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Center for Health Protection

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To: Joint Committee for Implementation of Measure 91
From: Tom Eversole, DVM, MS, Administrator, Center for Health Practice, Public Health Division
RE: ORELAP Laboratory Certification process (ORS 438.605 to 438.062 and OAR 333-064-0005 to 333-064-0065)
Date: 9 February 2015

The Oregon State Public Health Laboratory administers a robust laboratory certification program that can readily expand to certify labs that test marijuana. This memorandum describes the existing system and how such labs could be regulated by adding new analyses. If you would like more detailed material or have additional questions, please contact: Rosa Sepulveda Klein, Legislative Coordinator for the Public Health Division, Oregon Health Authority rosa.klein@state.or.us 503-803-4274

ORELAP background

The Oregon State Public Health Laboratory (OSPHL) of the Oregon Health Authority (OHA), Public Health Division (PHD) in concurrence with Oregon Department of Environmental Quality and Oregon Department of Agriculture was granted authority by the Oregon State Legislature to implement an environmental laboratory accreditation program. Approval of its program by the National Environmental Laboratory Accreditation Program (NELAP) to act as an accrediting authority established the Oregon Environmental Laboratory Accreditation a Program (ORELAP).

ORELAP was established by the 1999 Oregon Legislature to accredit environmental testing laboratories to national standards established and adopted by the NELAC Institute (TNI) as implemented by the National Environmental Protection Agency (EPA). Accrediting authorities such as ORELAP adhere to the NELAP Standards for accrediting laboratories. ORELAP was recognized as a national environmental laboratory accrediting authority by NELAP on February 29, 2000.

ORELAP is committed to following the current The National Environmental Laboratory Accreditation Program Institute (TNI) standards adopted at the Annual conference in July 2009. ORELAP must meet all requirements to maintain its status as a NELAP accrediting body. This includes having ORELAP approved assessors and certifying laboratories that comply with the TNI Standards as specified in the OAR rules.

Assessors

The ORELAP team is considered a leader in TNI standards, OSPHL currently has two full-time ORELAP approved assessors, who are Environmental Protection Agency (EPA) certified for microbiology, organic chemistry and inorganic chemistry, and TNI certified for quality systems. One assessor is certified as an assessor by the International Organization for Standardization.

All ORELAP labs are accredited in /through NELAP standards. The team uses ORELAP checklists as a support tool for their interview questions. An on-site assessment is performed to verify items addressed

in the ORELAP application and to evaluate the facility and analytical performance (i.e. methodologies), quality manual (QM) and proficiency testing (PT) review for conformance with the TNI Standards.

Fees

ORELAP is a fee-based program, which accepts applications from all qualified laboratories in-state and out of state that apply and submit the appropriate fees. Laboratories located in Oregon pay one of three levels of fees: Tier 1 at \$450, Tier 2 at \$900 and Tier 3 at \$1600. The Tiers are determined by the total number of fields of testing requested for accreditation.

ORELAP requires the list of analytes (i.e., substances or components) identified for assessment in order to determine the assessment fees, which are based on the number fields of testing and matrices.

Application Certification Process

ORELAP and the accreditation process may be found on our web site:

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

Laboratories seeking ORELAP accreditation to test marijuana will be required to complete an on-line application and to submit the following documents electronically:

Demonstration of Capability (DOC) summary forms

Quality Manual (QM)

Standard Operation Procedures (SOP) for each method or technology that the laboratory is seeking accreditation for

Complete NELAP Chapter 5 Quality Systems Checklist

Proficiency Test (PT) results for the last two years, sent by the PT Provider. PT Enrollment is required.

First Year: For those applying for primary accreditation, a complete on-site assessment is required in the first year and every other year thereafter to maintain accreditation.

Second Year: The accreditation cycle requires a re-application that lists current analytes, as well as electronic copies of new DOCs and the QM. Any revisions from the previous year's application must include electronic copies of new or updated SOP's and the completed NELAP chapter 56 Quality Systems checklist. There are no on-site reviews during the second year.

Once accredited by ORELAP, the application process includes:

- Application – three months before expiration
- Invoice – two months before expiration
- Review performance of proficiency testing, documents, correct application
- Complete certificate and scope of documents – one month before expiration

Shannon O'Fallon's (Senior Asst. Attorney General, Oregon Department of Justice) overview (Feb 4, 2015) listed OLCC Powers and Duties, which included the duty "require testing of marijuana items". These "marijuana items" need to be specified to ORELAP in order to add analyte codes to our electronic database. The codes will be matched to the standardized method.

ORELAP also requires the list of analytes to assess in order to include the analyte codes into the electronic Accreditation Certificate & Scope and for the electronic invoicing/billing.