

Underlined text has been added. ~~Strikethrough text~~ has been deleted.

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 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) and sections 91 to 99, chapter 614, Oregon Laws 2015. The Oregon Health Authority shall accept ORELAP accreditation for ORS 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, OL 2015, ch. 614, sec. 94.

Stats. Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620, OL 2015, ch. 614, sec. 94.

**333-064-0010**

**Scope**

(1) These rules apply to environmental testing laboratories seeking accreditation and performing environmental or agricultural testing, and laboratories testing cannabis and sampling as required by section 94, chapter 614, Oregon Laws 2015.

(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.

(3) Accreditation as described in these rules is required for all Oregon laboratories testing marijuana items as per the Oregon Liquor Control Commission, Oregon Laws 2015, chapter 614.

Stat. Auth.: ORS 448.150(1), 448.131, 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620, [OL 2015, ch. 614, sec. 94](#)

Stats. Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620, [OL 2015, ch. 614, sec. 94](#).

### 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) “Marijuana items” has the meaning given that term in section 91, chapter 614, Oregon Laws 2015.

(142)(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)~~(13)(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)~~14 "National Environmental Laboratory Accreditation Program (NELAP)" means the program established to oversee the implementation of the TNI Standards.

~~(14)~~15 "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)~~16 “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)~~17 "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.

(1718) "ORELAP approved assessor" means an assessor whose qualification has been evaluated by ORELAP and found to meet TNI Standards for laboratory on-site assessors.

(1819) "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.

(1920) "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.

(2021) "Public water system" means a water system as defined in OAR 333-061-0010.

(2122) "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.

(2223) "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.

(2324) "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.

(2425) "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.

(2526) "Solids" and "Chemical material" as a matrix means samples of soil, solid, sludge and other non-aqueous compounds including cannabinoid products and cannabinoid concentrates or extracts as defined in section 91, chapter 614, Oregon Laws 2015, analyzed under the guidance of the Resource, Conservation and Recovery Act.

(2627) "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.

(2728) "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.

(~~2829~~) "These rules" means the Oregon Administrative Rules encompassed by OAR 333-064-0005 through 333-064-0065.

(~~2930~~) "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.

(~~3031~~) "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 ~~184~~, 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)

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

#### **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) Each Advanced Technology Field of Testing has a multiplier of 7.

~~(E)~~ The total number of points is determined by first summing the number of fields of testing within each category (Basic, Moderate, ~~or~~ Complex or Advanced Technology) 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 electron capture detector (GC/ECD); tandem mass spectrometry (GC/MS/MS);~~

~~(E) Organic/Inorganic — metals — inductively coupled plasma/atomic emission spectrometry (ICP/AES); gas chromatography/high resolution mass spectrometry (GC/HRMS);~~

~~(F) Inorganic — metals — inductively coupled plasma/mass spectrometry (ICP/MS);~~

~~(G) Inorganic — metals — inductively coupled plasma/mass spectrometry (ICP/MS);~~

~~(H) Inorganic —~~

~~(I) Inorganic — ion chromatography/mass spectrometry (IC/MS);~~

~~(J) X-ray;~~

~~(K) Whole Effluent Toxicity (WET) immunoassay;~~

~~(L) Radiochemistry.~~

(d) Oregon laboratories will be charged \$1,000 and out-of-state laboratories will be charged \$1,200 for each of the following Advanced Technology Fields of Testing requested for accreditation:

(A) Organic — gas chromatography/tandem mass spectrometry (GC/MS/MS);

(B) Organic — high resolution gas chromatography/high resolution mass spectrometer (HiResGC/HiResMS);

(C) Organic — liquid chromatography/tandem mass spectrometry (LC/MS/MS);

(D) Microbiology — Polymerase chain reaction (PCR);

(E) Mycology and Parasitology — Filtration/Immunomagnetic Separation/Immunofluorescence Assay microscopy (Filtration/IMS/FA).

~~(d)~~ An additional fee of \$10 for Basic Fields of Testing, \$40 for Moderate Fields of Testing, and \$75 for Complex Fields of Testing, and \$150 for Advanced Technology 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, and \$165 for Advanced Technology 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 and chemical material.

~~(e)~~ Assessment fees must be paid before a routine on-site assessment will be performed.

~~(g)~~ 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