

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 samples under the guidance of the Clean Air Act (CAA), Clean Water Act (CWA), Safe Drinking Water Act (SDWA), the Resource, Conservation and Recovery Act (RCRA) and cannabis testing under ORS 475B.550 to 475B.590. Testing of water samples under ORS 448.150, Oregon's Drinking Water Quality Act, must be conducted by an ORELAP accredited laboratory..

Stat. Auth.: ORS 448.150(1), 448.131, 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620, 475B.565

Stats. Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620, 475B.565

333-064-0010

Scope

(1) These rules apply to:

(a) Laboratories seeking accreditation to perform environmental or agricultural laboratory testing;

(b) Laboratories seeking accreditation to perform sampling and laboratory testing of marijuana items as required by ORS 475B.565; and

(c) Accredited laboratories performing:

(A) Environmental or agricultural testing; or

(B) Sampling and testing of marijuana items.

(2) Accreditation as described in these rules is required for all 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.

Stat. Auth.: ORS 448.150(1), 448.131, 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620, 475B.565

Stats. Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620, 475B.565

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 a 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 a matrix means samples of biological tissue, excluding those of human origin.
- (5) "Cannabis Sampling" means an activity related to obtaining a representative sample of a marijuana item for purposes of testing in accordance with these rules and OAR 333-007-0300 to 333-007-0490.
- (6) "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.
- (7) "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.
- (8) "Drinking Water" as a 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.
- (9) "Fields of Accreditation" means those matrix, technology/method, and analyte combinations for which ORELAP offers accreditation.
- (10) "Laboratory" means a fixed location or mobile facility that collects or analyzes samples in a controlled and scientific manner with the appropriate equipment and instruments required by accredited sampling and testing methods.
- (11) "Marijuana item" has the meaning given that term in ORS 475B.550.
- (12) "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 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.
- (13) "Mobile Category 2 Laboratory" means any facility that:
 - (a) Analyzes 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.
- (14) "National Environmental Laboratory Accreditation Program (NELAP)" means the program established to oversee the implementation of the TNI Standards.
- (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.
- (16) "Non-Potable Water" as a matrix means aqueous samples, which are analyzed under the guidance of the Clean Water Act or the Resource, Conservation and Recovery Act.
- (17) "On-site assessment" means an on-site visit to the laboratory to verify items addressed in the ORELAP application and to evaluate the facility and analytical performance for conformance with the TNI Standards.
- (18) "ORELAP approved assessor" means an assessor whose qualification has been evaluated by ORELAP and found to meet TNI Standards for laboratory on-site assessors.
- (19) "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.
- (20) "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.
- (21) "Public water system" means a water system as defined in OAR 333-061-0010.
- (22) "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.
- (23) "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.
- (24) "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.
- (25) "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 approved accrediting body.
- (26) "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. Cannabinoid products and concentrates or extracts as defined in ORS 475B.550 shall be included in this matrix as solids.
- (27) "TNI" means the NELAC 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.
- (28) "TNI Standards" means the adopted 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.

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

(30) "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.

(31) "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 (that is 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)

333-064-0060

Fee Schedule

Fees will be charged to Oregon and out-of-state 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. Mobile category 2 laboratories require separate accreditation and are accredited to their vehicle identification numbers (VIN).

(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 accreditation requested for accreditation listed in subsections (2)(a) through (c) of this rule.

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

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

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

(D) Each Advanced Technology Field of Accreditation has a multiplier of 7.

(E) Cannabis Sampling only for application has a multiplier of 11.

(F) The total number of points is determined by first summing the number of fields of accreditation within each category (Basic, Moderate, 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 \$1,650, Tier 2 at \$2,640 and Tier 3 at \$3,960 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, will be charged an assessment fee as follows:

(a) Oregon laboratories will be charged \$90 and out-of-state laboratories will be charged \$120 for each of the following Basic Fields of Accreditation requested for accreditation:

- (A) Gravimetric;
- (B) Physical;
- (C) Probe.

(b) Oregon laboratories will be charged \$350 and out-of-state laboratories will be charged \$462 for each of the following Moderate Fields of Accreditation 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) General microbiology including but not limited to these three: (1) Chromofluorogenic; (2) Membrane Filter and /or Heterotrophic Plate Count (HPC); and (3) Multiple Tube Fermentation/Most Probable Number (MPN) (one fee applies for all);
- (H) Asbestos (bulk);
- (I) Asbestos — electron microscopy.

(c) Oregon laboratories will be charged \$500 and out-of-state laboratories will be charged \$660 for each of the following Complex Fields of Accreditation 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 (GC) volatiles, extractables;
- (E) Inorganic — metals — inductively coupled plasma/atomic emission spectrometry (ICP/AES);
- (F) Inorganic — metals — inductively coupled plasma/mass spectrometry (ICP/MS);
- (G) Inorganic — ion chromatography/mass spectrometry (IC/MS);
- (H) X-ray;
- (I) Whole Effluent Toxicity (WET) immunoassay;
- (J) Radiochemistry.

(d) Oregon laboratories will be charged \$1,000 and out-of-state laboratories will be charged \$1,440 for each of the following Advanced Technology Fields of Accreditation requested for accreditation:

- (A) Organic — gas chromatography/tandem mass spectrometry (GC/MS/MS);
- (B) Organic — high resolution gas chromatography/high resolution mass spectrometry (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);

(F) Cannabis Sampling.

(e) The following additional fees will be charged to Oregon laboratories for each additional matrix per field of accreditation for which the laboratory has requested accreditation:

(A) \$10 for Basic Fields of Accreditation.

(B) \$40 for Moderate Fields of Accreditation.

(C) \$75 for Complex Fields of Accreditation.

(D) \$150 for Advanced Technology Fields of Accreditation.

(f) The following additional fees will be charged to out-of-state laboratories for each additional matrix per field of accreditation for which the laboratory has requested accreditation:

(A) \$13 for Basic Fields of Accreditation.

(B) \$53 for Moderate Fields of Accreditation.

(C) \$100 for Complex Fields of Accreditation.

(D) \$198 for Advanced Technology Fields of Accreditation.

(3) For purposes of section (2) of this rule the matrices are:

(a) Air;

(b) Biological tissue;

(c) Drinking water;

(d) Non-potable water; and

(e) Solids.

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

(5) All laboratories must pay the appropriate on-site assessment fee per on-site assessment performed due to just cause according to TNI Standards.

(6) All Oregon 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 accreditation 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.

(7) All 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.

(8) All out of-state 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 accreditation 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.

(9) 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 (6)(a) and section (8) 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:

(a) Falsely purport to be ORELAP accredited;

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

(c) Use the TNI\NELAP 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