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**PERMANENT ADMINISTRATIVE RULES**

I certify that the attached copies\* are true, full and correct copies of the PERMANENT Rule(s) adopted on [ upon filing ] by the  
Oregon Health Authority, Public Health Division  
Date prior to or same as filing date  
333

Agency and Division  
Administrative Rules Chapter Number  
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to become effective [ upon filing ]. Rulemaking Notice was published in the [ June 2011 ] Oregon Bulletin.\*\*  
Date upon filing or later  
Month and Year

**RULE CAPTION**

Amendment of rules that govern accreditation of environmental testing laboratories

Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.

**RULEMAKING ACTION**

List each rule number separately (000-000-0000)

Secure approval of new rule numbers (Adopted or Renumbered rules) with the Administrative Rules Unit prior to filing.

**ADOPT:**

**AMEND:** 333-064-0005, 333-064-0010, 333-064-0015, 333-064-0025, 333-064-0030, 333-064-0035, 333-064-0050, 333-064-0060, 333-064-0065

**REPEAL:**

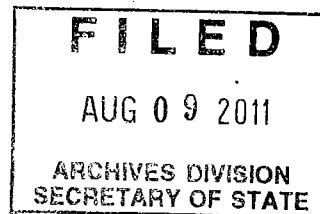
**RENUMBER:**

**AMEND & RENUMBER:**

Stat. Auth.: ORS 438.605 - 438.620, 448.131, 448.150, 448.280

Other Auth.:

Stats. Implemented: ORS 438.605 - 438.620, 448.280



**RULE SUMMARY**

The Oregon Health Authority, Public Health Division, Oregon State Public Health Laboratory is permanently amending Oregon Administrative Rules in chapter 333, division 64 pertaining to accreditation of laboratories. The proposed amendments will: 1) Change the Standard to which ORELAP accredits laboratories from the 2003 National Environmental Laboratory Accreditation Conference (NELAC) Standards to The NELAC Institute (TNI) 2009 Standards; 2) Change from charging assessment fees based on programs to matrices, which matches how laboratories are actually accredited to national standards; 3) Add language concerning the accreditation of mobile laboratories as required by the National Environmental Laboratory Accreditation Program (NELAP); 4) Add new technologies to ORELAP's fields of accreditation; 5) Increase fees to out-of-state laboratories requesting accreditation by Oregon in order to help cover the costs of the program; 6) Make revisions to procedures to reflect revisions to current practices; 7) Add clarifying language to help avoid misinterpretation.

*Melvin Kohn*  
Authorized Signer  
Melvin Kohn, MD, MPH  
Printed name  
8/3/11  
Date

\*With this original, file one photocopy of certificate, one paper copy of rules listed in Rulemaking Actions, and electronic copy of rules. \*\*The Oregon Bulletin is published the 1st of each month and updates rules found in the OAR Compilation. For publication in Bulletin, rule and notice filings must be submitted by 5:00 pm on the 15th day of the preceding month unless this deadline falls on a weekend or legal holiday, when filings are accepted until 5:00 pm on the preceding workday.

ARC 930-2005

PH 6-2011

OREGON ADMINISTRATIVE RULES  
OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION  
CHAPTER 333

**DIVISION 64**

**ACCREDITATION OF LABORATORIES**

**333-064-0005**

**Purpose**

These rules are for the purpose of implementing Oregon Revised Oregon Statutes (ORS) 438.605 to 438.620, 448.280 and the Oregon Drinking Water Quality Act of 1981. ORS 438.610 states that the Oregon Health Authority shall by adopting standards in concurrence with the accrediting body, implement an environmental laboratory accreditation program hereafter referred to as the Oregon Environmental Laboratory Accreditation Program (ORELAP). These rules establish requirements for the accreditation of laboratories analyzing environmental samples under the guidance of the Clean Air Act (CAA), Clean Water Act (CWA), Safe Drinking Water Act (SDWA), and the Resource, Conservation and Recovery Act (RCRA). The Oregon Health Authority shall accept ORELAP accreditation for 448.150(1) that states that water samples from public water systems shall be analyzed in a laboratory approved by the Oregon Health Authority. Stat. Auth.: ORS 448.150(1), 448.131, 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620

Stats. Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620

**333-064-0010**

**Scope**

- (1) These rules apply to environmental laboratories seeking accreditation and performing environmental testing.
- (2) Accreditation as described in these rules is required for all environmental laboratories reporting drinking water analysis results to the Oregon Health Authority except for Oregon Department of Agriculture Laboratory, Oregon Department of Environmental Quality Laboratory and the Oregon State Public Health Laboratory which must be certified by the United States Environmental Protection Agency for drinking water analysis.

Stat. Auth.: ORS 448.150(1), 448.131, 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620

Stats. Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620

**333-064-0015**

**Adoption by Reference**

All standards, listings and publications referred to in these rules are, by those references, made a part of these rules as though fully set forth. Copies are available through the Oregon Health Authority, Oregon State Public Health Laboratory.

Stat. Auth.: ORS 448.150(1), 448.131, 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620

Stats. Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620

### **333-064-0025**

#### **Definitions**

As used in these rules, unless the context indicates otherwise:

- (1) "Accrediting Body" means the official accrediting authority for the Oregon Environmental Laboratory Accreditation Program comprised of the Administrator of the Oregon State Public Health Laboratory or designee, the Laboratory Administrator of the Department of Environmental Quality or designee and the Laboratory Administrator of the Department of Agriculture or designee.
- (2) "Air" as matrix means air samples, which are analyzed for possible contaminants under the guidance of the Clean Air Act.
- (3) "Authority" means the Oregon Health Authority.
- (4) "Biological Tissue" as matrix means samples of biological tissue, excluding those of human origin, which are analyzed for the presence of possible environmental contamination.
- (5) "Clean Air Act (CAA)" means the enabling legislation, **42 U.S.C. 7401 et seq. (1974), Public Law 91-604, 84 Stat. 1676 Public Law 95-95, 91 Stat., 685 and Public Law 95-190, 91 Stat., 1399**, that empowers the EPA to promulgate air quality standards, monitor and enforce them.
- (6) "Clean Water Act (CWA)" means the enabling legislation under **33 U.S.C. 1251 et seq., Public Law 92-50086, Stat. 816** that empowers the EPA to set discharge limitations, write discharge permits, monitor and bring enforcement action for non-compliance.
- (7) "Drinking Water" as matrix means samples of presumed potable water and source water, which are analyzed for possible contaminants under the guidance of the Safe Drinking Water Act.
- (8) "Environmental laboratory" means a fixed location or mobile facility that analyzes environmental samples in a controlled and scientific manner.
- (9) "Fields of Accreditation" means those matrix, technology/method, and analyte combinations for which ORELAP offers accreditation.
- (10) "Fields of Testing" means those technologies for which ORELAP offers accreditation.
- (11)(a) "Mobile Category 1 Laboratory" means any facility, deployed for no more than six consecutive months and no more than six months during a calendar year, that:
  - (A) Analyzes environmental samples utilizing the staff and equipment from the parent fixed laboratory;
  - (B) Operates under the quality system of its parent fixed laboratory;
  - (C) Is capable of moving or being moved from site to site, such as but not limited to vans, trailers and motor coaches; and
  - (D) May operate under the fixed laboratory's accreditation.
- (12)(a) "Mobile Category 2 Laboratory" means any facility that:
  - (A) Analyzes environmental samples;
  - (B) Operates under its own quality system;
  - (C) Is capable of moving or being moved from site to site, such as but not limited to vans, trailers and motor coaches; and

- (D) Issues the final reports or is a mobile laboratory operating with a fixed laboratory's quality system, but is deployed for more than six consecutive months or more than six months in a calendar year.
- (b) Mobile category 2 laboratories require separate accreditation and are accredited to their vehicle identification numbers (VIN).
- (13) "National Environmental Laboratory Accreditation Program (NELAP)" means the program established to oversee the implementation of the TNI Standards.
- (14) "NELAP approved accrediting body" means a state or federal department/agency that has been approved by NELAP as being an entity whose accreditation and assessment program meets all of the requirements of the TNI Standards.
- (15) "Non-Potable Water" as matrix means aqueous samples, which are analyzed under the guidance of the Clean Water Act or the Resource, Conservation and Recovery Act.
- (16) "On-site assessment" means an on-site visit to the environmental laboratory to verify items addressed in the ORELAP application and to evaluate the facility and analytical performance for conformance with the TNI Standards.
- (17) "ORELAP approved assessor" means an assessor whose qualification has been evaluated by ORELAP and found to meet TNI Standards for laboratory on-site assessors.
- (18) "Primary Accreditation" means accreditation by a NELAP approved accrediting body based on a laboratory's compliance to TNI Standards after a review of the laboratory's application, quality manual, PT results and on-site assessment results as described in the TNI Standards.
- (19) "Proficiency testing (PT)" means the analysis of samples obtained from providers that meet the TNI standards for PT providers. The composition of the sample is unknown to the laboratory performing the analysis, and is used in part to evaluate the ability of the laboratory to produce precise and accurate results.
- (20) "Public water system" means a water system as defined in OAR 333-061-0010.
- (21) "Quality Manual (QM)" means a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of a laboratory to ensure the quality of its product and the utility of its product to its users.
- (22) "Resource Conservation and Recovery Act (RCRA)" means the enabling legislation, 42 U.S.C. section 6901 et seq. (1976), that requires the EPA to protect human health and protecting and monitoring the environment by regulating hazardous waste disposal practices.
- (23) "Safe Drinking Water Act (SDWA)" means the SDWA enacted in 1974 and the Safe Drinking Water Amendments of 1986, 42 U.S.C. 300f et seq., Public Law 93-523, that is the enabling legislation that requires the EPA to protect the quality of drinking water in the U.S. by setting maximum allowable contaminant levels, monitoring, and enforcing violations.
- (24) "Secondary Accreditation" means the recognition by reciprocity for the fields of accreditation, methods and analytes for which the laboratory holds current primary accreditation by another NELAP recognized accrediting body.
- (25) "Solids" as a matrix means samples of soil, sludge and other non-aqueous compounds analyzed under the guidance of the Resource, Conservation and Recovery Act.
- (26) "TNI" means the NELAC (National Environmental Laboratory Accreditation Conference) Institute. TNI is a voluntary organization of state and federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories.

(27) "TNI Standards" means the adopted 2009 TNI Standards (© 2009 The NELAC Institute), which are documents describing the elements of laboratory accreditation that was developed and established by the consensus principles of TNI and meets the approval requirements of TNI procedures and policies.

(28) "These rules" means the Oregon Administrative Rules encompassed by OAR 333-064-0005 through 333-064-0065.

(29) "Third party assessor" means an ORELAP approved assessor who has a current contract with the Oregon Health Authority to perform on-site assessments of laboratories for ORELAP and is not employed by the state agencies comprising ORELAP's accrediting body.

(30) "United States Environmental Protection Agency (EPA)" means the federal government agency with the responsibility for protecting public health and safeguarding and improving the natural environment (i.e., air, water, and land) upon which human life depends.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 438.605, 438.610, 438.615, 438.620, 448.131, 448.150(1), 448.280(1)(b) & (2)

Stats. Implemented: ORS 438.605, 438.610, 438.615, 438.620, 448.280(1)(b) & (2)

### **333-064-0030**

#### **Schedule for Requesting Accreditation, Period of Accreditation**

(1) Laboratories in Oregon will be considered to be accredited by ORELAP after the laboratory has requested accreditation, been evaluated by ORELAP and has met all criteria in accordance with OAR 333-064-0035.

(2) The accreditation period for each laboratory is for one year with subsequent accreditation periods beginning from the first day the laboratory is granted accreditation.

(3) Laboratories must reapply for ORELAP approval annually, with the application to be received by ORELAP 120 calendar days prior to the expiration of the current accreditation period and with all appropriate fees paid no less than 60 days prior to the expiration of their current certificate of accreditation.

(4) ORELAP-accredited laboratories may apply for accreditation of additional parameters (analytes, methods, matrices) at any time during their accreditation period with accreditation for such parameters expiring with the current accreditation period.

Stat. Auth.: ORS 448.150(1), 448.131, 448.280(1)(b) & (2), 438.610 & 438.615

Stats. Implemented: ORS 438.605, 438.610 & 438.615

### **333-064-0035**

#### **Approval Requirements**

(1) This rule and the TNI Standards describe the procedure for obtaining and maintaining accreditation.

(2) ORELAP accreditation can be granted, denied, suspended, or revoked in total or in part as described in the TNI Standards.

(3) In no case shall a laboratory be accredited that does not comply with the TNI Standards as specified in this rule.

(4) The elements for accreditation shall include but are not restricted to:

(a) Application for accreditation:

(A) ORELAP will make online, electronic applications available to all laboratories requesting an application.

(B) The laboratory must request ORELAP accreditation by completing and submitting to ORELAP an acceptable application that includes all elements as required by the TNI Standards. For primary accreditation this includes a completed application with all required documents. For secondary accreditation this includes a completed application with all of the required documents plus proof of accreditation from a primary accrediting body.

(b) Laboratory's participation in a biennial on-site assessment(s) as required by the TNI Standards. Environmental testing laboratories seeking initial, primary ORELAP accreditation shall not be granted accreditation prior to an acceptable on-site assessment;

(c) Laboratory's participation in proficiency testing (PT) and the obtaining of acceptable PT results according to the TNI Standards;

(d) A quality manual (QM) that includes all elements as set forth in the TNI Standards;

(e) Laboratory staff members that meet the TNI Standards for training and experience for their responsibilities within the environmental laboratory;

(f) Creation and retention of all records pertaining to samples and analyses, including chain of custody documents, log books, work sheets, raw data, calculations, quality assurance data, and reports according to TNI Standards;

(g) Laboratory's full payment of all appropriate fees as described in OAR 333-064-0060.

Stat. Auth.: ORS 448.150(1), 448.131, 448.280(1)(b)(2), 438.605, 438.610, 438.615 & 438.620

Stats. Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620

### **333-064-0050**

#### **Accreditation of Out-of-State and Mobile Category 2 Laboratories**

(1) ORELAP shall accredit out-of-state laboratories that are eligible for reciprocal accreditation provided:

(a) The laboratory is accredited by a state recognized as a NELAP accrediting body for those fields of testing (analytes, methods, matrices) in which the laboratory is requesting accreditation pursuant to this rule.

(b) The laboratory submits to ORELAP an acceptable application as described in OAR 333-064-0035(4).

(c) The laboratory pays all appropriate fees as described in OAR 333-064-0060.

(2) ORELAP may accredit out-of-state laboratories that are located in states that do not have a NELAP approved accrediting body for the fields of testing and matrices in which the laboratory desires accreditation provided that the laboratory complies with all the requirements in OAR 333-064-0035.

(3) ORELAP may accredit mobile category 2 laboratories that do not operate as an entity of an Oregon fixed base facility as out-of-state laboratories. Such laboratories must meet all of the requirements for out-of-state laboratories pursuant to these rules.

Stat. Auth.: ORS 448.150(1) & 448.131, 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620

Stats. Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620

### **333-064-0060**

#### **Fee Schedule**

Fees will be charged to Oregon in-state and out-of-state environmental laboratories according to the following schedule. A mobile category 2 laboratory that operates as an entity of an Oregon

fixed base facility will be considered an in-state laboratory, and one that does not operate as an entity of an Oregon fixed base facility will be considered an out-of-state laboratory. Mobile category 1 laboratories are covered under the parent fixed laboratory's accreditation and are not required to pay an additional fee.

(1) A non-refundable application fee must be paid for each application requesting accreditation for methods.

(a) For laboratories located in Oregon, one of three levels of fees, Tier 1 at \$450, Tier 2 at \$900 and Tier 3 at \$1,600 will be charged. The Tiers will be determined by the total number of points derived from the number of fields of testing requested for accreditation listed in subsections

(2)(a) through (c) of this rule.

(A) Each Basic Field of Testing has a multiplier of 1.

(B) Each Moderate Field of Testing has a multiplier of 3.

(C) Each Complex Field of Testing has a multiplier of 5.

(D) The total number of points is determined by first summing the number of fields of testing within each category (Basic, Moderate or Complex) and then multiplying the sums by their appropriate multiplier as given in this rule. The sum of these results determines the total number of points for each laboratory. Laboratories with a total of 1 to 10 points are to be considered Tier 1 laboratories, 11 to 25 points are Tier 2 laboratories and 26 or more points are Tier 3 laboratories.

(b) For each out-of-state laboratory requesting primary or secondary accreditation through ORELAP, one of three levels of fees, Tier 1 at \$1,375, Tier 2 at \$2,200 and Tier 3 at \$3,300 will be charged with each Tier determined according to subsection (1)(a) of this rule.

(c) If a new owner acquires the laboratory and wishes the laboratory to remain accredited, the laboratory must submit a new owner application, and may be required to pay the application fee and be subject to a new on-site assessment and payment of on-site assessment fees as described in this rule.

(2) Upon ORELAP's review of a laboratory's application, each laboratory requesting primary accreditation through ORELAP, when ORELAP personnel will be used for the assessment, the laboratory will be charged an assessment fee based on the number fields of testing and matrices as follows:

(a) Oregon laboratories will be charged \$90 and out-of-state laboratories will be charged \$100 for each of the following Basic Fields of Testing requested for accreditation:

(A) Chromofluorogenic (Microbiology);

(B) Membrane Filter and/or Heterotrophic Plate Count (Microbiology);

(C) Multiple Tube Fermentation/Most Probable Number (MPN) (Microbiology);

(D) Gravimetric;

(E) Physical;

(F) Probe.

(b) Oregon laboratories will be charged \$350 and out-of-state laboratories will be charged \$385 for each of the following Moderate Fields of Testing requested for accreditation:

(A) Inorganic Atomic absorption spectrometry;

(B) Inorganic Atomic fluorescence spectrometry;

(C) Inorganic-non-metals automated colorimetric;

(D) Inorganic-non-metals manual colorimetric;

(E) Inorganic-ion chromatography (IC);

- (F) Organic-liquid chromatography (LC);
  - (G) Organic-gas chromatography (GC) -- volatiles;
  - (H) Organic-gas chromatography (GC) -- extractables;
  - (I) Whole Effluent Toxicity Immunoassay;
  - (J) Asbestos (bulk);
  - (K) Asbestos – electron microscopy
  - (L) Radiochemistry.
- (c) Oregon laboratories will be charged \$500 and out-of-state laboratories will be charged \$550 for each of the following Complex Fields of Testing requested for accreditation:
- (A) Organic - gas chromatography/mass spectrometry (GC/MS) -- volatiles;
  - (B) Organic - gas chromatography/mass spectrometry (GC/MS) -- extractables;
  - (C) Organic – liquid chromatography/mass spectrometry (LC/MS);
  - (D) Organic – gas chromatography/tandem mass spectrometry (GC/MS/MS);
  - (E) Organic – gas chromatography/high resolution mass spectrometry (GC/HRMS);
  - (F) Inorganic - metals - inductively coupled plasma (ICP);
  - (G) Inorganic - metals - inductively coupled plasma/mass spectrometry (ICP/MS);
  - (H) Inorganic – ion chromatography/mass spectrometry (IC/MS);
  - (I) X-ray.
- (d) An additional fee of \$10 for Basic Fields of Testing, \$40 for Moderate Fields of Testing and \$75 for Complex Fields of Testing will be charged to Oregon laboratories, and an additional fee of \$11 for Basic Fields of Testing, \$44 for Moderate Fields of Testing and \$83 for Complex Fields of Testing will be charged to out-of-state laboratories for each additional matrix per field of testing for which the laboratory has requested accreditation. The matrices are:
- (A) Air;
  - (B) Biological tissue;
  - (C) Drinking water;
  - (D) Non-potable water;
  - (E) Solids.
- (e) Assessment fees must be paid before a routine on-site assessment will be performed.
- (f) All laboratories must pay the appropriate on-site assessment fee per on-site assessment performed due to just cause according to TNI Standards.
- (3) All Oregon environmental laboratories requesting primary accreditation through ORELAP where Oregon state assessor(s) will perform the on-site assessment must pay an on-site trip fee for each on-site assessment. For a mobile category 2 laboratory, the trip fees are waived if it is moved to the Oregon State Public Health Laboratory for the on-site assessment, and reduced to the amount in excess of its fixed base facility when moved to the fixed base facility if both are to be assessed at the same time.
- (a) On-site trip fees are \$350 for Tier 1, \$500 for Tier 2 and \$1,000 for Tier 3 laboratories with the Tiers determined according to subsection (1)(a) of this rule.
  - (b) All laboratories must pay the appropriate on-site trip fee for performing each required on-site assessment and additional assessments as requested by the laboratory for accreditation for additional fields of testing and matrices.
  - (c) All laboratories must pay the appropriate on-site trip fee per on-site assessment performed due to just cause according to TNI Standards.



(4) All environmental laboratories located in Oregon requesting primary accreditation through ORELAP where ORELAP has determined that third party assessors will be used, must pay ORELAP application assessment fees plus all third party assessors costs. ORELAP may require the laboratory to pay the on-site assessment costs directly to the third party assessor according to the schedule of the assessor for all required on-site assessments.

(5) All out of-state environmental laboratories must pay all on-site assessment costs incurred by ORELAP approved assessors to perform the on-site assessment including but not limited to transportation, per diem and wages during travel. For a mobile category 2 laboratory, the travel costs are waived if it is moved to the Oregon State Public Health Laboratory for the on-site assessment, and reduced to the amount in excess of its fixed base facility when moved to the fixed base facility if both are to be assessed at the same time. The excess amount is to be determined by those fields of testing and matrices requested for accreditation by the mobile lab that have not been requested by its fixed based facility. If third party assessors are used, ORELAP may require the lab to pay the on-site assessment costs directly to the assessor according to the schedule of the assessor for all required inspections.

(6) Accredited laboratories requesting additions to their fields of accreditation during the accreditation period must pay:

(a) The difference in cost of the application fee with a minimum fee of \$200;

(b) The difference in cost of the assessment fee;

(c) An on-site trip fee, as described in subsection (3)(a) and section (5) of this rule, based only on the additional parameters if ORELAP determines that an on-site assessment is required.

Stat. Auth.: ORS 438.605 - 438.620 & 448.280(1)(b) & (2)

Stats. Implemented: ORS 438.605 - 438.620

### **333-064-0065**

#### **Civil Penalties**

(1) In addition to any other penalty provided by law, the Oregon Health Authority, in collaboration with the accrediting body, may impose a civil penalty not to exceed \$500 per day per violation upon any and all laboratories that willfully or negligently commit any of the following:

(a) Falsely purport to be ORELAP accredited;

(b) Improperly use their ORELAP accreditation status in order to mislead;

(c) Use the TNINELAP logo in catalogs, advertisements, business solicitations, proposals, quotations, laboratory reports and other materials without proper authorization.

(2) The Oregon Health Authority reserves the right to pursue other remedies and may take any other disciplinary action against alleged violators.

(3) In establishing the amount of the penalty for each violation, the Oregon Health Authority will consider, but not be limited to the following factors:

(a) The gravity and magnitude of the violation;

(b) The laboratory's previous record of complying or failing to comply with this rule.

(c) The laboratory's history in taking all feasible steps or in following all procedures necessary or appropriate to correct the violation; and,

(d) Such other considerations as the Oregon Health Authority may consider appropriate.

(4) The Oregon Health Authority in collaboration the accrediting body may deny, suspend or revoke accreditation of any laboratory that fails to pay on demand a civil penalty that has become

due and payable, provided that it first gives the laboratory an opportunity for a hearing as outlined in ORS chapter 183.

Stat. Auth.: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620

Stats. Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620