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CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILING CAPTION: Miscellaneous Corrections, Supervised Physician Assistants Fluoroscopic Operations, and Licensed Dental Therapist Operating X-ray Devices

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AMEND: 333-106-0005

RULE TITLE: Definitions

NOTICE FILED DATE: 06/27/2022

RULE SUMMARY: OAR 333-106-0005 is amended to define the term dental therapist. This rule is amended to be compatible with ORS 679.603, dental therapy license.

RULE TEXT:
As used in this division, the following definitions apply:
(1) "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.
(2) "Added filtration" means any filtration that is in addition to the inherent filtration.
(3) "Advanced practice registered nurse (APRN)" means a clinical nurse specialist, certified nurse anesthetist, or nurse practitioner licensed or state certified by the Oregon State Board of Nursing.
(4) "Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

NOTE: The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

(5) "Applications training" means a vendor or manufacturer providing training for specific X-ray equipment.
(6) "A.R.R.T." means the American Registry of Radiologic Technologists.
(7) "Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an X-ray system or subsystem. The term includes the owner of an X-ray system or his or her employee or agent who assembles components into an X-ray system that is subsequently used to provide professional or

commercial services.
(8) "Attenuation block" means a block or stack, having dimensions 20 centimeters (cm) by 20 cm by 3.8 cm, of type 1100 aluminum alloy or other materials having equivalent attenuation.
(9) "Authority approved instructor" means an individual who has been evaluated and approved by the Authority to teach radiation safety.
(10) "Authority approved training course" means a course of training that has been evaluated and approved by the Authority.
(11) "Automatic exposure control (AEC)" means a device that automatically controls one or more technique factors in order to obtain at a pre-selected location(s) a required quantity of radiation. (See also "Photo timer".)
(12) "Barrier" (see "Protective barrier").
(13) "Beam axis" means a line from the source through the centers of the X-ray fields.
(14) "Beam-limiting device" means a device that provides a means to restrict the dimensions of the X-ray field.
(15) "Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.
(16) "C-arm X-ray system" means an X-ray system in which the image receptor and X-ray tube housing are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.
(17) "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.
(18) "Certified components" means components of X-ray systems that are subject to the X-ray Equipment Performance Standards promulgated under Public Law 90-602, the Radiation Control Agency for Health and Safety Act of 1968.
(19) "Certified system" means any X-ray system that has one or more certified component(s).
(20) "Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical or physical process.
(21) "Coefficient of variation (C)" means the ratio of the standard deviation to the mean value of a set of observations.
(22) "Computed tomography (CT)" means the production of a tomogram by the acquisition and computer processing of X-ray transmission data.
(23) "Computed radiography (CR)" means creating an X-ray image using plates consisting of a photo stimulable phosphor (PSP) that when exposed to radiation and then processed by a scanner, provides the information to a computer for display and manipulation.
(24) "Contact therapy system" means an X-ray system used for therapy with the tube port placed in contact with or within five centimeters of the surface being treated.
(25) "Control panel" means that part of the X-ray control upon which are mounted the switches, knobs, pushbuttons and other hardware necessary for manually setting the technique factors.
(26) "Cooling curve" means the graphical relationship between heat units stored and cooling time.
(27) "Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.
(28) "Dental therapist" means a person licensed to practice dental therapy under ORS 679.603.
(29) "Detector" (see "Radiation detector").
(30) "Diagnostic X-ray imaging system" means an assemblage of components for the generation, emission, and reception of X-rays and the transformation, storage, and visual display of the resultant X-ray image.
(31) "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.
(32) "Diagnostic-type protective tube housing" means a tube housing so constructed that the leakage radiation measured at a distance of one meter from the source does not exceed 100 milliroentgens (mR) in one hour when the tube is operated at its leakage technique factors.
(33) "Diagnostic X-ray system" means an X-ray system designed for irradiation of any part of the human body or animal body for the purpose of diagnosis or visualization.

(34) "Direct digital radiography (DR)"" means creating an X-ray image by sending signals directly from a digital image receptor to a computer for display and manipulation.
(35) "Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (see "Scattered radiation").
(36) "Entrance exposure rate" means the exposure free in air per unit of time.
(37) "Field emission equipment" means equipment which uses a tube in which electron emission from the cathode is due solely to the action of an electric field.
(38) "Filter" means material placed in the useful beam to absorb preferentially selected radiations.
(39) "Fluoroscopic benchmark" means a standard based upon the average cumulative fluoroscopic on-time normally found to be used for a specific fluoroscopic procedure at the site.
(40) "Fluoroscopic imaging assembly" means a subsystem in which X-ray photons produce a visible image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.
(41) "Fluoroscopic X-ray equipment operator" means any individual who, adjusts technique factors, activates the exposure switch or button of a fluoroscopic X-ray machine or physically positions patients or animals. Human holders, used solely for immobilization purposes (example being veterinarian human holders) are excluded from this rule.
(42) "Focal spot" means the area projected on the anode of the tube by the electrons accelerated from the cathode and from which the useful beam originates.
(43) "General purpose radiographic X-ray system" means any radiographic X-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.
(44) "Half-value layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.
(45) "Healing arts screening" means the testing of human beings using X-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by an Oregon licensed practitioner of the healing arts legally authorized to prescribe such X-ray tests for the purpose of diagnosis or treatment.
(46) "Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes and seconds, example being kVp x mA x second.
(47) "HVL" (see "Half-value layer").
(48) "Image intensifier" means a device, installed in its housing, which instantaneously converts an X-ray pattern into a corresponding light image of higher energy density.
(49) "Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident photons either into a visible image or into another form which can be made into a visible image by further transformations.
(50) "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.
(51) "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.
(52) "Irradiation" means the exposure of matter to ionizing radiation.
(53) "Kilovolt-peak" (see "Peak tube potential").
(54) "kV" means kilovolts.
(55) "kVp" (see "Peak tube potential").
(56) "kWs" means kilowatt second.
(57) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.
(58) "Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly except for:
(a) The useful beam; and

(b) Radiation produced when the exposure switch or timer is not activated.
(59) "Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:
(a) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, example being 10 milliampere seconds (mAs), or the minimum obtainable from the unit, whichever is larger.
(b) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of X-ray pulses in an hour for operation at the maximum-rated peak tube potential.
(c) For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.
(60) "Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.
(61) "Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential.
(62) "mA" means milliampere.
(63) "mAs" means milliampere second.
(64) "Maximum line current" means the root-mean-square current in the supply line of an X-ray machine operating at its maximum rating.
(65) "Mobile equipment" (see "X-ray equipment").
(66) "Non-radiologist practitioner" means an individual who practices medicine as a medical doctor (M.D.), doctor of osteopathic medicine (D.O), doctor of chiropractic medicine (D.C.), doctor of podiatric medicine (D.P.M.) or doctor of veterinary medicine (D.V.M.); and
(a) Are not specifically certified in diagnostic or therapeutic use of X-rays; and
(b) Are currently licensed by their respective Oregon licensing board.
(67) "Operator" means an individual who, under the supervision of a practitioner of the healing arts, handles ionizing radiation equipment, physically positions patients or animals, determines exposure parameters or applies the radiation for the diagnostic or therapeutic purposes intended.
(68) "Patient" means an individual subjected to healing arts examination, diagnosis, or treatment.
(69) "Peak tube potential" means the maximum value of the potential difference across the X-ray tube during an exposure.
(70) "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.
(71) "Photo timer" means a method for controlling radiation exposures to image receptors by measuring the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is a part of an electronic circuit which controls the duration of time the tube is activated (see also "Automatic exposure control").
(72) "PID" (see "Position indicating device").
(73) "Portable equipment" (see "X-ray equipment").
(74) "Position indicating device" means a device on dental X-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.
(75) "Primary dose monitoring system" means a system which will monitor useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been acquired.
(76) "Primary protective barrier" (see "Protective barrier").
(77) "Protective apron" means an apron made of radiation absorbing materials used to reduce radiation exposure.

(78) "Protected area" means an area shielded with primary or secondary protective barriers or an area removed from the radiation source such that the exposure rate within the area due to normal operating procedures and workload does not exceed any of the following limits:
(a) 2 milliroentgens (mR) in any one hour; or
(b) 100 mR in any one year.
(c) See OAR 333-120-0180 for additional information.
(79) "Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:
(a) "Primary protective barrier" means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure;
(b) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.
(80) "Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.
(81) "Qualified expert" means an individual, approved by the Authority, who has demonstrated, pursuant to these rules, that he/she possesses the knowledge, skills, and training to measure ionizing radiation, to evaluate radiation parameters, to evaluate safety techniques, and to advise regarding radiation protection needs. The individual shall:
(a) Be certified in the appropriate field by the American Board of Radiology, the American Board of Health Physics, the American Board of Medical Physics or the American Board of Nuclear Medicine Science; or
(b) Hold a master's or doctor's degree in physics, biophysics, radiological physics, health physics, or medical physics and have completed one year of documented, full time training in the appropriate field and also one year of documented, full time work experience under the general supervision of a qualified expert in the appropriate field. To meet this requirement, the individual shall have performed the tasks required of a qualified expert during the year of work experience; or
(c) Receive approval from the Authority for specific activities.
(82) "Quality control program" means a program directed at film processing and radiographic image quality whereby periodic monitoring of film processing is performed. Test films are compared against control film, either visually or by use of a densitometer, to determine if density or contrast have changed. Steps can then be taken to investigate such change and correct the problem. The X-ray machine itself can also be involved in the quality control program, as can other components of the imaging chain.
(83) "Radiation detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.
(84) "Radiation therapy simulation system" means a radiographic or fluoroscopic system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.
(85) "Radiograph" means an image receptor on which the image is created directly or indirectly by a pattern and results in a permanent record.
(86) "Radiographic imaging system" means any system whereby a permanent or semipermanent image is recorded on an image receptor by the action of ionizing radiation.
(87) "Radiological physicist" means an individual who:
(a) Is certified by the American Board of Radiology in therapeutic radiological physics, radiological physics, or x- and gamma-ray physics; or
(b) Has a bachelor's degree in one of the physical sciences or engineering and three years full-time experience working in therapeutic radiological physics under the direction of a physicist certified by the American Board of Radiology. The work duties must include duties involving the calibration and spot checks of a medical accelerator or a sealed source teletherapy unit; or
(c) Has a master's or a doctor's degree in physics, biophysics, radiological physics, health physics, or engineering; has had one year's full-time training in therapeutic radiological physics; and has had one year's full-time work experience in a radiotherapy facility where the individual's duties involve calibration and spot checks of a medical accelerator or a sealed source teletherapy unit.

(88) "Radiologist" or "oral radiologist" means a physician or dentist trained in the diagnostic use of X-rays and who is;
(a) Currently licensed by their respective Oregon licensing board; and
(b) Board certified by the American Board of Radiology (ABR) or American Osteopathic Board of Radiology (AOBR) or American Chiropractic Board of Radiology (DACBR) or Royal College of Physicians and Surgeons of Canada (RCPSC) or the American Board of Oral and Maxillo-Facial Radiology (ABOMFR) and currently licensed to practice medicine or dentistry in Oregon; or
(c) ABR board eligible after successfully completing the Accreditation Council for Graduate Medical Education accredited diagnostic radiology residency program.
(89) "Radiology physician's assistant" (R.P.A.)/ "registered radiology assistant" (R.R.A.).
(a) An R.P.A. means an American Registry of Radiologic Technologists (A.R.R.T.) technologist who has successfully completed an advanced training program and is certified by the Certification Board for Radiology Practitioner Assistants (CBRPA).
(b) An R.R.A means an A.R.R.T. technologist who has successfully completed an advanced training program and is certified by A.R.R.T.
(90) "R.T." means a radiologic technologist certified in radiography and currently licensed by the Oregon Board of Medical Imaging.
(91) "Rating" means the operating limits as specified by the component manufacturer.
(92) "Recording" means producing a permanent form of an image resulting from X-ray photons.
(93) "Registrant," as used in this division, means any person who owns or possesses and administratively controls an X-ray system which is used to deliberately expose humans, animals or materials to the useful beam of the system and is required by the provisions contained in divisions 100 and 101 of this chapter to register with the Authority.
(94) "Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero, sufficient to provide a steady state midscale reading.
(95) "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (see "Direct scattered radiation").
(96) "Screening" means the use of a systematic approach to obtain cursory examinations of a person or group of persons without regard to specific clinical indications.
(97) "Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system.
(98) "Secondary protective barrier" (see "Protective barrier").
(99) "Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.
(100) "SID" (see "Source-image receptor distance").
(101) "Source" means the focal spot of the X-ray tube.
(102) "Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.
(103) "Spot check" means a procedure which is performed to assure that a previous calibration continues to be valid.
(104) "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.
(105) "Spot-film device" means a device intended to transport or position a radiographic image receptor between the X-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.
(106) "SSD" means the distance between the source and the skin of the patient.
(107) "Stationary equipment" (see "X-ray equipment").
(108) "Stray radiation" means the sum of leakage and scattered radiation.
(109) "Supervision" means the supervising individual routinely reviews and monitors the work being performed. There

are three categories of supervision:
(a) "General supervision" means that the supervisor is not required to be on-site, but must be available for direct communication, either in person, by telephone, or other electronic means.
(b) "Direct supervision" means that the supervisor is physically present in the building and immediately available to furnish assistance as needed.
(c) "Personal supervision" means that the supervisor is physically present in the room during the performance of the procedure at all times.
(110) "Technique factors" means the conditions of operation. They are specified as follows:
(a) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
(b) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of X-ray pulses;
(c) For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.
(111) "Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.
(112) "Traceable to a national standard" means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.
(113) "Tube" means an X-ray tube, unless otherwise specified.
(114) "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and filament transformers and other appropriate elements when such are contained within the tube housing.
(115) "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.
(116) "Unprotected area" means any area in which the exposure rate, due to the use of the radiation machine under normal operating procedures and workload, exceeds any of the following limits:
(a) Two mR in any one hour;
(b) 100 mR in any seven consecutive days; or
(c) 500 mR in any one year.
(117) "Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the system to produce radiation.
(118) "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the X-ray field size at a given SID.
(119) "Visible area" means that portion of the input surface of the image receptor over which the incident X-ray photons are producing a visible image.
(120) "Wedge filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.
(121) "X-ray control" means a device which controls input power to the X-ray high-voltage generator and the X-ray tube. It includes equipment such as exposure switches (control), timers, photo timers, automatic brightness stabilizers and similar devices, which control the technique factors of an X-ray exposure.
(122) "X-ray equipment" means an X-ray system, subsystem, or component thereof. Types of equipment are as follows:
(a) "Mobile equipment" means X-ray equipment mounted on a permanent base with wheels and casters for moving while completely assembled and intended to be taken from one geographical location to another or from one room to another;
(b) "Portable equipment" means X-ray equipment designed to be hand-carried but not hand-held during operations.
(c) "Stationary equipment" means X-ray equipment which is installed in a fixed location; such as bolted to the floor or wall;
(d) "Transportable" means X-ray equipment installed in a vehicle or trailer;
(e) "Hand-held unit" means a self-contained X-ray machine designed so that it can be held in one or two hands to

perform intra-oral radiography or other Authority approved radiography.
(123) "X-ray equipment operator" means any individual who handles, adjusts technique factors, activates the exposure switch/ or button of an X-ray machine, or physically positions patients or animals for a radiograph (see "Operator").
(124) "X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.
(125) "X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the X-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the X-ray tube(s), high-voltage switches, electrical protective devices and other appropriate elements.
(126) "X-ray system" means an assemblage of components for the controlled production of X-rays. It includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.
(127) "X-ray subsystem" means any combination of two or more components of an X-ray system for which there are requirements specified in this division.
(128) "X-ray tube" means any electron tube which is designed to be used primarily for the production of X-rays.

STATUTORY/OTHER AUTHORITY: ORS 453.605 - 453.807

STATUTES/OTHER IMPLEMENTED: ORS 453.605 - 453.807

AMEND: 333-106-0055

RULE TITLE: General Requirements: X-ray Operator Training

NOTICE FILED DATE: 06/27/2022

RULE SUMMARY: OAR 333-106-0055 is amended to allow a dental therapist licensed by the Oregon Board of Dentistry to operate dental X- Ray equipment and supervise radiology students to operate dental X-ray equipment. This rule is amended to be compatible with ORS 679.621, scope of practice, authority of dental therapist to supervise.

RULE TEXT:

(1) The registrant shall assure that individuals who will be operating the X-ray equipment by physically positioning patients or animals, determining exposure parameters, or applying radiation for diagnostic purposes shall have adequate training in radiation safety.

(a) Radiation safety training records shall be maintained by the registrant for each individual who operates X-ray equipment. Records must be legible and meet the requirements in OAR 333-120-0690.

(b) When requested by the Authority, radiation safety training records shall be made available.

(2) Dental X-ray operators who meet the following requirements are considered to have met the requirements in section (1) of this rule:

(a) Currently licensed by the Oregon Board of Dentistry as a dentist, dental therapist, or dental hygienist; or

(b) Is a dental assistant who is certified by the Oregon Board of Dentistry in radiologic proficiency.

(c) Dental radiology students in an approved Oregon Board of Dentistry dental radiology course are permitted to take dental radiographs on human patients during their clinical training, under the direct supervision of a dentist, dental therapist, or dental hygienist currently licensed, or a dental assistant who has been certified in radiologic proficiency by the Oregon Board of Dentistry.

(3) Veterinary X-ray operators who meet the following requirements are considered to have met the requirements in section (1) of this rule:

(a) Currently licensed by the Oregon Veterinary Medical Examining Board as a veterinarian or a certified veterinary technician.

(b) Veterinary students enrolled in a radiology course approved by the Oregon Veterinary Medical Examining Board are permitted to take radiographs on animal patients during their clinical training under the direct supervision of a veterinarian or a certified veterinary technician who is currently licensed.

(4) Diagnostic medical X-ray operators who meet the following requirements are considered to have met the requirements of section (1) of this rule:

(a) Holds a current license from the Oregon Board of Medical Imaging; or

(b) Holds a current limited X-ray machine operator permit from the Oregon Board of Medical Imaging; or

(c) Is a student in an approved school of Radiologic Technology as defined in ORS 688.405 while practicing Radiologic Technology under the direct supervision of a radiologist who is currently licensed with the Oregon Medical Board or a radiologic technologist who is licensed with the Oregon Board of Medical Imaging; or

(d) Is a student in an Oregon Board of Medical Imaging approved limited permit program under a radiologic technologist who is licensed by the Oregon Board of Medical Imaging.

(5) All other types of X-ray operators must have completed an Authority approved radiation use and safety course.

(6) At a minimum, an Authority approved training course shall cover the following subjects:

(a) Nature of X-rays:

(A) Interaction of X-rays with matter;

(B) Radiation units;

(C) X-ray production;

(D) Biological effects of X-rays; and

(E) Risks of radiation exposure.

(b) Principles of the X-ray machine:

(A) External structures and operating console;
(B) Internal structures:
(i) Anode; and
(ii) Cathode.
(C) Operation of an X-ray machine;
(D) Tube warm up;
(E) Factors affecting X-ray emission:
(i) mA;
(ii) kVp;
(iii) Filtration; and
(iv) Voltage waveform.
(c) Principles of radiation protection:
(A) Collimation;
(B) Types of personal protection equipment and who must wear it;
(C) ALARA;
(D) Time, distance, shielding;
(E) Operator safety;
(F) Personal dosimetry:
(i) Types of dosimetry;
(ii) Proper placement of dosimetry; and
(iii) Situations that require dosimetry.
(G) Occupational and non-occupational dose limits.
(d) Radiographic technique:
(A) Factors affecting technique choice:
(i) Thickness of part;
(ii) Body composition;
(iii) Pathology; and
(iv) Film versus computed radiography (CR) and digital radiography (DR).
(B) How to develop an accurate chart;
(C) Low dose techniques;
(D) Pediatric techniques (does not apply to veterinary); and
(E) AEC Techniques.
(e) Darkroom:
(A) Safelights;
(B) Chemical storage;
(C) Film storage; and
(D) Darkroom cleanliness.
(f) Image processing:
(A) Automatic film processing;
(B) Dip tank film processing;
(C) Computed radiography (CR) processing; and
(D) Digital radiography (DR) processing.
(g) Image critique:
(A) Reading room conditions;
(B) Light box conditions;
(C) Image identification;
(D) Artifacts;

(E) Exposure indicators for CR and DR;
(F) Technical parameter evaluation; and
(G) Positioning evaluation.
(h) Veterinary X-ray use (for veterinary courses only):
(A) Types of animal restraints;
(B) Small animal versus large animal;
(C) Film holders; and
(D) Portable X-ray machine safety.
(i) Applicable federal and state radiation regulations including those portions of chapter 333, divisions 100, 101, 103, 106, 111, 120, and 124.
(7) In addition to the training outlined in section (6) of this rule, medical X-ray equipment operators using diagnostic radiographic equipment on human patients, and who are not regulated by the Oregon Board of Medical Imaging, must have 100 hours or more of instruction in radiologic technology including, but not limited to:
(a) Anatomy physiology, patient positioning, exposure and technique; and
(b) Appropriate types of X-ray examinations that the individual will be performing; and in addition
(c) Receive 200 hours or more of X-ray laboratory instruction and practice in the actual use of an energized X-ray unit, setting techniques and practicing positioning of the appropriate diagnostic radiographic procedures that they intend to administer.
(8) All X-ray operators shall be able to demonstrate competency in the safe use of the X-ray equipment and associated X-ray procedures.
(9) When required by the Authority, applications training must be provided to the operator before use of X-ray equipment on patients.
(a) Records of this training must be maintained and made available to the Authority for inspection.
(b) The training may be in any format such as hands-on training by a manufacturer’s representative, video or DVD instruction, or a training manual.
(10) X-ray equipment operators who have received their radiation safety training outside of Oregon will be considered to have met the training requirements in section (5) of this rule, if the Authority's or applicable Oregon Licensing Board's evaluation of their training or training and experience, reveals that they substantially meet the intent of section (6) of this rule.

STATUTORY/OTHER AUTHORITY: ORS 453.605 - 453.807

STATUTES/OTHER IMPLEMENTED: ORS 453.605 - 453.807

AMEND: 333-106-0060

RULE TITLE: General Requirements: Radiation Use and Safety Instructor Qualifications

NOTICE FILED DATE: 06/27/2022

RULE SUMMARY: OAR 333-106-0060 is amended to change Dentist and Hygienist to dentist and hygienist because these terms do not need to be capitalized in OAR.

RULE TEXT:

The training required in OAR 333-106-0055(1) must be taught by an Authority approved instructor. Approval will be based upon the following criteria.

(1) A medical use and safety instructor is an individual who is currently:

(a) Licensed as a Radiologic Technologist and approved as an education provider by the Oregon Board of Medical Imaging; or

(b) A dental radiation use and safety instructor is an individual who is currently licensed by the Oregon Board of Dentistry as a dentist, hygienist, or has been approved by the Oregon Board of Dentistry as a radiation use and safety instructor.

(2) A veterinarian radiation use and safety instructor is an individual who is currently:

(a) Licensed by the Oregon Veterinary Medical Examining board as a Veterinarian, or a Veterinary Technician; or

(b) Is currently licensed as a Radiologic Technologist by the Oregon Board of Medical Imaging, and has completed training specific to veterinarian radiography, including training in animal restraint, and has a minimum of two years of experience in taking veterinary radiographs.

(3) On a case by case basis, if an evaluation by the Authority reveals the individual has alternative qualifications that are substantially equivalent to the qualifications listed in subsections (1)(a), (1)(b), (2)(a) or (2)(b) of this rule or is an individual who is qualified under OAR 333-106-0005(80) as a qualified expert, or OAR 333-101-0230 as a Hospital Radiology Inspector.

STATUTORY/OTHER AUTHORITY: ORS 453.605 – 453.807

STATUTES/OTHER IMPLEMENTED: ORS 453.605 – 453.807

AMEND: 333-106-0205

RULE TITLE: Fluoroscopic X-ray Systems Requirements: Activation of the Fluoroscopic Tube

NOTICE FILED DATE: 06/27/2022

RULE SUMMARY: OAR 333-106-0205 is amended to allow a physician assistant to operate a fluoroscopic X-ray device without supervision when a Collaborative Practice Agreement has been established with their employer. This rule was amended to be compatible with ORS 688.510, certificate to practice fluoroscopy.

RULE TEXT:

(1) X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(2) Proper training in the operation of fluoroscopic X-ray equipment is required for all operators and shall include but not be limited to the following:

(a) Principles and operation of the fluoroscopic X-ray machine:

(A) Generating X-rays;

(B) kVp and mA;

(C) Image intensification;

(D) High level control versus standard operating mode;

(E) Magnification (multi-field);

(F) Automatic Brightness Control (ABC);

(G) Pulsed versus continuous X-ray dose rates;

(H) Image recording modes;

(I) Imaging Systems (TV and Digital); and

(J) Contrast, noise and resolution.

(b) Radiation units:

(A) Traditional units;

(B) SI units; and

(C) Dose Area Product.

(c) Typical fluoroscopic outputs:

(A) Patient skin entrance dose;

(B) Standard Roentgen per minute (R/min) dose rates; and

(C) High level/Boost enable Roentgen per minute (R/min) dose rates.

(d) Dose reduction techniques for fluoroscopy:

(A) Collimation;

(B) X-ray tube and image intensifier placement;

(C) Patient size versus technique selection;

(D) Grid use;

(E) Last image hold;

(F) Additional beam filtration;

(G) Gantry angles;

(H) Use of spacer cone; and

(I) Pulsed fluoroscopy.

(e) Factors affecting personnel dose:

(A) Patient dose;

(B) Scatter radiation;

(C) Tube and image intensifier placement; and

(D) Time, distance and shielding.
(f) Protective devices:
(A) Lead aprons and gloves;
(B) Thyroid collars;
(C) Protective glasses;
(D) Leaded drapes;
(E) Bucky slot cover; and
(F) Protective shields/barriers.
(g) Radiation exposure monitoring:
(A) Personnel monitors;
(B) Placement of personnel monitors; and
(C) Occupational and non-occupational dose limits.
(h) Biological effects of X-ray radiation:
(A) X-rays and particulate matter;
(B) Absorption variables (field size, dose rate, as an example);
(C) Scatter radiation;
(D) Cell sensitivity;
(E) Acute effects; and
(F) Latent effects.
(i) Applicable regulations:
(A) Federal; and
(B) Oregon Administrative Rules for the Control of Radiation to include, but not limited to, chapter 333, divisions 101, 103, 106, 111 and 120.
(3) The following operators are considered to have met the training requirements in section (2) of this rule:
(a) Radiologists currently licensed in Oregon;
(b) Non-radiologist practitioners who have successfully completed a training program from an Authority approved resource that meets section (2) of this rule. or have been operating fluoroscopic equipment prior to April 11, 2005;
(c) Radiologic technologists who have a permanent or temporary license from the Oregon Board of Medical Imaging (OBMI) to practice radiography;
(d) Physician assistants who have a fluoroscopy permit from the Oregon Board of Medical Imaging;
(e) R.P.A.s and R.R.A.s who are licensed by the OBMI; and
(f) Students currently enrolled in an approved school of Radiologic Technology as defined in ORS 688.405.
(4) Supervision requirements for operators of fluoroscopic equipment. The operation of fluoroscopic equipment by properly trained operators must comply with the following supervisory requirements:
(a) Radiologists may operate fluoroscopic equipment with no supervision.
(b) Non-radiologist practitioners who have had proper training in the use and operation of fluoroscopic X-ray equipment may operate fluoroscopic equipment without supervision provided that the registrant arranges to have a radiologist or medical or health physicist assist in:
(A) Developing fluoroscopic and radiation safety policies and procedures;
(B) Conducting an on-site practical evaluation of the non-radiologist practitioner's knowledge of radiation safety practices and ability to operate the fluoroscopic equipment; and
(C) At least annually, review the registrant's fluoroscopy program. The review includes an evaluation of the fluoroscopic on-times Quality Assurance reports, condition of fluoroscopic equipment and compliance with current rules. The registrant shall correct any deficiencies noted by the review.
(c) Radiologic technologists who have a permanent or temporary license from the OBMI to practice radiography may operate fluoroscopic equipment under the personal or direct supervision of a radiologist or a non-radiologist practitioner who has had proper training in the use and operation of fluoroscopic X-ray equipment.

(d) An APRN who has obtained an OBMI Limited Fluoroscopy Supervision Permit may provide personal supervision to radiologic technologists who have a permanent or temporary license issued from the OBMI to operate fluoroscopic equipment.
(e) Physician assistants with fluoroscopy permits may operate fluoroscopy equipment without supervision if they have entered into a collaborative agreement with a physician, podiatric physician or employer.
(f) R.R.A.s or R.P.A.s may operate fluoroscopic equipment under the direct supervision of a radiologist.
(g) Physician assistants licensed with the Oregon Medical Board while completing specific clinical experience pre-requisites to become eligible to take the OBMI fluoroscopy permit examination, may operate fluoroscopy equipment under personal supervision of the physician assistant's supervising physician, licensed radiologist, licensed radiographer or medical physicist.
(h) Students currently enrolled in an approved school of radiologic technology as defined in ORS 688.405, may operate fluoroscopic equipment under the personal supervision of a radiologist or an R.T. while in the clinical phase of training.
(5) The operation of fluoroscopic equipment is restricted to the healing arts exclusively for the purpose of localization and to assist physicians in obtaining images for diagnostic purposes.
(6) Overhead fluoroscopy is not to be used as a positioning tool for radiographic examinations except for those fluoroscopic examinations specified in the registrant's written policies/procedures for fluoroscopy.
(7) All images formed by the use of fluoroscopy shall be viewed, directly or indirectly, and interpreted by a radiologist, cardiologist, non-radiologist practitioner or other qualified specialist. R.R.A.s and R.P.A.s may issue a preliminary report; however, the final report must be issued by their supervising radiologist.
(8) Written procedures for fluoroscopic X-ray equipment operators shall be available at the worksite and include:
(a) A list of all individuals who are permitted to operate fluoroscopic X-ray equipment at the facility;
(b) A list of the fluoroscopic X-ray equipment that each operator is qualified to operate;
(c) Written procedures regarding the set up and operation of each fluoroscopic X-ray machine registered to the facility;
(d) Written radiation safety procedures pertaining to the use and operation of fluoroscopy; and
(e) The name and title of the individual who is responsible for overseeing the fluoroscopy program.
(9) Facilities shall determine, or cause to be determined, the typical patient entrance exposure rate for their most common fluoroscopic examinations. The determination shall be made using an attenuation block as described in OAR 333-106-0005 using measurement protocol in compliance with OAR 333-106-0210 and expressed in Roentgens per minute (R/min.) or milliRoentgens per minute (mR/min.). In addition, these entrance exposure rates shall be posted in the room where fluoroscopic examinations are conducted so that they are readily available to administrators, X-ray operators, patients and practitioners.
(10) Facilities that utilize fluoroscopy shall maintain a record of the cumulative fluoroscopic exposure time used for each examination. The record must indicate the patient's name, the type of examination, the date of the examination, the fluoroscopist's name, the fluoroscopic room in which the examination was done and the total cumulative fluoroscopic on-time for each fluoroscopic examination and:
(a) Established cumulative fluoroscopic on-time benchmarks for at least two (if applicable) of the most common types of fluoroscopic examinations performed at the facility's site in each of the following categories:
(A) Routine procedures performed on adults;
(B) Routine procedures performed on children;
(C) Orthopedic procedures performed in surgery;
(D) Urologic procedures performed in surgery;
(E) Angiographic procedures performed; and
(F) Interventional cardiac studies.
(b) Develop and perform periodic (not to exceed 12 month intervals) quality assurance studies to determine the status of each individual fluoroscopist's cumulative on-time in relation to the fluoroscopic benchmarks established for individual fluoroscopic examinations;
(c) Take appropriate action when the established benchmarks are consistently exceeded. The Radiation Safety

Committee (RSC) must review the results of the cumulative fluoroscopic on-time Quality Assurance Study and take corrective action regarding those individuals who have exceeded the benchmarks established by the facility for a particular procedure more than 10 percent of the total times the individual performed the procedure during the study period. Documentation of the RSC review, as well as any corrective actions taken, must be available for Authority review. Corrective actions, at a minimum, include:
(A) Notification of the individual; and
(B) Recommendation that the individual undergo additional coaching and training in the safe use of fluoroscopic equipment in order to assist them in reducing their cumulative fluoroscopic on-times.

STATUTORY/OTHER AUTHORITY: ORS 453.605 - 453.807

STATUTES/OTHER IMPLEMENTED: ORS 453.605 - 453.807

AMEND: 333-116-0020

RULE TITLE: Definitions

NOTICE FILED DATE: 06/27/2022

RULE SUMMARY: OAR 333-116-0020 is amended to correct the rule reference number from OAR 333-116-0740 to 333-116-0640 and to insert the word “and”.

RULE TEXT:

As used in this division, the following definitions apply:

(1) "Address of use" means the building or buildings identified on the license as the location(s) where radioactive material may be received, used, or stored.

(2) "Area of use" means location(s) at the address of use set aside for the purpose of receiving, using or storing radioactive material.

(3) "Associate Radiation Safety Officer" means an individual who:

(a) Meets the requirements in OAR 333-116-0640 and 333-116-0760; and

(b) Is currently identified as an Associate Radiation Safety Officer for the types of use of byproduct materials for which the individual has been assigned duties and tasks by the Radiation Safety Officer on:

(A) A specific medical use license issued by the Authority, U.S. Nuclear Regulatory Commission, or an Agreement State; or

(B) A medical use permit issued by the U.S. Nuclear Regulatory Commission master material licensee.

(4) "Attestation" means required training, experience and appropriate board certification is validated using the Nuclear Regulatory Commission’s form 313A.

(5) "Authorized Medical Physicist" means an individual who:

(a) Meets the requirements in OAR 333-116-0730, or 333-116-0905 and 333-116-0760; or

(b) Is identified as an authorized medical physicist or teletherapy physicist on:

(A) A specific medical use license issued by the Authority or an Agreement State or the US Nuclear Regulatory Commission;

(B) A medical use permit issued by a Commission master material licensee;

(C) A permit issued by a Commission or Agreement State broad scope medical use licensee; or

(D) A permit issued by a Commission master material license broad scope medical use permittee.

(6) "Authorized nuclear pharmacist" means a pharmacist who:

(a) Meets the requirements in OAR 333-116-0910.

(b) Is identified as an authorized nuclear pharmacist on an Authority, Agreement State, or U.S. Nuclear Regulatory Commission license that authorizes the use of radioactive material in the practice of nuclear pharmacy;

(c) Is identified as an authorized nuclear pharmacist on a license issued by an Authority, Agreement State, or U.S. Nuclear Regulatory Commission specific licensee of broad scope that is authorized to permit the use of radioactive material in the practice of nuclear pharmacy; or

(d) Is approved as an authorized nuclear pharmacist by a nuclear pharmacy licensed (authorized) by the Authority, the U.S. Nuclear Regulatory Commission, or an Agreement State to approve authorized nuclear pharmacists.

(7) "Authorized user" means a physician, dentist or podiatrist who:

(a) Meets the requirements listed in OAR 333-116-0660, 333-116-0670, 333-116-0680, 333-116-0683, 333-116-0687, 333-116-0690, 333-116-0700, 333-116-0710, 333-116-0720, and 333-116-0740;

(b) Is identified as an authorized user on an Authority, Agreement State, Licensing State or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material; or

(c) Is identified as an authorized user on a permit issued by an Authority, Agreement State, or U.S. Nuclear Regulatory Commission licensee of broad scope that is authorized to permit the medical use of radioactive material.

(8) "Black Box" means the radiopharmaceutical production purification system used in a PET facility.

(9) "Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose at a

distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.
(10) "Brachytherapy source" means an individual sealed source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose of radiation within a few centimeters, by surface, intracavitary, or interstitial application that is not designed to be disassembled by the user.
(11) "Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.
(12) "Dental use" means the intentional external administration of the radiation from radioactive material to human beings in the practice of dentistry in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.
(13) "Dentist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.
(14) "Diagnostic clinical procedures manual" means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.
(15) "High dose-rate remote afterloader" means a device that remotely delivers a brachytherapy source, with a dose rate in excess of two gray (200 rad) per hour, to the point or surface where the dose is prescribed.
(16) "Human Research Subject" means a living person that an authorized user, conducting research, obtains data resulting from the intentional internal or external administration of radioactive material, or the radiation from radioactive material, to the individual. For the purpose of these rules, unless otherwise noted, the term patient applies to a human research subject.
(17) "Low dose-rate remote afterloader" means a device that remotely delivers a brachytherapy source, with a dose rate of less than two gray (200 rad) per hour, to the point or surface where the dose is prescribed.
(18) "Management" means the chief executive officer or that individual's designee.
(19) "Manual Brachytherapy", as used in this part, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed on, or in close proximity, to the treatment site or inserted directly into the tissue volume.
(20) "Medical Event" means an event that meets the criteria in OAR 333-116-1000.
(21) "Medical institution" means an organization in which more than one medical discipline is practiced.
(22) "Medical use" means the intentional internal or external administration of radioactive material, or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.
(23) "Ministerial change" means a change that is made, after ascertaining the applicable requirements, by persons in authority in conformance with the requirements and without making a discretionary judgment about whether those requirements should apply in the case at hand.
(24) "Mobile nuclear medicine service" means the transportation and medical use of radioactive material.
(25) "Nuclear Pharmacist" means an authorized nuclear pharmacist, as defined in OAR 333-116-0020, who has received additional training, pursuant to OAR 333-116-0910 in the management and handling of radiopharmaceutical drugs and is authorized by license to receive, use, transfer, and dispose of such radiopharmaceutical drugs.
(26) "Ophthalmic physicist" means an individual who:
(a) Meets the requirements in OAR 333-116-0447 and OAR 333-116-0760; and
(b) Is identified as an ophthalmic physicist on a:
(A) Specific medical use license issued by the Authority, U.S. or Nuclear Regulatory Commission, or an Agreement State.
(B) Permit issued by an Agreement State, Authority, or U.S. Nuclear Regulatory Commission broad scope medical use licensee.
(C) Medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee; or
(D) Permit issued by a U.S. Nuclear Regulatory Commission master material licensee broad scope medical use permittee.

(27) "Output" means the exposure rate, dose rate or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.
(28) "Patient Intervention" means actions taken by a patient or human research subject, whether intentional or unintentional, interrupt or terminate the administration of radioactive materials or radiation.
(29) "PET" means Positron Emission Tomography.
(30) "PET Isotope Nuclear Pharmacy" means a licensed facility that compounds radiopharmaceuticals using positron emitting isotopes for use at licensed medical facilities.
(31) "PET cyclotron facility" means a facility that manufactures short-lived radioisotopes for use in compounding radiopharmaceuticals at a PET Isotope Nuclear Pharmacy.
(32) "PET Medical Facility" means a clinical nuclear medicine facility that utilizes positron-emitting isotopes for diagnostic imaging.
(33) "Pharmacist" means an individual licensed by a state or territory of the United States, The District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.
(34) "Physician" means a medical doctor or doctor of osteopathy licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.
(35) "Podiatric use" means the intentional external administration of the radiation from byproduct material to human beings in the practice of podiatry in accordance with a license issued by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.
(36) "Podiatrist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.
(37) "Positron Emission Tomography (PET) facility" means a facility comprised of an accelerator that produces positron-emitting isotopes, a radiopharmacy that specializes in preparation of PET radiopharmaceuticals, and/or a clinic that uses PET isotopes for medical diagnostic purposes.
(38) "Preceptor" means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, Radiation Safety Officer or an Associate Radiation Safety Officer. The preceptor must have previously met all of the applicable requirements and be so named on a radioactive materials license issued by the Authority, the Nuclear Regulatory Commission, an Agreement State or licensing state.
(39) "Prescribed dosage" means the specified activity or range of activity of a radiopharmaceutical or radioisotope as documented:
(a) In a written directive; or
(b) Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.
(40) "Prescribed dose" means:
(a) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
(b) For teletherapy, the total dose and dose per fraction as documented in the written directive;
(c) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or
(d) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.
(41) "Pulsed dose-rate remote afterloader" means a special type of remote afterloading device that uses a single source capable of delivering dose rates in the "high dose rate" range, but is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.
(42) "Radiation Safety Officer" means an individual who:
(a) Meets the requirements in OAR 333-116-0640, 333-116-0650, 333-116-0740 and 333-116-0760; or
(b) Is identified as a Radiation Safety Officer on:
(A) A specific medical use license issued by the Nuclear Regulatory Commission or Agreement State; or
(B) A medical use permit issued by a Nuclear Regulatory Commission master material licensee.

(43) "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.
(44) "Stereotactic Radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a dose to a tissue volume.
(45) "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.
(46) "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.
(47) "Teletherapy physicist" means the individual identified as the qualified teletherapy physicist on an Authority license.
(48) "Therapeutic Dosage" means a dosage of unsealed byproduct material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.
(49) "Therapeutic Dose" means a radiation dose delivered from a source containing byproduct material to a patient or human research subject for palliative or curative treatment.
(50) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.
(51) "Unit dosage" means a dosage intended for medical use in a single patient or human research subject that has been obtained from a manufacturer or preparer licensed by the Authority as a nuclear pharmacy.
(52) "Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.
(53) "Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in OAR 333-116-0125(1)(e), containing the following information:
(a) For any administration of quantities greater than 1.11 megabecquerels (30 uCi) of either sodium iodide I-125 or I-131: the dosage;
(b) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;
(c) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;
(d) For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;
(e) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or
(f) For all other brachytherapy:
(A) Prior to implantation: the radioisotope, number of sources, and source strengths; and
(B) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

STATUTORY/OTHER AUTHORITY: ORS 453.635

STATUTES/OTHER IMPLEMENTED: ORS 453.605 - 453.807

AMEND: 333-116-0105

RULE TITLE: Written Directives

NOTICE FILED DATE: 06/27/2022

RULE SUMMARY: OAR 333-116-0105 is amended by revising the statement to “For permanent implant brachytherapy: After implantation but before the patient leaves the post-treatment recovery area. The treatment site, the number of sources implanted, and total source strength implanted, and the date; or”. This rule is amended to be compatible with Nuclear Regulatory Commission’s (NRC) 10 CFR Parts 35.40.

RULE TEXT:

(1) A written directive must be prepared, dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 Megabecquerels (MBq) (30 microcuries (uCi)), or any therapeutic dosage of a radiopharmaceutical, or any therapeutic dose of radiation from radioactive material.

(a) If, because of the emergent nature of the patient’s condition, a delay in order to provide a written directive would jeopardize the patient’s health, an oral directive is acceptable.

(b) The information contained in the oral directive must be documented as soon as possible in writing in the patient’s record.

(c) A written directive must be prepared within 48 hours of the oral directive.

(2) The written directive must contain the patient or human research subject's name and the following:

(a) For any administration of quantities greater than 1.11 MBq (30 uCi) of sodium iodide I-131 or I-125; the dosage;

(b) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-131: the radiopharmaceutical dosage, and route of administration;

(c) For gamma stereotactic radiosurgery: target coordinates (including gamma angle), collimator size, plug pattern, total dose for the treatment, and the total treatment volume for each anatomically distinct treatment site;

(d) For teletherapy: the total dose, dose per fraction, number of fractions, treatment site, and overall treatment period;

(e) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(f) For permanent implant brachytherapy:

(A) Prior to implantation: treatment site, the radionuclide, number of sources and source strengths or dose; and

(B) After implantation but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources implanted, total source strength implanted, and the date; or

(g) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(A) Before implantation: The treatment site, radionuclide, and the dose; and

(B) After implantation but before completion of the procedure: The radionuclide, treatment site, number of sources, total source strength and exposure time (or the total dose), and date.

(3) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(4) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

(5) The licensee must retain the written directive in accordance with OAR 333-100-0057.

STATUTORY/OTHER AUTHORITY: ORS 453.635

STATUTES/OTHER IMPLEMENTED: ORS 453.605 - 453.807

AMEND: 333-116-0660

RULE TITLE: Training for Uptake, Dilution or Excretion Studies

NOTICE FILED DATE: 06/27/2022

RULE SUMMARY: OAR 333-116-0660 is amended by adding the statement “An authorized nuclear pharmacist who meets the requirements in OAR 333-116-0740 or OAR 333-116-0971 may provide the supervised work experience for paragraph (3)(b)(G) involving:”. In addition, the rule amendment will allow an Authorized User to supervise the training of eluting a generator system appropriate for preparation of radioactive drugs for imaging and localization studies. This rule is amended to be compatible with Nuclear Regulatory Commission’s 10 CFR Parts 35.290.

RULE TEXT:

Except as provided in OAR 333-116-0740, the licensee shall require the authorized user of a radiopharmaceutical listed in OAR 333-116-0300 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit webpage. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies as described in paragraphs (3)(a)(A) through (3)(b)(F) of this rule; and

(b) Pass an examination administered by diplomats of the specialty board that assesses knowledge and competence in radiation safety, radionuclide handling and quality control; or

(2) Is an authorized user under OAR 333-116-0670, 333-116-0680, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(3) Has completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include:

(a) Classroom and laboratory training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use;

(E) Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0660, 333-116-0670, 333-116-0680, and 333-116-0740 or U.S. Nuclear Regulatory Commission or equivalent Agreement State requirements. An authorized nuclear pharmacist who meets the requirements in OAR 333-116-0740 or OAR 333-116-0971 may provide the supervised work experience for paragraph (3)(b)(G) of this rule involving:

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;

(F) Administering dosages of radiopharmaceutical drugs to patients or human research subjects; and

(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(4) Has obtained written attestation that the individual has satisfactorily completed the requirements in section (3) of

this rule and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under OAR 333-116-0300 and OAR 333-116-0320. The attestation must be obtained from either:
(a) A preceptor authorized user who meets the requirements in OAR, 333-116-0660, 333-116-0670, 333-116-0680 or 333-116-0740 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or
(b) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in OAR 333-116-0660, 333-116-0670, 333-116-0680, or 333-116-0740 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in section (3) of this rule.

STATUTORY/OTHER AUTHORITY: ORS 453.635

STATUTES/OTHER IMPLEMENTED: ORS 453.605 - 453.807

AMEND: 333-120-0450

RULE TITLE: Precautionary Procedures: Procedures for Receiving and Opening Packages

NOTICE FILED DATE: 06/27/2022

RULE SUMMARY: OAR 333-120-0450 is amended to correct the rule reference numbers from OAR 333-118-0150, Table 3 to 333-118-0150(9) and OAR 333-118-0150(11) to 333-118-0150(9)(a).

RULE TEXT:

(1) Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in 49 CFR 173.435 Table of A1 and A2 Values for Radionuclides, must make arrangements to receive:

(a) The package when the carrier offers it for delivery; or

(b) Notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

(2) Each licensee must:

(a) Monitor the external surfaces of a labeled package for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as defined in OAR 333-118-0020;

(b) Monitor the external surfaces of a labeled package for radiation levels; and

NOTE: Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations, 49 CFR 172.403 and 172.436-440.

(c) Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

(3) The licensee must perform the monitoring required by section (2) of this rule as soon as practicable after receipt of the package, but not later than three hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than three hours from the beginning of the next working day if it is received after working hours.

(4) The licensee must immediately notify the final delivery carrier and the Authority, by telephone when:

(a) Removable radioactive surface contamination exceeds the limits of OAR 333-118-0150(9);

(b) External radiation levels exceed the limits of OAR 333-118-0150(9)(a).

(5) Each licensee must:

(a) Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

(b) Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

(6) Licensees transferring special form sources in licensee-owned or licensee-operated vehicles to and from a work site are exempt from the contamination monitoring requirements of section (2) of this rule, but are not exempt from the survey requirement in section (2) of this rule for measuring radiation levels, which is required to ensure that the source is still properly lodged in its shield.

STATUTORY/OTHER AUTHORITY: ORS 453.635

STATUTES/OTHER IMPLEMENTED: ORS 453.605 - 453.807

AMEND: 333-122-0380

RULE TITLE: Whole Body Imagers: Appropriate Uses

NOTICE FILED DATE: 06/27/2022

RULE SUMMARY: OAR 333-122-0380 is amended so that a qualified expert will inspect an X-ray screening device to ensure that the radiation output meets the standards outlined in ANSI/HPSM43.17-2009 rather than the manufacturer's specifications.

RULE TEXT:

(1) All X-ray scanning devices used for whole body imaging must meet the standards outlined in ANSI/HPSN43.17-2009 Radiation Safety for Personnel Security Screening Systems Using X-ray or Gamma Radiation.

(2) The X-ray scanning device will be used solely for the screening of inmates for the purpose of detecting illegal or dangerous items hidden on or inside the person. Screening will only be performed at the time of lodging or booking. If an inmate becomes a security threat due to potential contraband being introduced post-lodging, additional scans will be allowed.

(3) The X-ray scanning device shall not be used on pregnant females.

(4) The X-ray scanning device shall not be used for screening of staff or visitors.

(5) The X-ray scanning device shall not be used for medical purposes.

(6) Each X-ray operator must receive formal training as provided by the manufacturer and according to the information provided in the operator's manual.

(7) Annual safety refresher training, as defined in OAR 333-122-0005(3) must be provided for each device operator at intervals not to exceed 12 months.

(8) Records of training must be maintained per OAR 333-122-0170.

(9) The X-ray machine must be inspected annually by an Authority-approved qualified expert to ensure the radiation output meets the standards outlined in ANSI/HPSN43.17-2009.

(10) Records of all qualified expert evaluations and surveys shall be maintained in accordance with OAR 333-122-0240 for inspection by the Authority.

STATUTORY/OTHER AUTHORITY: ORS 453.605 – 453.807

STATUTES/OTHER IMPLEMENTED: ORS 453.605 – 453.807