

Secretary of State
STATEMENT OF NEED AND FISCAL IMPACT
A Notice of Proposed Rulemaking Hearing accompanies this form.

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ARCHIVES DIVISION
SECRETARY OF STATE

Oregon Health Authority, Public Health Division
Agency and Division

333
Administrative Rules Chapter Number

Environmental Laboratory Accreditation to Implement Marijuana Testing

Rule Caption (Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.)

In the Matter of:

Permanently amending Oregon Administrative Rules chapter 333, division 64 to add technologies and new fees for laboratories that want to become accredited to test marijuana under the Oregon Environmental Laboratory Accreditation Program (ORELAP) pursuant to licensure through the Oregon Liquor Control Commission (OLCC).

Statutory Authority:

ORS 438.605 - 438.620, 448.131, 448.150(1), 448.280(1)(b) & (2), OL 2015, ch. 614

Other Authority:

Statutes Implemented:

ORS 438.605 - 438.620, 448.280(1)(b) & (2), OL 2015, ch. 614

Need for the Rule(s):

Based upon the passage of HB 3400 (Oregon Laws 2015, chapter 614), laboratories testing marijuana items must be accredited under ORS 438.605 to 438.620. Currently, the Oregon Environmental Laboratory Accreditation Program (ORELAP), defined in ORS 438.605(1), accredits laboratories based on The National Environmental Laboratory Accreditation Conference Institute (TNI) standards. The ORELAP accreditation process will need to be changed to include a new field of testing, and expand the definitions of matrix to include marijuana items to be tested and to be accredited based on the assessment of Matrix-Technology/Method-Analyte to the TNI standards. ORELAP is a fee based program. The addition of the field of testing and the matrix per field of testing for which the laboratory has requested accreditation will require a rule change in the fee schedule to determine the appropriate assessment fee.

Documents Relied Upon, and where they are available:

ORELAP <https://public.health.oregon.gov/LaboratoryServices/EnvironmentalLaboratoryAccreditation/Pages/index.aspx>

TNI: The National Environmental Laboratory Accreditation Committee Institute

<http://www.nelac-institute.org/content/policy.php>

<http://www.nelac-institute.org/content/abdb.php>

Enrolled House Bill 3400, 2015 Regular Session <https://olis.leg.state.or.us/liz/2015R1/Downloads/MeasureDocument/HB3400/Enrolled>

Fiscal and Economic Impact:

Based on the addition of Advanced Technology Field of Testing, the applicable fees for filing an application for accreditation, an on-site assessment based on the field of testing and the on-site trip fees will not have a fiscal impact for the 39 existing accredited Oregon laboratories. Laboratories testing marijuana, seeking ORELAP accreditation pursuant to OLCC licensure, will be expected to complete an online application and submit the appropriate fees based upon the total number of fields of testing, which may include the "added" Field of Testing, Advanced Technology. The fiscal impact on the Oregon Health Authority's ORELAP staff will include hiring a qualified Laboratory Compliance Specialist 3 (ORELAP Assessor) to provide written marijuana guidelines for the incoming laboratories testing marijuana to become accredited to national standards; reviewing the required electronic documents submitted with online application; and helping to test and validate the computer program to assure the added marijuana items have been added to the ORELAP database. An Information Specialist will be needed to program the changes specified into the ORELAP database.

Statement of Cost of Compliance:

1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)):

There is no expected impact of cost of compliance on other state agencies, units of local government or the public.

Funding of the ORELAP is accomplished using fees to reimburse the program for cost of performing the activities and to provide documentation necessary to comply with TNI rules and criteria. The hiring of the new ORELAP Assessor at the Oregon State Public Health

Laboratory will offset the on-boarding workload of accepting new applications and review of required documentation from laboratories testing marijuana, scheduling on-site assessment, completing the ORELAP accreditation process and ongoing monitoring of proficiency testing performance for each laboratory. Currently, the ORELAP Administrator and Lead Assessor accredit 121 laboratories, 82 out-of-state and 39 in-states. ORELAP accreditation is significant to the 94 out-of-state labs, which include 4 EPA Regional laboratories, US Army Corps-Korea, UT and ID Public Health Labs, WSMR, and 39 in-state labs. Expired certificates of accreditation may have significant impact on the services the laboratories provide if new ORELAP Assessor is not hired. The impact on the ORELAP program is to have the appropriate number of staff to provide the support to continue ORELAP accreditation in a timely and efficient manner.

2. Cost of compliance effect on small business (ORS 183.336):

a. Estimate the number of small business and types of businesses and industries with small businesses subject to the rule:

There are 39 ORELAP accredited laboratories in the state of Oregon. Based upon the ORELAP Administrator's review of these laboratories, there are no current accredited ORELAP laboratories that will be impacted by the addition of Advanced Technology Fields of Testing and fee. It is anticipated that there may be 10-15 Oregon laboratories testing marijuana requesting accreditation. Oregon laboratories are expected to pay the appropriate on-site assessment fees based on the Advanced Technology Field of Testing for the testing of marijuana items, \$1,000.00, with each additional matrix per Advanced Technology Field of Testing for which the laboratory has requested accreditation, \$150.00. The out-of-state laboratories are expected to pay the on-site assessment based on the Advance Technology Field of Testing, \$1,200.00, with each additional matrix per Advanced Technology Field of Testing for which the laboratory has requested accreditation, \$165.00. The addition of the fees in rule will be used, as the other fees from other laboratories will be used, to reimburse the program for the cost of administering the ORELAP program.

b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services:

No projected reporting, record-keeping and other administrative activities are foreseen to be required for compliance.

Laboratories testing marijuana will need to meet the OLCC standards for recordkeeping but those standards are not part of laboratory accreditation.

c. Equipment, supplies, labor and increased administration required for compliance:

None. Laboratories will already have the equipment, procedures, and quality manuals to do the testing with or without accreditation. Laboratories not already doing proficiency testing will be required to subscribe to a proficiency testing program in order to be accredited.

How were small businesses involved in the development of this rule?

The ORELAP Lead Assessor has been in communication with many of the owners/testing personnel of marijuana testing laboratories to assure the methods/analytes are being addressed in preparation of the rule changes. The ORELAP Program Administrator and Lead Assessor have meetings every two months with the members of OTAC (ORELAP Technical Advisory Committee). OTAC exists to provide assistance in the interpretation of requirements and to provide advice on technical matters pertinent to the operation of ORELAP as well as a general forum for communication with stakeholders.

**Administrative Rule Advisory Committee consulted?: Yes
If not, why?:**

09-24-2015 5:00 p.m.	Brittany Sande	brittany.a.sande@state.or.us
Last Day (m/d/yyyy) and Time for public comment	Printed Name	Email Address