



Oregon

Environmental Laboratory Accreditation Program



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Oregon Health Authority, Public Health Division

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Q: What is the ORELAP process and how can I 'streamline' for maximum efficiency for both our lab and ORELAP?

A: Once your completed application has been submitted online, your application will be reviewed to assure methods and analytes are accurate; and submitted documents are checked for completeness and agreement with program requirements. The steps below are for your benefit as well as for ours since both of our time is important and we want to be efficient and complete especially for the initial visit. No surprises.

1. The following documents must be submitted electronically using your online ODIE account: Quality Manual, SOPs, DOCs, Method Validation, your confirmation of PT enrollment and your signed Letter of Compliance. Please refer to the ORELAP and Accreditation Process link <https://public.health.oregon.gov/LaboratoryServices/EnvironmentalLaboratoryAccreditation/Documents/getmaintain.pdf> Additional documents can be scanned into your ODIE application at any time, even after it has been locked.
2. PT reports are to be sent via email to ORELAP.PT@dhsosha.state.or.us direct from the PT provider- you must have completed two PT events, and passed.
3. The 2009 TNI Standard is your source for regulatory requirements and how to qualify for and maintain accreditation under NELAP. The standard must be purchased as it contains ISO 17025© material. It can be purchased at <http://nelac-institute.org/content/CSDP/standards.php>
4. To streamline the accreditation process and to assure all documents and supporting data are complete, use the internal audit as your indicator for readiness. Once you have purchased the 2009 TNI Standard, you may download the 2009 checklist for free. Prior to your on-site assessment, we request the laboratory performs an internal audit using the 2009 checklist for a self-evaluation to determine your laboratory is ready for the on site assessment. Besides just checking "Yes", identify where the information may be found (e.g. cite the SOP, or section of your quality manual). This helps ensure you have established an internal audit and corrective action process.
5. Submit the confirmation letter of the purchased TNI standards and the completed internal audit for review using your ODIE account. The internal audit must be complete prior to scheduling the onsite assessment.
6. Upon approval of the completeness of the application and all required documents, an invoice will be generated based on the requested field(s) of accreditation and other factors. Payments are made by check - please include the ORELAP ID on the memo line of the check for easier tracking. The invoice will have the information for mailing your check. ORELAP is a fee based program and we must assure payment has been received prior to scheduling an onsite assessment.

7. Once the desk review indicates that all requested documents have been provided and deemed acceptable, and payment has been received, an onsite assessment will be scheduled based on the pending schedule of ORELAP accredited laboratories for the “renewal” of onsite assessments.
8. The initial assessment of the laboratory will be scheduled in advance for a date mutually agreeable to ORELAP and the Laboratory. Your assessment will be approximately 3 days, dependent upon the fields of accreditation and the laboratory’s readiness.
9. The closing meeting on the last day of the onsite assessment will include the findings and recommendations. If there are findings, the Lead ORELAP assessor will convey those at the closing meeting. However, the Lead ORELAP assessor will compile the overall findings and input into the ODIE on-line program, and will submit a written final report with findings via email through the ODIE on line program.
10. The readiness of the laboratory will determine the length of time it will take for a laboratory to become ORELAP accredited. The more findings there are, means longer write up time for the assessor including additional review time by management staff, to generate an assessment report. The ORELAP assessors have 30 days to complete the assessment report, and the laboratory upon receipt of the report has a maximum of 30 days to respond with their Corrective Actions (CA). The ORELAP assessors will review the laboratory’s corrective actions to determine their acceptability. This review can take up to 30 days. If the corrective actions are not acceptable the laboratory is notified and the lab has up to 30 days to provide additional documentation to assure TNI compliance has been met. If the corrective actions are found acceptable, the lab will be notified and accreditation will be granted provided all of the other criteria are met (acceptability of PTs, fees paid, etc.). However, If the lab’s second attempt at corrective actions is found to be insufficient, the assessment ends and the lab’s accreditation is denied. The laboratory would need to reapply from the beginning.