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TEMPORARY ADMINISTRATIVE ORDER
INCLUDING STATEMENT OF NEED & JUSTIFICATION

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OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

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FILING CAPTION: Temporary rules for Oregon Environmental Laboratory Accreditation Program (ORELAP) remote assessments of accredited laboratories

EFFECTIVE DATE: 06/05/2020 THROUGH 12/01/2020

AGENCY APPROVED DATE: 06/04/2020

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NEED FOR THE RULE(S):

The Oregon Health Authority (Authority), Public Health Division, Oregon Laboratory Accreditation Program (ORELAP) is making temporary amendments to administrative rules in chapter 333, division 64, pertaining to on-site assessments for ORELAP accreditation of laboratories. The temporary rules will allow ORELAP, during the declaration of emergency related to COVID-19, to conduct remote assessments for the accreditation of laboratories in place of on-site assessments where the health and safety of the participants is a concern. The amendments will also waive the on-site trip fee for remote assessments. Lastly, the rule amendments update the effective dates of rules to be in alignment with the effective date of other amended rules. These amendments are directly related to Executive Order 20-03, COVID-19 travel concerns and social distancing protocols.

Due to COVID-19 travel restrictions and social distancing protocols, ORELAP is unable to perform on-site assessments of accredited laboratories in accordance with OAR chapter 333, division 64 and as directed by ORS 438.615 and ORS 475B.565. The amended temporary rules will allow ORELAP, during the Governor's declaration of emergency, to conduct remote assessments using electronic means to evaluate the laboratory's conformance to accreditation standards. The temporary amended rules will also waive the associated on-site trip fee.

JUSTIFICATION OF TEMPORARY FILING:

The Authority finds that failure to act promptly will result in serious prejudice to the public interest, the Authority, and accredited drinking water, cannabis, and environmental laboratories. These rules need to be adopted promptly so that statutory and rule requirements for laboratory accreditation can be met, ORELAP can evaluate whether laboratories are performing testing according to accreditation standards, the accreditation status of laboratories are maintained and the protection of public health is ensured during the Governor's declaration of emergency due to COVID-19.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

RULES:

333-064-0025, 333-064-0035, 333-064-0060

AMEND: 333-064-0025

RULE SUMMARY: Amendments to OAR 333-064-0025 "Definitions": Update the definition for "On-site assessment" to allow for electronic remote assessments during the Governor's declaration of emergency when an on-site visit would jeopardize the health and safety of the participants.

CHANGES TO RULE:

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) "Cannabis Tracking System" or "CTS" means the Oregon Liquor Control Commission's system for tracking the transfer of marijuana items and other information as authorized by ORS 475B.177.¶¶
- (7) "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.¶¶
- (8) "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.¶¶
- (9) "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.¶¶
- (10) "Fields of accreditation" means those matrix, technology/method, and analyte combinations for which ORELAP offers accreditation.¶¶
- (11) "Finished cannabinoid concentrate or extract" means a cannabinoid concentrate or extract that is in its final form ready for packaging for sale or transfer to a patient, designated primary caregiver or consumer.¶¶
- (12) "Finished cannabinoid product" means a cannabinoid product that is in its final form ready for packaging for sale or transfer to a patient, designated primary caregiver or consumer, and includes all ingredients whether or not the ingredients contain cannabinoids. ¶¶
- (13) "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.¶¶
- (14) "Marijuana item" has the meaning given that term in ORS 475B.550.¶¶
- (15) "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.¶
- (16) "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.¶
- (17) "National Environmental Laboratory Accreditation Program (NELAP)" means the program established to oversee the implementation of the TNI Standards.¶
- (18) "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.¶
- (19) "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.¶
- (20) "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. During a period when the Governor has declared a state of emergency due to an infectious disease, when an on-site visit would jeopardize the health and safety of the participants, assessments may be conducted remotely by electronic means to evaluate the facility for conformance to the TNI Standards.¶
- (21) "ORELAP approved assessor" means an assessor whose qualification has been evaluated by ORELAP and found to meet TNI Standards for laboratory on-site assessors.¶
- (22) "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.¶
- (23) "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.¶
- (24) "Public water system" means a water system as defined in OAR 333-061-0010.¶
- (25) "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.¶
- (26) "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.¶
- (27) "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.¶
- (28) "Scheduled proficiency testing" means a single complete sequence of circulation and scoring of proficiency testing sample for a participant in a proficiency test program with predefined opening and closing dates for any participant. ¶
- (29) "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.¶
- (30) "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.¶

(31) "Supplemental proficiency testing" means a PT study that may be from a lot previously released by a PT provider but that does not have a pre-determined opening date and closing date but the closing date cannot exceed 45 days from the opening date.¶

(32) "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.¶

(33) "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.¶

(34) "These rules" means the Oregon Administrative Rules encompassed by OAR 333-064-0005 through 333-064-0120.¶

(35) "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.¶

(36) "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.]

Statutory/Other Authority: ORS 438.605, 438.610, 438.615, 438.620, 448.131, 448.150(1), 448.280(1)(b), (2), 475B.555, 475B.565

Statutes/Other Implemented: ORS 438.605, 438.610, 438.615, 438.620, 448.280(1)(b), (2), 475B.555, 475B.565

AMEND: 333-064-0035

RULE SUMMARY: Amendments to OAR 333-064-0035 "Approval Requirements": Update of rule effective date to be in alignment with the effective date of the definitions rule (OAR 333-064-0025) for the amended definition of "on-site assessment". No proposed changes to rule text.

CHANGES TO RULE:

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.

Statutory/Other Authority: ORS 448.150(1), 448.131, 448.280(1)(b)(2), 438.605, 438.610, 438.615, 438.620, 475B.555, 475B.565

Statutes/Other Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615, 438.620, 475B.555, 475B.565

AMEND: 333-064-0060

RULE SUMMARY: Amendments to OAR 333-064-0060 "Fee Schedule": Update sections to waive the on-site assessment fee for remote assessments.

CHANGES TO RULE:

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. The trip fee is waived for remote assessment.¶

(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. The trip fee is waived for remote assessment.

Statutory/Other Authority: ORS 438.605 - 438.620, 448.280(1)(b), (2), 475B.555, 475B.565

Statutes/Other Implemented: ORS 438.605 - 438.620, 475B.555, 475B.565