



Oregon

Environmental Laboratory Accreditation Program



Department of Agriculture, Laboratory Division
Department of Environmental Quality, Laboratory Program
Oregon Health Authority, Public Health Division

Oregon State Public Health Laboratory
7202 NE Evergreen Pkwy, Suite 100
Hillsboro, OR 97124
PH (503) 693-4122
FAX (503) 693-5602

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Question: What is the Oregon Environmental Laboratory Accreditation Program (ORELAP) process and how can I “streamline” for maximum efficiency for both our laboratory and ORELAP?

Answer: Once your completed application has been submitted online through the ORELAP Data Input and Edit (ODIE) system, ORELAP can begin its review. ORELAP staff will review your requested fields of accreditation for accuracy. Submitted documents are checked for completeness and agreement with program requirements. The steps below will help the process move efficiently.

1. The following documents must be submitted electronically in ODIE: a signed copy of the certification of compliance, a quality manual, standard operating procedures (SOPs), technical director credentials (i.e., resume and transcripts), applicable demonstrations of capability (DOCs) and method detection limits (MDLs). These documents can be submitted in the window that opens when you click the “Complete Application” button. The file size limit for uploading a document is 10 megabytes. Contact ORELAP staff for larger file sizes.
2. Make sure you have completed two proficiency testing (PT) samples for each analyte found on The NELAC Institute’s (TNI) Fields of Proficiency Testing (FoPT) tables (<http://nelac-institute.org/content/NEPTP/fopt.php>) and for each *Cannabis* analyte. PT reports must be sent directly from the PT vendor to ORELAP.PT@odhsoha.oregon.gov. Most if not all PT vendors will allow you to select which agency you send PT reports to when you report the results. For ORELAP, select “Oregon”, “ORELAP”, “Oregon State Public Health Laboratory” or other similar name to ensure we receive them. ORELAP cannot accept any PT report directly from the laboratory.
3. The 2016 TNI Standard is your source for regulatory requirements and how to qualify for and maintain accreditation under the National Environmental Laboratory Accreditation Program (NELAP). The standard can be purchase from TNI at <http://nelac-institute.org/content/CSDP/standards.php?ap3=1> 2. Use the 2016 TNI Standard to conduct an internal audit of your laboratory as an indicator of readiness. A checklist for the 2016 TNI

Standard can be downloaded at <http://nelac-institute.org/content/NELAP/qsccheck2016-access.php>. Do not schedule an onsite assessment with ORELAP prior to performing an internal audit of your laboratory. The onsite assessment will determine whether your laboratory meets the standards for accreditation and can become accredited, it is not the time for correcting major deficiencies.

4. Upon an initial review of the completed application, an invoice will be emailed to the laboratory. Payment is made by check. Please include your ORELAP ID number and the invoice number on the memo line for easier tracking. If you cannot pay by check, contact ORELAP staff for alternatives. An onsite assessment cannot be performed prior to payment of an invoice. Late or missing payment is the most common delay in the process.

5. Following payment, a more thorough desk review and review of PT performance is conducted. Any issues will be communicated to the laboratory for correction.

6. Once desk review is finished, an onsite assessment will be scheduled with the laboratory for a mutually agreeable time. Assessments are scheduled for 1-5 days depending on the scope of the testing.

7. Within 30 calendar days after the end of the onsite assessment, ORELAP will provide an assessment report to the laboratory. The report will document any findings identified during the onsite assessment requiring corrective action from the laboratory. The laboratory must respond to these findings within 30 calendar days with a corrective action plan. ORELAP will review the corrective action plan and respond within 30 calendar days, indicating whether the corrective actions are acceptable or unacceptable. If any corrective actions are unacceptable, the laboratory must respond within 30 calendar days of ORELAP's response. This will be the laboratory's last chance to submit an appropriate corrective action plan. Not responding within 30 calendar days may result in denial of the laboratory's application. All of this takes place in the ODIE system online.

8. Once the assessment report findings have acceptable corrective actions, the assessment is closed, and the laboratory is issued an accreditation certificate.