen freezer shall be served by the equipment branch of the emergency system.

(f) All patient care-related telecommunications and information systems shall be powered from the essential electrical system. If installed, electronic surveillance systems including patient location, video/audio monitoring, and infant abduction prevention systems shall be served by the essential electrical system.

(7) Nurses' call system requirements for inpatient facilities and outpatient surgical facilities:

(a) General. Each patient room including diagnostic and treatment areas shall be served by at least one calling station for two-way voice communication, except as exempted elsewhere in this chapter. Each such bed shall be provided with a call button. Two call buttons serving adjacent beds may be served by one calling station. Calls shall activate a visible signal in the corridor at the doors to patient's rooms and in all nurses' work stations including clean utility rooms, soiled utility rooms, medication rooms, and the nursing station of the nursing unit. In multi-corridor nursing units, additional visible signals shall be installed at corridor intersections. All nurses' call stations shall be electronically supervised to indicate when connecting devices are inoperable. Nurses' calling systems that provide two-way voice communication shall be equipped with an indicating light at each calling station that lights and remains lighted as long as the voice circuit is operating.

(b) Emergency call system. A nurses' call emergency system shall be provided for each inpatient toilet, bath, sitz bath, shower room, imaging suite, and renal dialysis toilet room, except as exempted elsewhere in this chapter. This system shall be usable by a collapsed patient lying on the floor. Inclusion of a pull cord will satisfy this standard. The emergency call system shall be designed so that all signal lights will remain lighted until turned off at the patient's calling station. Provisions for emergency calls will also be needed in outpatient and treatment areas where patients may be subject to incapacitation, such as dressing areas and restrooms.

(c) Intensive care. In areas such as intensive care, recovery and pre-op where patients are under constant visual surveillance, the nurses' call system may be limited to a bedside button or station that activates a signal readily seen from the control station.

(d) Nurses' emergency. A calling station that may be used by nurses to summon assistance from other areas for non-life threatening situations shall be provided in each C-section, recovery, emergency examination or treatment area, and in intensive care units, nurseries, special procedure rooms, stress test areas, cardiac catheterization, out-patient surgeries, special procedure rooms, endoscopy, colonoscopy, bronchoscopy, emergency department triage/intake areas, and group areas for psychiatric patients. The call station may be located at the area nurse station in intensive care, nursery, recovery, and emergency department areas. This system shall activate a visual and audible signal at all nurse work areas in the unit and at an additional nurse station in a staffed area.

(e) In critical care, post anesthesia care unit recovery, and inpatient pre-op areas the nurse call system shall include provisions for an emergency code resuscitation alarm to summon assistance from outside the unit.

(f) Each operating room shall be provided with a system for emergency communication with the surgical control station that can be operated without the use of the hands, but which is not foot operated. (Refer to OAR 333-535-0110(3)(a))

(g) In non-invasive and non-critical care areas with CCTV and intercom to monitor the patient, such as radiation therapy and tomotherapy, a patient call station is not required.

(h) Nurse call stations are not required in psychiatric patient care rooms, but if provided, all hardware shall have tamper resistant fasteners and provisions shall be made for the easy removal or covering of call button outlets.

(8) Emergency Electric Service:

(a) General. An emergency source of electricity shall be provided and connected to certain circuits for lighting and power during an interruption of the normal electric supply in accordance with NFPA 99, NFPA 110, and OESC.

(b) Emergency electric services shall be provided to all services that must continue to function during any failure of the normal power source as required in NFPA 99 and OESC, including fire pump if installed. Sufficient fuel/power to operate the emergency electric services for a minimum of 96 hours shall be provided for inpatient facilities. The fuel system shall include a low level day tank alarm, transfer pump flow switch alarm, or other method to detect an interruption of flow between the main fuel tank and the day tank;

(c) Exhaust systems for internal combustion engines shall be of the critical silencer type and be installed to minimize objectionable noise to patient areas. Where a generator is routinely used for reduction of peak loads, protection of patient areas from excessive noise may become critical.

(d) Electrical plans shall include information indicating size of essential electrical service and load served by automatic transfer switch(es). Plans or specifications for facilities utilizing only one transfer switch shall include load calculation summaries showing the volt amp loads on the transfer switch.

(9) Fire Alarm Systems: All health care facilities shall be provided with fire alarm systems in accordance with the Authorities having Jurisdiction. Special attention shall be given to the use of fire alarm appurtenances in anesthetizing locations and control of air handling systems serving anesthetizing and infectious isolation areas.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 441.060

Stats. Implemented: ORS 441.060

Hist.: HD 11-1980, f. & ef. 9-10-80; Renumbered from 333-023-0200(32) HD 29-1988, f. 12-29-88, cert. ef. 1-1-89; Renumbered from 333-074-0360; HD 21-1993, f. & cert. ef. 10-28-93; OHD 1-2002, f. & cert. ef. 2-28-02; PH 14-2005, f. 8-10-05, cert. ef. 8-15-05; PH 10-2009, f. & cert. ef. 10-1-09

DIVISION 536

IN-HOME CARE AGENCIES

333-536-0000
Purpose

The purpose of these rules is to establish standards for licensure of In-Home Care Agencies.

Stat. Auth.: ORS 443.340

Stats. Implemented: ORS 443.305 - 443.355

Hist.: OHD 19-2002, f. 12-4-02, cert. ef. 2-1-03; PH 3-2004(Temp), f. & cert. ef. 2-6-04 thru 7-30-04; PH 22-2004, f. & cert. ef. 6-25-04; PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0005
Definitions

As used in OAR 333-536-0000 through 333-536-0125, the following definitions apply:

(1) "Abuse."

(a) As it applies to an adult, includes but is not limited to:

(A) Any physical injury caused by other than accidental means, or that appears to be at variance with the explanation given of the injury.

(B) Neglect that leads to physical harm through withholding of services necessary to maintain health and well-being.

(C) Abandonment, including desertion or willful forsaking of a person or the withdrawal or neglect of duties and obligations owed a person.

(D) Willful infliction of physical pain or injury.

(E) Use of derogatory or inappropriate names, phrases or profanity, ridicule, harassment, coercion, threats, cursing, intimidation or inappropriate sexual comments or conduct of such a nature as to threaten significant physical or emotional harm to a person.

(F) Wrongfully taking or appropriating money or property, of knowingly subjecting a person to harm by conveying a threat to wrongfully take or appropriate money or property, which threat reasonably would be expected to cause the person to believe that the threat will be carried out.

(G) Sexual contact with a non-consenting person or with a person considered incapable of consenting to a sexual act as described in ORS 163.315. As used in this paragraph, "sexual contact" has the meaning given that term in ORS 163.305.

(b) As is applies to a child, has the same meaning as "abuse" as that term is defined in ORS 419B.005.

(2) "Activities of daily living" means self-care activities that must be accomplished by an individual to meet his or her daily needs.

(3) "Agency" means In-Home Care Agency.

(4) "Branch office" means a location or site from which an in-home care agency provides services within a portion of the total geographic area served by the parent agency. The site of the branch office generally does not exceed one hour of travel time from the parent agency. The branch office is part of the in-home care agency and is located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the branch to independently meet the requirements of an in-home care agency.

(5) "Caregiver" means a person providing assistance with activities of daily living or assistance with personal care tasks, household and supportive services, or medication services as authorized by these rules.

(6) "Client representative" means:

(a) A parent, stepparent, foster parent, or other adult with primary caregiving responsibility for the client when the client is a child; or

(b) An individual, paid or unpaid, related or unrelated, who acts on behalf of, or cares for the client when the client is an adult.

(7) "Division" means the Public Health Division of the Oregon Health Authority.

(8) "Home health agency" has the meaning given that term in ORS 443.005.

(9) "Hospice program" has the meaning given that term in ORS 443.850.

(10) "In-home care agency" means an agency primarily engaged in providing in-home care services for compensation to an individual in that individual's place of residence. "In-home care agency" does not include a home health agency or portion of an agency providing home health services as defined in ORS 443.005.

(11) "In-home care services" means personal care services furnished by an in-home care agency, or an individual under an arrangement or contract with an in-home care agency, that are necessary to assist an individual in meeting the individual's daily needs, but do not include curative or rehabilitative services.

(12) "Licensed" means that the person or agency for which the term applies is currently licensed, certified, or registered by the proper authority within the State of Oregon.

(13) "Management experience" means the administration, supervision or management of individuals in a health related field including hiring, assigning, evaluating and taking disciplinary actions.

(14) "Medication administration" means administering medications to a client or directly supervising the client who is not able or not willing to self-direct, but may be physically able to perform the tasks. Medication administration includes but is not limited to taking the client's medications from original containers and putting the medications into closed secondary containers designed and manufactured for this purpose.

(15) "Medication assistance" means helping the client who is able to self-direct with one or more steps in the process of taking medication, but does not mean medication administration as defined in these rules. Examples of medication assistance include,

but are not limited to, opening the medication container, helping the client self-administer his or her medication, and assisting the client with one or more steps of medication administration at the client's direction.

(16) "Medication reminding" means providing a client with an audio, visual or oral reminder to take his or her medication when a client is able to self-direct.

(17) "Medication services" means medication assistance or medication administration but does not include medication reminding.

(18) "Nursing services" means the provision of services that are deemed to be the practice of nursing as defined by ORS 678.010. These services include but are not limited to the delegation of specific tasks of nursing care to unlicensed persons in accordance with the Oregon State Board of Nursing administrative rules, chapter 851, division 047. Nursing services are not rehabilitative or curative, but are maintenance in nature.

(19) "Parent agency" means the in-home care agency that develops and maintains administrative controls of subunits or branch offices.

(20) "Personal care services" means the provision of or assistance with tasks intended to supplement a client's own personal abilities which are necessary to accomplish the client's activities of daily living and other activities as described in OAR 333-536-0045(1), and are preventive and maintaining in nature.

(21) "Professional experience" means having a nursing, medical, therapeutic license, certificate or degree used to work in a health-related field or program or completion of a Division approved training program.

(22) "Qualified entity" means an entity whose training program has been approved by the Division.

(23) "Qualified individual" means an individual who:

(a) Has completed a Division approved training program; or

(b) Is currently licensed as a registered nurse, practical nurse, physician assistant, or pharmacist; or

(c) Is another health care professional not listed in subsection (23)(b) who has been approved by the Division to conduct training.

(24) "Registered nurse" (RN) means a person licensed under ORS Chapter 678.

(25) "Schedule caregivers" means to plan appointments for caregivers to deliver specific in-home care services to clients; the times and dates of these appointments are set by the in-home care agency.

(26) "Self-direct" means to be oriented and to know:

(a) The reason why each medication is taken, i.e. for what condition;

(b) The amount or dose of medication that needs to be taken;

(c) The route the medication needs to be taken; and

(d) The time of day the medication needs to be taken.

(27) "Stable and predictable" means a situation where the client's clinical and behavioral state is known, not characterized by rapid changes, and does not require continuous reassessment and evaluation.

(28) "Subunit" means an in-home care agency that provides for a parent agency in a geographic area different from that of the parent agency and generally exceeding one hour of travel time from the location of the parent agency.

(29) "Survey" means an inspection of an applicant for an in-home care agency license or a licensed in-home care agency to determine the extent to which the applicant or in-home care agency is in compliance with state in-home care agency statutes and these rules.

Stat. Auth.: ORS 443.340
Stats. Implemented: ORS 443.305 - 443.355
Hist.: OHD 19-2002, f. 12-4-02, cert. ef. 2-1-03; PH 3-2004(Temp), f. & cert. ef. 2-6-04 thru 7-30-04; PH 22-2004, f. & cert. ef. 6-25-04; PH 14-2007, f. 12-19-07, cert. ef. 1-1-08; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 11-2011, f. & cert. ef. 10-27-11; PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0007
Classification

(1) Agencies shall be classified according to the services provided (see Table 1). An agency shall be classified as:

(a) Limited; An agency that provides personal care services that may include medication reminding but does not provide medication assistance, medication administration, or nursing services;

(b) Basic; An agency that provides personal care services that may include medication reminding and medication assistance but does not provide medication administration or nursing services;

(c) Intermediate; An agency that provides personal care services that may include medication reminding, medication assistance and medication administration but does not provide nursing services; or

(d) Comprehensive; An agency that provides personal care services that may include medication reminding, medication assistance, medication administration and nursing services.

(2) Medication services training for caregivers employed by an agency classified as Basic, Intermediate or Comprehensive shall be provided by a qualified individual or entity.

(3) Agencies licensed by the Division must neither assume a descriptive title nor be held out under any descriptive title other than the classification title established by the Division and under which the agency is licensed. No agency licensed by the Division shall provide services or use a classification title in its advertising, publicity, or any other form of communication other than what the agency is licensed to provide.

[ED. NOTE: Tables referenced are available from the agency.]
Stat. Auth.: ORS 443.340
Stats. Implemented: ORS 443.315
Hist.: PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0010
Application for Licensure

(1) An agency that establishes, conducts, or represents itself to the public as providing in-home care services must be licensed by the Division and must comply with ORS 443.305 through 443.355 and these rules. The provisions of 443.305 through 443.355 do not apply to organizations licensed, registered or certified under ORS 101.030, 410.495, 443.410, 443.485, 443.725, 443.860, or 443.886. The provisions of 443.305 through 443.355 do not apply to independent individuals, volunteers, family, neighbors, or to agencies offering only housekeeping or on-call staffing for facilities, or to support services provided and funded by the Department of Human Services. Entities that provide referral or matching services that link in-home care services with clients are not required to be licensed under these rules, unless they do one or more of the following:

(a) Schedule caregivers (as defined in OAR 333-536-0005);

(b) Assign work;

(c) Assign compensation rates;

(d) Define working conditions;

(e) Negotiate for a caregiver or client for the provision of services; or

(f) Place a caregiver with a client.

(2) Application for a license to operate an in-home care agency shall be in writing on a form provided by the Division and shall include, but is not limited to, demographic, ownership and administrative information about the agency.

(3) If an owner or administrator has direct contact with a client, the owner or administrator must submit background information to the Division in accordance with OAR 333-536-0093 for the purposes of conducting a criminal records check.

(4) If any of the information delineated in an agency's most recent application changes at a time other than the annual renewal date, an agency shall submit a revised application to the Division within 30 days of the change.

(a) An agency that submits a revised application that contains a change to any of the following must obtain Division approval prior to implementation:

(A) Administrator;

(B) Agency classification;

(C) Branch and subunit; and

(D) Geographic service area exceeding one hour's travel time.

(b) In determining whether to grant approval for changes identified in subsection (4)(a) of this rule, the Division may request agency documents or records for review to determine compliance with in-home care licensing laws and rules, or may conduct an on-site inspection.

(5) No entity shall provide in-home care services or use the term "in-home care agency" in its advertising, publicity, or any other form of communication unless it holds a current valid license as an in-home care agency in accordance with the provisions within.

Stat. Auth.: ORS 443.340

Stats. Implemented: ORS 443.315 & 443.340

Hist.: OHD 19-2002, f. 12-4-02, cert. ef. 2-1-03; PH 3-2004(Temp), f. & cert. ef. 2-6-04 thru 7-30-04; PH 22-2004, f. & cert. ef. 6-25-04; PH 14-2007, f. 12-19-07, cert. ef. 1-1-08; PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0015

Review of License Application

Upon receipt of a completed initial application and the required fee, the Division shall conduct a survey in accordance with OAR 333-536-0041 of an agency or any subunit to determine if an agency or subunit is in compliance with these rules and ORS 443.305 through 443.355, and has the intent to provide in-home care services.

Stat. Auth.: ORS 443.340

Stats. Implemented: ORS 443.315 & 443.340

Hist.: OHD 19-2002, f. 12-4-02, cert. ef. 2-1-03; PH 3-2004(Temp), f. & cert. ef. 2-6-04 thru 7-30-04; PH 22-2004, f. & cert. ef. 6-25-04; PH 14-2007, f. 12-19-07, cert. ef. 1-1-08; PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0021

Approval of License Application

(1) The Division shall notify an applicant in writing if a license application is approved.

(2) A license shall be issued only for an agency and person(s) named in the application and may not be transferred or assigned.

(3) The license shall be conspicuously posted in an office that is viewable by the public.

Stat. Auth.: ORS 443.340

Stat. Auth.: ORS 443.315 & 443.340

Hist.: PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0023

Denial of License Application

If the Division intends to deny a license application, it shall issue a Notice of Proposed Denial of License Application in accordance with ORS 183.411 through 183.470.

Stat. Auth.: ORS 443.340

Stats. Implemented: ORS 443.325

Hist.: PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0025

Expiration and Renewal of License

Each license to operate an in-home care agency shall expire twelve months from the date of issue. If renewal is desired, the licensee shall make application at least 30 days prior to the expiration date upon a form prescribed by the Division.

Stat. Auth.: ORS 443.340

Stats. Implemented: ORS 443.305 - 443.350

Hist.: OHD 19-2002, f. 12-4-02, cert. ef. 2-1-03; PH 3-2004(Temp), f. & cert. ef. 2-6-04 thru 7-30-04; PH 22-2004, f. & cert. ef. 6-25-04; PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0031

Fees

(1) The fee for an initial in-home care agency license shall be $1,500. If the agency has subunits, the fee for an initial license shall be $1,500 for the parent agency, plus an additional $750 for each subunit.

(2) The fee for a renewed in-home care agency license shall be $750. If the agency has subunits, the fee for a renewed license shall be $750 for the parent agency, plus an additional $750 for each subunit.

(3) If the ownership of an agency changes other than at the time of the annual renewal, the licensure fee shall be $350, plus an additional $350 for each subunit.

(4) All application fees are non-refundable.

Stat. Auth.: ORS 443.340

Stats. Implemented: ORS 443.315 & 443.340

Hist.: PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0033

Denial, Suspension or Revocation of License

(1) A license for an in-home care agency may be denied, suspended or revoked by the Division when an in-home care agency has failed to comply with ORS 443.305 through 443.355 or with OAR chapter 333, division 536, including but not limited to an owner or administrator of the in-home care agency permitting, aiding or abetting any illegal act affecting the welfare of the client.

(2) The Division may deny, suspend or revoke the license of any in-home care agency for failure to comply with ORS 443.004.

(3) A failure to comply with ORS 443.305 through 443.355 includes but is not limited to:

(a) Failure to provide a written disclosure statement to a client or a client's representative prior to in-home care services being rendered;

(b) Failure to provide the contracted in-home care services; or

(c) Failure to correct deficiencies identified during a Division inspection or complaint investigation.

(4) If the Division intends to suspend or revoke an agency license, it shall do so in accordance with ORS 183.411 through 183.470.

Stat. Auth.: ORS 443.340

Stats. Implemented: ORS 443.315 and 443.325

Hist.: PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0035

Return of Agency License

Each license certificate in the licensee's possession shall be returned to the Division immediately upon the suspension or revocation of the license, failure to renew the license by the date of expiration, or if operation is discontinued by the voluntary action of the licensee.

Stat. Auth.: ORS 443.340

Stats. Implemented: ORS 443.315 & 443.340

Hist.: OHD 19-2002, f. 12-4-02, cert. ef. 2-1-03; PH 3-2004(Temp), f. & cert. ef. 2-6-04 thru 7-30-04; PH 22-2004, f. & cert. ef. 6-25-04; PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0041

Surveys

(1) The Division shall, in addition to any investigations conducted pursuant to OAR 333-536-0043, conduct at least one survey of each in-home care agency prior to services being rendered and

once every three years thereafter as a requirement of licensing and at such other times as the Division deems necessary.

(2) In lieu of an on-site inspection required by section (1) of this rule, the Division may accept a certification or accreditation from a federal agency or an accrediting body approved by the Division that state licensing standards have been met if an in-home care agency:

(a) Notifies the Division to participate in any exit interview conducted by the federal agency or accrediting body; and

(b) Provides copies of all documentation concerning the certification or accreditation requested by the Division.

(3) An in-home care agency shall permit Division staff access to any location from which it is operating its agency or providing services during a survey.

(4) A survey may include but is not limited to:

(a) Interviews of clients, client family members, agency management and staff;

(b) On-site observations of clients and staff performance;

(c) Review of documents and records;

(d) Client audits.

(5) An in-home care agency shall make all requested documents and records available to the surveyor for review and copying.

(6) Following a survey, Division staff may conduct an exit conference with an agency owner, administrator, or designee. During an exit conference, Division staff shall:

(a) Inform the agency owner, administrator or designee of the preliminary findings of the inspection; and

(b) Give the owner, administrator or designee a reasonable opportunity to submit additional facts or other information to the surveyor in response to those findings.

(7) Following a survey, Division staff shall prepare and provide the agency owner or administrator specific and timely written notice of the findings.

(8) If the findings result in a referral to another regulatory agency, Division staff shall submit the applicable information to that referral agency for its review and determination of appropriate action.

(9) If no deficiencies are found during a survey, the Division shall issue written findings to the agency owner or administrator indicating that fact.

(10) If deficiencies are found, the Division shall take informal or formal enforcement action in accordance with OAR 333-536-0117 or 333-536-0120.

Stat. Auth.: ORS 443.340
Stats. Implemented: ORS 443.315 & 443.340
Hist.: PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0042
Complaints

(1) Any person may make a complaint verbally or in writing to the Division regarding an allegation as to the care or services provided by an in-home care agency or violations of in-home care agency laws or regulations.

(2) The identity of a person making a complaint will be kept confidential.

(3) Information obtained by the Division during an investigation of a complaint or reported violation is confidential and not subject to public disclosure under ORS 192.410 through 192.505.

(4) Upon conclusion of an investigation, the Division may publicly release a report of its findings but may not include information in the report that could be used to identify the complainant or any client of an in-home care agency. The Division may use any information obtained during an investigation in an administrative or judicial proceeding concerning the licensing of an in-home care agency.

(5) An employee with knowledge of a violation of law or rules of the Division shall use the reporting procedures established by an in-home care agency before notifying the Division or other state agency of the inappropriate care or violation, unless the employee:

(a) Believes a client's health or safety is in immediate jeopardy; or

(b) Files a complaint in accordance with section (1) of this rule.

(6) If a complaint involves an allegation of criminal conduct or an allegation that is within the jurisdiction of another local, state, or federal agency, the Division shall refer the matter to that agency.

Stat. Auth.: ORS 443.340
Stats. Implemented: ORS 443.315, 443.340 & 443.355
Hist.: PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0043
Investigations

(1) An unannounced complaint investigation shall be carried out within 45 calendar days of receipt of the complaint and may include, but is not limited to:

(a) Interviews of the complainant, caregivers, clients, a client's representative, a client's family members, witnesses, and agency management and staff;

(b) On-site observations of the client(s), staff performance, client environment; and

(c) Review of documents and records.

(2) Should the complaint allegation represent an immediate threat to the health or safety of a client, the Division shall notify appropriate authorities to ensure a client's safety, and an investigation shall be commenced within two working days.

(3) An agency shall permit Division staff access to the agency during an investigation.

(4) An agency shall cooperate with investigations of allegations of client abuse and neglect conducted by the Department of Human Services, Oregon Health Authority, Adult Protective Services, and other agencies such as law enforcement.

Stat. Auth.: ORS 443.340
Stats. Implemented: ORS 443.315 & 443.340
Hist.: PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0045
Services Provided

(1) The services provided by an agency must include the safe provision of or assistance with, personal care tasks related to one or more of the following:

(a) Bathing;

(b) Personal grooming and hygiene;

(c) Dressing;

(d) Toileting and elimination;

(e) Mobility and movement;

(f) Nutrition/hydration and feeding;

(g) Medication reminding.

(2) An agency may provide medication reminding services for clients who can self-direct as defined in OAR 333-536-0005 if the agency:

(a) Documents the client's knowledge of the following information using a standardized form required by the Division:

(A) The reason why each medication is taken;

(B) The amount or dose of each medication that needs to be taken;

(C) The route the medication needs to be taken; and

(D) The time of day each medication needs to be taken.

(b) Retains a copy of the standardized form, signed by the client, where an agency has determined the client can self administer medications.

(3) An agency must evaluate whether a client can continue to self-direct at a minimum of every 90 days. If it is determined that a client can no longer self-direct, arrangements shall be made to transfer the client to an agency with a higher license classification within 30 days if the agency providing current services is not classified as such.

(4) All documentation required in sections (2) and (3) of this rule shall be kept in the client's record.

(5) In addition to personal care tasks, an agency may also provide one or more of the following services upon approval by the Division:

(a) Non-injectable medication assistance;

(b) Non-injectable medication administration; or

(c) Nursing services.

(6) An agency may also provide housekeeping and other supportive services. Such tasks include, but are not limited to:

(a) Housekeeping;

(b) Laundry;

(c) Shopping and errands;

(d) Transportation; and

(e) Arranging for medical appointments.

(7) If an agency has clients who receive only housekeeping and support services, the agency is not required to comply with the following rules for those specific clients: OAR 333-536-0065, 333-536-0070, 333-536-0075, 333-536-0080, 333-536-0085 and 333-536-0090.

(8) Services described in this rule shall be primarily provided at the client's residence. In addition, the services may be rendered at nonresidence locations as specified in the client's service plan.

Stat. Auth.: ORS 443.340

Stats. Implemented: ORS 443.315 & 443.340

Hist.: OHD 19-2002, f. 12-4-02, cert. ef. 2-1-03; PH 3-2004(Temp), f. & cert. ef. 2-6-04 thru 7-30-04; PH 22-2004, f. & cert. ef. 6-25-04; PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0050
Organization, Administration, and Personnel

(1) An agency shall clearly set forth in writing the organization, services provided, administrative control, and lines of authority and responsibility from the owner to the client-care level.

(a) An agency shall not assign administrative and supervisory functions to another agency or organization.

(b) An agency shall control and be responsible for all services provided.

(c) An agency shall be required to maintain administrative and professional oversight to ensure the quality of services provided.

(d) All agency records must be kept separate and distinct from other business entities.

(2) Geographic service area:

(a) An agency shall identify in writing the geographic area in which it generally intends to provide services.

(b) The geographic service area shall be within a distance from a parent agency which ensures appropriate and timely delivery and supervision of services with the following exception:

(A) An agency caregiver may accompany a client outside the geographic service area if all of the following conditions are met:

(i) A client has requested an agency caregiver to accompany the client; and

(ii) The travel plans are described and documented in a client's service plan.

(B) An agency shall require a caregiver who accompanies a client outside the geographic service area to:

(i) Document all services and care provided to the client on a daily basis;

(ii) Report to the agency administrator or designee either by phone or e-mail the status of the client before leaving the geographic service area and immediately upon return;

(iii) Check-in with the agency administrator no less than once per week if the travel results in the client and caregiver being gone for more than one week; and

(iv) Be certified in Cardiopulmonary Resuscitation (CPR).

(C) If the client's condition changes while traveling, the caregiver must contact the agency administrator or designee immediately.

(D) An agency shall develop policies and procedures which address what caregivers must do when their client's condition changes while the client and caregiver are out of the agency's geographic service area.

(3) If an agency operates a branch office:

(a) The branch office shall be located within the parent agency's geographic service area at a distance from the parent agency that generally does not exceed one hour's travel time.

(b) The branch office shall be operated under the management and supervision of the parent agency. Administrative and personnel functions must be retained at the parent agency. The branch office must not function as an independent agency.

(c) Services must not be provided from the branch office until the branch office has been added to the license of the parent agency in accordance with Division procedures.

(4) If an agency provides services from an office generally exceeding one hour of travel time located outside of a parent agency's geographic service area, that office will constitute a subunit of the agency. If the agency has subunits:

(a) The subunit shall have its own staff, separate from parent agency staff, and shall operate independently of the parent agency.

(b) The subunit shall independently meet all licensing requirements, be separately licensed from the parent agency, and pay a separate licensure fee.

(5) An agency's owner or designee shall:

(a) Assume full legal, financial, and overall responsibility for the agency's operation; and

(b) Serve as, or employ, a qualified administrator.

(6) An administrator shall meet the following qualifications:

(a) Possess a high school diploma or equivalent; and

(b) Have at least two years of professional or management experience in a health-related field or program or have completed a training program approved by the Division.

(7) An administrator or designee shall be accessible and available during all hours in which services are being provided to clients and must be able to be on site at the parent agency location within a timely manner as needed. An administrator shall assign, in writing, a qualified designee to act as administrator in his or her temporary absence.

(8) An administrator or designee shall be responsible for:

(a) Organizing and directing the agency's ongoing functions;

(b) Developing and implementing written and current policies and procedures necessary to direct the administrative, personnel, and client care operations of the agency, including but not limited to the requirements in these rules;

(c) Ensuring the completeness and accuracy of all information provided to the public regarding the agency and its services;

(d) Ensuring the provision of safe and appropriate services in accordance with written service plans;

(e) Ensuring that all individuals providing services for the agency meet the qualification, orientation, competency, training, and education requirements in the rules;

(f) Ensuring that personnel and client care practices are consistent with the agency's written policies and procedures.

(g) Ensuring that client care assignments are based on the caregiver's abilities, skills, and competence;

(h) Ensuring that the agency does not accept or retain clients for whom it does not have the capabilities or resources to provide services;

(i) Ensuring the timely internal investigation of complaints, grievances, accidents, incidents, medication or treatment errors, and allegations of abuse or neglect involving individuals providing services for the agency. An agency shall maintain in its records documentation of the complaint or event, the investigation, the results, and actions taken;

(j) Ensuring the timely reporting of allegations of abuse or neglect to the appropriate authority that includes but is not limited to the Department of Human Services, Oregon Health Authority, Public Health Division, or local law enforcement agency.

(9) Personnel records for all caregiver, nursing staff, and employees shall include at a minimum the following:

(a) Evidence of pre-employment screening;

(b) Evidence that the in-home care agency has conducted a criminal records check on all subject individuals in accordance with OAR 333-536-0093.

(A) The in-home care agency must ensure that a criminal records check has been conducted on all subject individuals employed by or volunteering for an agency on or after July 6, 2011.

(B) If the screening indicates that a subject individual has been convicted for crimes against an individual or property, the agency shall make a determination of the individual's fitness to provide care to clients in accordance with OAR 333-536-0093.

(c) Evidence that all position qualifications have been met, including required licensure;

(d) Current position job description(s) signed by the individual(s);

(e) Evidence of orientation, training, competency, and ongoing education;

(f) Evidence of annual performance evaluations; and

(g) Evidence of a valid driver's license with current auto insurance for each individual whose duties include transporting clients in motor vehicles.

(10) An agency shall comply with all applicable state and local laws, statutes, rules, and ordinances.

Stat. Auth.: ORS 443.340
Stats. Implemented: ORS 443.315 & 443.340
Hist.: OHD 19-2002, f. 12-4-02, cert. ef. 2-1-03; PH 3-2004(Temp), f. & cert. ef. 2-6-04 thru 7-30-04; PH 22-2004, f. & cert. ef. 6-25-04; PH 14-2007, f. 12-19-07, cert. ef. 1-1-08; PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0055
Disclosure, Screening, and Acceptance of Clients

(1) When an individual is accepted for agency service, a written disclosure statement shall be signed by the client or the client's representative. Evidence that the disclosure statement was given to the client or the client's representative shall be incorporated into the client's record.

(2) The disclosure statement must include the following:

(a) A description of the license classification and the services offered by the agency according to OAR 333-536-0045, including the extent of registered nurse involvement in the agency's operations and whether nursing services as described in OAR 333-536-0080 are provided;

(b) If the agency provides medication reminding or medication services, the qualifications of the individual(s) providing oversight of the agency's medication administration systems and the medication training and demonstration;

(c) A clear statement indicating that it is not within the scope of the agency's license to manage the medical and health conditions of clients who are no longer stable or predictable;

(d) The qualifications and training requirements determined by the agency for individuals providing direct client care;

(e) The charges for the services provided by the agency;

(f) A description of how the service plans are developed and reviewed and the relationship between the service plans and the cost of services;

(g) A description of billing methods, payment systems, and due dates;

(h) The policy for client notification of increases in the costs of services;

(i) The agency's refund policy;

(j) Criteria, circumstances, or conditions which may result in termination of services by the agency and client notification of such;

(k) Procedures for contacting the agency administrator or designee during all of the hours during which services are provided; and

(l) A copy of the client's rights as written in OAR 333-536-0060.

(3) An agency administrator or designee shall conduct an initial screening to evaluate a prospective client's service requests and needs prior to accepting the individual for service. The extent of the screening shall be sufficient to determine the ability of the agency to meet those requests and needs based on the agency's overall service capability. The screening shall be documented, dated and signed by the individual who conducted it.

(4) An agency shall only accept or retain individuals for services for whom it can ensure the following:

(a) The agency has the capability to meet the in-home care needs of the individual;

(b) The agency employs a sufficient number of trained and competent staff and has adequate resources to provide the requested or needed services; and

(c) The agency is able to coordinate its services with the care and services provided by other organizations and individuals.

(5) The agency shall notify the client, or the client's representative, of the need for a referral for medical or health services if the client's medical or health condition is no longer stable and predictable. The agency may continue to provide in-home care services in the client's residence, but must not manage, or represent itself as able to manage a client's medical or health condition that is not stable and predictable.

Stat. Auth.: ORS 443.340
Stats. Implemented: ORS 443.315 & 443.340
Hist.: OHD 19-2002, f. 12-4-02, cert. ef. 2-1-03; PH 3-2004(Temp), f. & cert. ef. 2-6-04 thru 7-30-04; PH 22-2004, f. & cert. ef. 6-25-04; PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0060
Clients' Rights

(1) The agency owner or administrator shall ensure that the agency recognizes and protects the following rights of each client:

(a) The right to be treated with dignity and respect;

(b) The right to be free from theft, damage, or misuse of one's personal property;

(c) The right to be given the informed choice and opportunity to select or refuse service and to accept responsibility for the consequences;

(d) The right to be free from neglect of care, verbal, mental, emotional, physical, and sexual abuse;

(e) The right to be free from financial exploitation;

(f) The right to be free from physical and chemical restraints;

(g) The right to voice grievances or complaints regarding services or any other issue without discrimination or reprisal for exercising such rights;

(h) The right to be free from discrimination in regard to race, color, national origin, gender, sexual orientation, or religion.

(i) The right to participate in planning of the services and care to be furnished, any changes in the services and care, the frequency of visits, and cessation of services;

(j) The right to have access to his or her client record;

(k) The right to have client information and records confidentially maintained by the agency;

(l) The right to be advised in writing, before care is initiated, of the charges for the services to be furnished, and the amount of payment that will be required from the client;

(m) The right to a written 30-day notice of termination of services by the agency that specifies the reason(s) for the termination with the following exceptions:

(A) The right to immediate oral or written notice of termination of services by the agency at the time the agency determines that the safety of its staff or the client cannot be ensured. If oral notice is given, the agency must also subsequently provide the client a written confirmation of the oral notice of termination of services.

(B) The right to a written 48-hour notice of termination of services by the agency in the event of non-payment in accordance with the agency's disclosed payment requirements.

(2) An agency shall provide each client with a written notice of the client's rights as a part of the disclosure statement, prior to furnishing care to a client. The client's rights notice shall also include:

(a) Procedures for filing a grievance or complaint with the agency;

(b) Procedures for filing a grievance or complaint with the Division, along with the telephone number and contact information of the Division; and

(c) Notice that the Division has the authority to examine clients' records as part of the Division's regulation and evaluation of the agency.

Stat. Auth.: ORS 443.340
Stats. Implemented: ORS 443.315 & 443.340
Hist.: OHD 19-2002, f. 12-4-02, cert. ef. 2-1-03; PH 3-2004(Temp), f. & cert. ef. 2-6-04 thru 7-30-04; PH 22-2004, f. & cert. ef. 6-25-04; PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0065
Service Plan

For clients receiving services described in OAR 333-536-0045, the services provided shall be in accordance with a written service plan developed in conjunction with a client or the client's representative based on the client's or the client's representative's request and an evaluation of the client's physical, mental, and emotional needs. The service plan must be consistent with the agency's capabilities.

(1) The agency administrator or designee shall conduct an initial evaluation of the client. The evaluation must be documented, dated, and signed by the individual who conducted the evaluation, and maintained in the client's agency record.

(2) The agency administrator or designee, in conjunction with the client or the client's representative, shall complete a written service plan within seven days after the initiation of services. The agency administrator or designee shall ensure that the service plan includes a list of individuals participating in development of the plan. The agency administrator or designee shall also sign and date the service plan when it is complete and acceptable to all individuals participating in development of the plan.

(3) The completed service plan shall be client-directed or client representative-directed and include at least the following:

(a) The schedule for the provision of services specifying a range of hours for services per month;

(b) The services to be provided, specifying the tasks to be conducted; and

(c) Pertinent information about the client's needs in relation to the services to be provided to ensure the provision of safe and appropriate care.

(4) A client or a client's representative may request changes in the service plan. All changes must be communicated to the caregiver(s) and documented.

(5) An agency shall maintain the original service plan and all updated service plans in each client's agency record. Complete and legible copies of the service plan shall be given to the client or client's representative upon request.

(6) The administrator or designee must conduct an initial visit at the client's residence within 30 days of the initiation of services to evaluate compliance by the caregiver(s) with the service plan and to assess the client's satisfaction. The initial visit must occur between the 7th and 30th day. An initial visit is not required when:

(a) A client cancels service on or before the 30th day;

(b) A client is residing in a nursing facility or a hospital; or

(c) A client refuses.

(7) The administrator or designee must conduct quarterly monitoring visits after the initial site visit. Quarterly monitoring visits may occur by phone or by other electronic means at the discretion of the administrator or designee under the following circumstances: impending discharge from services; relocation to a facility; when minimal services, such as one shift a month, would cause the client to incur undue financial burden; or, due to other circumstances that are justified in chart note(s). In no case shall the time between the in-person monitoring visits exceed a six-month period.

(8) Each monitoring visit to observe and report on the client's status must be documented, dated, and signed by the administrator or designee. The caregiver may be present during the monitoring visit.

(9) The administrator or designee must determine and document during a monitoring visit:

(a) Whether appropriate and safe techniques have been used in the provision of care;

(b) Whether the service plan has been followed as written;

(c) Whether the service plan is meeting the client's needs or needs to be updated;

(d) Whether the caregiver has received sufficient training for the client;

(e) Whether the client is satisfied with his or her relationship with the caregiver(s); and

(f) Whether appropriate follow-up is necessary for any identified issues or problems.

(10) If services are provided in a non-residential setting in accordance with the service plan, monitoring visits shall take place in the same setting that services are provided and must conform to the requirements set forth in this rule.

Stat. Auth.: ORS 443.340
Stats. Implemented: ORS 443.315 & 443.340
Hist.: OHD 19-2002, f. 12-4-02, cert. ef. 2-1-03; PH 3-2004(Temp), f. & cert. ef. 2-6-04 thru 7-30-04; PH 22-2004, f. & cert. ef. 6-25-04; PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0070
Caregiver Qualifications and Requirements

The personal care provided by an agency shall be rendered by qualified and trained employees under the supervision of the administrator or designee. The services shall be provided as requested by the client or client's representatives in accordance with these rules and the service plan.

(1) The agency owner or administrator shall ensure that the agency has qualified and trained employees sufficient in number to meet the needs of the clients receiving services.

(2) Caregivers must be at least 18 years of age and shall have sufficient communication and language skills to enable them to perform their duties and interact effectively with clients and other agency staff.

(3) Caregivers shall complete an agency-specific orientation, conducted by the agency administrator or designee, before independently providing services to clients.

(a) The orientation shall include, but not be limited to, the following subject areas:

(A) Caregivers' duties and responsibilities;

(B) Clients' rights;

(C) Ethics, including confidentiality of client information;

(D) The agency's infection control policies;

(E) A description of the services provided by the agency;

(F) Assignment and supervision of services;

(G) Documentation of client needs and services provided;

(H) The agency's policies related to medical and non-medical emergency response;

(I) The roles of, and coordination with, other community service providers;

(J) Information about what constitutes medication reminding and its specific limitations; and

(K) Other appropriate subject matter based on the needs of the special populations served by the agency.

(b) The content of the orientation, the date(s) and length, and the name(s) and signature(s) of the instructor(s) shall be clearly documented for each caregiver and maintained in personnel records.

(4) Caregivers shall complete appropriate training and must have their competency evaluated and documented by the administrator or designee before independently providing services to clients.

(a) Caregiver training shall be based on the services provided by the in-home care agency, including, as applicable, the following topics:

(A) Caregivers' duties and responsibilities;

(B) Recognizing and responding to medical emergencies;

(C) Dealing with adverse behaviors;

(D) Nutrition and hydration, including special diets and meal preparation and service;

(E) Appropriate and safe techniques in personal care tasks;

(F) Methods and techniques to prevent skin breakdown, contractures, and falls;

(G) Hand washing and infection control;

(H) Body mechanics;

(I) Maintenance of a clean and safe environment;

(J) Fire safety and non-medical emergency procedures;

(K) Assisting clients with self-directed or client representative-directed non-injectable medication administration; and

(L) Providing basic non-injectable medication services as described in OAR 333-536-0075.

(b) The content of the training, the date(s) and length, and name(s) and signature(s) of the instructor(s) shall be clearly documented for each caregiver and maintained in personnel records.

(c) Caregivers with proof of a current Oregon health-care related license or certificate are exempt from in-home caregiver training.

(d) Caregivers moving from one office to another in the same in-home care agency are not subject to additional training requirements, provided previous training is documented.

(e) Caregivers who have completed training previously, and have documentation of that training, shall have their competency evaluated by an agency representative, and any potential training may be limited to areas requiring improvement after the evaluation.

(f) Documentation of training and competency evaluation shall be included in the caregiver's personnel record.

(5) Caregivers shall receive a minimum of six hours of education related to caregiver duties annually. If a caregiver provides medication administration to a client, one additional hour of education shall be required annually related to providing medication administration.

(6) Caregiver Selection and Review of Service Plan.

(a) The skills of a caregiver must be matched with the care needs of a client. The administrator or designee must assign caregivers to specific clients based on the care needs of the clients and the skills of the caregivers.

(b) The client's service plan must be reviewed with each caregiver before the initial delivery of client care. The date of the review(s), the signature or a unique electronic identifier such as an individual's log-in and password into a computer program or an electronic stamp of the agency administrator or designee and the list of assigned caregivers must be documented.

(c) Caregivers must provide services to clients in accordance with the service plans.

Stat. Auth.: ORS 443.340
Stats. Implemented: ORS 443.315 & 443.340
Hist.: OHD 19-2002, f. 12-4-02, cert. ef. 2-1-03; PH 3-2004(Temp), f. & cert. ef. 2-6-04 thru 7-30-04; PH 22-2004, f. & cert. ef. 6-25-04; PH 14-2007, f. 12-19-07, cert. ef. 1-1-08; PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0075
Medication Services

(1) If an agency has been approved to provide non-injectable medication services, the services shall be rendered by persons who meet the requirements of section (10) of this rule. The services shall be provided as requested by the client or client's representatives in accordance with these rules, accepted standards of medication practice, and the service plan.

(2) If a client representative or family member performs the task of filling secondary non-injectable medication containers from which an agency caregiver is to administer medication, an agency shall:

(a) Obtain a signed agreement from the client representative or family member that identifies their obligation to:

(A) Provide a list of the client's medication and a physical description of each with any special instructions. The list must be updated when changes to the client's medication regimen are made;

(B) Keep the original labeled medication containers in the home for verification should the caregiver have questions; and

(C) Use closed non-injectable medication secondary containers designed and manufactured for that purpose that meet the labeling requirements of subsection (7)(d) of this rule.

(3) Agency staff shall obtain written or telephone orders from a physician or other legally recognized practitioner for all medications managed or administered by an agency under this rule and for any changes to those medications.

(a) Written orders shall be signed or confirmed by a physician or practitioner.

(b) Telephone orders shall be immediately recorded, dated, and signed by agency staff, and transmitted within 72 hours to the physician or practitioner for confirmation. The orders that have been signed or confirmed by the physician or practitioner shall be incorporated into the client's record within 30 days.

(4) An agency owner or administrator shall be responsible for developing and implementing safe and appropriate medication administration delivery systems and policies and procedures that include, but are not limited to:

(a) Provisions to ensure that each client receives the right medication, in the right amount, by the right route, and at the right time;

(b) Provisions to ensure that the caregivers are informed about the potential adverse reactions, side effects, drug-to-drug interactions and food-to-drug interactions, and contraindications associated with each client's medication regimen;

(c) Provisions to ensure that the caregivers promptly report problems or discrepancies related to each client's medication regimen to the caregivers' supervisor, agency administrator or designee;

(d) Provisions to ensure storage of medications at appropriate temperatures based on the manufacturer's recommendations; and

(e) Provisions to ensure the security and integrity of narcotics and controlled substances.

(5) A client's service plan must specify the medication tasks to be performed.

(6) Records for medication administration shall include, but are not limited to, the name of each medication, the dosage to be administered, the route of administration, the frequency of administration, client medication allergies and sensitivities, client specific indicators for administration of as needed medications and other special instructions necessary for safe and appropriate administration.

(7) Packaging and labeling:

(a) Prescription medications shall be in the original pharmacy containers and clearly labeled with the pharmacists' labels.

(b) Samples of medications received from the physician or practitioner shall be in the original containers and have the original manufacturers' labels.

(c) Over-the-counter medications shall be in the original containers and have the original manufacturers' labels.

(d) Secondary containers and all removable compartments must be labeled with the client's name, the specific time the medications in each compartment are to be administered, the date and time the secondary container was filled, and the name of the individual who filled the container.

(e) Liquid and non-pill medications that cannot be put in secondary containers shall be appropriately labeled.

(8) The provision of medication tasks as described in this rule shall be documented by the individuals performing the tasks. The documentation shall include the tasks completed, the date and signature of the individual(s) performing the task(s), and shall be maintained in accordance with agency policies and procedures.

(9) Visits by a registered nurse to evaluate a client's medication regimen and the provision of medication administration services shall be conducted and documented at least every 90 days for each client receiving medication administration services.

(10) Agency caregivers assigned to provide medication services must be given basic non-injectable medication training before providing the services. The medication training must include successful return demonstrations of non-injectable medications tasks by the caregivers.

(a) The medication training shall include at least the following areas:

(A) Medication abbreviations;

(B) Reading medication orders and directions;

(C) Reading medication labels and packages;

(D) Setting up medication labels and packages;

(E) Administering non-injectable medications:

(i) Pill forms, including identification of pills that cannot be crushed;

(ii) Non-injectable liquid forms, including those administered by syringe or dropper and eye and ear drops;

(iii) Suppository forms; and

(iv) Topical forms.

(F) Identifying and reporting adverse medication reactions, interactions, contraindications and side effects;

(G) Infection control related to medication administration; and

(H) Techniques and methods to ensure safe and accurate medication administration.

(b) Prior to providing medication services, caregivers shall demonstrate appropriate and safe techniques in the provision of medication tasks described in this rule.

(c) The content of the medication training, the dates and length of training, the identity of the qualified individual or qualified entity, evidence of successful return demonstrations, and the instructor's statement that the caregiver has been evaluated to be competent to provide the medication services described in this rule shall be clearly documented for each caregiver and maintained in the agency's personnel records.

(d) An individual with a current Oregon State Board of Nursing medication aide (CMA) certification is exempt from the training requirements in this rule.

Stat. Auth.: ORS 443.340

Stats. Implemented: ORS 443.315 & 443.340

Hist.: OHD 19-2002, f. 12-4-02, cert. ef. 2-1-03; PH 3-2004(Temp), f. & cert. ef. 2-6-04 thru 7-30-04; PH 22-2004, f. & cert. ef. 6-25-04; PH 14-2007, f. 12-19-07, cert. ef. 1-1-08; PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0080
Nursing Services

(1) If an agency has been approved to provide nursing services, the services must be provided by an Oregon-licensed registered nurse employed by the agency and provided only to a client whose medical condition and health status is stable and predictable. The services shall be provided as requested by a client or a client's representative and shall be in accordance with these rules, the applicable administrative rules of the Oregon State Board of Nursing (OAR chapter 851, division 047), and the service plan.

(2) Delegation of specific tasks of nursing care to unlicensed persons shall be conducted and documented by the registered nurse as required by the Oregon State Board of Nursing administrative rules chapter 851, division 047. A client's record shall contain documentation that all requirements within those rules have been met, including but not limited to: assessment, instruction, observation, supervision, and re-evaluation.

(3) A client's service plan shall include current identification of the delegated specific task(s) of nursing care to be provided and shall specify the caregivers to whom the task(s) have been delegated.

(4) The provision of nursing services as described in this rule shall be documented by the individual(s) providing the service(s) or performing the task(s). The documentation shall include the services(s) or task(s) completed, the date and signature of the individual(s) performing the service(s) or task(s), and shall be maintained in accordance with an agency's policies and procedures.

(5) For all medications and medical treatments managed or administered by an agency under this rule, and for any changes to those medications or medical treatments, a registered nurse shall obtain written or telephone orders from a physician or other legally recognized practitioner.

(a) Written orders shall be signed or confirmed by a physician or practitioner.

(b) Telephone orders shall be immediately recorded, dated, and signed by the registered nurse, and transmitted within 72 hours to the physician or practitioner for confirmation. The orders that have been signed or confirmed by the physician or practitioner shall be incorporated into the client's record within 30 days.

Stat. Auth.: ORS 443.340

Stats. Implemented: ORS 443.315 & 443.340

Hist.: OHD 19-2002, f. 12-4-02, cert. ef. 2-1-03; PH 3-2004(Temp), f. & cert. ef. 2-6-04 thru 7-30-04; PH 22-2004, f. & cert. ef. 6-25-04; PH 14-2007, f. 12-19-07, cert. ef. 1-1-08; PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0085
Client Records

(1) A client record shall be maintained for every client served by an agency, unless the client receives only housekeeping or support services, and shall be maintained in the agency's office.

(2) A legible, reproducible client record shall include at least the following:

(a) Identification data;

(b) Referral and intake information;

(c) Start-of-service date;

(d) Screening and disclosure documents and documentation required by these rules;

(e) Clients' rights documentation required by these rules;

(f) All client evaluation and assessment documentation;

(g) Client service plan and updates;

(h) Documentation of all services provided;

(i) Service and financial agreement signed by a client or a client's representative before the initiation of services that specifies the services to be provided in accordance with the service plan, and the costs for those services;

(j) End-of-services date; and

(k) End-of-service summary, including the dates of service and the disposition of the client.

(3) All entries and documents in the record must be recorded in ink, typescript, or computer-generated.

(4) All entries in a client's record must be dated and signed, or otherwise authenticated by the person making the entry. For purposes of this rule, authenticated means verification by the author that an entry in the client record is genuine. Electronic authentication is acceptable as long as there is a process for reconstruction of the information and there are safeguards to prevent unauthorized access to the records.

(5) A client record shall be maintained in a manner that renders it easily retrievable.

(6) Reasonable precautions must be taken to protect a client's record and information from unauthorized access, fire, water, and theft.

(7) In an effort to coordinate services and care with other providers, including but not limited to, hospice, home health, and family members, as required in OAR 333-536-0055(4)(c), charting notes within a client's home may be shared, as permitted by law.

(8) Authorized employees of the Division shall be permitted to review client records upon request. Photocopies of the records shall be made upon request.

(9) All clients' records shall be kept for a period of at least seven years after the date of last end-of-service.

(10) Clients' records are the property of the agency.

(11) If an agency changes ownership, all clients' records shall remain in the agency, and it shall be the responsibility of the new owner to protect and maintain these records.

(12) Before an agency terminates its business, the agency shall notify the Division where the clients' records will be stored.

Stat. Auth.: ORS 443.340

Stats. Implemented: ORS 443.315 & 443.340

Hist.: OHD 19-2002, f. 12-4-02, cert. ef. 2-1-03; PH 3-2004(Temp), f. & cert. ef. 2-6-04 thru 7-30-04; PH 22-2004, f. & cert. ef. 6-25-04; PH 14-2007, f. 12-19-07, cert. ef. 1-1-08; PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0090
Quality Improvement

An agency shall establish and maintain an effective, agency wide quality assessment and performance improvement program that evaluates and monitors the quality, safety and appropriateness of services provided by the agency, and shall include at a minimum:

(1) A method to identify, analyze and correct adverse events;

(2) A method to select and track quality indicators by high risk, high volume, problem prone areas and by the effect on client safety and quality of care;

(3) The quality improvement activities shall be conducted by a committee comprised of, at a minimum, agency administrative staff, an agency caregiver, and if the agency is classified as an

intermediate or comprehensive agency, an agency registered nurse; and

(4) Quality improvement activities shall be conducted and documented at least quarterly.

Stat. Auth.: ORS 443.340
Stats. Implemented: ORS 443.315 & 443.340
Hist.: OHD 19-2002, f. 12-4-02, cert. ef. 2-1-03; PH 3-2004(Temp), f. & cert. ef. 2-6-04 thru 7-30-04; PH 22-2004, f. & cert. ef. 6-25-04; PH 14-2007, f. 12-19-07, cert. ef. 1-1-08; PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0093
Criminal Records Checks

(1) For the purposes of this section, the following definitions apply:

(a) "Direct contact with" means to provide in-home care services and includes meeting in person with a potential or current client to discuss services offered by an agency or other matters relating to the business relationship between an agency and client;

(b) "Disqualifying condition" means a non-criminal personal history issue that makes an individual unsuitable for employment, contracting or volunteering for an agency, including but not limited to discipline by a licensing or certifying agency, or drug or alcohol dependency;

(c) "Subject individual" (SI) means an individual on whom an agency may conduct a criminal records check and from whom an agency may require fingerprints for the purpose of conducting a national criminal records check, including:

(A) An employee or prospective employee;

(B) A temporary worker, volunteer or owner of an agency who has direct contact with an agency client or potential client; and

(C) A prospective temporary worker, or volunteer or owner who may have direct contact with an agency client.

(d) "Vendor" means a researcher or company hired to provide a criminal records check on a subject individual.

(e) "Weighing test" means a process in which an agency considers available information to make a fitness determination when an SI has potentially disqualifying convictions or conditions.

(2) An agency shall conduct a criminal records check before hiring an SI and before allowing an SI to volunteer to provide services on behalf of the agency, if an SI will have direct contact with a client of the agency.

(3) An SI who has or will have direct contact with a recipient of in-home care services may not be employed or volunteer with an agency in any capacity if the criminal records check conducted reveals the SI has been convicted of a crime as described in ORS 443.004(3).

(4) An agency shall have a policy on criminal records check requirements that shall include weighing test actions should the records check screening indicate that an SI has been convicted for crimes against an individual or property other than those identified in ORS 443.004(3). The policy must include the following provisions for performing a weighing test:

(a) The agency shall consider circumstances regarding the nature of potentially disqualifying convictions and conditions including but not limited to:

(A) The details of incidents leading to the charges of potentially disqualifying convictions or resulting in potentially disqualifying conditions;

(B) The age of the SI at the time of the potentially disqualifying convictions or conditions;

(C) Facts that support the convictions or potentially disqualifying conditions; and

(D) Passage of time since commission of the potentially disqualifying convictions or conditions.

(b) Other factors that should be considered when available include but are not limited to:

(A) Other information related to criminal activity including charges, arrests, pending indictments and convictions. Other behavior involving contact with law enforcement may also be reviewed if information is relevant to other criminal records or shows a pattern relevant to criminal history;

(B) Periods of incarceration;

(C) Status of and compliance with parole, post-prison supervision or probation;

(D) Evidence of alcohol or drug issues directly related to criminal activity or potentially disqualifying conditions;

(E) Evidence of other treatment or rehabilitation related to criminal activity or potentially disqualifying conditions;

(F) Likelihood of repetition of criminal behavior or behaviors leading to potentially disqualifying conditions, including but not limited to patterns of criminal activity or behavior;

(G) Changes in circumstances subsequent to the criminal activity or disqualifying conditions including but not limited to:

(i) History of high school, college or other education related accomplishments;

(ii) Work history (employee or volunteer);

(iii) History regarding licensure, certification or training for licensure or certification; or

(iv) Written recommendations from current or past employers;

(H) Indication of the SI's cooperation, honesty or the making of a false statement during the criminal records check process, including acknowledgment and acceptance of responsibility of criminal activity and potentially disqualifying conditions.

(c) An agency shall consider the relevancy of an SI's criminal activity or potentially disqualifying conditions to the paid or volunteer position, or to the environment in which the SI will work, especially, but not exclusively:

(A) Access to medication;

(B) Access to clients' personal information;

(C) Access to vulnerable populations.

(5) An agency shall document the weighing test and place in the employee's file.

(6) A criminal records check shall be performed by:

(a) The Department of Human Services, Background Check Unit; or

(b) A vendor that:

(A) Is accredited by the National Association of Professional Background Screeners (NAPBS); or

(B) Meets the following criteria:

(i) Has been in business for at least two years;

(ii) Has a current business license and private investigator license, if required in the company's home state; and

(iii) Maintains an errors and omissions insurance policy in an amount not less than $1 million.

(7) An agency may use the Oregon State Police, Open Records Unit in order to fulfill the state records requirement for a criminal records check, however, an agency must still complete a nationwide check through a qualified vendor.

(8) A criminal records check must include the following:

(a) Name and address history trace;

(b) Verification that the SI's records have been correctly identified, via date of birth check and Social Security number trace;

(c) A local criminal records check, including city and county records for SI's places of residence for the last seven years;

(d) A nationwide multijurisdictional criminal database search, including state and federal records;

(e) A nationwide sex offender registry search;

(f) The name and contact information of the vendor who completed the records check;

(g) Arrest, warrant and conviction data, including but not limited to:

(A) Charge(s);

(B) Jurisdiction; and

(C) Date.

(h) Source(s) for data included in the report.

(9) An agency shall perform and document a query of an SI with the National Practitioner Data Bank (NPDB) and the List of Excluded Individuals and Entities (LEIE).

(10) All criminal records checks conducted under this rule shall be documented in writing and made part of the agency's personnel files.

(11) An agency that has a contract with the Department or Authority for the provision of in-home care services on or after July 1, 2012 and who is subject to the Department's criminal records check rules does not have to comply with section (12) of this rule.

(12) For an SI hired to work or volunteer for an agency on or after July 6, 2011, an agency shall have until October 1, 2012 to ensure that the agency is in compliance with section (3) of this rule.

(13) On or after July 1, 2012 an agency shall ensure that a criminal records check is performed on an SI every three years from the date of the SI's last criminal records check in accordance with these rules.

(14) Notwithstanding sections (12) and (13) of this rule, the Division and not the agency shall conduct a criminal records check on an owner or administrator of any agency who is subject to a criminal records check under subsection (1)(c) of this rule. The Division shall conduct a criminal records check:

(a) At the time of application for a person who applies for a license on or after July 1, 2012 and every three years thereafter.

(b) By July 1, 2013 for an agency that is licensed on or before July 1, 2012, and every three years thereafter.

Stat. Auth.: ORS 181.534, 443.004 & 443.340
Stats. Implemented: ORS 443.004 & 443.340
Hist.: PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0095
Waivers

(1) While all agencies are required to maintain continuous compliance with the Division's rules, these requirements do not prohibit the use of alternative concepts, methods, procedures, techniques, equipment, facilities, personnel qualifications or the conducting of pilot projects or research. Requests for exceptions to the rules must:

(a) Be submitted to the Division in writing;

(b) Identify the specific rule for which an exception is requested;

(c) Indicate the special circumstances relied upon to justify the exception;

(d) Identify what alternatives were considered, if any, and why alternatives (including compliance) were not selected;

(e) Demonstrate that the proposed exception is desirable to maintain or improve the health and safety of the clients, and will not jeopardize client health and safety; and

(f) Identify the proposed duration of the exception.

(2) Upon finding that an agency has satisfied the condition of this rule, the Division may grant an exception.

(3) An agency may implement an exception only after receipt of written approval from the Division.

Stat. Auth.: ORS 443.340
Stats. Implemented: ORS 443.315 & 443.340
Hist.: OHD 19-2002, f. 12-4-02, cert. ef. 2-1-03; PH 3-2004(Temp), f. & cert. ef. 2-6-04 thru 7-30-04; PH 22-2004, f. & cert. ef. 6-25-04; PH 14-2007, f. 12-19-07, cert. ef. 1-1-08; PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0105
Operating Without a License

If an agency is found to be operating without a valid license, the agency must, within 14 days of the receipt of an injunction obtained by the Division pursuant to ORS 443.327:

(1) Inform its clients that the agency can no longer provide services;

(2) Refund all fees collected from the clients for services not rendered; and

(3) Cease providing services to clients.

Stat. Auth.: ORS 443.340
Stats. Implemented: ORS 443.315, 443.325, 443.327 & 443.340
Hist.: PH 14-2007, f. 12-19-07, cert. ef. 1-1-08; PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0110
Violations

In addition to non-compliance with any law that governs an in-home care agency, it is a violation to:

(1) Refuse to cooperate with an investigation or survey, including but not limited to failure to permit Division staff access to the agency, its documents or records;

(2) Fail to implement an approved plan of correction;

(3) Refuse or fail to comply with an order issued by the Division;

(4) Refuse or fail to pay a civil penalty;

(5) Fail to comply with rules governing the storage of records following the closure of an agency;

(6) Fail to report suspected abuse of elderly persons as defined in ORS 124.050;

(7) Fail to return a license as provided in OAR 333-536-0035; or

(8) Operate without a license.

Stat. Auth.: ORS 443.340
Stats. Implemented: ORS 443.315 & 443.340
Hist.: PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0117
Informal Enforcement

(1) If during an investigation or survey Division staff document violations of in-home care licensing rules or laws, the Division may issue a statement of deficiencies that cites the law or rule alleged to have been violated and the facts supporting the allegation.

(2) Upon receipt of a statement of deficiencies, an agency shall be provided an opportunity to dispute the Division's survey findings but must still comply with sections (3) and (4) of this rule.

(a) If an agency desires an informal conference to dispute the Division's survey findings, the agency shall advise the Division in writing within 10 business days after receipt of the statement of deficiencies. The written request must include a detailed explanation of why the agency believes the statement of deficiencies is incorrect.

(b) An agency may not seek a delay of any enforcement action against it on the grounds the informal dispute resolution has not been completed.

(c) If an agency is successful in demonstrating the deficiencies should not have been cited, the Division shall reissue the statement of deficiencies, removing such deficiencies and rescinding or modifying any remedies issued for such deficiencies. The reissued statement of deficiencies shall state that it supersedes the previous statement of deficiencies and shall clearly identify the date of the superseded statement of deficiencies.

(3) A signed plan of correction must be mailed to the Division within 10 business days from the date the statement of deficiencies was received by the agency. A signed plan of correction will not be used by the Division as an admission of the violations alleged in the statement of deficiencies.

(4) An agency shall correct all deficiencies within 60 days from the date of the exit conference, unless an extension of time is requested from the Division. A request for such an extension shall be submitted in writing and must accompany the plan of correction.

(5) The Division shall determine if a written plan of correction is acceptable. If the plan of correction is not acceptable to the Division, the Division shall notify the agency owner or administrator in writing:

(a) Identifying which provisions in the plan the Division finds unacceptable;

(b) Citing the reasons the Division finds the provisions unacceptable; and

(c) Requesting that the plan of correction be modified and resubmitted no later than 10 business days from the date notification of non-compliance was received by the agency owner or administrator.

(6) If the agency does not come into compliance by the date of correction reflected on the plan of correction or 60 days from the date of the exit conference, whichever is sooner, the Division may propose to deny, suspend or revoke the agency license or impose civil penalties.

Stat Auth.: ORS 443.340
Stats. Implemented: ORS 443.315, 443.325 & 443.340
Hist.: PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0120
Formal Enforcement

(1) If during an investigation or survey Division staff document a substantial failure to comply with in-home care licensing laws or rules, or if an agency fails to pay a civil penalty imposed under ORS 443.325 and these rules, the Division may issue a Notice of Proposed Suspension or Notice of Proposed Revocation in accordance with ORS 183.411 through 183.470.

(2) The Division may issue a Notice of Imposition of Civil Penalty for violations of in-home care licensing laws.

(3) At any time the Division may issue a Notice of Emergency License Suspension under ORS 183.430(2).

(4) If the Division revokes an agency license, the order shall specify when, if ever, the agency may reapply for a license.

(5) The Division may reissue an agency license that has been suspended or revoked after the Division determines that compliance with these rules has been achieved.

Stat. Auth.: ORS 443.340
Stats. Implemented: ORS 443.315, 443.325 & 443.340
Hist.: PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

333-536-0125
Civil Penalties

(1) An agency that violates in-home care laws or rules, an administrative order, or settlement agreement is subject to the imposition of a civil penalty not to exceed $1,000 per violation and may not total more than $2,000.

(2) An individual who operates an in-home care agency without a license is subject to the imposition of a civil penalty not to exceed $500 a day per violation.

(3) In determining the amount of a civil penalty, the Division shall consider whether:

(a) The Division made repeated attempts to obtain compliance;

(b) The licensee has a history of non-compliance with in-home care licensing laws and rules;

(c) The violation poses a serious risk to the public's health; and

(d) There are mitigating factors, such as a licensee's cooperation with an investigation or actions to come into compliance.

(4) The Division shall document its consideration of the factors in section (2) of this rule.

(5) Each day a violation continues is an additional violation.

(6) A civil penalty imposed under this rule shall comply with ORS 183.746.

(7) Failure to comply with ORS 443.305 through 433.355 includes but is not limited to:

(a) Failure to provide a written disclosure statement to the client or the client's representative prior to in-home care services being rendered;

(b) Failure to provide the contracted in-home care services; or

(c) Failure to correct deficiencies identified during a Division inspection or complaint investigation.

Stat. Auth.: ORS 431.262 and 443.340
Stats. Implemented: ORS 443.315, 443.325, 443.327 & 443.340
Hist.: PH 10-2012, f. 6-26-12, cert. ef. 7-1-12

DIVISION 540

CAREGIVER REGISTRIES

333-540-0005
Purpose and Scope

(1) These rules establish minimum standards for the operation and licensure of caregiver registries.

(2) A caregiver registry may provide services in addition to establishing and maintaining a list of qualified private contractor caregivers, but these rules do not govern those additional services.

(3) A caregiver registry may be subject to additional licensure requirements if it qualifies as an in-home care agency, home health agency, or referral agency as defined in ORS 443.005 and 443.305.

(4) A caregiver registry may not employ or compensate, directly or indirectly, caregivers placed on its list, schedule caregivers although they may maintain calendars that track caregiver availability and for referral fee purposes, assign a caregiver to a client, define working conditions, or negotiate for a caregiver or client for the provision of services.

Stat. Auth.: ORS 443.105
Stats. Implemented: ORS 443.105
Hist.: PH 9-2010, f. 6-17-10, cert. ef. 7-1-10

333-540-0010
Definitions

As used in this division, the following definitions apply:

(1) "Abuse":

(a) As it applies to an adult, includes but is not limited to:

(A) Any physical injury caused by other than accidental means, or that appears to be at variance with the explanation given of the injury.

(B) Neglect that leads to physical harm through withholding of services necessary to maintain health and well-being.

(C) Abandonment, including desertion or willful forsaking of a person or the withdrawal or neglect of duties and obligations owed a person.

(D) Willful infliction of physical pain or injury.

(E) Use of derogatory or inappropriate names, phrases or profanity, ridicule, harassment, coercion, threats, cursing, intimidation or inappropriate sexual comments or conduct of such a nature as to threaten significant physical or emotional harm to a person.

(F) Wrongfully taking or appropriating money or property, of knowingly subjecting a person to harm by conveying a threat to wrongfully take or appropriate money or property, which threat reasonably would be expected to cause the person to believe that the threat will be carried out.

(G) Sexual contact with a non-consenting person or with a person considered incapable of consenting to a sexual act as described in ORS 163.315. As used in this paragraph, "sexual contact" has the meaning given that term in ORS 163.305.

(b) As it applies to a child, has the same meaning as "abuse" as that term is defined in ORS 419B.005.

(2) "Activities of daily living" means activities related to personal care and include but are not limited to bathing or showering and personal hygiene, dressing and grooming, mobility including walking and transferring, elimination, and eating.

(3) "Caregiver" means a person on a caregiver registry list that may be hired directly by a client or client representative to provide caregiver services to a client within the client's place of residence.

(4) "Caregiver registry" or "Registry" means an agency that prequalifies, establishes and maintains a list of qualified private contractor caregivers that is provided to a client for caregiver services within the client's place of residence.

(5) "Caregiver services" means providing assistance with the activities of daily living and can include more skilled services such as medication reminders, medication assistance, or medication administration or nursing services if the caregiver has the necessary licensure, certification, skills, education, or training to safely provide the skilled services.

(6) "Client" means an individual to whom caregiver services are provided.

(7) "Client representative" means an individual, paid or unpaid, related or unrelated, who acts on behalf of the client when the client is an adult.

(8) "Division" means the Oregon Health Authority, Public Health Division.

(9) "Parent agency" means a caregiver registry that develops and maintains administrative controls of subunits.

(10) "Satisfactory reference" means a positive, verifiable reference, either verbal or written, from a former employer or other person not related to the individual that affirms the ability of the individual to provide caregiver services.

(11) "Subunit" means a caregiver registry that provides services for a parent agency in a geographic area different from

that of the parent agency and generally exceeding one hour of travel time from the location of the parent agency.

(12) "Survey" means an inspection of a caregiver registry to determine the extent to which the registry is in compliance with laws applicable to caregiver registries, including this division.

Stat. Auth.: ORS 443.105
Stats. Implemented: ORS 443.005 & 443.105
Hist.: PH 9-2010, f. 6-17-10, cert. ef. 7-1-10

333-540-0015
Application for Caregiver Registry License; Renewal

(1) A person may not establish, conduct or maintain a caregiver registry, or represent to the public that the person is a caregiver registry, without first obtaining a caregiver registry license from the Division.

(2) A person shall apply for a license on a form prescribed by the Division and shall include:

(a) The applicable fee, including fees for subunits, as applicable; and

(b) Forms and fingerprints if requested by the Division, to enable the Division to conduct a criminal background check on the owner and manager of the caregiver registry and any subunits.

(3) The Division shall review the application, verify compliance with these rules, and conduct an on-site inspection prior to granting or denying a license.

(4) The Division shall notify an applicant in writing if a license application is approved, and shall include the license that shall be posted in a conspicuous place.

(5) Each license shall be issued only for the caregiver registry or subunit named in the application and shall not be transferable or assignable. If the ownership of the caregiver registry changes, the new owner shall apply for a license.

(6) If the Division intends to deny a license application, it shall issue a Notice of Proposed Denial of License Application in accordance with ORS 183.411 through 183.470.

(7) An owner or manager's criminal history that reasonably raises questions about that person's ability to appropriately operate or manage a caregiver registry may be grounds for denial of an application.

(8) The Division may deny a license application or renewal application if an applicant fails to comply with these rules.

(9) No entity shall provide caregiver registry services or use the term "caregiver registry" in its advertising, publicity, or any other form of communication unless it holds a current valid license as a caregiver registry in accordance with these rules.

(10) If any of the information in a caregiver registry's most recent application changes at a time other than the annual renewal date, the caregiver registry shall notify the Division in writing within 60 days of the change.

(11) A caregiver registry license shall be renewed annually. Each licensee shall submit:

(a) A renewal application form prescribed by the Division within 60 days of the license expiring;

(b) The applicable fees; and

(c) Forms and fingerprints if requested by the Division, to enable the Division to conduct a criminal background check on the owner and manager of the caregiver registry and any subunits.

(12) The Division shall notify an applicant in writing if a license renewal application is approved, and shall include the license that shall be posted in a conspicuous place.

(13) If the Division intends to deny a license renewal application, it shall issue a Notice of Proposed Denial of License Application in accordance with ORS 183.411 through 183.470.

(14) An owner or manager's criminal history that reasonably raises questions about that person's ability to appropriately operate or manage a caregiver registry may be grounds for denial of an application.

Stat. Auth.: ORS 443.105
Stats. Implemented: ORS 443.035, 443.045 & 443.100
Hist.: PH 9-2010, f. 6-17-10, cert. ef. 7-1-10

333-540-0020
Licensure Fees

(1) The fee for a new caregiver registry license is $1,500, plus an additional $750 for each subunit.

(2) The fee for renewal of a caregiver registry license is $750, plus $750 for each additional subunit.

(3) If the ownership of a caregiver registry changes at a time other than the annual renewal date, the new owner's caregiver registry licensure fee shall be $350, plus $350 for each additional subunit.

Stat. Auth.: ORS 443.105
Stats. Implemented: ORS 443.035
Hist.: PH 9-2010, f. 6-17-10, cert. ef. 7-1-10

333-540-0025
Caregiver Registry Organization, Administration, and Personnel

(1) A caregiver registry shall have written policies and procedures that include but are not limited to:

(a) The organization of the Registry;

(b) Services provided by the Registry;

(c) The relationship between the caregiver registry and caregivers placed on the registry;

(d) Fees charged to caregivers and clients;

(e) Selection of caregivers for placement on the registry and for removal from the registry;

(f) A process for ensuring that a caregiver has satisfied basic competency requirements and has the necessary education, skills and training to provide the level of care the caregiver proposes to offer to clients;

(g) Procedures for conducting criminal background checks on caregivers, including a description of criminal convictions that disqualifies a caregiver from being placed on the registry, in accordance with OAR 333-540-0035;

(h) A process for dealing with a complaint from a client, a member of a client's family, or a client's representative, about a caregiver or the caregiver registry;

(i) A process for reporting suspected abuse or neglect of a client to the Division and other appropriate agencies; and

(j) Record keeping, including physical security of documents and record confidentiality.

(2) A caregiver registry shall provide each caregiver who meets the requirements for placement on the registry with an orientation that includes, but is not limited to, the following:

(a) Review of the registry's policies and procedures;

(b) Requirements for placement on the registry;

(c) Requirements for continuation of caregivers' names on the registry;

(d) Reasons for removal from the registry;

(e) Requirements for reporting abuse and/or neglect; and

(f) Continuing education requirements.

(3) A caregiver registry shall require caregivers placed on the registry to report, within 10 days, any:

(a) Criminal conviction;

(b) Arrest, indictment, or charge for a sexual offense or property crime;

(c) Disciplinary action taken by a licensing board or agency;

(d) Citation for driving while under the influence of intoxicants; and

(e) Revocation of driving privileges.

(4) A caregiver registry shall not delegate any administrative functions to another agency or organization.

(5) A caregiver registry's owner or designee shall:

(a) Assume full legal, financial, and overall responsibility for the caregiver registry's operation; and

(b) Serve as or employ a qualified manager.

(6) A manager of a caregiver registry hired on or after July 1, 2010 shall have:

(a) A high school diploma or equivalent; and

(b) At least two years of professional or management experience.

(7) A caregiver registry manager shall designate, in writing, a qualified individual to act as manager in his or her absence.

(8) A caregiver registry manager or designee shall be responsible for:

(a) Organizing and directing the caregiver registry's ongoing functions;

(b) Developing and implementing written and current policies and procedures necessary to direct the administrative operations of the caregiver registry, including but not limited to the requirements in these rules;

(c) Ensuring the completeness and accuracy of all information provided to the public regarding the caregiver registry and its services;

(d) Ensuring that all caregivers on the registry meet the qualifications required by these rules and the caregiver registry policies;

(e) Cooperating with the Division in the event of a survey or investigation; and

(f) Ensuring the timely reporting of allegations of abuse or neglect to the appropriate authority that includes but is not limited to the Division or local law enforcement agency.

Stat. Auth.: ORS 443.105
Stats. Implemented: ORS 443.105
Hist.: PH 9-2010, f. 6-17-10, cert. ef. 7-1-10

333-540-0030
Requirements for Placement on Caregiver Registry; Continuing Education

(1) In order to be placed on a caregiver registry a caregiver must be at least 18 years of age and have sufficient communication and language skills to enable them to perform their duties and interact effectively with clients and registry staff.

(2) A caregiver registry shall, prior to placing a caregiver on its registry:

(a) Conduct a criminal background check in accordance with OAR 333-540-0035;

(b) Verify the caregiver's licensure status, if applicable, with the appropriate licensing agency;

(c) Conduct a face-to-face interview with the individual;

(d) Obtain at least two satisfactory references for the individual that the individual has worked for within the past five years; and

(e) Ensure that the caregiver has satisfied basic competency requirements and has the necessary education, skills and training to provide the level of care the caregiver proposes to offer to clients.

(3) A caregiver placed on a registry shall annually complete three hours of continuing education on topics related to the caregiver services the caregiver offers to clients.

Stat. Auth.: ORS 443.105
Stats. Implemented: ORS 443.105
Hist.: PH 9-2010, f. 6-17-10, cert. ef. 7-1-10

333-540-0035
Criminal Background Checks

(1) A caregiver registry shall, prior to placing a caregiver on its registry, conduct or arrange for a criminal background check through the Oregon state police or a private vendor.

(2) If the criminal background check or other information obtained by a caregiver registry indicates a caregiver has been convicted of a crime against a person or property that reasonably raises questions about the ability of that caregiver to safely provide caregiver services, the caregiver registry shall notify the individual in writing that they have been found unfit to be placed on the registry.

(3) A caregiver registry shall keep the information obtained from criminal background checks confidential and use it solely to determine a caregiver's eligibility to be placed on the registry.

(4) A caregiver registry shall perform a criminal background check on a caregiver placed on the registry every three years.

Stat. Auth.: ORS 443.105
Stats. Implemented: ORS 443.105
Hist.: PH 9-2010, f. 6-17-10, cert. ef. 7-1-10

333-540-0040
Caregiver Registry Records

(1) A caregiver registry shall:

(a) Keep records for each caregiver placed on the registry including, but not limited to:

(A) Documentation of the required criminal background check;

(B) Documentation of satisfactory references;

(C) Documentation that the caregiver has satisfied basic competency requirements and has the necessary education, skill and training to provide the services proposed to be offered to clients;

(D) Documentation that the caregiver received the caregiver registry's orientation;

(E) Documentation of continuing education;

(F) Documentation of licensure status, if applicable;

(G) A copy of picture identification; and

(H) Upon acceptance to the registry, and every three years afterwards, proof of current driver's license and auto insurance for any caregiver who provides transportation services for clients.

(b) Maintain a record of clients served by caregivers on the registry, including but not limited to the client's name, contact information, and address.

(c) Maintain client records in a manner that makes them easily retrievable.

(d) Maintain records of any complaints received and documentation of any investigation conducted by the Division or other investigative body, including any action taken and any corrective action required.

(e) Keep caregiver and client records for at least seven years from the date a caregiver is terminated with the caregiver registry.

(2) Documents kept in registry files, including but not limited to background checks, reference checks, verification of basic competency and skill requirements, and training certificates must be legible and dated, signed, or otherwise authenticated by the administrator or the administrator's designee.

(3) If a caregiver registry changes ownership, all records shall remain in the registry, and it shall be the responsibility of the new owner to protect and maintain these records for at least seven years from the date a caregiver is terminated with the caregiver registry.

(4) Before a registry terminates its business, the registry shall notify the Division where the records will be stored.

(5) Caregiver registry records shall be maintained in a secure manner that protects the confidentiality of the records, and protects the records from destruction or theft.

Stat. Auth.: ORS 443.105
Stats. Implemented: ORS 443.105
Hist.: PH 9-2010, f. 6-17-10, cert. ef. 7-1-10

333-540-0045
Caregiver Registry Disclosure Statements

(1) A caregiver registry shall provide a disclosure statement to:

(a) A caregiver, prior to placing a caregiver on the registry; and

(b) To a client who intends to hire a caregiver from the caregiver registry, as soon as a caregiver registry is notified that a caregiver may be hired.

(2) Both the caregiver and client disclosure statements must state: "The client or the client's representative is responsible for selecting, interviewing, hiring, scheduling, and supervising the work of the caregivers."

(3) In addition to section (2) of this rule, a caregiver registry disclosure statement provided to a caregiver shall include, but is not limited to:

(a) Information on the services offered by the caregiver registry;

(b) Fees charged to a caregiver, if applicable;

(c) Insurance and bonding requirements, if applicable;

(d) Criminal background checks and disqualifying convictions;

(e) Information on the orientation process; and

(f) Information on the process for verifying the competency, education, skills and training of a caregiver.

(4) In addition to section (2) of this rule, a disclosure statement provided to a client shall include but is not limited to:

(a) The extent to which the client may be responsible for payroll taxes, wage and hour claims, and any other employment related costs;

(b) Fees charged by a caregiver registry to a client, if any, and that 30 days notice is required before any fee increases or changes in billing or payment procedures;

(c) Whether a caregiver has liability insurance and/or is bonded;

(d) Services that may be offered by a caregiver;

(e) The extent to which the registry verifies that a caregiver has a current driver's license and auto insurance if those services are provided;

(f) The process the caregiver registry uses to ensure that a caregiver meets basic competency requirements and has the necessary training, education and skills to provide the caregiver services offered by a caregiver to a client;

(g) The process for placing a caregiver on a caregiver registry;

(h) A description of the criminal background checks required for a caregiver;

(i) How to file complaints about the caregiver registry or a caregiver to the caregiver registry and the Division, including reports of abuse or neglect; and

(j) A description of client rights including but not limited to:

(A) The right to be treated with dignity and respect;

(B) The right to be free from theft, damage, or misuse of one's personal property;

(C) The right to be given the informed choice and opportunity to select or refuse service and to accept responsibility for the consequences;

(D) The right to be free from neglect and from verbal, mental, emotional, physical and sexual abuse;

(E) The right to be free from financial exploitation;

(F) The right to be free from physical and chemical restraints;

(G) The right to voice grievances or complaints regarding services or any other issue without discrimination or reprisal for exercising such rights;

(H) The right to be free from discrimination in regard to race, color, national origin, gender, sexual orientation, or religion; and

(I) The right to participate in planning of the services to be provided by a caregiver and care to be furnished, any changes in the services and care, the frequency of visits, and cessation of services, except where the health and safety of the caregiver is at risk.

(5) A caregiver registry shall document that a copy of the disclosure statement was given to the caregiver, client or client's representative and shall place this documentation in a caregiver's file and in the caregiver registry's records.

Stat. Auth.: ORS 443.105
Stats. Implemented: ORS 443.105
Hist.: PH 9-2010, f. 6-17-10, cert. ef. 7-1-10

333-540-0050
Complaints

(1) Any person may make a complaint verbally or in writing to the Division regarding an allegation against a caregiver registry of a violation of law applicable to a caregiver registry.

(2) The identity of a person making a complaint will be kept confidential.

(3) An investigation will be carried out as soon as practicable after the receipt of a complaint.

(4) Information obtained by the Division during an investigation of a complaint or reported violation under this rule is confidential and not subject to public disclosure under ORS 192.410 through 192.505.

(5) Upon the conclusion of the investigation, the Division may publicly release a report of its findings but may not include information in the report that could be used to identify the complainant or any client of the caregiver registry. The Division may use any information obtained during an investigation in an administrative or judicial proceeding concerning the licensing of a caregiver registry.

(6) If the complaint involves an allegation of criminal conduct or an allegation that is within the jurisdiction of another local, state, or federal agency, the Division will refer the matter to that agency.

Stat. Auth.: ORS 443.105
Stats. Implemented: ORS 443.105
Hist.: PH 9-2010, f. 6-17-10, cert. ef. 7-1-10

333-540-0055
Investigations

(1) As soon as practicable after receiving a complaint, taking into consideration the nature of the complaint, Division staff will begin an investigation.

(2) A caregiver registry shall permit Division staff access to the caregiver registry place of business during an investigation.

(3) An investigation may include but is not limited to:

(a) Interviews of the complainant, caregivers, clients, a client's representative, a client's family members, witnesses, caregiver registry management and staff;

(b) On-site observations of caregiver registry management, staff, or caregivers; and

(c) Review of documents and records.

Stat. Auth.: ORS 443.105
Stats. Implemented: ORS 443.105
Hist.: PH 9-2010, f. 6-17-10, cert. ef. 7-1-10

333-540-0060
Surveys

(1) The Division shall, in addition to any investigations conducted under OAR 333-540-0055, conduct at least one general survey of each caregiver registry to determine compliance with caregiver registry laws every three years and at such other times as the Division deems necessary.

(2) A caregiver registry shall permit Division staff access to the caregiver registry place of business during a survey.

(3) A survey may include but is not limited to:

(a) Interviews of caregivers, clients, client representatives, client family members, and caregiver registry management and staff;

(b) On-site observations of caregiver registry management, staff, or caregivers; and

(c) Review of documents and records.

(4) A caregiver registry shall make all requested documents and records available to the surveyor for review and copying.

(5) Following a survey, Division staff may conduct an exit conference with the caregiver registry owner or his or her designee. During the exit conference Division staff shall:

(a) Inform the caregiver registry representative of the preliminary findings of the inspection; and

(b) Give the person a reasonable opportunity to submit additional facts or other information to the surveyor in response to those findings.

(6) Following the survey, Division staff shall prepare and provide the caregiver registry owner or his or her designee specific and timely written notice of the findings.

(7) If the findings result in a referral to another regulatory agency, Division staff shall submit the applicable information to that referral agency for its review and determination of appropriate action.

(8) If no deficiencies are found during a survey, the Division shall issue written findings to the caregiver registry owner or designee indicating that fact.

(9) If the surveyor's written notice of findings indicates that the caregiver registry was in compliance with caregiver registry laws and no deficiencies were cited, the caregiver registry's owner or designee shall sign and date the written notice and return it to the Division.

(10) If deficiencies are found, the Division shall take informal or formal enforcement action in compliance with OAR 333-540-0070 or 333-540-0075.

Stat. Auth.: ORS 443.105
Stats. Implemented: ORS 443.019 & 443.105
Hist.: PH 9-2010, f. 6-17-10, cert. ef. 7-1-10

333-540-0065
Violations

In addition to non-compliance with any law that governs a caregiver registry, it is a violation to:

(1) Refuse to cooperate with an investigation or survey, including but not limited to failure to permit Division staff access to the caregiver registry place of business, its documents or records;

(2) Fail to implement an approved plan of correction;

(3) Refuse or fail to comply with an order issued by the Division;

(4) Refuse or fail to pay a civil penalty;

(5) Fail to comply with rules governing the storage of records following the closure of a caregiver registry;

(6) Fail to report suspected abuse of elderly persons as defined in ORS 124.050;

(7) Fail to return a license as provided in OAR 333-540-0085; or

(8) Operate without a license.

Stat. Auth.: ORS 443.105
Stats. Implemented: ORS 443.105
Hist.: PH 9-2010, f. 6-17-10, cert. ef. 7-1-10

333-540-0070
Informal Enforcement

(1) If, during an investigation or survey Division staff document violations of a law governing a caregiver registry, the Division may issue a statement of deficiencies that cites the law alleged to have been violated and the facts supporting the allegation.

(2) A signed and dated plan of correction must be received by the Division within 10 business days from the date the statement of deficiencies was mailed to the caregiver registry. A signed plan of correction will not be used by the Division as an admission of the violations alleged in the statement of deficiencies.

(3) A caregiver registry shall correct all deficiencies within 60 days from the date of the exit conference, unless an extension of time is requested from the Division. A request for such an extension shall be submitted in writing and must accompany the plan of correction.

(4) The Division shall determine if a written plan of correction is acceptable. If the plan of correction is not acceptable to the Division, the Division shall notify the owner of the caregiver registry, in writing or by telephone:

(a) Identifying which provisions in the plan the Division finds unacceptable;

(b) Citing the reasons the Division finds them unacceptable; and

(c) Requesting that the plan of correction be modified and resubmitted no later than 10 working days from the date the letter of non-acceptance was mailed to the owner.

(5) If the caregiver registry does not come into compliance by the date of correction reflected on the plan of correction or 60 days from date of the exit conference, whichever is sooner, the Division may propose to deny, suspend, or revoke the caregiver registry's license, or impose civil penalties.

Stat. Auth.: ORS 443.105
Stats. Implemented: ORS 443.045 & 443.105
Hist.: PH 9-2010, f. 6-17-10, cert. ef. 7-1-10

333-540-0075
Formal Enforcement

(1) If, during an investigation or survey, Division staff document a failure to comply with caregiver registry laws, the Division may issue a Notice of Proposed Suspension or Notice of Proposed Revocation in accordance with ORS 183.411 through 183.470.

(2) The Division may issue a Notice of Imposition of Civil Penalty for violations of caregiver registry laws.

(3) At any time the Division may issue a Notice of Emergency License Suspension under ORS 183.430(2).

(4) If the Division revokes a caregiver registry license, the order shall specify when, if ever, the caregiver registry may reapply for a license.

Stat. Auth.: ORS 443.105
Stats. Implemented: ORS 443.045 & 443.105
Hist.: PH 9-2010, f. 6-17-10, cert. ef. 7-1-10

333-540-0080
Civil Penalties

(1) A caregiver registry that violates caregiver registry laws, including OAR 333-540-0065 (violations), is subject to the imposition of a civil penalty not to exceed $1,000 per violation and may not total more than $2,000.

(2) In determining the amount of a civil penalty, the Division shall consider whether:

(a) The Division made repeated attempts to obtain compliance;

(b) The licensee has a history of noncompliance with caregiver registry laws;

(c) The violation poses a serious risk to the public's health;

(d) The licensee gained financially from the noncompliance; and

(e) There are mitigating factors, such as a licensee's cooperation with an investigation or actions to come into compliance.

(3) The Division shall document its consideration of the factors in section (2) of this rule.

(4) Each day a violation continues is an additional violation.

(5) A civil penalty imposed under this rule shall comply with ORS 183.745.

Stat. Auth.: ORS 443.105
Stats. Implemented: ORS 443.045
Hist.: PH 9-2010, f. 6-17-10, cert. ef. 7-1-10

333-540-0085
Return of Agency License

A caregiver registry shall return its license to the Division immediately if the registry:

(1) Voluntarily decides to stop operating a registry;

(2) Has its license suspended or revoked; or

(3) Fails to renew its license.

Stat. Auth.: ORS 443.105
Stats. Implemented: ORS 443.045
Hist.: PH 9-2010, f. 6-17-10, cert. ef. 7-1-10

333-540-0090
Applicability of Rules

(1) A caregiver registry already in operation on July 1, 2010 shall apply to the Division for a license and pay the applicable fee by August 1, 2010.

(2) The Division shall allow a caregiver registry already in operation on July 1, 2010, three months from its date of application before an on-site inspection is conducted, in order to allow a caregiver registry to come into compliance with these rules.

(3) A caregiver registry already in operation on July 1, 2010 shall conduct criminal background checks on all caregivers placed on its registry prior to July 1, 2010 if the caregiver has not had a criminal background check in the last three years.

Stat. Auth.: ORS 443.105
Stats. Implemented: ORS 443.035, 443.100, & 443.105
Hist.: PH 9-2010, f. 6-17-10, cert. ef. 7-1-10

DIVISION 545

PURPOSE, APPLICABILITY AND DEFINITIONS FOR CERTIFICATE OF NEED

333-545-0000
Purpose of Certificate of Need

(1) ORS Chapter 442 establishes state planning for health services and facilities in light of the following findings and in furtherance of health planning policies of the state as established through legislative and executive agency action. The certificate of need program of the Public Health Division has as its purpose the achievement of reasonable access to quality health care, at a reasonable cost. Therefore, decisions regarding proposed new health services and facilities shall be made for reasons having to do with the most urgent community health needs in the various parts of the

state. The burden of proof for need and viability shall be on the applicant, taking these legislative findings into account:

(a) Many citizens are unable to pay for necessary health care, being covered neither by private insurance nor by publicly funded programs such as Medicare and Medicaid;

(b) Health care costs are rising at rates which exceed substantially the general rate of inflation;

(c) There is insufficient price competition in the delivery of health care services and therefore insufficient cost consciousness among providers, payors and consumers;

(d) There are inadequate incentives for the use of less costly and more appropriate alternative levels of health care;

(e) There is insufficient or inappropriate use of existing capacity; there are duplicated services; and there is failure to use less costly alternatives in meeting significant health needs; and

(f) There are insufficient primary and emergency medical care services in medically underserved areas of the state.

(2) In responding to the legislative findings listed in section (1) of this rule and to health planning policies of the state, the certificate of need program shall be administered with the goal of containing capital investment and the objectives of:

(a) Promoting development of more effective methods of delivering health care;

(b) Improving distribution of health care facilities and services;

(c) Controlling increase of health care costs, including the promotion of improved competition between providers;

(d) Promoting planning for health care services at the facility, regional and state levels;

(e) Maximizing the use of existing health care facilities and services which represent the least costly and most appropriate levels of care; and

(f) Minimizing the unnecessary duplication of health care facilities and services.

(3) The division recognizes that:

(a) The objective of reasonable access must be tempered by acknowledgment that decentralized services may not be safe, effective, or economical if utilization is below identified standards;

(b) The objective of reasonable cost in any part of the state requires consideration of the actual and potential capacity of all facilities and services available or feasible to serve persons resident in that part of the state, so as to maximize the use of existing capacity, minimize unnecessary duplication, and give priority to the least costly alternatives feasible to meet significant health needs;

(c) Realistically, price competition among providers of any given type of institutionally-based care is limited and may jeopardize quality, so that regulation of market entry through certificate of need, and maintenance of quality through strict licensure standards, is necessary;

(d) Market competition between providers of institutional and alternative care contributes to the objective of reasonable access to quality health care at reasonable cost by reducing the likelihood of utilization of higher cost care when lower cost care would meet health needs, and should, therefore, be encouraged;

(e) Public and private funds available for health care and related social services are limited by available revenues and by demand for other expenditures. Therefore, institutionally-based health care capacity should be regulated so that the proportions of available funds, whether publicly or privately paid, committed to less or more intensive service levels are determined by the balance of needs among the population to be served, rather than by pressure to fully utilize excess institutional capacity;

(f) Health care regulatory, planning, and public and private reimbursement mechanisms should be coordinated so as to give incentives to providers to select the least costly treatment consistent with acceptable risk, and to give necessary care in the least costly setting;

(g) Specific projects to modernize facilities at a particular facility do not necessarily contribute to the statewide objective of reasonable access to quality health care at a reasonable cost, and must be carefully reviewed against that standard.

Stat. Auth.: ORS 431.120(6), 442.025 & 442.315
Stats. Implemented: ORS 431.120(6), 442.025 & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94; OHD 11-1998, f. & cert. ef. 10-22-98

333-545-0010
Purpose and Applicability of Rules

(1) OAR 333-545 through 670 establish procedures for the certificate of need program.

(2) OAR 333-545 through 670 apply to the division and persons subject to provisions of the certificate of need law.

(3) The authority for OAR 333-545 through 670 is ORS 431.120(6) and 442.315.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94; OHD 11-1998, f. & cert. ef. 10-22-98

333-545-0020
Definitions

As used in OAR 333-545 through 670 unless the context requires otherwise:

(1) "Adjusted Admission" means the sum of all inpatient admissions divided by the ratio of inpatient revenues to total patient revenues.

(2) "Administrator" means the administrator of the Public Health Division.

(3) "Amendment to an Application" means any substantial change in the data on which the application is based; a substantial change in either the proposed services, equipment, construction, price, project schedule, financing of the project, budget of the project, or financial position of the applicant; or other changes which the division determines to constitute an amendment which may directly affect the division's decision or which substantially change the proposal.

(4) "Affected Person" means a person who, as determined by the division, either has an interest in the outcome of the division's proceeding or represents a public interest. "Affected person" has the same meaning as given to "party" under ORS 183.310(6) and includes:

(a) Each person or agency entitled as of right to a hearing before the division;

(b) Each person or agency named by the division to be a party; and

(c) Any person requesting to participate before the division as a party or in a limited party status which the division determines either has an interest in the outcome of the division's proceeding or represents a public interest in such result. The division's determination is subject to judicial review in the manner provided by ORS 183.482 after the division has issued its final order in the proceedings.

(5) "Applicant" means a person intending, or who is required, to apply for a certificate of need. The applicant must be the person making or obligating the expenditure or the person who holds the facility license.

(6) "Bed Capacity" means the maximum number of inpatient care bed spaces in a facility which can be made readily available for inpatient use in accord with Public Health Division rules governing acute inpatient care and Seniors and People with Disabilities Division rules governing long-term care facilities:

(a) Inpatient beds permanently removed from service to allow conversion of rooms for other than direct inpatient nursing care will not be considered part of "bed capacity," if the space for these beds is no longer readily available for inpatient use. Temporary removal of beds from patient rooms for purposes of cleaning, maintenance, renovation, or nonuse is allowable without a change in "bed capacity";

(b) In the case of licensed special inpatient care facilities, "bed capacity" refers to the number of patient care stations;

(c) In determining the number of approvable beds in a hospital remodel project, "bed capacity," as defined in this section, may be adjusted on the basis of an evaluation of the proportion of private rooms. The number of bed spaces set up as private, single patient

rooms in each general medical, surgical and obstetrical unit at the time the application is submitted, shall be compared to the total bed capacity of each unit at that time. For each unit in which the ratio of private bed spaces to total bed spaces does not equal or exceed 20 percent, to the nearest whole number of bed spaces, the number of private bed spaces necessary to cause each unit to reach that ratio shall be calculated. In review of the project, if the applicant so desires, a compensating number of semi-private rooms will be considered as having capacity for only one bed space. This adjustment will facilitate remodeling of general units to include 20 percent private rooms, when desired, without ultimately increasing total licensed bed capacity at the facility;

(d) A patient room shall be considered as being readily available for use at its maximum potential bed capacity in accord with per bedroom space requirements of the Public Health Division or Seniors and People with Disabilities Division when the placement of such beds requires no or only minor alterations to conform to Public Health Division or Seniors and People with Disabilities Division rules. Minor alterations include installation of such items as additional electrical outlets, over bed lights, oxygen and vacuum outlets, and cubicle curtains, but do not include the moving of walls or the addition of required plumbing fixtures except when rough plumbing has previously been done.

(7) "Complete Application (Application)" means an application substantially as described in division 580 of this chapter, which contains all the information specified in the application form and instructions necessary to enable a proper review and decision.

(8) "Days" unless otherwise specified, mean calendar days. In determining elapsed time for notices, etc., the first day is not counted. In this context, "first day" is the date of mailing of the notice. If the last counted day falls on a weekend or holiday, the last day is the next business day.

(9) "Develop" has the meaning given the term "develop" in ORS 442.015(9) and includes arrangements or commitments for financing, which, under applicable state law, are binding upon a health care facility.

(10) "Director" means the director of the Oregon Health Authority.

(11) "Division" means the Public Health Division.

(12) "Expenditure" or "Capital Expenditure" means an expenditure which, under generally accepted accounting principles, is not properly chargeable as an expense of operation and maintenance and includes leases or comparable arrangements, or donations which would have been a capital expenditure if the lease, comparable arrangement, or donation had been a purchase. Interest charges are not included in determining the amount of capital expenditures.

(13) "Gross Revenue" means the sum of daily hospital service charges, ambulatory service charges, ancillary service charges, and other operating revenue. "Gross revenue" does not include contributions, donations, legacies, or bequests made to a hospital without restriction by the donors.

(14) "Health Maintenance Organization (HMO)" has the meaning given the term in ORS 442.015(11).

(15) "Health Service Area" refers to one of three areas into which the State of Oregon has been divided for health planning purposes. These areas are defined as follows:

(a) Health service area I includes Clackamas, Clatsop, Columbia, Multnomah, Tillamook, and Washington Counties;

(b) Health service area II includes Benton, Coos, Curry, Douglas, Jackson, Josephine, Lane, Lincoln, Linn, Marion, Polk, and Yamhill Counties;

(c) Health service area III includes Baker, Crook, Deschutes, Gilliam, Grant, Harney, Hood River, Jefferson, Klamath, Lake, Malheur, Morrow, Sherman, Umatilla, Union, Wallowa, Wasco, and Wheeler Counties.

(16) "Inpatient" means a person who has been admitted to a health care facility and who remains for at least one overnight stay. Inpatients, discharged from a health care facility for purposes of utilizing non-hospital owned or operated diagnostic or treatment equipment, and who are then returned as an inpatient of the same health care facility within a 24-hour period, are considered "inpatients," despite their temporary absence from such facility.

(17) "Licensed Health Care Facility" refers to the license to offer specified health services, issued to a hospital by the state Public Health Division or to a nursing home by the Seniors and People with Disabilities Division. The license is not necessarily issued to the owner of the property, but to the provider. Any change in provider requires a new license. A certificate of need is required when a change of provider results in a new hospital or long-term care facility or service, as defined in OAR 333-550-0010(2) and (3)(a).

(18) "Net Revenue" means gross revenue minus deductions from revenue.

(19) "Operating Expenses" means the sum of daily hospital service expenses, ambulatory service expenses, ancillary expenses, and other operating expense, excluding income taxes.

(20) "Project Cost" as used in the fee schedule, OAR 333-565-0000(4), means the greater of:

(a) "As built project cost," in accord with Capital Expenditure Estimate Form CN-3, line (i), of the application;

(b) Projected annual operating expense for the first full year of operation of a service.

(21) "Proposal" or "Project" means an expenditure for one or more new health services for which the applicant intends to apply under a single certificate of need application as required by ORS 442.315.

(22) "Public Hearing" or "Reconsideration Hearing" means a contested case hearing held pursuant to ORS Chapter 183.

(23) "Service" or receipt of any notice, order, or document shall be accomplished by the division when the document is mailed, and by any other party when the document is received by the division.

(24) "Service Area" means a group or area from which the applicant expects to draw a substantial portion of patients. Such area must be identified in the application, and its use must be substantiated. Service areas of other applicants and health care facilities may overlap. Not all patients in the applicant's service area need to be expected to receive their health services from the applicant.

(25) "State Agency" means the Office of the Director of the Oregon Health Authority.

(26) "Total Deductions from Gross Revenue" or "Deductions from Revenue" means reductions from gross revenue resulting from inability to collect payment of charges. Such reductions include bad debts; contractual adjustments; uncompensated care; administrative, courtesy and policy discounts and adjustments, and other such revenue deductions. The deduction shall be net of the offset of restricted donations and grants for indigent care.

(27) "Type A Rural Hospital" refers to a hospital which is small and remote, has 50 or fewer beds and is greater than 30 miles from another acute inpatient care facility, and which has been designated a Type A rural hospital by the Office of Rural Health.

(28) "Type B Rural Hospital" refers to a hospital which is small and rural and has 50 or fewer beds, and is 30 miles or less from another acute inpatient care facility, and which has been designated a Type B rural hospital by the Office of Rural Health.

[ED. NOTE: Forms referenced are available from the agency.]

Stat. Auth.: ORS 431.120(6), 442.015 & 442.315

Stats. Implemented: ORS 431.120(6) & 442.315

Hist.: HD 13-1994, f. & cert. ef. 4-22-94; OHD 11-1998, f. & cert. ef. 10-22-98

DIVISION 550

PROJECTS OR PROPOSALS SUBJECT TO CERTIFICATE OF NEED REVIEW

333-550-0000
Categories that Are "Subject" or "Exempt"

(1) Any person not excluded under section (2) or (3) of this rule, or not excluded pursuant to ORS 441.065, that proposes to offer or develop a new hospital, as defined in ORS 442.015(17) and OAR 333-550-0010(2) or offer or develop a new long-term

care facility or service, as defined in ORS 442.015(18) and OAR 333-550-0010(3) is subject to certificate of need review by the division. Persons subject to review under ORS 442.315 include:

(a) Hospitals, including special inpatient care facilities; and

(b) Long-term care facilities (nursing homes).

(2) Pursuant to ORS 442.325(1) and (2), a certificate of need shall be required when an HMO proposes to develop or establish a health care facility, or proposes health services normally subject to review under OAR 333-550-0010. However, any activity of an HMO which does not involve the direct delivery of health services, but, instead, consists of arrangements for indirect delivery of health services through contracts with providers, shall be exempt from the certificate of need law.

(3)(a) Except as required in ORS 442.315(1) and OAR 333-550-0010(1) through (3) for a new hospital or new skilled nursing or intermediate care service or facility not operating as a Medicare swing bed program, rural hospitals as defined in ORS 442.470(5)(a)(A) and (B) and OAR 333-545-0020(27) and (28) are exempt from certificate of need requirements;

(b) Rural hospitals which are exempt from review under subsection (a) of this section are required to report any action taken by the hospital that would have required a certificate of need if this exemption did not exist. Within 90 days of undertaking any project that would have otherwise been subject to certificate of need, the hospital shall notify the Public Health Division in writing. This notification shall include a detailed description of the project to be undertaken and include at least the following information:

(A) The amount of capital expenditure involved;

(B) A budget forecast for the first three years of operation showing gross revenues, direct expenses, indirect expenses and deductions from revenue; and

(C) The units of service per year for the first three years of operation.

(4) The division shall review all components of a project for which a health service related linkage exists, including any project components which, if they were to be done independently, would not be subject to review. Section (6) of this rule will be used to determine whether a health service related linkage exists.

(5) A project which includes multiple "subject" components as integral parts shall be reviewed according to the schedules and procedures applicable to the component or part, or combination of these, which requires the most stringent review.

(6) A series of projects having a health service related linkage which in the aggregate exceeds any of the certificate of need thresholds described in OAR 333-550-0010 is subject to the certificate of need law as a single proposal when 12 months or less can be expected to elapse or have elapsed between the completion of the first component of the project and the start of the next component of the project. A health service related linkage exists between any projects which affect a single health service, patient care unit, or area within the facility; or a series of projects which cannot be independently constructed:

(a) The start date of a project component shall be considered to be the earliest of the following dates:

(A) The date on which construction or remodeling work associated with the project begins; or

(B) The date that any new service, area, or facility associated with the project begins to treat patients.

(b) The completion date shall be considered to be the date on which the new service, area, or facility begins to treat patients.

(7) Where a particular health service is involved, the division shall apply the appropriate need methodology for that service adopted in administrative rule, if any.

Stat. Auth.: ORS 431.120(6), 442.015, 442.315, 442.325 & 442.347
Stats. Implemented: ORS 431.120(6), 442.315, 442.325 & 442.347
Hist.: HD 13-1994, f. & cert. ef. 4-22-94; OHD 11-1998, f. & cert. ef. 10-22-98

333-550-0010
Health Services Subject to Review

(1) Pursuant to ORS 442.315(1), a certificate of need must be obtained from the division prior to the offering or development of any new hospital or new skilled nursing or intermediate care service or facility, other than a facility, as defined in ORS 441.065.

(2) A new hospital is any facility that did not offer inpatient hospital services on a regular basis within its service area within the prior 12-month period and is initiating or proposing to initiate such services. For the purposes of this section, the service area of an existing general hospital will be determined in accordance with the provisions of OAR 333-590-0040 but shall not extend beyond a seven-mile radius from the main hospital campus. A new hospital is not created by the reinstatement of services by an established hospital which has experienced an interruption of services of less than 12 months. A change in category of license for an already operating hospital does not create a new hospital unless the hospital proposes to offer one or more new services not encompassed within its existing license (e.g., a facility for the treatment of alcoholism or drug abuse which proposes to offer inpatient psychiatric services). A new hospital does not include the expansion of an existing hospital at its current site; but it does include any replacement, rebuilding or relocation of an existing hospital that involves a substantial increase or change in the services offered. The definition of "rebuilding" contained in subsection (3)(c) of this rule will also be used for the purposes of this section. For the purposes of this section, a substantial increase in services will be considered to include any increase in the total facility bed capacity or in the bed capacity of any hospital service of greater than ten beds or ten percent of the bed capacity of the facility or service. A substantial change in the services offered will be considered to include any establishment of a new health service, as defined in section (4) of this rule.

(3) A new skilled nursing or intermediate care service or facility includes any of the following:

(a) The initiation of inpatient skilled nursing or intermediate care services by a new facility or by a health care facility that did not offer such services within the prior 12-month period. A change in ownership of a long-term care facility is not considered to constitute establishment of a new facility. A change in the services of an existing long-term care facility is not considered to constitute the establishment of a new facility or service, unless the new services are not within the scope of services allowable under a long-term care facility license and require licensure under a hospital licensure category;

(b) An increase in the skilled nursing or intermediate care bed capacity of a long-term care facility by more than 10 beds or more than 10 percent of the current long-term care bed capacity, whichever is less, within a two-year period after the most recent previous increase in beds at the facility. The date of the most recent increase in capacity will be considered to be the date on which a revised license was issued by the Seniors and People with Disabilities Division reflecting the new licensed capacity. In calculating 10 percent of a facility's capacity, the division will round up to the nearest whole number;

(c) The rebuilding of an existing long-term care facility. "Rebuilding" is considered to include any construction project in which at least 50 percent of the square footage of the existing building or buildings is demolished and replaced through new construction; or remodeling which is so extensive that the cost of the remodeling is at least 50 percent of the estimated replacement cost of the facility; or remodeling which involves replacement through new construction of at least 50 percent of the facility's structural bed capacity;

(d) The relocation of an existing long-term care facility building to a new site;

(e) The relocation of existing long-term care beds from one licensed health care facility to another.

(4) A new hospital health service is any health services except basic health services as defined in ORS 442.315(9) that were not offered in or through the hospital on a regular basis within the 12-month period prior to the time such services are proposed to be offered, provided that the annual operating expenses exceed $500,000 in the first full year of operation at normal levels of utilization. Such operating expenses shall include a full allotment of

ongoing expense items attributable to the health service. In other words, if any expense item is budgeted in the first year of operation at a level substantially lower than that which will be incurred routinely in future years, the routine level of allocation will be used. However, the development of operating units or areas of the hospital dedicated exclusively to the provision of ambulatory surgery services shall not be subject to review. In addition, the reinstatement of an established service which has been interrupted for less than 12 months shall not be considered to constitute the establishment of a new service.

(5) In determining whether annual operating expenses for a proposed new hospital service exceed $500,000, the division will consider all direct and indirect costs which are properly allocable to the service, whether or not such costs are already being incurred.

(6) A service is considered to have been established as an existing service once it has been continuously offered by the hospital for a period of at least 12 months.

(7) In determining, under section (4) of this rule, whether a health service has been or will be offered on a regular basis, the division shall consider, as appropriate and among others, the following:

(a) Whether there was or will be a change in staffing in terms of quantity, training or qualifications;

(b) Whether there has been or will be substantial change in the amount of reimbursement as a result of the proposed service;

(c) Whether there has been or will be substantial change in the standards of care, levels of care, or methods of care;

(d) Whether there has been or will be substantial change in the type or category of patients;

(e) Whether there has been or will be a fixed and definable area for the primary use of the service;

(f) Whether there has been or will be specialized equipment available for use in connection with the service;

(g) The number of patients served during the last 12 months versus the number of patients expected to be served in the subsequent 12 months; and

(h) The current maximum number of patients which can be served versus the proposed maximum number of patients to be served.

(8) Section (7) of this rule can also be used to distinguish one health service from another.

(9) In determining, under section (4) of this rule, whether a health service is or will be offered in or through a hospital, the division shall consider, as appropriate, the following:

(a) Whether or not the majority of patients served or to be served by such health services are the hospital's patients;

(b) Whether or not the staff or portions of the staff for the health service will be employed or contracted by the hospital;

(c) Whether the hospital will receive reimbursement for the rendering of health services;

(d) Whether inpatients of a hospital will be served; and

(e) The type of legal entity involved, its ownership, and its corporate parts and relationships.

(10) Pursuant to ORS 442.315(6), a certificate of need shall not be transferred. A transfer will be considered to have occurred if there is a change in ownership of a service, item of equipment, or facility prior to the completion of a project for which a certificate of need has been issued, provided that the change of ownership will result in the provision of affected services in a substantially different manner of different location from that contemplated in the certificate of need application.

(11) Nothing in this chapter limits the responsibility of the applicant to provide, or the division to require sufficient data on which to assess the capital costs and the financial impact of a proposal prior to issuing a certificate of need decision. Where determined appropriate by the division, Forms CN-3 through CN-9 and additional forms, when necessary, together with suitable explanations and required narrative, will be required of a lessor, owner, or other provider of land and/or improvements to the applicant. See division 580.

[ED. NOTE: Forms referenced are available from the agency.]

Stat. Auth.: ORS 431.120(6), 442.015 & 442.315

Stats. Implemented: ORS 431.120(6) & 442.315

Hist.: HD 13-1994, f. & cert. ef. 4-22-94; OHD 11-1998, f. & cert. ef. 10-22-98; PH 29-2004, f. & cert. ef. 9-23-04

DIVISION 555

CERTIFICATE OF NEED LETTERS OF INTENT

333-555-0000
Letters of Intent, Required

(1) Pursuant to ORS 442.315(2), all applicants for a certificate of need shall submit a letter of intent. Such letter of intent shall be filed prior to implementing any part of the project. In cases in which more than one party is potentially subject to review, both parties shall file letters of intent. However, as provided in OAR 333-570-0010(3), only one application will be required if such a project is ruled subject to review.

(2) Letters of intent shall be sent to the Public Health Division.

(3) If the division believes that any person is considering or undertaking a project for which a certificate of need might be required or for which a letter of intent is required under section (1) of this rule, but that person has not submitted a letter of intent, the division may order the person to submit a letter of intent for the project, or may institute proceedings in the circuit courts to enforce obedience to applicable statutes, rules, or orders by injunction or by other processes, mandatory or otherwise, as provided in ORS 442.315(10).

Stat. Auth.: ORS 431.120(6) & 442.315

Stats. Implemented: ORS 431.120(6) & 442.315

Hist.: HD 13-1994, f. & cert. ef. 4-22-94; OHD 11-1998, f. & cert. ef. 10-22-98

333-555-0010
Letters of Intent, Filing Periods

(1) Applicants may submit letters of intent at any time during the calendar year.

(2) Applications which are ruled subject to full review under OAR 333-555-0030(1) may not be filed sooner than the first day of the month following the publication and mailing of notice of the letter of intent in the *Certificate of Need Update*, published monthly by the division. For example, a letter of intent submitted in the first half of May would have a notice published in the June 1 edition of the *Certificate of Need Update*. The application could then be submitted no earlier than July 1.

(3) A letter of intent automatically expires 365 days following the division's ruling under OAR 333-555-0030. No extension will be granted. An applicant may anticipate the expiration of a current letter of intent by filing a new letter of intent, upon which the division will rule under OAR 333-555-0030. In order to ensure that the previous letter of intent does not expire before an application can be submitted under the new letter of intent, the applicant should file the new letter of intent at least 60 days in advance of the expiration of the previous letter of intent.

Stat. Auth.: ORS 431.120(6) & 442.315

Stats. Implemented: ORS 431.120(6) & 442.315

Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-555-0020
Letters of Intent, Application Form

(1) The contents of the letter of intent shall provide sufficient information to support necessary rulings by the division. The division shall determine, from the letter of intent, whether or not the proposed project is subject to the certificate of need law. A person submitting a letter of intent shall disclose all information which may affect the division's ruling under certificate of need law. There shall be sufficient information to determine the provision(s) of division 550 of this chapter under which a project may be subject. There shall also be sufficient information to determine whether review of the project may be abbreviated under division 560 of this chapter. Finally, sufficient information shall be provided so that other parties with an interest in the project may have fair opportunity to submit inquiries, letters of intent, and competing applications for delayed review under division 560 of this chapter.

(2) The letter of intent shall be submitted on Form LOI-1. If additional information is needed to meet the requirements of section (1) of this rule, the division shall inform the person filing the letter of intent in advance or in response to the letter of intent under OAR 333-555-0030(1)(d).

[ED. NOTE: Forms referenced are available from the agency.]

Stat. Auth.: ORS 431.120(6) & 442.315

Stats. Implemented: ORS 431.120(6) & 442.315

Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-555-0030

Letters of Intent, Notification

(1) As soon as possible after receiving and reviewing a letter of intent, the division shall send copies of the letter of intent to any persons known to the division as offering similar services to residents of the area which would be served by the project, together with a notice that the division will consider comments regarding the proposed letter of intent if such comments are received at least two working days prior to the deadline for the division's ruling on the letter of intent. The purpose of providing such notice is informational, so that the division can gather data that may be relevant to its decision regarding the letter of intent. Persons who are sent copies of the letter of intent or who submit comments on the letter of intent are not considered to be parties in the division's review of the letter of intent. The division will not recognize any affected parties in regard to a letter of intent other than the party submitting the letter of intent. Within 15 days of receipt, the division shall give written notification to the person filing the letter of intent and to any parties who have submitted comments of its ruling that:

(a) The proposal is not subject to the certificate of need law and state the reasons; or

(b) The proposal is subject to full review under the certificate of need law;

(c) The proposal is subject to the certificate of need law, and is eligible for abbreviated review pursuant to OAR 333-560-0010 and 333-560-0020; or

(d) The letter of intent contains insufficient information to make a determination;

(e) The proposal is subject to certificate of need law and is eligible for expedited review pursuant to OAR 333-560-0110 and 333-560-0120.

(2) Letters of intent containing insufficient information to make a determination shall not satisfy the requirement of OAR 333-555-0000(1) nor 333-555-0010(2).

(3) Except as provided under section (4) of this rule, a ruling under subsection (1)(a) of this rule may not be made to terminate if the person who filed the letter of intent can demonstrate that the person's position has changed in a material and substantial way as a result of relying on such ruling.

(4) Rulings under subsection (1)(a) of this rule apply only to the costs and other relevant conditions as stated in the letter of intent. If these costs or other conditions change or if the person submitting the letter of intent fails to submit information which could affect the division's ruling, the ruling will not apply to the project, and a new letter of intent will be required.

(5) Following the division's ruling on a letter of intent, applicant may request a meeting, or "preapplication conference" with division staff, to discuss development of the application.

(6) If the original letter of intent contains insufficient information to make a determination regarding appropriate review categories, the division shall notify the person filing the letter of intent under subsection (1)(d) of this rule that additional information must be provided in writing. Within 15 days of receipt of sufficient written information, the division shall give written notification under section (1) of this rule.

(7) The division may, on its own initiative and at its discretion, extend the time period for response to a letter of intent, as specified in section (1) of this rule, to up to 30 days, in the case of letters of intent that raise complex issues or that require research or consultation by division staff. If the division elects to extend this time period, the division will inform the person filing the letter of intent and any other parties receiving notice under section (1) of this rule.

(8) If additional information or modifications to a letter of intent are received from the person filing the letter of intent prior to the division's ruling under section (1) of this rule, the deadline for the division's ruling will be 15 days after receipt of such additional information or modification.

Stat. Auth.: ORS 431.120(6) & 442.315

Stats. Implemented: ORS 431.120(6) & 442.315

Hist.: HD 13-1994, f. & cert. ef. 4-22-94

DIVISION 560

ABBREVIATED CERTIFICATE OF NEED REVIEW, DELAY OF REVIEW, WAIVER OF REVIEW FOR FACILITIES, AND EXPEDITED REVIEW

333-560-0010

Abbreviated Certificate of Need Review for Specific Projects

The following types of projects are eligible for abbreviated review:

(1) The establishment of new health services or new facilities which, based on documentation submitted by the applicant and found acceptable by the Division, will predominantly or exclusively service medically indigent patients:

(a) Such documentation should include any admissions policies or needs tests to be used by the applicant in determining the appropriateness of admissions. Documentation should also include information on projected revenues for the facility or service, including the sources of such revenues;

(b) If the facility or service, in the future, wishes to provide services to persons who are not medically indigent, either because of a change of ownership or for other reasons, the applicant must submit a new letter of intent detailing the proposed changes in the population to be served. The Division may consider such a change to constitute the establishment of a new health service subject to review, if it concludes that the patients to be served will no longer be predominantly medically indigent, and if it concludes that there will be a substantial impact on the cost of patient care;

(c) For the purposes of this section, persons will be considered to be medically indigent if they are uninsured by either public or private insurers or payers for the types of services being proposed and if their household or family income is equal to or less than 200 percent of the poverty income established in federal regulations. Except for projects involving long-term care facilities or services, persons will also be considered to be medically indigent if they are eligible for Medicaid services.

(2) Partnerships or joint ventures between hospitals/health systems and existing non-hospital-based, long-term care facilities neither of which is owned or controlled by the same entity, when all of the following criteria are met:

(a) The project does not result in a net increase in licensed long-term care beds in the service area. In this context "service area" has the same meaning as it is given in OAR 333-610-0030(1);

(b) The partnership or joint venture is for a minimum of two years and is terminable only for cause. As used in this rule, the term "partnership" is intended to be defined broadly, so that it covers collaboration beyond just a legal partnership including, but not limited to, a jointly owned corporation or a limited liability corporation. Not withstanding OAR 333-550-0010(3)(a), if the beds operated under the partnership or joint venture are proposed to be sold or otherwise transferred, the transfer shall be subject to the full review process detailed in division 570 of this chapter and to the application and review criteria established in division 580, or if applicable, an expedited review under this chapter. If as part of the partnership or joint venture, conversion of existing space within a hospital building occurred, expedited review cannot later be sought under 333-560-0110. If the beds operated under the partnership or joint venture are to be relocated back to the non-hospital-based, long-term care facility the bed relocation is eligible for an abbreviated review;

(c) The hospital/health system and the long-term care facility can demonstrate to the satisfaction of the Division that projected per diem inpatient routine service costs in the partnership or joint venture setting (calculated in conformance with Medicare cost report parameters) will not exceed 125 percent of the per diem routine service cost limitation computed by the fiscal intermediary for freestanding skilled nursing facilities in its urban or rural location during the first two years of operation. The routine cost limitation may be adjusted, as appropriate, to allow for reasonable inflation as measured by the DRI (HCFA) McGraw Hill Nursing Facility Market Basket Index;

(d) The applicant shall submit a completed copy of Forms CN-3 and CN-11. The applicant shall also submit a summary for the first two years of operation of projected revenue, expenses, operating income, non-operating revenue and net income with and without the project;

(e) Projects approved under OAR 333-560-0010(2) are subject to the full review process detailed in division 570 of this chapter and to the application and review criteria established in division 580, or, if applicable, an expedited review under this chapter, if the cost limitation required under subsection (2)(c) of this rule is not maintained for the first two years of operation.

(3) A project involving the relicensing of long-term care beds by a facility participating in a Seniors and People with Disabilities Division approved Nursing Home Vision 2000 Project ("Vision 2000 Project"), if all of the following conditions are met:

(a) The number of long-term care beds to be added by the facility does not exceed the number of long-term care beds delicensed by the facility because of participation in the Vision 2000 project; and

(b) Relicensure of beds to be added will occur within five years of the date that the first bed or beds were delicensed at the facility because of participation in the Vision 2000 Project; and

(c) Notwithstanding OAR 333-565-0000(4), an application fee of $1,500 is paid;

(d) The following applies to Seniors and People with Disabilities Division approved Vision 2000 Projects:

(A) Notwithstanding any contrary provision in OAR chapter 333, during the five-year period referred to in subsection (3)(b) of this rule, the delicensed beds will be counted as existing long-term care beds for determining the need for additional long-term care beds in the geographical service area under division 610 of this chapter. The delicensed beds will not be considered existing long-term care beds for the purpose of 333-560-0110 and 333-560-0120;

(B) Notwithstanding paragraph (3)(d)(A) of this rule, if a Vision 2000 Project participating facility notifies the Division in writing of its intention not to seek relicensure of some or all the beds within the five-year period, these beds will not be counted as existing long-term care beds for determining the need for additional long-term care beds in the geographical service area under division 610 of this chapter, and the facility will be foreclosed from seeking the addition of these beds under section (3) of this rule;

(C) The sale of a Vision 2000 Project participating facility does not affect the ability of the facility to seek the addition of beds under section (3) of this rule as long as the other requirements of the rule are met.

(4) Development of a freestanding hospice facility, as that term is used in OAR 333-500-0010(1)(a), if all the following conditions are met:

(a) The number of freestanding hospice facilities that can be approved under this section is limited to a total of six. Facilities approved under this section will be required to report the information specified in subsection (4)(e) of this rule to the Certificate of Need Program which will allow it to monitor the effect of these facilities and to develop appropriate rules by which to judge the need for any future facilities;

(b) Projects will be considered for abbreviated review in the order in which a completed letter of intent is received for the project. The provisions of OAR 333-560-0030 shall not apply;

(c) The applicant shall submit a completed copy of Forms CN-1 and CN-3;

(d) The applicant shall submit a population-based needs assessment for the proposed facility. The needs assessment shall include, but not be limited to, the following elements:

(A) A discussion of why this facility is needed in the geographic area served by the applicant. This discussion shall take into account the actual and projected death rates by age and sex; an estimate of how many of those individuals would have been eligible for hospice services and the historical utilization of hospice services; an estimate of how many of those individuals would have benefited from inpatient hospice care and the historical utilization of inpatient care for hospice patients; the applicant's market share of hospice services and any anticipated changes in that market share; the effect of the proposed facility on the utilization of inpatient care in all settings both by the patients served by the applicant and by other hospice providers in the geographic area (if any); projected population growth by age and sex for the area; and household composition, particularly the number of people living alone by age and sex. The discussion shall also include information about the availability of inpatient care in the geographic area, an explanation of why it is preferable for patients to receive care in the proposed facility as opposed to other possible settings and an explanation of how the availability of the proposed facility will impact the continuum of care available in the geographic area; and

(B) A projected income statement for the first five years of operation of the facility accompanied by a narrative explaining the assumptions underlying the projections. Information concerning payer source, number of admissions, numbers of deaths and discharges, and length of stay shall be provided. If the facility is to provide residential care beds, such information shall also be provided for those beds. The income statement shall follow the format used by Form CN-5.

(e) The applicant agrees to provide the following information to the Certificate of Need Program on an annual basis for a period of five years after the facility begins operation:

(A) An income statement accompanied by a narrative discussion of the information provided. Information concerning payer source, number of admissions, numbers of deaths and discharges, and length of stay shall be provided. If the facility provides residential care beds, such information shall also be provided for those beds. The income statement shall follow the format used by Form CN-5;

(B) A statement with supporting data discussing the impact on the age adjusted rates of nursing home and hospital deaths in the geographic area served by the applicant; the impact on the rate of hospice admissions to nursing homes and hospitals in the area; and the impact on the rate of deaths of hospice patients in nursing homes and hospitals; and

(C) A statement discussing data collected from a satisfaction survey tool which measures whether families and other persons closely associated with the patient were satisfied with the different aspects of their loved one's end-of-life care and the environment provided by the facility.

(5) Development of a new Oregon State Hospital facility.

(a) A project for a new Oregon State Hospital is not required to meet any review criteria and notwithstanding OAR 333-565-0000(4) an application fee is not required.

(b) Notwithstanding OAR 333-560-0020(5), the granting of abbreviated review may be rescinded following an informal hearing only if the Division finds that the project is not a new Oregon State Hospital facility.

[ED. NOTE: Forms referenced are available from the agency.]

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 431.120(6) & 442.315

Stats. Implemented: ORS 431.120(6) & 442.315

Hist.: HD 13-1994, f. & cert. ef. 4-22-94; HD 14-1994(Temp), f. & cert. ef. 4-28-94; HD 9-1995(Temp), f. & cert. ef. 11-14-95; HD 3-1997, f. & cert. ef. 2-3-97; OHD 5-1998, f. & cert. ef. 6-16-98; OHD 11-1998, f. & cert. ef. 10-22-98; OHD 10-2002, f. 7-3-02 cert. ef. 7-5-02; PH 10-2003(Temp), f. & cert. ef. 7-31-03 thru 1-15-04; PH 2-2004, f. & cert. ef. 1-16-04; PH 15-2008, f. & cert. ef. 10-7-08

333-560-0020
Procedures for Abbreviated Review

(1) Abbreviated review may be granted by the division either upon request by the applicant or on the division's own initiative. Decisions to grant or to not grant abbreviated review shall be based on a letter of intent which has been properly filed by the applicant under OAR 333-555-0000 through 333-555-0020 and on the division's findings concerning the applicable criteria for abbreviated review under OAR 333-560-0010. In addition to a letter of intent, applicants seeking abbreviated review shall submit information and narrative necessary to allow the division to make findings regarding the applicable criteria for abbreviated review.

(2) The division shall provide written notification to the applicant that abbreviated review is:

(a) Denied and state the reason; or

(b) Granted.

(3) If abbreviated review is granted, the proposal is exempt from the full review process detailed in division 570 of this chapter, with the exception of OAR 333-570-0070(4) through (10); and from the application requirements and review criteria established in division 580. The notification to the applicant shall include a proposed order granting the certificate of need. Such an order shall contain findings sufficient to justify the granting of abbreviated review, but need contain no other findings.

(4) The proposed order on an abbreviated review is subject to an informal hearing, as provided in OAR 333-570-0070(5) through (9). Notwithstanding the provisions of OAR 333-570-0070(8), within ten days following the close of an informal hearing on an abbreviated review, the division will either issue a final order approving the application, or will rescind its granting of abbreviated review and require the project to undergo full review.

(5) The granting of abbreviated review may be rescinded following an informal hearing only if:

(a) The division finds that the project does not meet the criteria for abbreviated review; or

(b) The division finds that significant issues have been raised regarding the appropriateness of the proposed project.

(6) The final order in an abbreviated review is subject to a reconsideration hearing, as provided in OAR 333-570-0070(10) and division 670 of this chapter.

(7) Projects granted a certificate of need under the abbreviated review provisions are not exempt from the monitoring and reporting requirements of OAR 333-575-0000 and 333-575-0010.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-560-0030
Delayed or Simultaneous Review

(1) An applicant who has submitted a letter of intent may request the division to delay consideration of an application for the purpose of simultaneous review. The division may, on its own initiative, delay consideration of an application pursuant to subsection (1)(b) and section (2) of this rule:

(a) The requesting party must state reasons for the request which shall include the determination in section (2) of this rule and must show reasonable evidence supporting the request;

(b) A request and determination that an application will be subject to simultaneous review must be made prior to the first of the affected applications being declared complete by the division. Although a determination may be made at the letter of intent stage, delay of review will not begin until the application is submitted and declared complete. However, if a delay is already in effect, additional applications may be considered as part of the simultaneous review process if they are declared complete before one of the events in section (3) of this rule occurs.

(2) The division may delay the consideration of an application for the purpose of simultaneous review when the division has determined that all of the following conditions have been met:

(a) More than one letter of intent sufficient for a ruling by the division has been received;

(b) Each letter of intent proposes to provide a similar service or to meet closely related needs to substantially the same area and population;

(c) There is a reasonable expectation that the approval of two or more applications in question may not be justified; and

(d) There is a reasonable expectation that the additional application(s) to be submitted will be declared complete by the division not later than 105 days after the division commences the delay of the first application held for simultaneous review.

(3) The start of review of an application must occur the day after the first of the following events:

(a) Lapse of 105 days from written declaration by the division of completeness of the first application, without receipt of a second complete application;

(b) Actual receipt of a second complete application, unless additional applicants have been granted simultaneous review;

(c) Notice or information that additional applications will not be received within 105 days of written declaration of completeness of the first application; or

(d) Receipt, by the division, of additional applications which are not declared complete within 105 days of written declaration of completeness of the first application.

(4) In the event that a proposal is subject to simultaneous review in more than one service area, review will not start on any of the affected applications in any of the service areas until one of the events listed in section (3) of this rule has occurred in each service area.

(5) Once consideration of the application is commenced, the division shall notify the applicant that a simultaneous review is in effect.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94; OHD 11-1998, f. & cert. ef. 10-22-98

333-560-0100
Facility Waiver Limitations

A certificate of need facility waiver does not authorize a hospital to develop a new inpatient hospital facility or provide new long-term care services.

Stat. Auth.: ORS 431.120(6), 442.315 & 442.342
Stats. Implemented: ORS 431.120(6), 442.315 & 442.342
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-560-0110
Expedited Review for Relocation or Replacement of Long-Term Care Beds

Under certain circumstances, the Public Health Division may approve relocation or replacement of existing long-term care beds under the expedited review process set forth in this rule and OAR 333-560-0120 without the analysis of service area need specified in OAR 333-610-0030 when all of the following conditions are met:

(1) Relocation or replacement, under this rule, shall include:

(a) Rebuilding of all or part of a long-term care facility within its service area; or

(b) Relocation of all or part of the beds in two existing long-term care facilities within the same service area, at either one of the facilities, or at a new location in the service area; or

(c) Combinations of the above;

(d) For the purposes of this rule, relocation or replacement shall not include the conversion of existing space within a hospital building;

(e) Regardless of subsection (b) of this section, if the applicant can demonstrate to the satisfaction of the Public Health Division that a location outside of the original service area is appropriate based upon the unique nature and characteristics of the population served by the facility and can satisfactorily demonstrate the appropriateness of an alternative site for the replaced facility, the Public Health Division may waive the requirement that the beds be relocated or replaced within the original service area. To qualify under this subsection, the applicant must demonstrate to the satisfaction of the Public Health Division that the facility has a statewide or regional service area and that it specializes in serving a distinct population with unique medical needs such as children or ventilator

dependent individuals with specific programmatic services. Only beds which serve this type of distinct population are eligible for relocation or replacement under this subsection.

(2) The applicant shall submit, with the letter of intent, a copy of a letter that has been sent to Seniors and People with Disabilities requesting irrevocable delicensure of the relocated or replaced beds, effective as of the date of licensure of the replacement beds. The Public Health Division will confirm that Seniors and People with Disabilities has received the letter before ruling the project eligible for expedited review. The applicant must provide a written statement to the Public Health Division stating that it will not withdraw this letter if it is granted a certificate of need for its project.

(3) In any event, the relocation or replacement process shall not result in a net increase in the number of licensed long-term care beds in the geographical service area except as provided under OAR 333-550-0010(3)(b) or 333-560-0110(1)(e) when applicable.

(4) If the project involves construction of a new facility, the design and construction of the entire relocated or replaced facility must meet all Senior and People with Disabilities criteria for new construction standards in long-term care facilities or has received a waiver from Seniors and People with Disabilities based on a showing that full compliance with new construction standards is not required. If the project involves relocating beds to an existing facility, the patient rooms that will house the relocated beds and areas of the existing facility that support the relocated beds must meet all Seniors and People with Disabilities criteria for new construction standards in long-term care facilities or a waiver must be obtained from Seniors and People with Disabilities based on a showing that full compliance with new construction standards is not required. The applicant must submit schematic plans for the project.

(5)(a) The applicant must demonstrate, to the satisfaction of the Public Health Division, that the physical environment for patients and the ability to provide patient care both at the new setting and, if it remains open, at the original setting will significantly improve as a result of the proposed project. The Public Health Division may waive this requirement if the applicant can demonstrate, to Health Service's satisfaction, that failure to undertake the project will result in serious adverse economic consequences for the applicant that will jeopardize its ability to continue to provide nursing facility services. A waiver under this section will only be granted if the applicant can demonstrate to the satisfaction of the Public Health Division that the physical environment for patients and the ability to provide patient care will remain the same or improve as a result of the project. The Public Health Division may, at its discretion, perform an on-site evaluation of all existing facilities involved.

(b) Examples of the types of improvements that the Public Health Division may consider under this section include, but are not limited to: reduction of the number of residents in rooms; increased square footage per resident rooms; increased or remodeled dining, activities, social services, therapy, kitchen, laundry, and nursing station space; improved fire and life safety; improved resident toilet, hand washing and bathing areas; improved electrical systems including alarms and call systems; and improved heating and ventilation systems.

(6) The applicant shall demonstrate, to the satisfaction of the Public Health Division, that the applicant's proposal is financially viable and shall indicate the impact on patient charges. The applicant must demonstrate financial viability and the impact on charges at the new setting. If the original setting remains open, the applicant must demonstrate that reducing the number of beds at the original setting will not adversely impact the financial condition of that facility. Applicants must submit completed Forms CN-3 through CN-12 and a narrative discussion of the items identified in OAR 333-580-0060. Forms or narrative discussion which are not relevant to the proposal need not be completed, however. Applicants should contact the Public Health Division to determine which forms and narrative discussion are relevant to their proposal.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94; OHD 1-1998, f. & cert. ef. 1-6-98; PH 28-2004, f. & cert. ef. 8-19-04

333-560-0120
Procedures for Expedited Review

(1) The expedited review process shall be initiated upon the written request of the applicant, payment of the fee specified in OAR 333-565-0000(4), and submission of four copies of the completed forms and narrative discussion identified in section (2) of this rule. The forms and narrative discussion must be completed to the satisfaction of the Public Health Division. As soon as possible after receiving and reviewing such forms and narrative, the Public Health Division shall notify the applicant whether or not the forms and narrative discussion are complete. Within five working days of the date that the Public Health Division notifies the applicant that the forms and narrative discussion identified in section (2) of this rule are complete, the Public Health Division shall rule the project eligible for expedited review. Notwithstanding the previous sentence, however, a project shall not be ruled to be eligible for expedited review sooner than the date of the Public Health Division ruling on the letter of intent for the project.

(2) Projects undergoing expedited review are exempt from the full review process detailed in division 570 of this chapter, with the exception of OAR 333-570-0070(3) to (10); and from the application requirements and review criteria established in division 580 of this chapter, with the exception of OAR 333-580-0060, 333-580-0090 and 333-580-0100. Applicants must complete Forms CN-1 through CN-12 and submit four copies of these forms along with four copies of the narrative discussion required by OAR 333-580-0060 at the time that expedited review is requested under section (1) of this rule. Forms which are not relevant to the proposal need not be completed, however. Applicants should contact the Public Health Division to determine which forms are relevant to their proposal.

(3) If all of the conditions specified in OAR 333-560-0110 have been met, the Public Health Division shall issue a proposed order granting the certificate of need for the project. The date of this proposed order shall be no later than 15 days from the date that the Public Health Division rules the project eligible for expedited review. Such an order shall contain findings to justify the granting of a certificate of need under this rule and OAR 333-560-0110, but need contain no other findings.

(4) Projects granted a certificate of need under the expedited review provisions are not exempt from the monitoring and reporting requirements of OAR 333-575-0000 and 333-575-0010.

[ED. NOTE: Forms referenced are available from the agency.]
Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94; OHD 11-1998, f. & cert. ef. 10-22-98; PH 28-2004, f. & cert. ef. 8-19-04

333-560-0130
Expedited Review for Relocation of Long-Term Care Beds to Hospitals

(1) Under certain circumstances, the Public Health Division may approve relocation of existing long-term care beds to a hospital-based setting under the expedited review process set forth in this rule without the analysis of service area need specified in OAR 333-610-0030, provided that all of the following conditions are met:

(a) The long-term beds are relocated from one existing long-term care facility to not more than one location which is or will be licensed as a long-term care facility at the time of the relocation and is within the same standard metropolitan statistical area or within 15 miles of the hospital, whichever is greater.

(b) The project involves the relocation of not more than 50 percent of the licensed long-term care beds from one site to another.

(c) The applicant shall submit, with the letter of intent, a letter to Seniors and People with Disabilities Division requesting irrevocable delicensure of the remaining long-term beds at the facility from which the beds are transferred pursuant to this rule, which request shall be effective as of the date of licensure of the beds being transferred. The Public Health Division will determine

whether this letter provides substantial assurance that the remaining beds will in fact be delicensed. No application will be approved under this rule unless the Public Health Division determines that such assurance exists.

(d) The facility from which the long-term care beds are to be transferred shall be closed as a long-term care facility and shall not offer or develop a new skilled nursing or intermediate care service or facility as described in OAR 333-550-0010(3) without approval pursuant to full certificate of need review.

(e) Notwithstanding subsections (1)(c) and (1)(d) of this rule, the facility from which beds are relocated may be allowed to continue operation if it can be demonstrated to the satisfaction of the division that the continued operation of the facility is necessary to maintain adequate bed capacity in the service area and provided that it reduces its current licensed bed capacity by twice as many beds as are relocated.

(f) The design and construction of the renovated space must either meet all Seniors and People with Disabilities Division criteria for new construction standards in long-term care facilities or receive a waiver from Seniors and People with Disabilities Division based on a showing that full compliance with the new construction standards is not appropriate. The applicant shall submit schematic plans for the proposed project.

(g) Serious structural and fire and life safety problems, or other problems significantly affecting the care and well-being of patients must be demonstrated to exist at the facility whose beds are proposed to be relocated. The procedure for demonstrating these physical problems is the same as that set out in OAR 333-560-0110(7)(a) through (d).

(h) The applicant must demonstrate to the satisfaction of the division that projected per diem inpatient routine service costs in the hospital-based setting (calculated in conformance with Medicare cost report parameters) will not exceed 125 percent of the per diem routine service cost limitation computed by the Medicare fiscal intermediary for freestanding skilled nursing facilities in its urban or rural location during the first two years of operation. The routine cost limitation may be adjusted, as appropriate, to allow for reasonable inflation as measured by the DRI (HCFA) McGraw Hill Nursing Facility Market Basket Index. Notwithstanding anything to the contrary in the two immediately preceding sentences, if the hospital has owned or controlled the long-term care facility from which it proposes to move beds for at least three years, the applicant must demonstrate to the satisfaction of the Division that projected per diem actual inpatient routine service costs in the hospital-based setting will either not exceed 125 percent of actual per diem inpatient routine service costs experienced in its current setting during the first two years of operation or will not exceed 125 percent of the per diem routine service cost limitation computed by the Medicare fiscal intermediary for freestanding skilled nursing facilities in its urban or rural location during the first two years of operation.

(i) The applicant shall submit a completed copy of Forms CN-3 and CN-11. The applicant shall also submit a summary for the first two years of operation of projected revenue, expenses, operating income, non-operating revenue and net income with and without the project.

(j) Projects approved under this rule are subject to the full review process detailed in division 570 of this chapter and to the application and review criteria established in division 580, or if applicable, an expedited review under this chapter, if the cost limitations required under subsection (1)(h) of this rule are not maintained for the first two years of operation of the relocated beds.

(2) For the purposes of this rule, relocation shall include the conversion of existing space within a hospital building to house the relocated long-term care beds.

(3) The procedure for expedited review set out in OAR 333-560-0120 is not applicable to projects proposed under this rule. For the purposes of OAR 333-560-0130 the following procedure shall be followed:

(a) The expedited review process shall be initiated upon the written request of the applicant, payment of the fee specified in OAR 333-565-0000(4) and submission of the information and materials necessary to support the request for expedited review as specified in section (1) of this rule. Within 5 working days of the date that the division notifies the applicant that the necessary information and materials have been provided, the division shall rule the project eligible for expedited review. Notwithstanding the previous sentence, however, a project shall not be ruled to be eligible for expedited review sooner than the date of the division's ruling on the letter of intent for the project.

(b) If all of the conditions specified in section (1) of this rule have been met, the division shall issue a proposed order granting the certificate of need for the project. The date of this proposed order shall be no later than 20 working days from the date of the division's finding under OAR 333-560-0110(7)(c) or (d), as applicable. Such an order shall contain findings to justify the granting of a certificate of need under this rule but need contain no other findings.

(c) Projects undergoing expedited review under this rule are exempt from the full review process detailed in division 570 of this chapter, with the exception of OAR 333-570-0070(4) through (10); and from the application and review criteria established in division 580.

(d) Projects undergoing expedited review under this rule are not exempt from the monitoring and reporting requirements of OAR 333-575-0000 and 333-575-0010.

Stat. Auth.: ORS 431.120(6), 442.315 & 442.015
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 3-1997, f. & cert. ef. 2-3-97

333-560-0140
Accelerated Certificate of Need Review for Specific Projects

The following types of projects are eligible for accelerated review: The development of a "new hospital" as that term is defined in OAR 333-550-0010(2) when all of the following conditions are met:

(1) The new hospital is the result of a relocation of an existing general hospital under OAR 333-500-0070(1)(a) and does not involve a "substantial increase in services" or "change in the services offered" as those terms are defined in OAR 333-550-0010(2) and determined by the Authority;

(2) The existing general hospital must be delicensed and acute inpatient care must not be provided at that location without approval pursuant to certificate of need review. The applicant must provide the Public Health Division with assurances that this condition will be met. No application will be approved under this section without adequate assurances of these conditions as determined by the Authority;

(3) New hospital health services will not be offered for a period of three years after licensure of the new facility. A new hospital health service must have been offered at the applicant's existing hospital for a period of at least one year prior to the licensure of the new facility in order for such service not to be considered a new hospital health service when offered at the new facility. For purposes of this section, the term "new hospital health service" has the same meaning as is found in OAR 333-550-0010(4) and 333-550-0010(5) through (9) apply to this definition. Projects approved under this section are subject to the full review process detailed in division 570 of this chapter and to the application and review criteria established in division 580 if a new hospital health service is offered at the new facility within this three year period. The applicant must provide the Public Health Division with assurances that this condition will be met. No application will be approved under this section without adequate assurances of these conditions as determined by the Authority;

(4) The location of the new general hospital will not result in the loss of the critical access status of an existing federally designated critical access hospital;

(5) A general hospital, unaffiliated with the applicant, proposes to relocate its main hospital campus into the service area of applicant's existing hospital. As used in this section, the term "unaffili-

ated" means under independent ownership or control. The Authority must have ruled, based upon a letter of intent, that the relocation of the unaffiliated hospital is not subject to certificate of need review. As used in this section, the term "service area" will be determined in accordance with the provisions of OAR 333-550-0010(2).

(6) The applicant must demonstrate, to the Authority's satisfaction, that relocation of the unaffiliated hospital will have an adverse economic impact on the applicant's hospital operations and that this adverse impact will jeopardize the applicant's ability to continue to operate. The applicant must further demonstrate to the Authority's satisfaction that loss of applicant's services will result in a significant decrease in provider competition and consumer choice.

(7) The new hospital will be sited within the boundaries of the service area of the hospital that is proposing to relocate into the service area of the applicant's existing hospital. In addition, the applicant's new hospital must be located at a site that is no further than half the distance between the main campus of the hospital that is proposing to relocate into the applicant's service area and either the new site of the main campus of the hospital that is proposing to relocate into the applicant's service area or the site of any other existing general hospital.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: PH 29-2004, f. & cert. ef. 9-23-04

333-560-0150
Procedures for Accelerated Review

(1) The accelerated review process will be initiated upon the written request of the applicant and payment of the fee specified in OAR 333-565-0000(4). Decisions to grant or not to grant accelerated review will be based on a letter of intent which has been properly filed by the applicant under 333-555-0000 through 333-555-0020 and on the Authority's findings concerning whether the conditions for accelerated review under 333-560-0140 and the requirements of this rule have been met. In addition to a letter of intent, applicants seeking accelerated review must submit sufficient information and narrative to allow the Authority to make findings regarding the conditions and requirements for accelerated review set out in 333-560-0140 and this rule. The applicant must provide the letter of intent and other materials submitted for review in both electronic and paper formats.

(2) The Authority will hold at least one public meeting in the geographical area affected by the proposed relocation prior to issuing a decision. The purpose of the public meeting is to discuss issues relevant to the project under review and to allow submission of documents or other evidence relevant to the application:

(a) Authority staff will chair and conduct the meeting.

(b) Any person may speak at a public meeting, and any person who speaks at the public meeting may be questioned by the Authority's staff. No questions by other than staff of the Authority will be allowed, unless permission is given by the chair. The chair may set time limits for testimony in order to assure a timely and equitable presentation of information.

(c) Notice of the public meeting will be given to the applicant; any hospitals located in the affected service areas; newspapers providing general circulation to the affected service areas; and persons who have requested and been granted designation as affected parties.

(d) The Authority will not unnecessarily delay scheduling the public meeting(s).

(3) The applicant must provide the Authority with the following documents:

(a) A copy of a city council or county board of commissioners resolution supporting the siting of the facility in its jurisdiction. A city council resolution is required if the facility is to be located within the boundaries of a city, otherwise a county board of commissioners resolution is required; and

(b) Proof that zoning approval for the facility has been applied for or obtained.

(4) The division will provide written notification to the applicant that accelerated review is:

(a) Denied and state the reason; or

(b) Granted.

(5) If accelerated review is granted, the proposal is exempt from the full review process detailed in division 570 of this chapter, with the exception of OAR 333-570-0070(3) through (10); and from the application requirements and review criteria established in division 580. The notification to the applicant will include a proposed order granting the certificate of need. Such an order will contain findings sufficient to justify the granting of accelerated review, but need contain no other findings.

(6) The proposed order on an accelerated review is subject to an informal hearing, as provided in OAR 333-570-0070(5) through (9). Notwithstanding the provisions of 333-570-0070(8), within ten days following the close of an informal hearing on an accelerated review, the Authority will either issue a final order approving the application, or will rescind its granting of accelerated review and require the project to undergo full review.

(7) The granting of accelerated review may be rescinded following an informal hearing only if:

(a) The Authority finds that the project does not meet the criteria for accelerated review; or

(b) The Authority finds that significant issues have been raised regarding the appropriateness of the proposed project.

(8) The final order in an accelerated review is subject to a reconsideration hearing, as provided in OAR 333-570-0070(10) and division 670 of this chapter.

(9) Projects granted a certificate of need under the accelerated review provisions are not exempt from the monitoring and reporting requirements of OAR 333-575-0000 and 333-575-0010.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: PH 29-2004, f. & cert. ef. 9-23-04

DIVISION 565

CERTIFICATE OF NEED FEES AND PENALTIES

333-565-0000
Fees, Application for Certificate of Need

(1) The Public Health Division sets application fees for certificates of need (checks shall be payable to the Public Health Division).

(2) The application fees shall not be waived, except in the case of projects which are intended to predominantly serve medically indigent persons provided that such projects are eligible for abbreviated review under OAR 333-560-0010(1).

(3) Application fees shall not be refundable after the application is considered complete by the Division, except as provided under subsection (6)(b) of this rule.

(4) The application fee for projects shall be in accordance with the fee schedule contained in **Table 4**.

(5) An applicant who has submitted an application which was withdrawn before being declared complete may receive a refund of 90 percent of the application fee, less any legal fees incurred by the Division in review of the application or its letter of intent, provided that the applicant makes a written request for return of the fee. However, incomplete applications which are not completed within one year of their initial submission shall not be eligible for any refund of the fee.

(6) If the total project costs reported upon completion of the project under OAR 333-575-0000(8) differ by more than 10 percent from the costs projected in the initial application, the Division will:

(a) Order the applicant to pay an additional fee, if the actual costs upon completion would have required a higher fee under section (4) of this rule; or

(b) Make a refund to the applicant, if the actual costs upon completion would have resulted in a lower fee than that which was paid at the start of the review.

[ED. NOTE: Tables referenced are available from the agency.]
Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 4432.120(6) & 442.315

Hist.: HD 13-1994, f. & cert. ef. 4-22-94; OHD 11-1998, f. & cert. ef. 10-22-98; PH 19-2008, f. 12-17-08, cert. ef. 1-1-09

333-565-0010
Civil Penalties

(1) The Public Health Division may impose civil penalties upon any person who violates ORS 442.315 through 442.347, any rule promulgated thereunder, or any order issued by the Division under this authority, including the violation of any condition set forth in an order granting a certificate of need.

(2) A notice of civil penalty shall include a statement of appeal rights as provided in ORS 183.745.

(3) Civil penalties imposed under this rule shall not exceed $500 a day per violation.

Stat. Auth.: ORS 431.120(6), 431.262 & 442.315
Stats. Implemented: ORS 431.120(6), 431.262 & 442.315
Hist.: PH 3-2009, f. & cert. ef. 4-20-09

DIVISION 570

CERTIFICATE OF NEED REVIEW REQUIREMENTS AND PROCEDURES

333-570-0010
Submission of Certificate of Need Application

After the letter of intent is properly filed and the waiting period determined under OAR 333-555-0010 has elapsed, an applicant which is not eligible for abbreviated review shall submit to the division:

(1) Four completed copies of the application form provided by the division which shall be substantially as shown in division 580 of this Chapter; and

(2) The appropriate application fee made payable to the State Treasurer.

(3) Only one applicant is required to apply for a certificate of need for any one project. If more than one party has submitted a letter of intent and been ruled subject to review for the same project, the parties shall decide among themselves who will apply for the certificate of need. If these parties cannot agree on who shall apply, they may submit competing applications. In such cases, the applications will be reviewed under the simultaneous review procedures in OAR 333-560-0030.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-570-0020
Initial Review of Application

(1) After receiving the application and fee, the division shall notify the applicant in writing not later than 15 days after receipt by the division of the application and fee that:

(a) The application is complete;

(b) The application is not complete, and request additional information; or

(c) The application is not complete and is being returned to the applicant for necessary revision and resubmission.

(2) An application shall not be found incomplete if it contains the information prescribed and adopted by rule by the division as being necessary.

(3) If the division fails to make a determination within 15 days after receipt of the application and fee, the application shall be automatically considered by the division as complete.

(4) An application which remains incomplete for at least one year following its submission shall be considered to have been withdrawn.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-570-0030
Notice

(1) After determining an application complete, the division shall provide by direct mailing written notification to the following that the application is complete:

(a) The applicant;

(b) Any health care facilities and HMOs located in the service area which provide similar institutional health services;

(c) The chairperson of the council;

(d) Newspapers providing general circulation to the affected community; and

(e) Persons who have requested and been granted designation as affected parties.

(2) Notices shall include the following information:

(a) The division, under ORS 442.315 and this chapter, is considering the application;

(b) A proposed schedule of review to include, but not limited to:

(A) The date by which the division must render a decision pursuant to OAR 333-570-0070(1);

(B) That persons potentially affected may request to receive correspondence relating to the application; and

(C) The mailing address for all communications relating to the application for a certificate of need.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94; OHD 11-1998, f. & cert. ef. 10-22-98

333-570-0040
Additional Information

Following receipt of a complete certificate of need application, the division may request or accept additional information only if such information is necessary for the division to make an equitable and informed decision through application of applicable rules.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-570-0050
Modification to Application

(1) An applicant may withdraw its certificate of need application from review at any time.

(2) An applicant may amend its application provided that such amendments are received not later than 45 days following submission of a complete application. This section applies only during the course of review of an application and does not apply to an application undergoing reconsideration or appeal:

(a) In accord with OAR 333-545-0020(3), any substantial change in a proposal shall be considered an amendment, whether or not such change is in response to concerns raised by the division. Amendments include, but are not limited to, modifications such as those described in 333-575-0000(4)(a) to (k). Clarifications or explanations of aspects of a proposal, which do not involve material changes in the project, will not be considered amendments;

(b) Amendments proposed after 45 days following submission of a compete application may be made only if the division agrees to accept the amendment;

(c) The division may condition the consideration of any amendments submitted after the deadline stated in this section on the applicant granting an extension of the review period sufficient, in the division's judgment, to allow consideration of the new material.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-570-0060
Public Meeting

(1) Any person affected by an application which is not subject to abbreviated review may request the division to hold a public meeting and, if the request is timely, the division shall hold such a meeting. The purpose of the public meeting is to discuss issues rel-

evant to the application(s) under review and to allow submission of documents or other evidence relevant to the application.

(2) Requests for a public meeting shall be made not later than 21 days before the division's decision is due. Applicants and other interested parties are advised to submit requests for public meetings at the earliest possible opportunity, because in some cases the division may issue its proposed order more quickly than required.

(3) The division may hold a public meeting at its initiative.

(4) Any person may speak at a public meeting, and any person who speaks at the public meeting may be questioned by the division's staff. No questions by other than staff of the division will be allowed, unless permission is given by the chair.

(5) The administrator of the Public Health Division, or the administrator's designee, shall chair and conduct the meting.

(6) Notice of a public meeting during the course of review shall be served on the parties specified in OAR 333-570-0030(1).

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-570-0070
Decision on Approval or Denial of Application

(1) Within 90 days of a written declaration by the division of a complete application not eligible for abbreviated review, unless time is extended pursuant to subsection (c) of this section or OAR 333-560-0030, the division shall:

(a) Make written findings and a decision; and

(b) Serve by registered or certified mail on the following, the findings, decision and notice of opportunity for reconsideration:

(A) The applicant; and

(B) Persons who have requested and been granted designation as affected parties.

(c) The 90-day time frame for review may be extended by the division with the written agreement of the applicant. In the case of applications subject to simultaneous review under OAR 333-560-0030, extension of the time frame for review will require the written agreement of all applicants involved in simultaneous review, and the same extension must be applied to all such applications. If an applicant submits additional information within two weeks of the date that the proposed or final decision is due, the division may extend the time frame for review on its own initiative, in order to allow sufficient time to review the material submitted.

(2) The chairperson of the council shall be sent a copy of the findings and decision by regular (not registered or certified) mail.

(3) The division may approve or deny the application in whole or in part:

(a) The division may place conditions on an application which is being approved that apply to the implementation of the project. Any condition must be directly related to the project under review and to review criteria and standards which have been adopted into rule;

(b) A binding arrangement allowing purchase of the site, should the application be approved, or acquisition itself, is required to have occurred before an application may be approved.

(4) The decision reached according to section (1) of this rule shall be the "proposed decision" referred to in ORS 442.315(5)(a) and shall become the final decision of the division unless, within ten days after service of the "proposed decision," the request for informal hearing is received by the division.

(5) Upon request of the applicant or any affected person who is dissatisfied with the proposed decision, the division shall grant an informal hearing prior to a final decision. A request for an informal hearing must be received by the division within ten days after service of the proposed decision. The division will give notice of the date, time and place of the informal hearing and will hold the hearing not later than 15 days following receipt of the request.

(6) The informal hearing is for the purpose of providing an opportunity to the applicant or any affected person requesting the hearing to discuss the proposed decision with the division. The hearing may include the provision of new information, or other actions that may result in the division amending its proposed decision. The application may be modified at the informal hearing only if the provisions of OAR 333-570-0050(2) are met.

(7) The informal hearing will be conducted in the following manner:

(a) The informal hearing will be conducted by the administrator, or the administrator's designee;

(b) No minutes or transcript of the informal hearing will be made;

(c) The party requesting the informal hearing does not have to be represented by counsel and will be given ample opportunity to present information;

(d) Other affected parties will be allowed to testify at the informal hearing following the requestor's testimony;

(e) Only staff of the Public Health Division will be allowed to question people testifying at the informal hearing, unless permission is given by the hearing officer for others to question those testifying;

(f) The administrator, or the administrator's designee, may set time limits for testimony in order to assure a timely and equitable presentation of information;

(g) The party requesting the informal hearing may be requested by the administrator, or the administrator's designee, to submit, in writing, new information that has been presented orally;

(h) The administrator, or the administrator's designee, may allow information to be submitted after the adjournment of the informal hearing. In such an instance, a specific date for receiving such information will be established and will serve as the date when the informal hearing will be considered closed.

(8) The division will render a final decision within ten days of the closing of the informal hearing.

(9) When a request for informal hearing has been made in a timely manner but is later withdrawn, the order on the affected application shall become final either on the date the request is withdrawn or ten days from the date of service of the proposed order, whichever comes later.

(10) The final decision of the division shall be subject to a reconsideration hearing according to provisions of division 670 of this chapter, if a petition for hearing is received within 60 days after service of the final decision.

(11) A certificate of need granted to a health care facility is the property of the licensed provider, not of the owner of a physical plant, if these are different.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-570-0080
Reports of Reviews Being Conducted

At least annually, the division shall prepare reports of reviews being conducted, the status of each review being conducted, reviews completed since the last such report, and a general statement of the findings and decision made for completed reviews.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

DIVISION 575

MONITORING OF IMPLEMENTATION AND COMPLETION OF PROJECTS WITH CERTIFICATES OF NEED

333-575-0000
Monitoring of Implementation, Completion and Project Changes Subsequent to Approval

(1) The Public Health Division shall require reporting by the applicant necessary and sufficient to monitor the project to assure that it conforms to the certificate of need as issued by the division.

(2) The division shall require reporting by the applicant, not less often than once every three months of the project's progress following date of the certificate of need issuance (until the project is complete). Reporting required by this section shall be on Form

SIM-1. Any applicant who fails to provide such reports for one year shall be deemed to have abandoned its certificate of need for the project, provided that the division has requested such reports in writing.

(3) A change of size or type in any of the items in section (4) of this rule, from that specified in the certificate of need shall be reported by the applicant to the division not later than 15 days prior to the change, and shall be approved or denied in advance of the change by the division. Such reporting shall be on Forms SIM-1 and SIM-2 which shall be obtained from the division as needed.

(4) Items in which a change in subject to advance reporting in accordance with section (3) of this rule are:

(a) Change of site, or significant changes in location of the project on the site;

(b) General arrangement or relocation of department areas or other sections within the project;

(c) An increase or decrease of ten percent or more in allocated space for the project;

(d) Number of beds;

(e) Increase or decrease of potential bed capacity (shelled-in or finished space for beds);

(f) Modifications of lease or purchase agreements unless the changes will increase or decrease cost of the least or purchase agreements by less than ten percent (reported according to accepted accounting principles); or new lease or purchase agreements (reported according to accepted accounting principles);

(g) Project costs or construction cost increase or decrease in excess of ten percent of the approved totals;

(h) Project completion dates later than 90 days after the approved project schedule contained in the application;

(i) Financing term, interest rate on borrowings, amount of borrowings, balloon payments, or loan fees if these changes singly or in combination will result in cost or charge increase of ten percent or more in the total cost of the project including interest or in charges to the patient;

(j) The addition of a new health service or expenditure which was not specified in the application or order issuing the certificate of need; or

(k) Changes in the applicant's corporate status or ownership (except stock transfers), including but not limited to development of a joint venture or partnership as a part of the implementation of the project.

(5) When a project is found to have substantially exceeded the scope of an approved certificate of need, as defined in section (4) of this rule, and the division has not approved the project changes or cost overrun, or both, the division may institute proceedings in the circuit courts to enforce obedience to the certificate of need order issued by the division, as provided in ORS 442.315(6) and (10).

(6) For any projects that involve remodeling or new construction, the applicant shall provide written notification to the division of the date the project is to be occupied for service.

(7) Before construction, remodeling or modernization begins, the applicant shall submit to the division the final architectural plans of the project, as required by Division 675 of this Chapter.

(8) Upon completion of the project for which a certificate of need was issued, the applicant shall report to the division actual final capital expenditures as a revision of Form CN-3 of the application form and total project cost including interest as a revision of Form CN-4.

(9) Upon completion of a project, as indicated by submission to the division of correctly completed Forms SIM-1, CN-3, and CN-4, the division shall respond within 30 days with a statement acknowledging that the project is complete. The division shall also either acknowledge that the project is within the scope of the approved certificate of need and any approved changes to the certificate of need or shall indicate areas that are not within the scope of the approved certificate of need. If the project is not within the scope of the approved certificate of need, the division may seek an injunction from the circuit courts or other action to enforce obedience to the certificate of need order, as provided in ORS 442.315(6) and (10). The division's monitoring of projects, and the requirements that the applicant report to division concerning projects, terminate at the time a project is completed.

(10) A project is considered to be completed on the date that the new service, area, facility, or equipment begins to treat patients. The certificate of need shall be considered to have expired at the time that the project for which it was issued is completed.

[ED. NOTE: Forms referenced are available from the agency.]

Stat. Auth.: ORS 431.120(6) & 442.315

Stats. Implemented: ORS 431.120(6) & 442.315

Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-575-0010

Financial Reporting Requirements

Applicants are subject to the following financial policy and reporting requirements following approval of a certificate of need application, when these reporting requirements have not been met during the review process itself. The applicant shall report on the receipt of the items listed below, on Form SIM-1:

(1) Each applicant must submit within 30 days after it becomes available, a copy of the financial feasibility report if the applicant arranges for such a report.

(2) When a bond rating report is issued in conjunction with a proposed bond issue to fund a certificate of need proposal, the applicant must submit a copy of the report to the division within 30 days of its issuance

(3) When debt financing is used for a certificate of need project, the actual rate of interest obtained must be reported within 30 days of securing financing.

[ED. NOTE: Forms referenced are available from the agency.]

Stat. Auth.: ORS 431.120(6) & 442.315

Stats. Implemented: ORS 431.120(6) & 442.315

Hist.: HD 13-1994, f. & cert. ef. 4-22-94

DIVISION 580

CERTIFICATE OF NEED APPLICATION INSTRUCTIONS AND FORMS

333-580-0000

General Instructions

All applications must be completed in accordance with the instructions contained in this division. Only those parts which are pertinent and appropriate to the proposed project need be completed, but when a particular criterion or section is not applicable, the applicant must briefly explain why it does not apply. All documents submitted to the Public Health Division are public information. Assistance, or additional copies of the certificate of need rules, can be obtained upon request by contacting: Certificate of Need Review Coordinator, Public Health Division, 800 N.E. Oregon, #21, Portland, OR 97232. Phone: (971) 673-1108. Review of all applications not subject to abbreviated review under OAR 333-560-0010 will be governed by the following considerations:

(1) The review process is governed by divisions 545 through 670 of OAR chapter 333.

(2) An application must have been preceded by a letter of intent on which the division has ruled; and the waiting period defined in OAR 333-555-0010 must have been completed.

(3) A single application should be filed for a project involving two or more project types when most aspects of the overall project are interdependent for purposes of making a decision.

(4) All application contents must be typed or legibly printed.

(5) To assist in achieving the equitable and objective review and determination, all replies required by this division should be as complete as possible. Incomplete applications will delay the review process.

(6) Any schedules or continuation sheets called for must be attached to the applicable section.

(7) External documents (e.g., an applicant's long-range plan, or consultant's study report, etc.) may be incorporated by reference as part of the application to avoid duplication of effort by the applicant. When this option is taken, the application *must* show the

chapter, page or section reference number of the external document where the respective responses are contained, and the document referenced must be provided to the division.

(8) Burden of proof for justifying need and viability of a proposal rests with the applicant.

(9) Each certificate of need application must be accompanied by an application fee made payable to the Public Health Division, in the amount as shown in the Fee Schedule, OAR 333-565-0000(4).

(10) The division must make a determination of completeness of all pertinent sections of the application with 15 days of receiving it, as provided in OAR 333-570-0020. The division will notify the applicant in writing of the determination of any additional information needed, or of completeness.

(11) Any amendments to the application must be in writing, and will be considered in reference to OAR 333-570-0050. Amendments may cause the application to be treated as a new application if submitted more than 45 days following the division's written determination that the application is complete, unless the division agrees to accept the amendment.

(12) Applications may be withdrawn at any time without prejudice (OAR 333-570-0050(1)). Applicants shall notify the division in writing of any withdrawal. Application fee refunds may only be made if withdrawal is made in writing prior to the division's determination of completeness (OAR 333-565-0000(3) and (5)), or if the actual costs of a completed project are over ten percent less than the approved costs (OAR 333-565-0000(6)(b)).

(13) Applicants must complete all appropriate sections of the application, and submit to the division the required number of copies of application forms (printed on white paper), and all attachments describing the project, or responding to the review criteria.

(14) Upon request by the applicant, the division may waive the requirement for the completion of some parts of the application. This will provide an opportunity for the applicant and the division to eliminate unnecessary collection and submission of information.

(15) Applicants for a certificate of need shall provide four copies of the *entire* application to: Certificate of Need Review, Public Health Division, 800 N.E. Oregon, #21, Portland, OR 97232. Four copies shall also be submitted to the division of any amendments to the application or supplementary materials.

(16) Preapplication conferences are encouraged; and these application instructions are designed to make application for a certificate of need relatively simple. However, Public Health Division staff are available to further assist the applicant in this process.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-580-0010
Application Format

The application should be presented in four sections:

(1) Section A — Introduction;

(2) Section B — Narrative discussion addressing the proposal's relationship to the statutory certificate of need review criteria as defined in OAR 333-580-0040 through 333-580-0060;

(3) Section C — Completed required forms; and

(4) Section D — Appendices.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-580-0020
Section A — Introduction

The applicant shall provide a short introductory narrative of the proposal outlining the major aspects of the proposal.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-580-0030
Section B — Review Criteria

(1) The applicant must demonstrate in narrative form that its proposal satisfies the criteria specified in OAR 333-580-0040 to 333-580-0060 and the applicable service-specific need methodologies and standards in divisions 585 through 645. The application must have narrative sections corresponding to each section of OAR 333-580-0040 to 333-580-0060 (those statements labeled "(1)," "(2)" etc.). In each section, the criterion to be addressed is shown in italics. An explanation of the way in which the criterion is to be addressed and specific issues to be discussed is then provided. The narrative should address each of these issues.

(2) The division will make findings and base its decision on the extent to which the applicant demonstrates that the criteria and standards referenced in section (1) of this rule are met. Criteria will be considered to have been met if the applicant can demonstrate that the questions posed in the criteria can be answered in the affirmative. An application will be decided in accordance with the statutes and rules in effect at the time of filing of a completed letter of intent for that application. A completed letter of intent will be considered to have been filed only if the division finds that it includes all of the information required under OAR 333-555-0020(1).

(3) Each relevant issue in the outline of criteria must have a written explanatory response which includes supporting evidence and identifies the source of evidence, assumptions, methodologies used in projections, estimates, etc.

(4) Applicants are encouraged to include any additional information relevant to the review criteria which was not specifically requested by the state, but which would further support the proposal.

(5) Applicants must demonstrate to the division that a proposal is approvable. All other application sections are supportive of this section.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94; OHD 11-1998, f. & cert. ef. 10-22-98

333-580-0040
Need

Applicants must provide a narrative discussion of each of the following:

(1) Criterion: Does the service area population need the proposed project?

(a) The applicant must identify the service area's need for the proposal in the past, present and future;

(b) In establishing the magnitude of present and future need for each service element, the applicant will:

(A) Use appropriate indicators of a population's need (i.e., population-based use-rates, population-based "medical necessity" rates, or established productivity standards);

(B) Use the standards and need methodologies specified in divisions 585 through 645 of OAR chapter 333 applicable to the services or facilities being proposed;

(C) Consider industry standards and historical experience as appropriate comparisons where plans are silent;

(D) In the case of nursing home beds, determine whether the added beds are consistent with plans adopted by the relevant area agency on aging and the state Seniors and People with Disabilities Division.

(2) Criterion: If the project involves remodeling or replacement of an existing health facility structure, are there significant functional inefficiencies, obsolescence or structural problems which the facility has which seriously compromise the effective delivery of health care to patients, and which would be substantially corrected by the proposed project? The narrative should:

(a) Identify and demonstrate all significant functional inefficiency (including physical access) problems;

(b) Identify and demonstrate all significant obsolescence problems; and

(c) Identify and demonstrate all significant structural problems.

(3) Criterion: Will the proposed project result in an improvement in patients' reasonable access to services? The applicant will identify any potential problems of accessibility including traffic

patterns; restrictive admissions policies; access to care for public-paid patients; and restrictive staff privileges or denial of privileges.

(4) Criterion: If the project proposes to serve the needs of members of a health maintenance organization, do these members need the proposed project, considering the special needs and health care utilization rates of this population?

(a) HMOs shall:

(A) Identify the needs of their members, subscribers and enrollees for the proposal;

(B) Demonstrate that the identified needs are reasonable when related to the health care costs of present and future members, subscribers and enrollees;

(C) Describe the proposal's potential for reducing the use of inpatient care in a community through an extension of preventive health services and the provision of more systematic and comprehensive health services;

(D) Identify the availability, and estimate the cost, of obtaining proposed beds, services or equipment from existing providers in the area, who are not HMOs.

(b) A certificate of need shall be issued to meet the needs or reasonably anticipated needs of group members when beds, services or equipment are not available from non-plan providers in the area to be served. Beds, services or equipment are not available to an HMO from a non-HMO provider unless:

(A) They would be available through a long-term contract of sufficient duration and with sufficient provisions for notice of termination to enable the HMO to negotiate an alternative contract with another non-HMO provider, or to develop facilities and/or service capabilities and operate same after notice of contract termination from the non-HMO provider;

(B) They would be available and accessible to physicians associated with the HMO on a basis comparable to physicians not affiliated with the HMO (e.g., HMO physicians have or will have staff privileges);

(C) They could be provided by a non-HMO provider in a manner that can demonstrate to be as cost effective as if they were developed and operated by the HMO; and

(D) They would be available in a manner that is consistent with the HMO's basic method of operation (e.g., acute care centralized at one non-HMO provider as opposed to contracts for care at multiple non-HMO providers).

Stat. Auth.: ORS 431.120(6), 442.315 & 442.325
Stats. Implemented: ORS 431.120(6), 442.315 & 442.325
Hist.: HD 13-1994, f. & cert. ef. 4-22-94; OHD 11-1998, f. & cert. ef. 10-22-98

333-580-0050
Availability of Resources and Alternative Uses of Those Resources

Applicants must provide a narrative discussion of each of the following:

(1) Criterion: Does the proposed project represent the most effective and least costly alternative, considering all appropriate and adequate ways of meeting the identified needs?

(a) The applicant must demonstrate that the best price for the proposal has been sought and selected;

(b) The applicant must demonstrate that proposed solutions to identified needs represent the best solution from among reasonable alternatives:

(A) Internal alternatives:

(i) The applicant must list the major internal operational adjustments considered which could lower the cost and improve the efficiencies of offering the beds, equipment or service;

(ii) The applicant must demonstrate that the alternative considered represents the best solution for the patients, and discuss why other alternatives were rejected;

(iii) If the proposal is for an inpatient service, whether new or expanded, applicant must demonstrate this method of delivery is less costly than if done on an outpatient basis;

(iv) The applicant must demonstrate that the selected architectural solution represents the most cost effective and efficient alternative to solving the identified needs.

(B) External alternatives:

(i) If the proposed beds, equipment or services are currently being offered in the service area, applicant must demonstrate:

(I) Why approval of the application will not constitute unnecessary duplication of services;

(II) Why the proposal is an efficient solution to identified needs;

(III) Why the proposal represents the most effective method of providing the proposal; and

(IV) That the applicant can provide this proposal at the same or lower cost to the patient than is currently available.

(ii) If paragraphs (A)(i) to (A)(iv) of this subsection cannot be demonstrated, the applicant must show that without the proposal, the health of the service area population will be seriously compromised.

(C) Less costly alternatives of adequate quality:

(i) If a less costly and adequately effective alternative for the proposal is currently available in the area, the applicant must demonstrate why its proposal is:

(I) Not an unnecessary duplication; or

(II) A more efficient solution to the identified needs.

(ii) Applicants must demonstrate that the identified needs of the population to be served cannot be reasonably served under current conditions, or by alternative types of service or equipment or equal quality to the proposal. "Alternatives of adequate quality" does not imply that they need be exactly like those being proposed, but only that they meet identified needs at state approved levels.

(D) If there are competing applications for the proposal, each applicant must demonstrate why theirs is the best solution, and why a certificate of need should be granted them.

(2) Criterion: Will sufficient qualified personnel, adequate land, and adequate financing be available to develop and support the proposed project? The applicant must demonstrate that there are, or will be sufficient physicians in the area to support the proposal; sufficient nurses available to support the proposal; sufficient technicians available to support the proposal; adequate land available to develop the proposal and accommodate future expansion; and the source(s) and availability of funds for the project.

(3) Criterion: Will the proposed project have an appropriate relationship to its service area, including limiting any unnecessary duplication of services and any negative financial impact on other providers?

(a) The applicant must identify the extent to which the proposal and its alternatives are currently being offered to the identified service area population, or, in the case of acute inpatient beds, could be offered on the basis of an analysis under division 590 of this chapter;

(b) The applicant will discuss to the best of his or her knowledge, any negative impact the proposal will have on those presently offering or reimbursing for similar or alternative services. Areas to be discussed are utilization, quality of care, and cost of care;

(c) The applicant must demonstrate that jointly operated or shared services between the applicant and other providers have been considered and the extent to which they are feasible or not;

(d) The applicant must demonstrate that all necessary support services and ancillary services for the proposal are available at acceptable levels to insure that patients will have the necessary continuity in their health care.

(4) Criterion: Does the proposed project conform to relevant state physical plant standards, and will it represent any improvement in regard to conformity to such standards, compared to other similar services in the area?

(a) The proposed project must comply with state licensing, architectural and fire code standards;

(b) If the proposal is already being offered in the defined service area, the applicant must describe, to the best of his or her knowledge, to what degree the existing service complies with state licensing, architectural and fire code standards.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-580-0060
Economic Evaluation

Applicants must provide a narrative discussion of each of the items below. The entity actually proposing to implement a certificate of need must submit the required financial data. Additional financial data may be required to be presented by the applicant or a related entity to isolate the financial activities of the proposal:

(1) Criterion: Is the financial status of the applicant adequate to support the proposed project, and will it continue to be adequate following implementation of the project?

(a) Any financial forecasts which deviate significantly from the financial statements of the five-year historical period presented in the application must be fully explained and justified;

(b) An applicant must describe how it will cover expenses incurred by the proposal in the event the proposal fails to meet budgeted revenues in any forecasted year;

(c) Applicants must discuss the results of ratio analysis required by Form CN-9 and OAR 333-580-0100(4), explaining strengths and weaknesses. The discussion should refer to each ratio as detailed in **Table 1** of OAR 333-580-0100(4). Specifically:

(A) Applicants must describe their debt capability in terms of the required ratio analysis;

(B) The discussion of liquidity should include comments on the adequacy of cash, the collection period for patient accounts receivable, and the payment period for accounts payable;

(C) The profitability ratios required by OAR 333-580-0100(4) and Form CN-9 must be discussed.

(d) Board designated assets: The intended uses of this fund are to be discussed in general terms. Alternative uses or contingent availability of these funds, such as to meet a cash requirement, also need to be addressed. Additionally, the proportion (percent) of depreciation that was or is to be funded is to be identified for each financial period presented;

(e) The applicant must discuss the availability of other sources of funding, including, but not limited to, donor restricted assets, assets of parent or subsidiary corporations, or a related foundation which may be acquiring assets and/or producing income that is for the purpose of, or could be used for the purpose of, capital expenditure by the applicant;

(f) Money market conditions must be discussed in terms of their impact on project financing, including interim financing, if applicable. Include the month and year in which financing is to be secured in this narrative:

(A) The estimated rate of interest must be justified by the applicant. If debt financing is secured before or during the review process, the actual rate of interest obtained should be reported within 30 days of securing financing;

(B) When a bond rating report is issued before or during the review period in conjunction with a proposed bond issue to fund a certificate of need proposal, the applicant must submit a copy of the report to the division within 30 days of its issuance;

(C) The financing term selected must be supported with evidence showing the benefits of its selection.

(g) Patient days, admissions and other units of service used in forecasting projected expenses and revenues, both for the facility as a whole and for services affected by the proposed project, must be consistent with projections used to determine area need. All assumptions must be discussed;

(h) An applicant must identify and explain all inflation assumptions and rates used in projecting future expenses and in completing the forms described in OAR 333-580-0100. It is important that the assumptions used by the applicant in preparing financial forecasts be carefully considered. All relevant factors pertaining to historical experience of the applicant, together with upcoming changes affecting the future, should be considered in forecasting the financial condition of the entity. Specifically:

(A) Projected changes in wages and salaries should be based on historical increases or known contractual obligations and planned future personnel increases. Considerations should include expected full-time equivalent staffing levels, including increases resulting from the proposal;

(B) Projected deductions from revenues should be explained and justified;

(C) Expected changes in the intensity and/or complexity of services provided must be considered in addition to the rate of inflation in arriving at an overall rate of increase in revenues or expenses;

(D) Projected gross revenue must reflect:

(i) Patient day increases/decreases;

(ii) Outpatient activity increase/decrease;

(iii) All debt service coverage requirements; and

(iv) Other significant impacts the proposal will make on revenue projections.

(i) Each applicant must submit within 30 days, a copy of the financial feasibility report if the applicant arranges for such a report and it becomes available before or during the review period.

(2) Criterion: Will the impact of the proposal on the cost of health care be acceptable?

(a) The applicant must discuss the impact of the proposal both on overall patient charges at the institution and on charges for services affected by the project:

(A) An applicant must show what the proposal's impact will be on the gross revenues and expenses per inpatient day and per adjusted patient day;

(B) When a health service is affected by the proposal, an applicant must demonstrate what impact the proposal will have on related patient charges and operating expenses. Expenses and patient charges for individual health services will be compared to historical and forecasted rates of increase for the facility as a whole.

(b) The applicant must discuss both the proposed or actual charges for the proposed service and the profitability of the proposed service, compared to other similar services in the state (if any);

(c) The applicant must discuss the projected expenses for the proposed service, and demonstrate the reasonableness of these expense forecasts;

(d) If the proposed service is currently not being provided in the area, the applicant should identify potential travel cost savings by:

(A) Establishing what the existing travel costs are to patients;

(B) Establishing what the travel costs will be to patients after implementation of the proposal; and

(C) Showing what the difference is between the figures in paragraphs (A) and (B) of this subjection.

(e) The applicant must discuss the architectural costs of the proposal:

(A) An applicant must demonstrate that the existing structure will last long enough to derive full benefits from any new construction or remodeling;

(B) General construction costs must be within reasonable limits (within high/low range as described in the most current issue of the Dodge Research Report adjusted for location).

[ED. NOTE: Tables and Forms referenced are available from the agency.]
Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-580-0070
Special Requirements for Certain Types of Proposals

(1) As required by ORS 442.584, applications proposing any of the technologies or services selected for assessment by the Health Resources Commission must include the information specified in section (2) of this rule. This requirement shall not apply until such time as the Health Resources Commission has selected the technologies that it will assess under ORS 442.583.

(2) Applications for projects involving any equipment or services selected for assessment by the Health Resources Commission must include the following information in a separately identified section or appendix to the application:

(a) The estimated number of patients needing the service or procedure who are not currently being served and who cannot be served by existing programs in the service area;

(b) The anticipated number of procedures to be performed per year for a five-year period commencing on the date the service is started or the technology is acquired;

(c) The anticipated number of patients to be served by the applicant, based on the incidence in the population to be served or the conditions for which the technology or service will be used;

(d) Clinical indications for ordering use of the technology or service, with appropriate references to relevant literature;

(e) An estimate of the treatment decisions likely to result from the technology or service;

(f) A proposed method for collecting data on the patients served, costs engendered directly or indirectly and the health outcomes resulting from use of the technology or service.

(3) The information required under this rule will not be used as a basis for any decision to approve or deny any application.

Stat. Auth.: ORS 431.120(6), 442.315 & 442.584
Stats. Implemented: ORS 431.120(6), 442.315 & 442.584
Hist.: HD 13-1994, f. & cert. ef. 4-22-94; OHD 11-1998, f. & cert. ef. 10-22-98

333-580-0080
General Instructions for Section C — Completion of Forms

Applicants must complete Forms CN-1 through CN-12 and include these forms with the application, except that forms which are not relevant to the proposal need not be completed. Applicants should contact the Public Health Division to determine which forms are relevant to their proposal. Additional tables and graphs may be provided, and should appear as appendices in Section D and be referenced to the applicable discussion and criteria in Section B. Form CN-1 should be included as the first page of the application (after any cover pages and table of contents).

[ED. NOTE: Forms referenced are available from the agency.]
Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-580-0090
Completion of Architectural Forms

In completing Form CN-3, "Capital Expenditure Estimate," all costs identified on this form, which will be incurred at a future date, must reflect the effects of inflation.

[ED. NOTE: Forms referenced are available from the agency.]
Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-580-0100
Completion of Financial Forms

The applicant must submit financial information regarding the proposed service and the facility or organization as a whole on Forms CN-4 through CN-12. Projects with costs of under $1,000,000 need only forecast three years financial information. Other projects should forecast five years. If there is more than one entity with a financial interest in a proposal, the entity actually proposing to implement the project must submit the required financial data. Additional financial data may be required to be presented regarding other entities with an involvement in the project. All forms should be filled out using the accrual basis of accounting, unless the division has specifically approved another method:

(1) In completing Form CN-4, "Project Cost Estimate," the applicant should fill in all of the appropriate fund sources.

(2) In completing Form CN-5, "Income Statement," Form CN-6, "Balance Sheet," and Form CN-7, "Statement of Changes in Financial Position," the applicant should provide all line items requested. The applicant may use its own facility format if it includes all the line items requested, but in such cases the format used by the applicant should include a reference to the appropriate certificate of need form number.

(3) In completing Form CN-8, "Debt Service Coverage," the applicant should forecast debt service coverage using the accrual basis of accounting. Debt service coverage is to be computed as follows:

$$\frac{\text{Net Income + Depreciation + Interest Expense}}{\text{Principal + Interest Expense}}$$

(4) The applicant should complete Form CN-9, "Ratio Analyses," for the years requested. Financial performance of the applicant organization proposing the project will be evaluated by commonly accepted health care industry indicators related to financial soundness, plausibility of economic assumptions used, and overall effect on patient charges. These financial ratios are listed in **Table 1**. Applicants must use the formulas shown in **Table 1** in completing Form CN-9:

(a) If an applicant believes that some analysis, in addition to the Ratio Analysis, gives a more appropriate measure, the applicant may present such other analysis, together with an explanation of why it is more appropriate. The division will determine whether or not such alternative analysis is acceptable;

(b) As used in this rule:

(A) "Net Operating Income" means total operating revenue less total operating expenses;

(B) Total operating revenue is exclusive of nonoperating revenue;

(C) "Fund Balance" means the unrestricted fund balance at the end of the period;

(D) Average annual outpatient revenue and inpatient days should be taken from the applicant's audited financial data.

(5) In completing Form CN-10, "Volume-Adjusted Expenses and Revenues," the number of patient days used must be consistent with those cited elsewhere in the application. Unless otherwise approved by the division, historical figures will be derived from the Annual Reports of health facility utilization required by ORS 442.463.

(6) In completing Form CN-11, "Financial Analysis for Individual Services," all new or proposed revenue-producing clinical or nonclinical services which, by themselves, qualify for certificate of need review whether alone or a subpart of a project, must each have a financial analysis separate from the institution as a whole, and a separately-completed Form CN-11.

(7) In completing Form CN-12, "Sources and Uses of Funds for the Proposed Project," the applicant must provide all items requested.

(8) In providing all of the financial forecasts required by this rule, the applicant must base its forecast on estimates of the most probable financial position, results of operations, and changes in financial position for future periods. "Most probable" means that the assumptions have been evaluated by management and that the forecast is based on management's judgment of the most likely set of conditions and its most likely course of action.

[ED. NOTE: Tables and Forms referenced are available from the agency.]
Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

DIVISION 585

GENERAL CRITERIA FOR DEMONSTRATION OF NEED IN CERTIFICATE OF NEED APPLICATIONS

333-585-0000
General Criteria for Demonstration of Need in Certificate of Need Applications

The applicant is responsible for providing information to the Public Health Division to adequately demonstrate that the applicant's proposal satisfies criteria specified in applicable rules:

(1) General criteria, application instructions and forms are contained in division 580 of this chapter. As part of meeting these criteria and requirements for a particular health service, the applicant must provide an analysis using the applicable methodology for demonstration of need for that service as adopted by the division elsewhere in this chapter.

(2) In the event that an applicant, at the time of filing a letter of intent, is proposing a service for which the division has not adopted, as rule, a methodology for demonstration of need; or for which the adopted methodology may appear to require modification

or clarification; the applicant may request, or the division or the applicant may initiate, rulemaking procedures under the state Administrative Procedure Act. In such circumstances, the division will make reasonable efforts to complete rulemaking procedures prior to the first possible filing date for the proposed application under this chapter, based on the letter of intent and other information received However, the actual application may raise unanticipated issues necessitating additional rulemaking procedures prior to written findings and decision by the division.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

DIVISION 590

DEMONSTRATION OF NEED FOR ACUTE INPATIENT BEDS AND FACILITIES

333-590-0000
General

The applicant, in providing information to the Public Health Division to demonstrate need for a proposed new hospital, must satisfy the criteria specified in the Certificate of Need Application Instructions (division 580). This response will include completing an analysis using the methodology of the division (division 590).

Stat. Auth.: 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-590-0010
Definitions

As used in is division:

(1) "Acute Inpatient Care" means care provided in hospital beds, involving at least one overnight use of a bed. Acute inpatient care does not include skilled nursing facility, intermediate care facility, long-term care or supportive routine care for chronic disease or disability, convalescent care, or rest cures. Neither does acute inpatient care include outpatient or clinic care, emergency room care, outpatient laboratory tests, or ambulatory surgery. Acute inpatient care does include general medical/surgical care and short-stay specialty and sub-specialty acute care, including but not limited to gynecological, obstetrical, pediatric, ICU/CCU, psychiatric, alcoholism, chemical dependency, and rehabilitation care.

(2) "Acute Inpatient Bed" means a space with physical facilities which is being used to provide inpatient care to a patient located in a hospital and is intended primarily for occupancy by a patient who will be fed, lodged and treated on an overnight basis, except that newborn nursery bassinets, neonatal intensive care and labor room beds are not included.

(3) "Acute Inpatient Bed Capacity" is defined in OAR 333-545-0020(6), and means any space which could be made readily available for use as an acute inpatient bed, even if this space is not presently being used for this purpose.

(4) "Population-Based Discharge and Use-Rates" means rates based on geographical area patient origins and population rather than on the statistics of utilization of a single facility.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94; OHD 11-1998, f. & cert. ef. 10-22-98

333-590-0020
Estimates of Need

The assumptions and methods described in this division are applicable to the interpretation of OAR 333-580-0040. Their practical purpose is to generate a range of quantitative estimates, against which to weigh the impact of qualitative factors, in determining bed need. This composite approach is necessary, in the absence of theoretically perfect and complete information about past, present and future.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-590-0030
Assumptions

The following general assumptions are made with respect to the balance between bed capacity and anticipated future utilization. In specific cases, certain assumptions may or may not apply:

(1) The annual patient days needed by the population of a health service area can be more confidently forecasted than the demand at a single hospital or local market area.

(2) Hospital service area patient days can be more confidently forecasted by isolating the trends in the area's population from trends in the area's use-rate (annual patient days per 1,000 population). The two trends can then be recombined by multiplication.

(3) Population-based acute inpatient use-rates (annual patient days in nonfederal, nonspecialty, short-term Oregon hospitals, divided by forecasted Oregon population) have declined for the past ten years, and are likely to continue to decline for the next ten years:

(a) Within the area to be served by the proposal, factors such as changing age structure of the population, transportation patterns and locations of physician specialists, may modify this effect, as may changes in the intensity or types of services delivered; and documented commitments to develop other procompetitive initiatives such as alternative delivery systems, selective contracting, successful competitive bidding, and other market oriented changes;

(b) At the applicant's request, the division may modify the general assumption that use-rate will decline. One basis for such modification can be documentation (which the division can validate) by the applicant that its facility does, or proposes to provide 30 percent or more of its services to meet elective acute care needs (which cannot be met at existing facilities in the hospital service area as defined in OAR 333-590-0050(1)) to individuals not residing within 50 miles by road in the case of nonemergency acute services; or 25 miles by road in the case of emergency acute services. In such a case, the applicant's population base for purposes of calculating use-rate will take into account the number of persons from outside the area to be served by the facility who are projected to use the facility;

(c) At the request of the applicant, the division may also modify the general assumption that use-rate will decline if the applicant provides documentation (which the division can validate) that its facility proposes to provide all or some of its services to members, subscribers and enrollees of institutions, HMOs or health care plans. In such cases, the population to be served by the facility will be considered to be the members, subscribers and enrollees of such institutions, HMOs or health care plans who reside in the facility's service area. In cases where the applicant provides or proposes to provide only a portion of its services to such members, subscribers and enrollees, the population to be served by the proposal will be adjusted on a proportionate basis. Assumptions as to the use-rate of such members, subscribers or enrollees will be based either on past experience of the institution, HMO or health care plan or, in the case where no past experience exists, on past experience of similar institutions, HMOs or health care plans in the state;

(d) At the request of the applicant, the division may also modify the general assumption that use-rate will decline if the applicant documents that its facility is either:

(A) A medical or other health professions' school; or

(B) A multidisciplinary clinic; or

(C) A specialty center; or

(D) A facility established or operated by a religious body or denomination to meet the needs of members of such religious body or denomination for care and treatment in accordance with their religious or ethical convictions, when these religious and ethical convictions demonstrably preclude use of established health care facilities in the area, and particular health care facilities provided for the purpose of rendering health care to such members. Utilization and beds at such facilities shall not be counted when considering the need for services at other facilities in the hospital service area.

(e) In such cases as stipulated in paragraph (d)(A), (B), (C), or (D) of this section, modification of the basic use-rate assumption shall be based on documentation (which the division can validate) by the applicant that a population different from or in addition to the hospital service area population (as defined in OAR 333-590-0050(1)) is served or will be served by the facility, and that this population has experienced trends in hospital use-rates which are different from those in the applicant's health service area. The use-rate assumption shall be modified only to the extent that the additional service area population or geographic area is taken into account. For example, if an applicant demonstrates that it draws patients from the entire state, then the use-rate would be assumed to decline at the statewide historical rate of decline.

(4) The share of patient days captured by a hospital in a given service area will generally be stable for the next ten years, unless local factors change.

(5) In estimating future market share, current hospital discharge data will be the basis against which the effects of factors such as population shifts; changes in future or past hospital location, service mix, age mix, or reimbursement mix; documented commitments to develop procompetitve initiatives such as alternative delivery systems, selective contracting and successful competitive bidding; and other evidence which may indicate changes in market share, such as projected decreases in market shares of other facilities, will be evaluated. The burden of proof shall be on the applicant.

(6) The use-rate of persons, ages 0–14, 15–44, 45–64, or 65 plus, from counties of origin expected to contribute substantially to future utilization of the hospital should be taken into account in interpreting quantitative estimates of future general use-rates, patient days and bed need.

(7) The number of beds needed to provide an anticipated range of patient days in a given hospital should be calculated to include an allowance for enough excess capacity to meet statistically estimated peak demand, taking into account number of beds, proximity to other hospitals, and feasibility of improved utilization through effective scheduling and other manage-ment actions.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-590-0040
Determination of Service Area for Existing Hospitals

For purposes of divisions 545 through 670 of OAR chapter 333, the service area for an existing general hospital will be defined as including those zip codes from which either ten percent or more of the hospital's discharges originate, or in which the hospital has at least a 20 percent market share. Minor adjustments to the boundaries of the hospital service area may be made to create a contiguous service area or to conform more closely to the boundaries of demographic units for which census data are reported (county, county census division, enumeration district, or zip codes if conversion has been done).

(1) Discharge and patient day market shares in the service area of the applicant facility should be calculated from the most recent statewide patient origin studies. Changes in relative market shares should be examined if two or more such studies are available. Appropriate steps should be taken to adjust for comparability between these studies if they differ in number of hospitals included, and/or other pertinent factors. More recent patient origin data on a less than statewide basis may also be considered if a method of adjustment for balance-of-state origins and utilization acceptable to the division and the applicant can be developed prior to filing the application.

(2) Federal (V.A.) hospitals may be excluded from the calculation of discharge and patient day market shares, and from other steps in this methodology, but if federal hospitals are excluded from any step, they must be excluded from all steps. For instance, market shares cannot be calculated using nonfederal patient days when the service area use-rate is calculated based on combined federal and nonfederal patient days. If explicit adjustments for projected declines in users eligible for care in federal facilities acceptable to the division and the applicant can be developed prior to filing the application, this factor must be considered.

(3) In the absence of evidence to the contrary, current market shares will be expected to be stable. Factors to which consideration may be given include population shifts; different rates of population growth among subareas within the hospital service area; changes in hospital location service mix, age mix, reimbursement mix, transportation patterns, locations of physician specialists; projected changes in amount or types of utilization among other providers with market shares in the hospital service area; and documented commitments to develop procompetitive initiatives such as alternative delivery systems, selective contracting, successful competitive bidding, and other market oriented changes.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94; PH 29-2004, f. & cert. ef. 9-23-04

333-590-0050
Bed Need Methodology for Proposed New Hospitals

The method for estimating bed need at a proposed new general hospital shall be consistent with the principles enumerated in OAR 333-590-0030, and the legislative findings and policy of ORS 442.025:

(1) Determine the service area of the applicant facility as those zip codes from which either ten percent or more of the hospital's discharges are reasonably expected to originate, or in which the hospital would have at least a 20 percent market share. Minor adjustments to the boundaries of the service area may be made to create a contiguous service area or to conform more closely to the boundaries of demographic units for which census data are reported (county, county census division, enumeration district, or zip codes if conversion has been done). If a project proposes to serve a population group with special needs or beliefs, those factors must be taken into consideration as indicated in OAR 333-590-0030(3).

(2) Determine the estimated population for the hospital service area identified in section (1) of this rule for the benchmark years 1970, 1980, 1985, 1990 and 1995, as a basis for estimating population for individual past and future years. Available historical information regarding changes in hospital service area, because of factors identified in section (1) of this rule, may justify numerical adjustments to base populations and increments under each of the following steps:

(a) For 1970 and 1980, use the available U.S. census counts;

(b) For 1985, use the estimates developed by the Center for Population Research and Census at Portland State University;

(c) For 1990 and 1995, official population forecasts developed by the Center for Population Research and Census (CPRC) should be used. If previously prepared forecasts are not available from CPRC for the service area, then the applicant should contact the division to prepare a joint request for preparation of a service area forecast compatible with county and state forecast series. The applicant shall pay any associated costs. All reports prepared by CPRC must be made available to the division;

(d) To ensure the consistency of special forecasts prepared by CPRC for applicant facilities, the division may develop a memorandum of understanding with CPRC which specifies that the method used to produce these special forecasts is the same as that used to produce the official county-level forecasts coordinated to the state forecasts;

(e) If CPRC does not make available single-year projections, use linear interpolation to obtain estimated service area population for years between 1980, 1985, 1990 and 1995;

(f) The most recent CPRC estimates for years prior to the present year will be utilized;

(g) If age-specific forecasts are available, changes over time in the age composition of the service area population should be examined, and their implications for use-rates taken into consideration.

(3) Determine current year hospital service area and historical health service area population-based discharge and patient day use-rates from statewide patient origin studies. More recent patient origin data on a less than statewide basis may also be considered if

a method of adjustment for balance-of-state origins and utilization acceptable to the division and applicant can be developed. The historical rate of change in health service area average use-rate shall be estimated by the median of the annual percentage changes for the years 1977 through 1983. For health service areas I, II and III, the annual rates of change are, respectively, minus 2.875 percent, minus 0.774 percent, and minus 2.788 percent. This general assumption regarding future use-rate may be modified if one or more of the conditions specified in OAR 333-590-0030(3)(b), (c) or (d) are met:

(a) Determine current year and historical utilization, by the service area population of existing facilities, using available patient origin studies and data from the Annual Reports for Hospitals for each of the prior ten years, unless a request is approved to use the Medicare Cost Reports. List, chronologically, factors which may have affected these statistics, such as population shifts, and changes in hospital location, service mix, age mix, reimbursement mix, transportation patterns, locations of physician specialists, and changes in the intensity or types of services delivered;

(b) Estimate future utilization rates by the hospital service area population, based on CPRC projected age/sex breakdowns, according to consideration of each of a range of age/sex adjusted use-rates based on the most recent available statewide patient origin study for:

(A) The state as a whole;

(B) The health service area;

(C) The nearest facilities with service mixes most comparable to the proposed facility;

(D) The nearest facilities with comprehensive service mixes;

(E) Available HMO age/sex use-rate data for California, Oregon and Washington.

(4) Develop a consistent and reasonable set of well-documented assumptions regarding the appropriate use-rates reviewed in section (3) of this rule, and regarding the extent to which utilization at the proposed hospital will be "new" utilization and the extent to which it will replace utilization at existing hospitals.

(5) Analyze the advantages and disadvantages of both "new" and "replacement" components of utilization, with respect to both the population to be served and existing facilities, considering the legislative findings cited in ORS 442.025 with respect to reasonable access to quality health care at a reasonable cost.

(6) Given all information from the preceding steps, and the five- and ten-year population estimates, compute the range of possible future patient days in five years and in ten years at the facility, allowing appropriate adjustments for out-of-area utilization and other special factors or considerations indicated in OAR 333-590-0030(3). The division will assume that health service area use-rates will decline for the next ten years at the rate indicated in section (3) of this rule. The burden of proof for any different assumption will be on the applicant.

(7) Convert each computed value of forecasted patient days based on preceding sections of this rule to average daily census (ADC).

(8) For each of the values computed under section (7) of this rule, estimate the statistical variability, or standard deviation, of the daily census by the following rules:

(a) For hospitals with an ADC of 50 or greater, the standard deviation of the daily census is estimated as 5.08 + .064 ADC;

(b) For hospitals with an ADC less than 50, the estimate of the standard deviation is indicated in **Table 1**:

Table 1

Average Daily Census	Estimated Standard Deviation
10	4.0
15	5.0
20	5.6
25	6.2
30	6.7
35	7.2
40	7.6
45	8.0

(9) Estimate the statistically expected daily census at the facility by applying an appropriate multiplier to the results of section (8) of this rule, and adding that product to the results of section (7) of this rule. Select the appropriate multiplier by the following rules:

(a) If the facility is more than ten miles by road from the nearest alternative facility, use a multiplier of 2.88 to assure an available bed on all but one day out of each 500 days, a 99.8 percent probability;

(b) If the facility is ten miles or less by road from the nearest alternative facility, use a multiplier of 2.33 to assure an available bed on all but four days out of each 365, a 99 percent probability.

(10) Using a ten-year projection from the calendar year of submission of the application, and the analysis in sections (4) and (5) of this rule, select from the results of section (7) of this rule the most likely average daily census, noting the assumption in section (6) of this rule. Include consideration of the following factors:

(a) Whether it is planned that new health services will be added, or existing ones expanded, decreased or deleted; the best feasible mathematical estimates of appropriate utilization levels and patient days generated because of such changes; and the best available evidence of whether these will be "new" days areawide, or will shift present areawide utilization patterns for the service(s), or both;

(b) Whether any new or expanded services will involve:

(A) Adding physicians up to, but not beyond, established minimum physician-to-population ratios for applicable specialists; or

(B) Adding physicians beyond such ratios.

(c) Utilization generated as a result of addition of physician staff members, up to ratios specified in paragraph (10)(b)(A) of this rule may be considered in addition to utilization projected using the use-rate assumption in section (3) of this rule. In the event that the proposed situation is as in paragraph (10)(b)(B) of this rule, the estimated utilization so generated will not be counted as need. Physician-to-population ratios will not be used as a basis for reducing projected utilization derived from the basic use-rate assumptions in section (3) of this rule;

(d) Established minimum physician-to-population ratios for various specialties are to be derived from the following references: **Report of the Graduate Medical Education National Advisory Committee to the Secretary, Department of Health and Human Services,** Vol. II, Modeling, Research and Data Technical Panel, DHHS Publication No. (HRA) 81–652, September 1980, p. 22; and M.A. Bowman, et. al., **"Estimates of Physician Requirements for 1990 for the Specialties of Neurology, Anesthesiology, Nuclear Medicine, Pathology, Physical Medicine and Rehabilitation, and Radiology,"** Journal of the American Medical Association, 250 (November 18, 1983): 2623–27, p. 2625. Physician-to-population ratios are to be derived using the estimated physician requirements in each specialty nationwide for the year 1990 from these studies; and the middle series projection of the 1990 U.S. population from "Projections of the Population of the United States: 1982 to 2050 (Advance Report)," Population Estimates and Projections, Series P-25, No. 922, Bureau of the Census, October 1982. This projection is 249,731,000 persons.

(11) Select, from the results of section (9) of this rule, the peak daily census associated with the result of section (10) of this rule. If this number of beds exceeds the present number of acute inpatient beds within 50 miles by road of the population to be served, the applicant must evaluate the extent to which admissions scheduling by the applicant or by existing institutions could alleviate the need for new beds. The division shall evaluate the extent to which procedures and treatments that could be accomplished on an outpatient basis are planned to be handled on an inpatient basis at the applicant facility, and may make a compensatory adjustment in the bed need estimate. In performing this evaluation, the division shall consult with professional review organizations, third-party payers, and professional and provider organizations. One indication of need for compensatory adjustment may be a case mix adjusted Medicare diagnosis related group (DRG) length of stay or admission rate in excess of those at comparable facilities.

(12) If the result of section (11) of this rule indicates that added beds may be needed in the proposed hospital service area, an

applicant for a new facility shall weight its against the availability of beds at other facilities within 50 miles by road of the proposed facility's location and against the feasibility of alternative health care services, under OAR 333-590-0060.

(13) A certificate of need will be issued to meet the indicated need based on sections (11) and (12) of this rule, if supported by provisions of OAR 333-590-0060 and the division's findings on the criteria in division 580.

(14) If the number of beds proposed at the applicant facility cannot be justified under these general acute inpatient rules, a certificate of need for new specialty beds will not be issued unless an adjustment is indicated because conversion of other beds to sufficient specialty beds to meet calculated specialty bed need is not architecturally and economically feasible.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-590-0060
Relationship of Proposed New Hospitals to Existing Health Care System

An applicant proposing a new acute inpatient facility, rather than replacement or expansion of an existing facility, must weigh its plans against the availability of beds at existing, reasonably accessible facilities, especially those within the proposed service area of the applicant; and against the feasibility of development of alternative facilities and services. To develop a quantitative estimate of the situation, the following methodology will be used. Its results are to be evaluated against factors such as quality of care; types of services; levels of care available; anticipated changes in hospital locations, patient origins, service mix, age mix, reimbursement mix, transportation patterns, population shifts, and locations of physician specialists; and documented commitments to develop pro-competitive initiatives such as alternative delivery systems, selective contracting, successful competitive bidding, and other market oriented changes:

(1) Identify as other significant providers, those hospitals located within the service area of the applicant facility.

(2) For the applicant and for each other significant provider, estimate the anticipated commitment ratio, considering the ratio of each facility's patient days originating from the service area of the applicant facility, to the total patient days originating from that service area, using the most recent available statewide patient origin data, or a more recent less than statewide study, properly adjusted for balance-of-state origins and utilizations.

(3) Calculate expected first year average daily census at the applicant facility, based on OAR 333-590-0050(7), and for each other significant provider for that year.

(4) Calculate peak daily census for that year at each facility by applying the methodology in OAR 333-590-0050(6) through (9) to the service area and utilization statistics for these facilities, using a multiplier of 2.33 in order to adjust for the low probability that all facilities will simultaneously be full.

(5) Estimate the commitment of beds by each facility to the hospital service area at peak occupancy as defined in section (4) of this rule, by multiplying the results of section (4) of this rule by the commitment ratios calculated in section (2) of this rule.

(6) To estimate available beds at each facility, subtract the peak occupancy of each, as defined in section (4) of this rule, from:

(a) The capacity defined in OAR 333-590-0010(3); and

(b) The measure in subsection (a) of this section, plus "shelled space," that is, convertible space which requires construction rather than merely changing furniture.

(7) Estimate the number of beds in excess of peak occupancy which could readily be committed to the service area of the applicant, by multiplying the results from section (6) of this rule by the commitment ratios developed in section (2) of this rule.

(8) Taking into consideration the factors listed at the beginning of this rule, evaluate the feasibility and costs of meeting the estimated future need at the applicant facility, as determined under OAR 333-590-0050, from the inventory of available beds identified in section (6) of this rule. Consider the financial feasibility of utilizing "shelled space" rather than new construction. The impact of approval of the proposal on the financial viability of facilities which share the applicant's market area shall be evaluated by the division using the financial ratios specified in OAR 333-580-0100(3) and (4).

(9) If need for acute inpatient beds is not demonstrated under OAR 333-590-0050; or if need is demonstrated but, under this rule, it is found that the need can be met by utilization of available beds at existing facilities which are within 50 miles by road of the proposed facility's location; the applicant must consider whether an alternative health facility, such as a freestanding emergency center, backed up by one or more existing acute inpatient facilities, would be the least costly way to solve the applicant's problem of meeting health care needs of the population involved. In addition, the applicant may prepare an analysis related to:

(a) Whether one or more of the factors indicated in OAR 333-590-0030(3)(b), (c) or (d) is likely to generate at least 30 percent or more of reasonably estimated acute inpatient care utilization by the population proposed to be served, and if so;

(b) Whether the applicant can document unsuccessful good faith efforts, prior to submission of the letter of intent, to arrange for utilization of existing facilities and/or services (if any such facilities or services exist within 50 miles by road of the proposed facility's location), consistent with meeting the needs of the population to be served in the least costly, least duplicative manner; and, if OAR 333-590-0030(3)(c) applies, consistent with the intended HMO service model and the provisions of section (10) of this rule.

(10) The division shall take into account the acute inpatient care needs of members, subscribers and enrollees of institutions, HMOs or health care plans, as defined in OAR 333-545-0020(14), that operate or support particular health care facilities for the purpose of rendering health care to such members, subscribers and enrollees:

(a) An applicant to serve such groups shall:

(A) Identify the needs of their members, subscribers and enrollees for the proposed facility or service;

(B) Demonstrate that the identified needs are reasonable when related to the health care costs of present and future members, subscribers and enrollees;

(C) Describe the proposal's potential for reducing the use of inpatient care in the community through an extension of preventive health services and provision of more systematic and comprehensive health services;

(D) Identify the availability, and estimate the cost, of obtaining proposed beds, services or equipment from existing providers in the proposed hospital service area, other than the applicant.

(b) A certificate of need shall be issued to meet the needs or reasonably anticipated needs of such group members when beds, services or equipment are not available from non-plan providers in the area to be served. Beds, services or equipment are not available to an HMO from a non-HMO provider unless:

(A) They would be available through a long-term contract of sufficient duration and with sufficient provisions for notice of termination to enable the HMO to negotiate an alternative contract with another non-HMO provider, or to develop facilities and/or service capabilities and operate same after notice of contract termination from the non-HMO provider;

(B) They would be available and accessible to physicians associated with the HMO on a basis comparable to physicians not affiliated with the HMO (e.g, HMO physicians have or will have staff privileges);

(C) They could be provided by a non-HMO provider in a manner that can demonstrate to be as cost effective as if they were developed and operated by the HMO; and

(D) They would be available in a manner that is consistent with the HMO's basic method of operation (e.g., acute care centralized at one non-HMO provider as opposed to contracts for care at multiple non-HMO providers).

(11) Based on subsections (9)(a) and (b), and (10)(a) and (b) of this rule, the division may consider proposed findings of need and feasibility, taking into account such factors as:

(a) At least 70 percent of the population to be served is more than 50 miles by road from the nearest hospital with 45,000 patient days or more in the most recent year for which data are available;

(b) Population base sufficient to sustain the new facility or service;

(c) Community effectively isolated from reasonable access to acute care services, given road and weather conditions;

(d) Financial condition of applicant adequate to handle consequences of failure of facility or service to open or to stay open, without financial impact on proposed population to be served;

(e) Whether the proposed service(s) and bed capacity(ies) represent the least costly approach, in relation to capital and operating expenses, to meet acute inpatient care need;

(f) Whether the facility, sized as required under subsection (e) of this section, is designed so that future expansion would be architecturally feasible;

(g) Restrictive admissions policies;

(h) Access to care for public paid patients;

(i) Restrictive staff privileges and/or denial of privileges at existing and proposed facilities.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94; OHD 11-1998, f. & cert. ef. 10-22-98

DIVISION 600

DEMONSTRATION OF NEED FOR 24-HOUR HEALTH FACILITY INPATIENT CHEMICAL DEPENDENCY SERVICES

333-600-0000
General

In providing information to the Public Health Division to demonstrate need for various types of chemical dependency treatment services, the applicant must satisfy the criteria in the Certificate of Need Application Instructions (division 580). In completing the discussion of service area needs required by OAR 333-580-0040, the applicant should use the methodology in this division (division 600).

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-600-0010
Definitions

The definitions of OAR 333-590-0010 also apply to this division. The following definitions categorize specific types of chemical dependency treatment services. Certificate of need is required for sections (1) and (3) of this rule if the project involves the establishment of a new facility:

(1) "Medical Facility-Based Detoxification" means a short-term treatment, provided in a hospital during which medication is used under continuous medical supervision to restore physiological functioning.

(2) "Nonmedical Facility-Based Detoxification" means primarily nonmedical treatment by means of rest and fluid, with intermittent or limited medical supervision, not provided in a hospital, to restore physiological functioning.

(3) "Inpatient Hospital Services" means all medical and nursing services provided to persons who require 24-hour supervision as a result of acute or chronic medical and/or psychiatric illnesses associated with chemical dependency. Inpatient services may be delivered in a general or specialty hospital.

(4) "Residential Treatment Services" means services designed to facilitate treatment and rehabilitation of the chemically dependent person by creating a structured, therapeutic environment. Residential treatment services may be provided in the following:

(a) "Twenty-four hour residential treatment" means treatment in a residential treatment facility, non-hospital based, housing individuals who require 24-hour support and supervision;

(b) "Partial residential treatment" means a part-time day and night and/or weekend residential treatment facility for people who are able to work, or able to live at home, but not both, and who may need further support or supervision.

(5) "Rehabilitation Services" means a facility-based program of rehabilitation usually greater than 30 days.

(6) "Residential Maintenance Care" means 24-hour care other than that previously defined as detoxification, residential treatment, or rehabilitation and may include care provided in foster homes, small group homes, or boarding homes for chemically dependent persons.

(7) "Outpatient Treatment" means individual, family, or group services provided in a physician's office or clinic; generally on an individual appointment basis rather than the structured, scheduled group programs covered in subsection (4)(b) of this rule.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94; OHD 11-1998, f. & cert. ef. 10-22-98

333-600-0020
Principles

(1) Chemical dependency service systems should provide a continuum of care which gradually increases demands for personal responsibility.

(2) Chemical dependency services systems should allow entry at any point in the treatment continuum based on individual need.

(3) All levels of chemical dependency treatment should be readily available for use with no person remaining too long at one level because of the lack of services at the next level.

(4) The chemical dependency service system should be designed to allow people to remain in less intensive treatment modes longer than in the initial, more intensive modes.

(5) Chemical dependency services should be delivered in the least expensive, least restrictive setting required to produce the desired results.

(6) Chemical dependency services systems should provide a variety of treatment approaches to meet any given level of need.

(7) Quick geographical access is considered essential for outpatient care, detoxification care and day treatment. If 90 percent of the chemically-dependent persons in the proposed service area who need to use a specific non-24-hour treatment program such as outpatient, day treatment, or detoxification are more than 35 miles by road from existing programs of the type that is needed, then more treatment capacity may be needed in a location accessible to the population.

(8) Quick geographical access is not considered essential for inpatient hospital care or other types of 24-hour treatment programs. If 90 percent of the chemically-dependent persons in the proposed service area who need to use a specific 24-hour treatment program such as inpatient hospital, residential treatment, rehabilitation, or residential maintenance care are more than 75 miles by road from existing programs of the type that is needed, then more beds may be needed in a location more accessible to the population.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-600-0030
Need Methodology

The method for estimating the needed number of beds or service capacity for each type of chemical dependency treatment setting consists of the following steps:

(1) For a service which is designed to serve persons in the present service area of a given hospital or hospitals, determine the hospital service area according to OAR 333-590-0040.

(2) For a service with a geographical targeting different from section (1) of this rule, evaluate the proposed service area according to OAR 333-600-0020(7) and (8), considering also the likelihood of contractual commitments to serve specific groups of potential clients.

(3) Determine the estimated population for the service area for the calendar year five years beyond the letter of intent year of the application.

(4) Obtain the estimated number of problem drinkers in the service area in five years for adults by calculating seven percent of the service area's population age 19 and over; and for adolescents by calculating 19 percent of the 12–18 year old population.

(5) Determine the estimated number of problem drinkers who will seek treatment in a one-year period, by calculating 15 percent of the number derived in section (4) of this rule.

(6) Determine the specific levels and kinds of services required to meet the need, for all services other than outpatient: Multiply the number derived in section (5) of this rule by the beds per contact figure from **Table 1**, for the particular type of chemical dependency treatment service requested and divide by .90 to allow for occupancy variations. For outpatient service, utilize the service ratios figures in **Table 1**:

Table 1

Chemical Dependency Treatment Services	Beds per Contact	Service Ratios
Medical facility-based detoxification	.0014	1
Nonmedical facility-based detoxification	.0127	9
Inpatient hospital services	.0072	5
Residential treatment, 24-hour	.00689	49
Residential treatment, partial (day, night, or weekend)	.00641	46
Rehabilitation (long-term)	.00336	24
Residential maintenance care	.01160	83
Outpatient care	---	781

(7) Determine the number of existing beds or service capacity for each of the service elements in the service area.

(8) Subtract the level of existing services determined in section (7) of this rule from the projected need for services derived in section (6) of this rule.

(9) Evaluate the estimated need against the principles in OAR 333-600-0020 to determine need for proposed service.

(10) Although separate bed need standards are not established for specialty types of chemical dependency beds, the division recognizes that chemical dependency beds could be used to deliver various subspecialty services, such as adolescent or geriatric chemical dependency programs, and programs for patients with both a mental illness and a chemical dependency problem ("dual diagnosis" patients).

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

DIVISION 610

DEMONSTRATION OF NEED FOR LONG-TERM CARE SERVICES

333-610-0000
General

In order to demonstrate need for nursing home beds, an applicant must satisfy the criteria specified in the Certificate of Need Application Instructions (division 580). Where appropriate, responses to these instructions shall be based on the methodology of this division (division 610).

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-610-0010
Definitions

As used in this division:

(1) "Alternative Services" means any long-term care services other than nursing homes.

(2) "Adult Foster Care" means supervised living, like licensed residential care facility (home for the aged) but for five or fewer persons.

(3) "Closed System Provider" means a facility or campus arrangement offering a continuing care contract for both unsupervised housing and licensed nursing facility care.

(4) "Community Services/Nonresidential Services" means alternative services which do not involve 24-hour living outside of one's own home and may include in-home services or services provided outside of the home, such as meals, social activities, clinics, classes, organized day programs, etc.

(5) "Continuing Care Contract" means a legally binding agreement between an individual and a closed system provider, which remains in effect for longer than two years, sometimes for the resident's lifetime. The contract states what shelter and services the home will provide to the resident over the time specified, and it states what obligations, including financial obligations, the resident will have to the home for the same time period. The contract will specify the nursing home services that the community will provide to residents, but will not be solely for the purpose of providing nursing home services. The primary purpose of the contract will be to provide a living situation to elderly persons who will usually be ambulatory and in good health upon entry into the community. Continuing care contracts are known by a variety of names, including life care contracts, entrance fee agreements, sustaining gift contracts, occupancy agreements, accommodation fee agreements, member trust fund contracts, founders' fees contracts, and community residence agreements.

(6) "Home for the Aged/Rest Home." See licensed residential care facility.

(7) "Home Nursing Care" or "Home Health Service" means nursing care provided in the home by a private duty nurse, visiting nurse, proprietary home care agency, or county home health agency.

(8) "In-Home Services" means alternative services delivered to the home; may include telephone reassurance, home delivered meals, housekeeper, heavy chores, homemaker, personal care, home nursing care, special care or therapy.

(9) "Institutional Care" means nursing home care.

(10) "Intermediate Care Facility (ICF)" means a licensed long-term care facility (nursing home) providing care for persons with significant but stable health problems requiring availability of a registered nurse for one eight-hour shift daily, five days a week, together with additional light or heavy aide care. ICFs for the mentally retarded are not included in this definition.

(11) "Licensed Residential Care Facility" (formerly called home for the aged). Under ORS 443.400(5), this type of substitute home/supervised living means "a facility that provides, for six or more physically handicapped or socially dependent individuals, residential care…". Under Seniors and People with Disabilities Division rules, residents may not require continuous nursing care but may require routine medication; special diets; assistance with activities of daily living; palliative skin care; simple dressings; maintenance of casts, braces, and prostheses. Periodic licensed nursing care (catheter irrigation, dressing change, or periodic injections) may be provided on contract just as in a person's own home.

(12) "Long-Term Care Facility (LTCF)" refers to Oregon's current licensing category for all nursing home beds, as defined in Seniors and People with Disabilities Division licensure rules, whether freestanding or part of a hospital, and whether the patients are at skilled level of care or intermediate level.

(13) "Long-Term Care Services/Continuum of Care" means the entire set of possible services for persons in need of long-term health and/or social services.

(14) "Nursing Home" means long-term care facility, as defined in Seniors and People with Disabilities Division licensure rules, providing skilled and/or intermediate level nursing care.

(15) "Personal Care" means physician prescribed, registered nurse supervised, services delivered by trained individuals, including: Basic personal hygiene; bowel and bladder care; assistance with self-administered medications and oxygen; assistance with mobility, transfers and comfort; assistance with meal preparation and feeding; care of confused and/or mentally ill client; first aid and handling of emergencies; housekeeping necessary for health

and safety; assistance to and from appointments; monitoring of client status.

(16) "Retirement Home" means a place where relatively independent older persons live together with little supervision with some common services such as housekeeping and some meals provided.

(17) "Satellite Apartment" means a periodically supervised living arrangement associated with a home for the aged, nursing home, or other 24-hour residential facility.

(18) "Semi-Independent Living" means cooperative small group living in freestanding housing, with limited supervision and assistance on the basis of daily or less frequent visits.

(19) "Skilled Nursing Facility (SNF)" means a licensed long-term care facility providing care for persons with severe and/or unstable health problems which cannot be managed at the intermediate care level, requiring the availability of a registered nurse 24 hours daily, seven days a week, but not requiring the levels of nursing, physician and specialized services available in a hospital.

(20) "Substitute Home/Supervised Living" means nonmedical alternative services involving 24-hour care and supervision. In Oregon, includes licensed residential care facility (home for the aged), adult foster care, satellite apartments, or semi-independent living.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-610-0020
Principles

The following principles will be applied in the review of applications for certificate of need for nursing home beds:

(1) Clinical and epidemiological research indicates that, on the average, 30 nursing home beds per 1,000 persons age 65 and over would be sufficient to meet the need for care for those functional deficits for which nursing home care is medically necessary and cost effective. This does not include utilization which is socially convenient rather than medically necessary. The experience of some states and some Oregon counties indicates that when sufficient alternatives are available, a ratio of less than 30 nursing home beds per 1,000 persons age 65 and over may be sufficient to meet the population's needs.

(2) Oregon data are consistent with section (1) of this rule. Because about ten percent of Oregon nursing home residents are not age 65 and over, and to allow for local variations, a goal of 40 beds (actually, a range of 35 to 45) (per 1,000 persons age 65 and older is hereby set, 33 percent greater than the research figure in section (1) of this rule. No county should exceed this bed ratio; although, as noted in section (1) of this rule, ratios well under 40 beds per 1,000 persons age 65 and over are often sufficient to meet community needs.

(3) By 1991, there shall be no more than 40 nursing home beds per 1,000 persons age 65 and over in any Oregon county:

(a) For counties which had 54 or fewer beds per 1,000 in 1980, the goal is to be reached by 1986;

(b) For counties which had more than 54 beds in 1980, or have population densities below the state median, up to five additional years are allowed (see **Tables 1**, **2**, and **3**), recognizing the greater amount of time required to organize the expansion of alternative care under such circumstances.

(4) An average county or service area minimum occupancy of 95 percent, before adding beds, is to be used except when plans of state agencies utilizing beds, anticipated population changes, plans of other service area providers, and considerations of maintaining access at reasonable cost indicate that 90 percent is appropriate.

(5) Proposed beds are evaluated in relation to the entire local long-term care system; to resources in the local service area and in the health service areas as a whole; to plans of state and local agencies; and to state policies expressed by the legislature. Additional beds will not be approved simply on the basis of "need" at a specific facility.

(6) Need should be projected on the basis of forecasted elderly population in three years. This time period will be extended for counties with population densities below the state median. It will be shortened when utilization of beds by state agencies has declined, and compensating utilization of alternative care has occurred and is projected to continue.

(7) For future years, population projections prepared and published by the Portland State University Center for Population Research and Census (CPRC) in **Population Projections**, **Oregon and Its Counties: 1980 to 2000**, **June 1984**, will be used unless the applicant can demonstrate invalidity. If existing projections are shown to be invalid, an alternative acceptable to both the Public Health Division and CPRC will be substituted.

(8) Separate capacity levels for ICF and SNF beds are not set because these bed categories are not separately licensed.

[ED. NOTE: Tables & Publications referenced are available from the agency.]
Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-610-0030
Need

The following method is an extension of the general requirements for analysis of need set forth in OAR 333-580-0040(1):

(1) Determine service area:

(a) Except as provided in subsections (b) and (c) of this section, the geographical service area of the applicant will be considered to be the county in which the facility is located;

(b) Service areas in health service area III are defined as follows: Hood River, Sherman and Wasco Counties; Crook, Deschutes and Jefferson Counties; Gilliam, Morrow and Wheeler Counties; Union and Wallowa Counties; Baker County; Malheur County; Grant County; Harney County; Lake County; Umatilla County; and Klamath County;

(c) An applicant may propose an alternative service area to that specified in subsection (a) or (b) of this section. Such alternative service area, if accepted by the division, will be applied only to the review of the applicant's proposal, and shall not affect the applicability of subsections (a) and (b) of this section to other applications. The appropriateness of such an alternative service area must be demonstrated by the applicant to the division's satisfaction. In demonstrating the appropriateness of the proposed alternative service area, the applicant shall discuss and provide data on the following:

(A) Patient origin and length of stay by zip code for admissions for the most recent completed fiscal or calendar year for all nursing homes in the proposed service area. The applicant should list zip code of origin and length of stay for each admission, but should not use any patient names. The proposed service area should account for at least 75 percent of all admissions to service area nursing homes. It is recognized that nursing homes other than the applicant may sometimes be unwilling to provide such data but at a minimum data must be provided for the applicant facility, and documentation must be submitted to show that other facilities were asked to provide data;

(B) Travel patterns and highways between the proposed service area and adjacent areas;

(C) Historical market patterns for health and other services; and

(D) Geographic or other considerations that might delineate the proposed areas as a distinct service area.

(2) Estimate population age 65 and over in service area:

(a) As a basis for estimating service population for particular past and future years, determine the population age 65 and over in the service areas as of 1970, 1980 through 1985, 1990 and 1995;

(b) For 1970 and 1980, use the U.S. census counts;

(c) For 1990 and 1995, use the projections provided in **Population Projections, Oregon and Its Counties: 1980 to 2000**, Center for Population Research and Census (CPRC), Portland State University, June 1984;

(d) For 1981 through 1986, use estimates of population age 65 and over developed by CPRC;

(e) Estimate the population age 65 and over for the tenth year prior to the application through 1979 using the following method:

(A) Determine the ratio of elderly to total population in both 1970 and 1980 by dividing the population over age 65 by the total population for each of these years;

(B) Estimate these ratios for the tenth year prior to the application through 1979 by applying linear interpolation to the 1970 and 1980 ratios from paragraph (A) of this subsection;

(C) Obtain estimates for total service area population in each year from the tenth year prior to the application through 1979 from CPRC's "Inter-Censal Estimates of Oregon, by County: 1970–1980," April 1982;

(D) To estimate the population age 65 and over for the tenth year prior to the application through 1979, multiply the ratio in paragraph (B) of this subsection by the total population from paragraph (C) of this subsection for each year.

(f) To estimate the population age 65 and over for the years 1987 through 1989, apply linear interpolation to the 1985 and 1990 figures for population age 65 and over;

(g) To estimate the population age 65 and over for any of the years 1991 through 1994 (if required by subsection (11)(a) of this rule), apply linear interpolation to the 1990 and 1995 projections of population age 65 and over.

(3) Obtain historical nursing home patient days: For each of the last 10 years, from the Annual Reports for nursing homes and hospital-based long-term care facilities, obtain the October 1 through September 30 yearly total patient days of nursing home care delivered in the service area.

(4) Determine historical use-rates:

(a) Based on section (2) of this rule, prepare a table, showing for each 10 years prior to the application to the fifth year following the year of submission of the application, the estimated age 65 and over population for the service area;

(b) Add to the table, a column, based on section (3) of this rule, showing annual historical patient days for each year from 10 years prior to the application to present;

(c) Determine use-rates (number of patient days per 1,000 persons age 65 and over in the service area) by dividing each figure entered under subsection (b) of this section, by the corresponding figure entered under subsection (a) of this section, divided by 1,000.

(5) Determine potential patient days: To the table prepared in section (4) of this rule, add columns as follows:

(a) For each year from 10 years prior to the application to present, the number of licensed nursing home beds (including hospital-based) in the service area. The two most recent years are available from the division. Historical data are available from the Seniors and People with Disabilities Division;

(b) For each bed number in subsection (a) of this section, multiply by 365 to obtain potential calendar year patient days available in the service area.

(6) Determine average occupancy: To the table prepared in sections (4) and (5) of this rule, add a column computed by dividing the historical patient days for each year, by the potential patient days, and converting to percent.

(7) Evaluate occupancy:

(a) If, in the most recent October 1 through September 30 year for which Annual Report data are available, average occupancy for the service area was 95 percent or more, more beds may be needed;

(b) If average occupancy for the service area was less than 95 percent, more beds may not be needed. Applicant must demonstrate, under these circumstances, that a combination of factors will assure 95 percent service area occupancy if the application is approved. Such factors may include the plans of state agencies utilizing nursing home beds; projected increases of user populations; plans of other nursing home providers in the service area;

(c) If 95 percent service area occupancy cannot be demonstrated, but 90 percent can be demonstrated, and applicant demonstrates that approval would result in maintaining access to nursing home care in the service area at reasonable cost, the beds may be needed.

(8) If, under section (7) of this rule, beds may be needed, proceed with the analysis.

(9) Determine future bed inventory: To the most recent available Seniors and People with Disabilities Division inventory of licensed nursing home beds (including hospital-based) in the service area, make the following adjustments:

(a) Add beds in the service area not yet licensed, for which there is an approved certificate of need in effect;

(b) Subtract beds in the service area for which there is a documented commitment to the division for delicensure within the next three years.

(10) Determine the year by which to demonstrate need:

(a) Ordinarily, this will be three years after the calendar year of the letter of intent;

(b) If, according to **Table 1**, the estimated 1985 population density of the service area is in the lowest quartile of Oregon counties, this will be five years;

(c) If the population density is in the second quartile, this will be four years;

(d) If the data available from the central offices of the state agencies utilizing nursing home care in the service area meet the following criteria, then the indicated times in subsections (a), (b) and (c) of this section will be shortened by one year:

(A) Utilization of nursing home care in the service area by state agencies has decreased during the most recent 12 months;

(B) Utilization of alternative care in the service area by state agencies has increased, correspondingly, in the most recent 12 months;

(C) Projections and plans for utilization of nursing home care in the service area, and for alternative care, by state agencies, indicate stabilization or continuance of the trends in paragraphs (A) and (B) of this subsection, respectively.

(11) Construct table for analysis of need:

(a) Provide a column for each of the five years starting with the letter of intent year;

(b) Provide a row for the service area population age 65 and over for each year, estimated in section (2) of this rule;

(c) Provide a row for each of the following possible use-rates:

(A) The 1980 service area bed supply per 1,000 persons age 65 and over, based on **Table 2**;

(B) The upper and lower bed supply objectives from **Table 3** for the year identified in section (10) of this rule;

(C) The most recent use-rate identified in section (4) of this rule, divided by 365;

(D) The use-rate based on a projection of the use-rates for the last 10 years, divided by 365;

(E) If the series of use rates in section (4) of this rule shows a maximum or a minimum year prior to the most recent year, the use-rate based on a projection of the use-rates for the years starting with that maximum or minimum year, divided by 365;

(F) Standard bed supply figures of 30, 35, 40, and 45 nursing home beds per 1,000 persons age 65 and over.

(d) Review prior years' bed supply as tabulated in section (5) of this rule in order to determine whether the rates projected in paragraphs (c)(D) and (E) of this section reflect changes in utilization with constant bed supply, or changes in utilization correlated with changes in bed supply. If the latter is the case, calculate alternative projections for paragraphs (c)(D) and (E) of this section;

(e) Review performance and plans of state agencies utilizing nursing home and alternative care, as obtained for section (10) of this rule, in order to determine whether alternatives to the projections in paragraphs (c)(C), (D) and (E) of this section, adjusted numerically because of the performance and the plans, would lead to different projected rates and should also be tabulated.

(12) Complete table for analysis of need: Fill in the table constructed in section (11) of this rule by multiplying the estimated service area population age 65 and over (second row), for each year, by the various flat, projected and adjusted use-rates indicated in subsections (11)(c), (d) and (e) of this rule. For each use-rate based projection (those based on the assumptions in paragraphs (11)(c)(C), (D) and (E) of this rule), divide the result of this multiplication by 0.95, in order to assume 95 percent occupancy.

(13) Evaluate impact of application: Add the requested beds to the existing future inventory in section (9) of this rule. Compare the result to the column of the table completed in section (12) of this rule for the year selected in section (10) of this rule, and to the bed need indicated for that year in a county or service area plan, if available, that meets the criteria of section (14) of this rule.

(14) Service area plans: For use in analysis by the division, a county or service area plan must meet the following criteria:

(a) Satisfy the service area definition in section (1) of this rule;

(b) Cover a time period, year-by-year, of at least five years, projecting:

(A) Nursing home caseloads; and

(B) Alternative care caseloads.

(c) Be within the yearly upper limits on service area bed supply established by application of section (10) and paragraph (11)(c)(B) of this rule, unless an analysis under subsection (16)(b) of this rule demonstrates that higher limits are justified;

(d) Be prepared by the local area agency on aging and/or the state Seniors and People with Disabilities Division, and approved by the Seniors and People with Disabilities Division.

(15) Compare application to state goals:

(a) If a service area plan as defined in section (14) of this rule is available, the applicant is expected to demonstrate consistency with that plan and justify any inconsistencies;

(b) If there is no service area plan as defined in section (14) of this rule, then, depending on the relationship of the impact of the application on bed supply to the upper and lower bed supply objectives identified in paragraph (11)(c)(B), subsections (c), (d) or (e) of this section will apply;

(c) If approval of the application would result in:

(A) More beds than the 1980 ratio identified in **Table 2**, if that ratio is above the lower limit identified in paragraph (11)(c)(B) of this rule; or

(B) More beds than the upper limit identified in paragraph (11)(c)(B) of this rule; or

(C) Addition of beds in a service area which includes all or part of any county which is in the highest quartile of beds per 1,000 persons age 65 and over (see **Table 2**, or subsequent annual revisions as available), then the applicant is expected to demonstrate under subsection (16)(b) of this rule that, by the calendar year identified for paragraph (11)(c)(B) of this rule, there are no feasible long-term care alternatives to an increase in nursing home beds.

(d) If none of paragraphs (c)(A), (B) or (C) of this section are the case, and the approval of the application would result in:

(A) Maintaining the 1980 ratio identified in **Table 2**, if that ratio is above the lower limit identified in paragraph (11)(c)(B) of this rule but below the upper limit; or

(B) Falling below that ratio, but above the lower limit identified in paragraph (11)(c)(B) of this rule, then the applicant is expected to show that alternative care capacity in the locality has not been increasing; that nursing home utilization has not been decreasing; and there is no reasonable expectation that these utilization rates would change in those respective directions prior to the year determined in section (10) of this rule. Alternatively, applicants whose projects fall into one of the categories of this subsection may demonstrate need under the criteria specified in subsection (16)(b) of this rule.

(e) If neither subsection (c) nor (d) of this section is the case, then approval of the application would result in increasing the 1980 ratio identified in **Table 2**, up to or closer to the lower limit identified in paragraph (11)(c)(B) of this rule. In this case, the applicant is expected to inventory the alternative capacity and utilization in the locality and to indicate the criteria under which the nursing home will refer prospective patients to each alternative rather than admit them to the nursing home.

(16) Justification of bed capacity above state goals:

(a) If the criteria in subsection (15)(a), (d) or (e) of this rule apply and are satisfied, beds in the service area may be added or relocated provided all criteria specified in OAR 333-580-0040 through 333-580-0060 are met;

(b) If subsection (15)(c) of this rule applies, then the applicant must demonstrate that there are no feasible long-term care alternatives in the service area by the calendar year identified in paragraph (11)(c)(B) of this rule by demonstrating that at least one of the following conditions exist:

(A) Applicant must show that superior and accessible alternatives to the proposed added or relocated beds, in terms of appropriateness, efficiency, effectiveness or cost, have not been developed, and cannot be developed by this provider or another potential provider in time to meet needs, or would not be financially feasible; or have insufficient capacity, which could not be expanded in time to meet needs, or expansion is not financially feasible;

(B) Applicant may show that utilization of service area nursing home beds by persons under age 65 (mentally or emotionally disturbed, mentally retarded or developmentally disabled, alcohol or drug dependent, or physically handicapped) is occurring in numbers greater than 15 percent of the service area nursing home average daily census. This may justify adding or relocating beds under subsection (15)(c) of this rule to the extent that the placements are appropriate under the authorization criteria of the central offices of the state Department of Human Services;

(C) Applicant must show that the efficiency and appropriateness of utilization of existing nursing home beds and alternatives in the service area is as high as can be expected;

(D) Applicant must show that persons for whom nursing home care is necessary would experience serious problems in terms of availability, accessibility and cost in obtaining such care without the added or relocated beds;

(E) If proposal involves either permanent or "swing" utilization of hospital beds as long-term care beds, and subsection (15)(c) of this rule applies, applicant must present a justification consistent with paragraphs (A) to (D) of this subsection;

(F) If subsection (15)(c) of this rule applies, applicant may demonstrate need by showing that there is provider commitment to phase out (close, or convert to other uses) sufficient presently existing, specific beds so as to bring the local level of nursing home capacity back below the limit at which subsection (15)(c) of this rule would apply for future years, within 12 months after the projected opening of beds if the application is approved.

[ED. NOTE: Tables & Publications referenced are available from the agency.]

Stat. Auth.: ORS 431.120(6) & 442.315

Stats. Implemented: ORS 431.120(6) & 442.315

Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-610-0060
Hospital Long-Term Care Beds

(1) Long-term care facility services and beds offered in or through a hospital must be separately licensed by the Seniors and People with Disabilities Division. Therefore, the creation of a long-term care facility by a hospital will be considered to constitute the establishment of a new health care facility, subject to review under OAR 333-550-0010(1). Additions to the bed capacity of such facilities will be subject to review if such additions are greater than 10 percent of the existing capacity of the long-term care facility, or greater than 10 beds, whichever is less, as provided in OAR 333-550-0010(3).

(2) When a hospital proposes to create a new long-term care facility which will either be associated with, or located in, the hospital; or increase the number of long-term care beds (as defined in OAR 333-610-0010(12)) in such a facility by more than 10 beds or 10 percent of the facility's bed capacity, whichever is less, or when a hospital proposes to relocate long-term care beds to such a facility, the project will be subject to certificate of need on the same basis as any freestanding nursing home project would be under OAR 333-610-0000 to 333-610-0030.

Stat. Auth.: ORS 431.120(6) & 442.315

Stats. Implemented: ORS 431.120(6) & 442.315

Hist.: HD 13-1994, f. & cert. ef. 4-22-94; HD 3-1995(Temp), f. & cert. ef. 8-18-95; HD 10-1995, f. & cert. ef. 11-14-95

333-610-0070
Swing Long-Term Care Beds in Hospitals

When a hospital proposes to utilize a given number of its licensed hospital acute beds intermittently as skilled nursing facility swing beds under applicable federal regulations, the hospital is expected to submit a letter of intent to the Public Health Division. The organized and regular provision of skilled nursing facility services within the licensed physical plant of the hospital may be subject to review as a new long-term care facility under OAR 333-550-0010(3)(a). In addition:

(1) The proposal will not be subject to county-specific nursing home bed need criteria under OAR 333-610-0000 to 333-610-0030 because it will not create permanent new nursing home beds. The division, in reviewing the proposal for need under OAR 333-580-0040 and for alternative uses of resources under OAR 333-580-0050, will take into consideration such factors as:

(a) Health policy of the state, as reflected in ORS 410.010, 410.020, 410.050 and 410.060; ORS Chapter 442 generally; and other applicable statutes;

(b) Interpretation of that policy, as reflected in the plans and administrative rules of the Health Division and the Senior and Disabled Services Division. In considering strategies for increasing the accessibility of nursing home beds, priority will be given to increasing the utilization of appropriate alternative care (thereby freeing up existing nursing home beds), rather than increasing the number of nursing home beds;

(c) Comparative experience with, and quality of, long-term care provided by staff in licensed acute care hospitals and in licensed long-term care facilities.

(2) The division, in reviewing the proposal for financial feasibility under OAR 333-580-0060, will take into consideration such factors as:

(a) A conservative projection of Medicare utilization according to the current stringent "skilled" level of care criteria of the fiscal intermediaries;

(b) Estimated potential for diversion of public and private funds now available for alternative care into facility-based long-term care when the patient needs involved could be met, at equal or lesser cost, through provision of alternative care;

(c) Balanced against section (3) of this rule, estimated potential for diversion of public and private funds now available for acute care into facility-based and alternative long-term care;

(d) Comparative costs of long-term care provided in licensed hospitals and in licensed long-term care facilities, and the feasibility of the hospitals contracting for skilled care in an existing long-term care facility at equal or lesser cost; and

(e) Potential that the proposal will or will not increase Medicare costs, per illness episode, beyond those allowed for under diagnosis-related groups reimbursement.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94; OHD 11-1998, f. & cert. ef. 10-22-98

333-610-0080
Residential Care Beds in Long-Term Care Facilities

When a long-term care facility chooses to obtain a Seniors and People with Disabilities Division license as a "licensed residential care facility" as described in OAR 333-610-0010(11) for all, or for a separate and distinct part of its currently licensed long-term care facility bed capacity, it is not required, under statute, to accept a correspondingly reduced Seniors and People with Disabilities Division "long-term care facility" license as described in OAR 333-610-0010(12). Federal regulations, however, may require this under some circumstances. The following certificate of need rules will apply at such time that appropriate, coordinated licensing rules are adopted by the Seniors and People with Disabilities Division:

(1) Future reconversion of such beds from residential care to long-term care (nursing home) beds will be considered an expansion of the then existing Seniors and People with Disabilities Division licensed long-term care facility service, and may be subject to the certificate of need law under applicable thresholds regarding expansions in long-term care bed capacity; and

(2) In evaluating a reconversion project, the division shall give strong consideration to the costs, compared to new construction, and to the comparative quality and cost of care currently provided at the facility; and

(3) Reconversion projects as described in this rule will be subject to county-specific bed need criteria under OAR 333-610-0020 to 333-610-0030.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-610-0090
Intermediate Care Facilities for the Mentally Retarded

Distinct part intermediate care beds for mentally retarded or developmentally disabled individuals, when the facility houses any individuals who require nursing care services of a level, frequency and duration equivalent to intermediate facility care nursing as defined by the Seniors and People with Disabilities Division, must be licensed by the Seniors and People with Disabilities Division, rather than by the Addictions and Mental Health Division, and are subject to certificate of need according to ORS Chapter 442. In determining need, the division shall take into account long-range plans of the Addictions and Mental Health Division; shall consider comparative bed ratios in other states; and shall search, review and analyze existing professional literature and reports. The division shall evaluate local, substate, regional and statewide need, considering access, quality and costs. Public and private facility beds shall be considered as equivalent for purposes of meeting the limited need for this category of care.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-610-0100
Intermediate Care Facilities for the Mentally or Emotionally Disturbed

Distinct part intermediate care beds for mentally or emotionally disturbed individuals, when the facility houses any such individuals who require nursing care services of a level, frequency and duration equivalent to intermediate care facility nursing as defined by the Seniors and People with Disabilities Division, must be licensed by the Seniors and People with Disabilities Division, rather than by the Addictions and Mental Health Division, and are subject to certificate of need according to ORS Chapter 442. In determining need, the division shall take into account long-range plans of the Addictions and Mental Health Division; shall consider comparative bed ratios in other states; and shall search, review and analyze existing professional literature and reports. The division shall evaluate local, substate, regional and statewide need, considering access, quality and costs. Public and private facility beds shall be considered as equivalent for purposes of meeting the limited need for this category of care.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-610-0110
Intermediate Care Facilities for Chemically Dependent Persons, Including Alcoholics

Distinct part intermediate care beds for Chemically dependent persons, including alcoholics, when the facility houses any such individuals who require nursing care services of a level, frequency and duration equivalent to intermediate care facility nursing as defined by the Seniors and People with Disabilities Division, must be licensed by the Seniors and People with Disabilities Division, rather than by the Addictions and Mental Health Division, and are subject to certificate of need according to ORS Chapter 442. In determining need, the division shall take into account long-range plans of the Addictions and Mental Health Division; shall consider comparative bed ratios in other states; and shall search, review and analyze existing professional literature and reports. The division shall evaluate local, substate, regional and statewide need, considering access, quality and costs. Public and private facility beds

shall be considered as equivalent for purposes of meeting the limited need for this category of care.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

DIVISION 615

DEMONSTRATION OF NEED FOR PSYCHIATRIC INPATIENT BEDS

333-615-0000
General

The purpose of this division is to assure provision of accessible, quality care with the least incremental impact in overall community health care capital and operating costs. Treatment of the psychiatric patient requires special staff, facilities, programs and management policies. These may be accomplished either in a unit in a general hospital, or in a specialized hospital. In order for Oregon to have a complete mental health system, both general hospital units and multispecialty units are needed. However, because of Oregon's population size and distribution, the need for subspecialty services is limited, and the need for local access to quality general psychiatric inpatient care is great. Therefore, the number of large, multispecialty, freestanding units feasible in Oregon is limited. The applicant, in providing information to the Public Health Division to demonstrate need for psychiatric inpatient beds other than those directly operated by the federal Veterans' Administration or the state Addictions and Mental Health Division, must satisfy the criteria specified in the Certificate of Need Application Instructions (chapter 333, division 580). Where appropriate, responses to these instructions shall be based on the following:

(1) The methodology of this division (division 615), in order to estimate the appropriate number of psychiatric beds; and

(2) Comparison of estimates of costs and quality arising from conversion of certain of the identified existing licensed capacity, to estimates of costs and quality generated by creation of a new facility.

(3) Statements of preference or priority in this division are expressions of general policy based on Oregon statute and the current literature. Such statements do not necessarily preclude possible approval of an application embodying a less preferred or a lower priority characteristic. Rather, the applicant must bear the burden of demonstrating that any such features are compensated for by other aspects of a proposal, in order to best achieve the policy of ORS 442.025(1). For example, freestanding units under new licenses are not precluded, but the lack of feasible alternatives which better implement state policy must be demonstrated.

(4) In reviewing applications for psychiatric inpatient beds, the division, recognizing that treatment of the psychiatric patient requires special staff, facilities, programs and management policies, shall critically evaluate any proposal for a psychiatric unit which incorporates:

(a) Routine interchangeability of general psychiatric and general acute care in the same unit or on a "swing bed" basis;

(b) Conversion of existing licensed capacity to psychiatric use amounting to no more than minimal cosmetic changes to existing patient rooms without meeting state licensing standards in applicable Public Health Division rules, or Joint Commission on Accreditation of Healthcare Organization standards, as appropriate;

(c) Consideration of costs outweighing adequate quality;

(d) Evidence of insufficient opportunity for potentially affected clinicians to present their views and to obtain serious consideration of these views by any applicant.

(5) To be ruled complete, an application for psychiatric beds must include a narrative organized in the following sequence of separate major sections:

(a) A complete response to each rule of division 615;

(b) If a new facility is proposed, analysis under division 590, the rules for acute hospital beds in general;

(c) Based on the foregoing, and other information included directly or as appendix materials or exhibits, a complete response to the general application form narrative instructions regarding the general statutory criteria which apply to all health care facility requests, in the sequence given in the instructions.

Stat. Auth.: ORS 431.120(6), 442.025 & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-615-0010
Definitions

The definitions of OAR 333-590-0010 shall apply, in addition to the following:

(1) As used in this division, "alternatives" include, but need not be limited to, the following:

(a) Nonhospital, 24-hour residential treatment;

(b) Hospital or nonhospital day or partial hospitalization programs;

(c) Outpatient treatment by a qualified mental health professional (a licensed psychiatrist or clinical psychologist, a psychiatric nurse practitioner within the legal scope of practice, or licensed or registered clinical social worker); and

(d) Outpatient treatment through a mental health program approved by the Addictions and Mental Health Division.

(2) As used in this division, psychiatric "subspecialty beds" do not include general or adult beds, nor chemical dependency treatment beds (see division 600 of this chapter), but do include:

(a) Holding rooms and freestanding mental health emergency centers, created by a public or private agency under ORS 426.241, in response to legislative policy reductions in the operating capacity of Oregon State Hospital with respect to patients originating in the service area, when the general psychiatric inpatient unit or units in that service area, as defined in OAR 333-615-0030(1)(b), do not offer appropriate programs to meet the needs of the anticipated utilizing population;

(b) Child;

(c) Adolescent;

(d) Geriatric;

(e) Drug;

(f) Secure;

(g) Long-term intensive treatment;

(h) Long-term maintenance care; and

(i) Dual diagnosis (person with both a mental health and a substance abuse diagnosis).

(3) Psychiatric inpatient service areas are defined in OAR 333-615-0030 according to the principles stated in OAR 333-615-0020.

(4) Quality of psychiatric inpatient care for purposes of this division is defined in OAR 333-615-0050.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-615-0020
Principles

Under ORS 442.025(1), state policy gives priority to the achievement of reasonable access to quality health care at a reasonable cost. It is legislative policy under ORS 430.610(3) that to the greatest extent possible, mental health services be delivered in the community where the person lives in order to achieve maximum coordination of services and minimum disruption in the life of the person. Under ORS 430.021(3), it is state policy to encourage and assist community general hospitals to establish psychiatric services. Consistent with legislative policy, priority is given in this division to establishment of access to local hospitalization in geographically distributed, quality psychiatric units, within community hospitals; and hospitalization is to be utilized only when an individual's needs cannot be safely and effectively met by less costly alternatives. The following principles, therefore, are applicable to this division:

(1) Service areas for general psychiatric beds other than those directly operated by the state Addictions and Mental Health Division or the federal Veterans' Administration, shall be delineated so as to encourage the greatest feasible utilization of community

hospitals, and of alternatives to hospitalization, by both private and public patients. The division will use as a basis for general psychiatric inpatient service areas the state administrative districts. The districts are based on natural market areas defined by geographical barriers, transportation networks and historical patterns of general trade. In addition, community mental health services in Oregon are organized on a county or multicounty basis, compatible with these districts, thus facilitating planning and coordination with, and access to, local inpatient services in such districts.

(2) Service areas for psychiatric specialty beds, other than those directly operated by the state Addictions and Mental Health Division or the federal Veterans' Administration, as defined in OAR 333-615-0010(2), other than holding rooms, shall be delineated so as to assure availability of quality service at reasonable cost in economically viable subspecialty units:

(a) Factors to be considered in delineating such service areas shall include the sizes of the respective populations at risk in Oregon; the current rates of inpatient hospitalization in Oregon for those groups; and the availability, accessibility, quality and levels of utilization of existing inpatient services addressing the needs of those groups in Oregon. These factors will generally lead to delineation of subspecialty service areas according to health service area, multiple health service area or statewide boundaries;

(b) In order to assure viable, quality subspecialty units, economies of scale shall be given greater weight than geographical distribution;

(c) In estimating subspecialty need, the state will consider the population ratios proposed in "total system" models such as Nebraska (1981) and California (1981);

(d) For each subspecialty service, an applicant will be expected to indicate the anticipated percentage and origins of utilization from outside the general psychiatric service area, based on section (1) of this rule, in which the facility is, or will be located, and to provide the evidence and assumptions related to the analysis.

(3) Service areas for holding rooms shall be based on local considerations of access, demand and feasibility.

(4) The development of a number of psychiatric units, of economically and programmatically viable size, in general hospitals, rather than the development of a few large, multispecialty, freestanding facilities, shall be emphasized. The division recognizes that equivalent programs, in terms of quality, can be developed in either setting, to meet the needs of particular populations; that, in order to attract and retain staff, as well as for quality program design and economic efficiency, consideration must be given to minimum feasible unit size; but that, nonetheless, programs located within acute general hospitals have the advantage of close administrative relationships and proximity to acute medical and surgical consultation, diagnosis and treatment. Among the considerations leading to an emphasis on geographically decentralized psychiatric units in general hospitals, are the following:

(a) Improved geographic access in the various regions of the state, and therefore;

(b) Greater likelihood of reduced utilization of state and federal hospitals for short-stay intensive inpatient care;

(c) Reduced separation of psychiatric patients and staffs from specialty medical care for psychiatric patients at a reasonable cost, substantial numbers of whom have that need;

(d) Improved access to quality psychiatric staff for general medical patients;

(e) Greater access to diversity in medical and support staff, and extent of ancillary services available;

(f) Possibility of reduced construction and operating costs, through development of economically and programmatically viable sized units by conversion of small amounts of existing licensed capacity, where available, rather than new, large scale freestanding construction;

(g) Relative ease of reconversion of the unit at minimal cost, to other hospital associated use if psychiatric utilization is so low as to necessitate closing the unit;

(h) Smaller size of unit necessary to maintain quality at reasonable cost per treatment, because indirect costs are spread over a larger base; and reduced impact of smaller unit on ability of other, existing units, serving the same population, to maintain quality at reasonable cost per treatment.

(5) Demonstration of need for general psychiatric beds will be population based, rather than facility based. According to Office for Oregon Health Policy and Research studies of actual utilization in Oregon, taken together with legislative reduction of the number of inpatient days mandated for coverage under group health insurance policies in Oregon, the "range of need" criteria based on the then available literature and consultant advice, together with existing provisions in this chapter, provide adequate safeguards against overbedding, but the legislative policy requires more stringent standards for demonstration that any proposed beds are the appropriate response to need for psychiatric care. Therefore, there shall be a moderate standard of evidence of need if a project would result in up to .40 beds per 1,000 population in a service area in the third year after the date of the letter of intent; and a high standard, if the result would exceed .40. The bed-to-population ratio shall not be taken, by itself, as evidence justifying a certain number of beds in a service area. In determining need, the division shall take into account and the applicant shall supply, for each factor in subsections (a) to (f) of this section, a numerical, descriptive and analytic response sufficient for the division to take each factor into account:

(a) The historical utilization of psychiatric inpatient beds by persons in the service area involved;

(b) The historical utilization in other Oregon service areas of comparable size, population and characteristics; and

(c) Based on the level of placement criteria developed by the Office for Oregon Health Policy and Research or developed by insurers under ORS 743.556(16)(b), findings that, with limited exceptions based on clinical judgment in individual cases, inpatient beds are needed for immediate, short-range control of symptoms and protection of the patient when less intensive or supportive placement will not suffice; or for immediate, short-range protection of the community;

(d) The major portion of nonstate, nonfederal inpatient stays are expected to be 12 to 15 days. Approximately 10 percent of stays, at most, are expected to be longer term: Seriously disturbed, usually younger, patients for whom the benefits of 30 to 40 days of hospitalization exceed those of brief hospitalization followed by systematic, long-term residential or outpatient care; and a limited number of chronically mentally ill persons who cannot be maintained safely in the community;

(e) Inpatient beds are not considered the major resource for continued treatment of the typical schizophrenic patient, which, according to the literature, is usually most effective and economical when provided in other ways;

(f) Alternatives, as defined in OAR 333-615-0010(1), do not replace necessary inpatient utilization as described in subsections (c), (d) and (e) of this section, but are usually more effective and economical for meeting other needs for mental health treatment and care.

Stat. Auth.: ORS 430.021(3), 430.610(3), 431.120(6), 442.025, 442.315 & 743.556(16)

Stats. Implemented: ORS 431.120(6) & 442.315

Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-615-0030
Estimates of Need

The following methods are applicable to the interpretation of OAR 333-580-0040(1):

(1) Based on OAR 333-615-0020(1), service areas for general psychiatric beds shall be identified as follows:

(a) Geographic service areas for general acute, nonsubspecialty psychiatric beds, other than those directly operated by the state Addictions and Mental Health Division or the federal Veterans' Administration, may be less than an entire health service are in order to maximize access provided there is sufficient projected population in the third year after the date of the letter of intent to make possible an economically feasible inpatient unit of acceptable quality, low capital cost and low operating costs. Thus, for example in health service area I, Clatsop-Columbia-Tillamook could be considered separately from Multnomah-Washington-Clackamas. Within a given health service area, all service areas shall be defined at one time, rather than proceeding application by application;

(b) The service areas described in subsection (a) of this section shall in general consist of single state administrative districts, or combinations of such areas. Available patient origin data may be interpreted by the division and taken into account in adding or deleting minor portions of such areas, or in combining districts. The division shall consider whether a lesser area, or a combination of areas, will better serve the policies and principles of this division; whether there are, or will be, enough clinicians in practice to staff the program; and whether there will be sufficient diversity of staff to meet the needs of the service area. The geographical units on which general psychiatric inpatient service areas shall be based will be the 14 state administrative districts, which are as follows:

(A) In health service area I: Clatsop-Columbia-Tillamook; Multnomah-Washington-Clackamas;

(B) In health service area II: Marion-Polk-Yamhill; Benton-Linn-Lincoln; Lane; Douglas; Coos-Curry; Jackson-Josephine;

(C) In health service area III: Hood River-Sherman-Wasco; Crook-Deschutes-Jefferson; Klamath-Lake; Gilliam-Grant-Morrow-Umatilla-Wheeler; Baker-Union-Wallowa; Harney-Malheur.

(c) The service areas identified in subsection (b) of this section shall be used for population-based review, as required by state and federal law. The methods of this division are intended to assure that population needs are met by the service or services within the service area. Different facilities within a given service area share the responsibility for meeting the needs of the population of that area;

(d) Based on OAR 333-615-0020(2), the geographic service areas for subspecialty psychiatric beds, other than those directly operated by the state Addictions and Mental Health Division or the federal Veterans' Administration, as defined in OAR 333-615-0010(2), other than holding rooms, shall be the state as a whole;

(e) The geographic service areas for holding rooms shall be determined by the division on a case-by-case basis;

(f) Clinicians in each part of the state are encouraged to work with prospective applicants to develop proposals which meet the general psychiatric inpatient needs of individual service areas and/or subspecialty service areas.

(2) Need for beds per 1,000 population in the service area shall be evaluated in relation to availability of alternatives according to the following criteria. A complete description of all alternatives under subsection (a) or (b) of this section means more than a list; it means at least, for each type of alternative listed in OAR 333-615-0010(1), an inventory with provider names, addresses, bed or slot capacity, and occupancy or utilization averages for each of the past several years:

(a) If a proposed project would result in up to .40 beds, other than those directly operated by the state Addictions and Mental Health Division or the federal Veterans' Administration, per 1,000 population in the third year following the date of the letter of intent, a complete description of all alternatives, as defined in OAR 333-615-0010, available in the service area shall be required; there shall be substantial evidence that appropriate existing alternatives in the service area will be fully utilized; there shall be substantial evidence that further development of alternatives by the applicant is not feasible; and there shall be substantial evidence that further development of less costly or more effective alternatives by any other prospective provider is not feasible. In addition, with respect to the proposed project itself, there shall be substantial evidence that project design and program alternatives have been considered and evaluated comparatively, with the least costly one selected that will meet identified need without substantial adverse impact on the quality of patient care;

(b) If the consequence of approval of a project would be in excess of .40 beds per 1,000 population in the third year following the date of the letter of intent, evidence submitted by the applicant shall:

(A) Demonstrate an average occupancy of applicant's existing capacity, if any, in excess of the appropriate criterion in **Table 1**, based on the method in section (3) of this rule, for the year ending September 30 prior to the formal application; and

(B) Be comprehensive with respect to the availability and feasibility of appropriate alternatives by meeting the requirements of subsection (a) of this section.

(c) The division may take into account evidence with respect to problems of quality or cost in other units serving the area in evaluations under subsection (b) of this section;

(d) In future years, by amendment of this rule, the division may raise the population-based limit at the same time as programmed decreases in utilization of state and federal beds serving the service area take place. This, however, may not be necessary if alternatives become more available and the scope of reimbursement is expanded. Because of the factors cited in OAR 333-615-0020(5), it may be appropriate, in future years, to reduce the population-based limit.

(3) When expansion of an existing unit is under consideration, an allowance for peak-to-average utilization ratios may be made:

(a) An average bed utilization consistent with the principles and methods of this division shall be evaluated for peak bed need by applying to the anticipated average census, a formula taking into account the anticipated peak demand, allowing for greater peak-to-average ratios for smaller units;

(b) The average census entered into the formula shall be consistent with the principles and methods of this division and justified by the applicant on the basis of historical utilization from the service area and any reasonably anticipated growth in the population at risk;

(c) The method to be used should be analogous to that found in OAR 333-590-0050, except that the standard deviation is estimated by raising the anticipated average census to the 0.468 power rather than taking its square root (the 0.500 power). The standard deviation is then multiplied by a factor of 2.06 (7.30 days/year at or above 100 percent occupancy) for units in service areas with other, interacting units, or a factor of 2.33 (3.65 days/year at or above 100 percent occupancy) or a unit which is the only one in its service area, or which can be shown not to interact with others in its service area;

(d) The results of calculations according to this method, for a range of values are shown in **Table 1**;

(e) The calculation in subsection (c) of this section does not take into account the extent to which elective admissions could be postponed, so as to smooth out the variations and reduce the peak-to-average ratio. This calculation only sets an upper limit of peak bed need for a given average bed need;

(f) The division will not automatically approve an application requesting the peak needs indicated by the formula without examining the schedulability of the proposed case load and the commitment to scheduling on the part of the applicant.

(4) General considerations applicable to review of need for psychiatric inpatient beds include the following:

(a) As with hospital inpatient beds in general and in other specialties, new psychiatric beds, whether general or subspecialty, except under unusual circumstances with respect to nonavailability, access and less costly alternatives, shall not be approved if the net effect of the project would be additional licensed short-term acute inpatient capacity (other than state Addictions and Mental Health Division operated or federal hospital beds) in the psychiatric

service area, unless additional acute hospital beds are justified in that area by the criteria for acute inpatient beds in division 590 of this chapter. The principles and methods in division 590 shall apply in reviewing applications for psychiatric beds to the extent that the issues involved are not addressed in this division;

(b) Unusual circumstances shall be determined in relation to an evaluation of the feasibility of meeting service area needs by the higher priority methods indicated in OAR 333-615-0040;

(c) Review of subspecialty beds other than chemical dependency inpatient beds, holding rooms, and freestanding mental health emergency centers shall take into account historical service area utilization and substantiated projections, rather than according to the population-based criteria for general psychiatric beds in this rule. The service areas for subspecialty beds are defined in subsections (1)(d) and (e) of this rule. Need for subspecialty units shall be evaluated with respect to population-based need; availability of existing capacity in the service area; effect on viability of existing quality providers; and proposed size of the unit in relation to economies of scale;

(d) Chemical dependency inpatient beds shall be reviewed according to the principles and methods of division 600 of this chapter;

(e) Need for holding rooms and freestanding mental health emergency centers shall be evaluated in relation to local considerations of access, demand and feasibility.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 431.120(6) & 442.315

Stats. Implemented: ORS 431.120(6) & 442.315

Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-615-0040

Availability of Alternative Uses for Resource

The following principles shall be applicable to the interpretation of OAR 333-580-0050(1) and (2). The term "quality unit" is explained in OAR 333-615-0050:

(1) The methods of meeting acute psychiatric bed need, in order of preference, shall be:

(a) Conversion of existing licensed space to purposes of psychiatric treatment where such conversion is feasible to provide an adequate inpatient program at less cost than building new licensed space, especially when the average daily census for the facility as a whole for the most recent year ending September 30, converted to expected peak occupancy under the methods of OAR 333-590-0050(8) and (9), does not exceed the current licensed number of beds at the facility;

(b) A project resulting in the smallest feasible net increase in acute licensed capacity within an existing general hospital or specialty hospital license, especially when the average daily census to the facility as a whole, for the most recent year ending September 30, converted to expected peak occupancy under the methods of OAR 333-590-0050(8) and (9), equals or exceeds the current licensed number of beds at the facility;

(c) A separately licensed new psychiatric hospital, not part of a general hospital, that will provide adequate psychiatric inpatient care at the most reasonable charges per day and per spell of treatment, for care that must be rendered on an inpatient basis, taking into consideration the factors in OAR 333-615-0000(2).

(2) A proposed psychiatric inpatient bed project shall be related to alternatives, as defined in OAR 333-615-0010(1), with preference given in the following order:

(a) Projects which include development of alternative care resources as part of the project, if an unmet need for such resources in the service area is demonstrated;

(b) Projects for which formal arrangements, together with triage criteria and mechanisms, are documented in the application with respect to all levels of low cost alternative care resources listed in OAR 333-615-0010(1). Documentation of triage criteria and mechanisms should include discussion of the relation of such criteria to the level of placement criteria developed by the Office of Health Policy and insurers under ORS 743.556(16)(b). Applicants should show that their triage criteria and mechanisms will be consistent with such level of care screening criteria.

(3) If, in the service area defined in OAR 333-615-0030(1), there does not exist a quality unit of minimum economically viable size, sections (1) and (2) of this rule apply.

(4) If, in the service area defined in OAR 333-615-0030(1), there does exist one quality unit, and its occupancy (from the designated service area) is above the appropriate criterion in **Table 1** for the year ending September 30 preceding the formal application, and available private acute beds do not exceed the interim population-based limit indicated in OAR 333-615-0030(2), a minimum economically viable increment may be needed. In addition to sections (1) and (2) of this rule, the following options will be considered, in order of preference:

(a) The existing quality unit may be expanded;

(b) An additional unit in the service area may be developed, provided that considerations of cost, access and quality outweigh the estimated economic advantages, if any, of expansion of the existing unit.

(5) If, in the service area defined in OAR 333-615-0030(1), there exist two or more units, sections (1), (2) and (4) of this rule apply, preference being given to expansion of the highest quality existing unit unless consideration of the factors in subsection (4)(b) of this rule leads to preference for an additional unit.

(6) In evaluating the relationship of any proposed project to the existing health care system of the service area, the division shall address possible compromising of quality of care. The division shall consider the conformity to state safety and program standards of both the proposed project and existing, related health services now provided to the population of the service area; the impact of the project, once completed and operational, upon the financial ability of providers of related services to maintain present quality; and the feasibility that the proposed project will be sufficiently efficient to maintain quality standards at reasonable cost. Impact on total community health care costs, not merely charges per day or charges per stay, shall be considered.

[ED. NOTE: Tables referenced are available from the agency.]

Stat. Auth.: ORS 431.120(6), 442.315 & 743.556(16)

Stats. Implemented: ORS 431.120(6) & 442.315

Hist.: HD 13-1994, f. & cert. ef. 4-22-94

333-615-0050

Quality and Costs

All proposed psychiatric beds must meet the licensure, certification and accreditation criteria of the Public Health Division, Medicare and the Joint Commission on on Accreditation of Healthcare Organizations, as appropriate. "Quality" for purposes of review of certificate of need proposals is a description of threshold factors to be considered, not a presumption of clinical judgment, nor a substitute for the licensing or accreditation functions. A proposal for a quality psychiatric unit shall include explicit policies, and specific examples and detail regarding each factor below:

(1) Triage criteria and mechanisms, including documentation that such criteria and mechanisms will be consistent with the level of placement criteria developed by the Office of Health Policy and insurers under ORS 743.556(16)(b);

(2) Data and record systems;

(3) Length of stay related to treatment goals, and averaging no more than 15 days for treatment of adults;

(4) Nonmaintenance, high-level treatment goals beyond mere restoration to the level just permitting release;

(5) Low recidivism; compare to data available;

(6) Rates which reflect low capital and operating costs and a justifiable rate of return; and

(7) Rapid access to quality general and multispecialty medical inpatient care.

Stat. Auth.: ORS 431.120(6), 442.315 & 743.556(16)

Stats. Implemented: ORS 431.120(6) & 442.315

Hist.: HD 13-1994, f. & cert. ef. 4-22-94

DIVISION 645

DEMONSTRATION OF NEED FOR REHABILITATION SERVICES

333-645-0000
General

(1) The purpose of this division is to assure provision of accessible, quality care with the least incremental impact in overall community health care costs. Rehabilitation services assist people with a wide range of physical disabilities, focused on gaining optimum mobility and functioning. Least costly alternatives will be considered in determining an appropriate level of care.

(2) The applicant, in providing information to the Public Health Division to demonstrate need for inpatient rehabilitation services, must satisfy the criteria specified in the Certificate of Need Application Instructions (division 580) and in this division (division 645).

(3) Division 645 is not intended to apply to rehabilitation beds in long-term care facilities.

Stat. Auth.: ORS 431.120(6) & 442.315
Stats. Implemented: ORS 431.120(6) & 442.315
Hist.: HD 13-1994, f. & cert. ef. 4-22-94