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

333-064-0020
Severability

These rules are severable. If any rule or part thereof or the application of such rule to any person or circumstance is declared invalid, that invalidity shall not affect the validity of any remaining portion of these rules.

Stat. Auth.: ORS 448.150(1) & 448.131, 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 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)

333-064-0030
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

333-064-0040
Action Response for Laboratory Drinking Water Analysis Results
(1) If an accredited laboratory is authorized by the water supplier to report results of analyses required by OAR 333-061-0036 and performed by the laboratory directly to the Oregon Health Authority (Authority), then it must do so within 10 days after the end of the month, or within 10 days after the end of the monitoring period.
(2) If a result exceeds the maximum contaminant level (MCL) specified in OAR 333-061-0030:
(a) The accredited lab that issues the final test report must:
(A) Validate the results of any sample analysis and report that analysis directly to the Authority and to the water supplier within 48 hours or two business days of completing the analytical run if the sample analysis:
(i) Exceeds the MCL for nitrate as specified in OAR 333-061-0030(1); or
(ii) Is positive for coliform bacteria.
(B) Report any sample analysis directly to the Authority and to the water supplier within 24 hours or on the next business day after validating a sample result that exceeds the MCL for any chemical analyte specified in OAR 333-061-0030 other than nitrate.
(C) Report any sample analysis directly to the Authority and to the water supplier within 24 hours or on the next business day after obtaining a sample result from a subcontracted laboratory, if the sample analysis:
(i) Exceeds the MCL for nitrate as specified in OAR 333-061-0030(1) or is positive for coliform bacteria; or
(ii) Exceeds the MCL for any chemical analyte specified in OAR 333-061-0030 other than nitrate upon validating the sample analysis.
(b) Accredited, subcontracted laboratories must:
(A) Validate the results of any sample analysis and report that analysis to their client laboratory within 48 hours or two business days of completing the analytical run if the analysis:
(i) Exceeds the MCL for nitrate as specified in OAR 333-061-0030(1); or
(ii) Is positive for coliform bacteria.

(B) Report any sample analysis to their client laboratory within 24 hours or on the next business day after validating a sample result that exceeds the MCL for any chemical analyte specified in OAR 333-061-0030 other than nitrate.
(3) The laboratory must notify the public water system and, if authorized by the water system, the Authority of all unregulated contaminants detected and their concentrations from each specific method used to measure the regulated contaminants.
(4) The laboratory must use report forms that have been approved by the Authority for reporting drinking water test results to the Authority.
Stat. Auth.: ORS 448.150(1) & 448.131
Stats. Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620

333-064-0045
Procedure for Contesting Actions of ORELAP
The procedure for contesting the actions of ORELAP regarding denial, suspension and revocation of accreditation, or other changes in accreditation status is in accordance with the Administrative Procedures Act, ORS 183.
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

333-064-0055
Display of Certificate
Accredited environmental laboratories shall post or display their most recent ORELAP accreditation certificate and their ORELAP-accredited fields of testing in a prominent place in the laboratory facility.

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 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/Immunoflurorescence 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

333-064-0100
Marijuana Item Sampling Procedures and Testing
(1) For purposes of this rule the definitions in OAR 333-007-0310 apply unless the context indicates otherwise.
(2) Sampling.
(a) A laboratory must prepare marijuana item sampling policies and procedures that contain all of the information necessary for collecting and transporting samples from a marijuana item in a manner that does not endanger the integrity of the sample for any analysis required by this rule. These policies and procedures must be appropriate to the matrix being sampled.
(b) Sampling policies and procedures must be accredited by ORELAP prior to any marijuana samples being taken. The policies and procedures must be consistent with the following ORELAP sampling protocols approved by the accrediting body, incorporated by reference:
(A) Usable Marijuana: ORELAP-SOP-001 Rev 3.0; and
(B) Concentrates, Extracts, and Products: ORELAP-SOP-002 Rev 3.1.[Sampling protocols may be found on the ORELAP and Cannabis Testing webpage, public.health.oregon.gov/LaboratoryServices/EnvironmentalLaboratoryAccreditation/Pages/cannabis-info.aspx]
(c) Laboratory personnel that perform sampling must:

(A) Comply with the education and training requirements in the sampling protocols referenced in subsection (2)(b) of this rule;
(B) Follow the laboratory's accredited sampling policies and procedures;
(C) Follow chain of custody procedures consistent with TNI EL Standard V1M2 5.7 and 5.8;
(D) After taking samples document the samples in accordance with subsection (2)(e) of this rule and if sampling for a licensee record the sampling and transfer information in the Commission's seed to sale system, as required by the Commission; and
(E) Take care while sampling to avoid contamination of the non-sampled material. Sample containers must be free of analytes of interest and appropriate for the analyses requested.
(d) A sufficient sample size must be taken for analysis of all requested tests and the quality control performed by the testing laboratory for these tests.
(e) A laboratory must comply with any recording requirements for samples and sample increments in the accredited policies and procedures and at a minimum:
(A) Record the location of each sample and sample increment taken.
(B) Assign a field identification number for each sample, sample increment and field duplicate that have an unequivocal link to the laboratory analysis identification.
(C) Assign a unique identification number for the test batch in accordance with OAR 333-007-0370 and TNI EL standard requirements.
(D) Have a documented system for uniquely identifying the samples to be tested to ensure there can be no confusion regarding the identity of such samples at any time. This system must include identification for all samples, sample increments, preservations, sample containers, tests, and subsequent extracts or digestates.
(E) Place the laboratory identification code as a durable mark on each sample container.
(F) Enter a unique identification number into the laboratory records. This number must be the link that associates the sample with related laboratory activities such as sample preparation. In cases where the sample collector and analyst are the same individual, or the laboratory pre-assigns numbers to sample containers, the unique identification number may be the same as the field identification code.
(f) Combining sample increments.
(A) Sample increments collected from the same batch of usable marijuana must be combined into a single sample by a laboratory prior to testing. Sample increments from a batch of a cannabinoid concentrate, extract or product may be combined into a single sample by a laboratory prior to testing if the cannabinoid concentrate, extract or product has a certified control study.
(B) Sample increments and samples collected from different batches may not be combined, except as permitted by OAR 333-007-0360.
(C) Field duplicates may not be combined with the primary samples.
(3) THC and CBD testing validity. When testing a sample for THC and CBD a laboratory must comply with additional method validation as follows:
(a) Run a laboratory control standard in accordance with TNI standards requirements within acceptance criteria of 70 percent to 130 percent recovery.
(b) Analyze field duplicates of samples within precision control limits of plus or minus 20 percent RPD, if field duplicates are required.
(4) Calculating total THC and total CBD.
(a) Total THC must be calculated as follows, where M is the mass or mass fraction of delta-9 THC or delta-9 THCA:

M total delta-9 THC = M delta-9 THC + 0.877 x M delta-9 THCA.
(b) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA:
M total CBD = M CBD + 0.877 x M CBDA.
(c) Each test report must include the total THC and total CBD.
(5) Report total THC and total CBD as Dry Weight. A laboratory must report total THC and Total CBD content by dry weight calculated as follows:
P total THC(dry) = P total THC(wet) / [1-(P moisture/100)]
P total CBD(dry) = P total CBD(wet) / [1-(P moisture/100)]
(6) Calculating RPD and RSD.
(a) A laboratory must use the following calculation for determining RPD:

Relative Percent Difference

$$\%RPD = \frac{|(sample - duplicate)|}{(sample + duplicate)/2}\ x\ 100$$

(b) A laboratory must use the following calculation for determining RSD:

Standard Deviation

$$S = \sqrt{\frac{\sum_{i=1}^{n}(x_i - \bar{x})^2}{(n-1)}}$$

Relative Standard Deviation

$$\%RSD = \frac{S}{\bar{x}}\ x\ 100$$

(c) For purposes of this section:
(A) S = standard deviation.
(B) n = total number of values.
(C) x_i = each individual value used to calculate mean.
(D) $\bar{x}$ = mean of n values.
(d) For calculating both RPD and RSD if any results are less than the LOQ the absolute value of the LOQ is used in the equation.
(7) Tentative Identification of Compounds (TIC).
(a) If a laboratory is using a gas chromatography mass spectrometry instrument for analysis when testing cannabinoid concentrates or extracts for solvents and determines that a sample may contain compounds that are not included in the list of analytes the laboratory is testing for the laboratory must attempt to achieve tentative identification.
(b) Tentative identification is achieved by searching NIST 2014 or an equivalent database (>250,000 compounds).
(c) A laboratory shall report to the licensee or registrant and the Authority or the Commission, depending on which agency has jurisdiction, up to five tentatively identified compounds (TICS) that have the greatest apparent concentration.

(d) Match scores for background subtracted or deconvoluted spectra should exceed 90 percent compared to library spectrum.
(A) The top five matches over 90 percent must be reported by the lab
(B) TIC quantitation is estimated by comparing analyte area to the closest internal standard area and assuming a response factor (RF) =1.
(8) A laboratory must provide:
(a) Any pesticide test result to the Department of Agriculture upon that agency's request.
(b) A sample or a portion of a sample to the Department of Agriculture upon that agency's request, document the chain of custody from the laboratory to the Department, and document that the sample or portion of the sample was provided to the Department in the Commission's seed to sale tracking system.
(9) A laboratory performing tests for a licensee must enter any information required by the Commission in the Commission's seed to sale tracking system.
(10) A laboratory performing tests for a registrant must comply with the documentation requirements in OAR 333-007-0370 and must maintain the documentation required in these rules for at least three years and provide that information to the Authority upon request.
(11) The Authority may, in its discretion, deviate from TNI Standards in order to comply with OAR 333-007-0400 to 333-007-0500 and these rules based on the state's needs.
(12) On and after January 1, 2018, a laboratory must be able to demonstrate that its LOQ is below any action level established in OAR 333-007-0400 and 333-007-0410, Exhibit A, Tables 3 and 4.
(13) Non-compliance testing. A laboratory that conducts a quality control or research and development test for a registrant or licensee may use methods not approved by the Authority but the laboratory may not identify those test results as accredited results.
Stat. Auth.: ORS 438.605, 438.610, 438.615 & 438.620, 475B.555
Stats. Implemented: ORS 438.605, 438.610, 438.615 & 438.620, 475B.555

333-064-0110
Reporting Marijuana Test Results
(1) For purposes of this rule the definitions in OAR 333-007-0310 apply unless the context indicates otherwise.
(2) A test report must clearly identify for the licensee or registrant:
(a) Whether a sample has exceeded an action limit for an analyte in Exhibit A, Tables 3 or 4, or has otherwise failed a test as described in OAR 333-007-0300 to 333-007-0500.
(b) A "detected" pesticide result as required in section (6) of this rule.
(c) The batch unique identification number required under OAR 333-007-0350 and the test batch number associated with the samples tested, as required by OAR 333-064-0100.
(d) On and after July 1, 2017, identification of the test as a compliance test or a quality control or research and development test.
(3) Within 24 hours of completion of the laboratory's data review and approval procedures a laboratory must report all failed tests for testing required under OAR 333-007-0300 to 333-007-0500 except for failed water activity, whether or not the lab is reanalyzing the sample under OAR 333-007-0450:
(a) Into the Commission's seed to sale tracking system if performing testing for a licensee; and
(b) To the Authority electronically at www.healthoregon.org/ommp if performing testing for a registrant, along with a copy of the test order information required in OAR 333-007-0315.

(4) The laboratory must report all test results required under OAR 333-007-0300 to 333-007-0500 that have not been reported under section (3) of this rule into the Commission's seed to sale tracking system if performing testing for a licensee.
(5) A laboratory must determine and include on each test report its limit of quantification (LOQ) and action level for each analyte listed in OAR 333-007-0400 Table 3 and OAR 333-007-0410 Table 4.
(6) When reporting pesticide testing results the laboratory must include in the report any target compound that falls below the LOQ that has a signal to noise ratio of greater than 5:1 and meets identification criteria with a result of "detected." This additional reporting is not required if the laboratory's LOQ is less than or equal to one half of the action level in Table 3.
(7) A laboratory must include in a test report the results of all associated batch quality control samples, with the date of analysis of the quality control samples and the acceptance limits used to determine acceptability.
(a) Batch quality control samples are the method blank and laboratory control sample.
(b) The report must clearly show the association to the client samples in the report by listing the batch identification numbers.
(8) A laboratory that is reporting failed test results to the Commission or the Authority in accordance with section (3) of this rule must report the failed test at the same time or before reporting to the licensee or registrant.
(9) If requested by the Authority, a laboratory must report sampling and testing information to the Authority, in a manner prescribed by the Authority.
(10) Test results expire after one year.
Stat. Auth.: ORS 475B.555
Stats. Implemented: ORS 475B.555