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**NOTICE OF PROPOSED RULEMAKING**  
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333  
OREGON HEALTH AUTHORITY  
PUBLIC HEALTH DIVISION

**FILED**

02/25/2022 2:12 PM  
ARCHIVES DIVISION  
SECRETARY OF STATE

FILING CAPTION: Changes to Oregon Environmental Laboratory Accreditation Program (ORELAP) fees

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 03/21/2022 5:00 PM

*The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.*

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Filed By:  
Public Health Division  
Rules Coordinator

HEARING(S)

*Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.*

DATE: 03/18/2022

TIME: 1:00 PM

OFFICER: Staff

ADDRESS: Microsoft Teams - Video/teleconference call

Due to COVID-19 the PSOB is not open to  
the public & meetings are held remotely  
Portland, OR 97232

SPECIAL INSTRUCTIONS:

Due to COVID-19, public meetings are  
being held remotely. To provide oral  
testimony during this hearing, please  
contact

publichealth.rules@dhsosha.state.or.us  
to sign-up and receive the link for the  
Microsoft Teams video conference.

Alternatively, you may dial 971-277-  
2343, Phone conference ID 117 648 889# for audio  
only.

NEED FOR THE RULE(S)

The Oregon Environmental Laboratory Accreditation Program (ORELAP) accredits laboratories based upon standards established by the National Environmental Laboratory Accreditation Program (NELAP) and 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 Oregon statute related to cannabis. ORELAP accredits Oregon drinking water, environmental and cannabis laboratories as well as provides primary and secondary accreditation to laboratories outside of Oregon.

ORELAP provides an on-site assessment for accredited laboratories every two years and for new laboratories seeking accreditation to ensure they are complying with accreditation standards. ORELAP is directed by state statutes to maintain an accreditation program for laboratories performing SDWA and cannabis compliance testing. ORELAP also offers accreditation to support other federal programs where it is not required by state statutes, including CAA, CWA, and RCRA.

ORELAP is a fee-based program within the Oregon State Public Health Laboratory. Funding of ORELAP is accomplished using fees to reimburse the program for cost of performing all accreditation activities performed by ORELAP staff to ensure compliance to all TNI (The NELAC Institute) standards, federal regulations and state rules and statutes. ORELAP has the statutory responsibility to accredit laboratories for drinking water compliance testing and Cannabis compliance testing. ORELAP also offers testing in support of the Clean Air Act

ORELAP is projected to have a budget shortfall in the next biennium. ORELAP's current fees are some of the lowest in the country and have not increased for in-state laboratories since the inception of the program in 1999. A fee revision is needed to ensure that ORELAP can provide timely and quality accreditations that meet established standards and regulatory requirements to best serve ORELAP's clients and protect the health of Oregonians. In addition, there are proposed changes to the ORELAP fee structure for simplification and to ensure fees are appropriate for the work required to perform laboratory accreditations of differing complexity.

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#### DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

None

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#### STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

The rule updates would increase accreditation fees in a way that scales with the complexity and scope of the laboratory's testing. The fees would not be determined by the community the laboratory serves or the laboratory ownership. Many accredited laboratories perform compliance testing for public water systems, which vary in size and demographics (e.g., trailer parks, city water). The increase in accreditation fees would likely indirectly impact public water systems by raising their testing fees in proportion with the size of the public water system. We do not perceive this having a measurable impact on racial equity. The proposed fees were set to provide adequate funding to the accreditation program while minimizing impact to the accredited laboratories and the communities they serve. Adequate funding for the accreditation program is paramount to providing oversight of drinking water testing in public water systems. In addition, Cannabis laboratories provide compliance testing of marijuana items that are used by a diverse customer base. Providing adequate oversight of Cannabis testing in Oregon is critical to protecting public health and ensuring positive health outcomes for all communities. The Klamath Tribes laboratory director provided written comments for the rules advisory committee and raised a question about cost deferment for non-profit laboratories. This may have an impact on racial equity, but because ORELAP is fee-funded by statute, the idea of cost deferment based on non-profit status is not currently possible for the program. It is also important to clarify that many laboratories are participating on a voluntary basis.

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#### FISCAL AND ECONOMIC IMPACT:

The rule updates are proposing changes to the ORELAP fee structure and increases to its fees. ORELAP's fees use a complex tiered structure that scales up based on each laboratory's accreditation needs. The proposed fee increases are wide-ranging and impact all of ORELAP's clients; the proposed fees include a switch to a five-tier system from three tiers in order to better address the disparity in program time required to assess small laboratories as compared to very large laboratories. In-state annual application fees would increase by \$750 to \$4,200. Biennial on-site assessment fees would increase by \$110 to \$400 for the first program in each field of accreditation, while a biennial "Trip Fee" for on-site

assessments would be eliminated. Out-of-state application fees would see increases of \$1,450 to \$7,190. Out-of-state assessment fees would be brought in line with in-state fees through decreases of \$40 to increases of \$340. These proposed changes would ensure the sustainability of ORELAP and support current ORELAP staff to perform timely and quality accreditations of drinking water, environmental and cannabis laboratories to established national and state standards to protect the health of Oregonians.

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**COST OF COMPLIANCE:**

*(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).*

(1) ORELAP accredits some municipal and tribal owned laboratories. These laboratories will see their accreditation fees increase. Increases in the accreditation fees may result in laboratories raising their testing fees. State, federal, & local programs, the public, and anyone who utilizes these laboratories may see increased costs to have samples tested.

(2)(a) There are approximately 73 small business environmental or cannabis laboratories subject to this rule. These laboratories will see their accreditation fees increase. These small business laboratories will likely increase their testing fees to offset increased accreditation fees. This may result in increased costs to other small businesses, individuals, or organizations that utilize the services of commercial testing laboratories.

(b) Small business laboratories are not expected to have significantly more requirements for reporting, recordkeeping and other administrative activities for compliance, including costs of professional services. The fee increases will require fiscal planning from the regulated entities.

(c) Small business laboratories are not expected to need more equipment, supplies, labor, or administration for compliance with this rule. The fee increases will require fiscal planning from the regulated entities.

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**DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):**

Laboratory stakeholders were invited to take part in a Rules Advisory Committee (RAC) Meeting. Some of these stakeholders are suspected to qualify as small businesses.

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**WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES**

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AMEND: 333-064-0060

**RULE SUMMARY:** Proposed amendments to OAR 333-064-0060 "Fee Schedule": Add two additional levels, or tiers, to the application fee structure for in-state and out-of-state laboratories, changing from a 3-tier system to a 5-tier system. Increase the fees assigned to each tier of the in-state and out-of-state application fee structure. Modify the point ranges assigned to each tier of the in-state and out-of-state application fee structure. Remove language specifying that assessment fees are due only when ORELAP personnel perform the assessment. Increase the assessment fees for each of the 4 fields of accreditation categories for in-state and out-of-state laboratories. Divide whole effluent toxicity (WET) and immunoassay into separate technologies under the complex fields of accreditation category. Remove the onsite assessment trip fee from rules. Remove rules requiring laboratories to pay third party assessor costs to ORELAP.

**CHANGES TO RULE:**

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~~five levels of fees, Tier 1 at ~~\$451,200~~, Tier 2 at ~~\$902,200~~, Tier 3 at ~~\$3,400~~, Tier 4 at ~~\$4,600~~, and Tier ~~35~~ at ~~\$1,65,800~~ 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, 26 to 40 points are Tier 3 laboratories, 41 to 55 points are Tier 4 laboratories, and ~~25~~6 or more points are Tier ~~35~~ laboratories.¶

(b) For each out-of-state laboratory requesting primary or secondary accreditation through ORELAP, one of ~~three~~five levels of fees, Tier 1 at ~~\$1,63,100~~, Tier 2 at ~~\$4,850~~, Tier 3 at ~~\$6,950~~, Tier ~~24~~ at ~~\$2,6409,050~~, and Tier ~~35~~ at ~~\$3,9611,150~~ will be charged with each Tier determined according to ~~subsection (1)(a)~~paragraphs (1)(a)(A) through (F) 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 an assessment fee as follows:~~¶

~~(a) Laboratories will be charged \$1200 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 \$462600 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 \$66.~~¶

~~(c) Laboratories will be charged \$1,000 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;¶
- ~~(K) Oregon laboratories will be charged \$1,000 and out-of-state Immunoassay;¶~~
- (L) Asbestos - electron microscopy.¶
- (d) 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 use third party 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 third party assessors will be used, must pay alls to provide assessment services. In this event, the laboratory will still pay the assessment fee described in this fee schedule to ORELAP. Upon the laboratory's consent to the third party assessment, ORELAP will pay the third party assessor's costs to ORELAP upon the laboratory's written consent to the third party assessment.¶~~
- (8Z) 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 laboratory that have not been requested by its fixed based facility. ~~If third party assessors are used, the out-of-state laboratory must pay all the third party assessor's costs to ORELAP upon the laboratory's written consent to the third party assessment.~~

(98) 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.~~

Statutory/Other Authority: ORS 438.605 - 438.620, 448.280, 475B.555, 475B.565

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