Oregon

Environmental Laboratory Accreditation Program

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ORELAP and the Accreditation Process (revised 10/27/2015)

Introduction

The Oregon Environmental Laboratory Accreditation Program (ORELAP) requires that environmental, drinking water, and cannabis testing laboratories meet the standards as adopted by the National Environmental Laboratory Accreditation Program (NELAP). The current standards used by ORELAP are the 2009 TNI Standards for the Laboratory Sector: *Volume 1 Management and Technical Requirements for Laboratories Performing Environmental Analysis.* The consequence of not adhering to the Standards is loss of ORELAP accreditation for all or part of the laboratory's accredited analytical fields of testing, analyte or method. Accreditation can be denied at the application level, temporarily suspended for not more than six months, or revoked in part or in total.

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 Please review and understand (at a minimum) the following chapters from the Standard as they pertain to your laboratory:

- Proficiency Testing*
- Quality Systems – General Requirements*
- Asbestos Testing
- Chemical Testing
- Microbiological Testing
- Radiological Testing
- Toxicity Testing

* Required for all labs regardless of scope of accreditation

Application Process

ORELAP's accreditation process is defined within a two-year cycle. Laboratories may request a Primary or a Secondary accreditation.

Requests for *Primary* accreditation require submission of the following:

- The completed on-line application
- The following documents submitted electronically:
  - Demonstration Of Capability (DOC) raw data and summary.
  - Method Validation packages for any requests regarding an application for a new field of accreditation.
  - Quality Manual (QM)
  - Standard Operating Procedures (SOP) for each method or technology the laboratory is seeking accreditation for.
    - Access the complete 2009 TNI Checklist online at http://www.nelac-institute.org/content/NELAP/qscheck2009-access.php
- Please include references to your QM and SOPs in the appropriate boxes for review when relevant instead of simply checking "yes".
- Proficiency Test results for the last two years, sent by the PT Provider

Laboratories requesting *Secondary* recognition must submit the following:

- Completed online application
- A copy of the laboratory's current Certificate of Accreditation and Fields of Accreditation (FOA) from the primary Accrediting Authority (AA).

Note: 'Completed' means all questions have been answered either 'yes' or 'no' on the Quality System Checklist, and if "yes" to reference the laboratory's documents that apply.

To access ORELAP's online application system, referred to as 'ODIE' (ORELAP Data Input and Edit), connect to the ORELAP website at www.healthoregon.org/orelap and click on the 'Login to ODIE' link.

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.

The second year of the accreditation cycle requires a re-application that lists current analytes, as well as electronic copies of new DOC's and the Quality Manual. Any revisions from the previous year's application must include electronic copies of new

or updated SOP's and the 2009 TNI checklist with the relevant modules completed. While the second year re-application process and review will be thorough, there are no on-site reviews during the second year.

Fees are calculated and invoiced by ORELAP. All application fees must be paid prior to the technical review or assessment, and are non-refundable.

The application packet will be denied if any part is judged to be incomplete or inadequate.

Technical Manager

The laboratory must identify the technical manager(s). The technical manager is a Full-time member of the staff of an environmental laboratory who exercises actual day-to-day supervision of laboratory procedures and reporting of results. You may appoint one or more technical managers for the appropriate fields of testing. His/her name must appear in the NELAP national database. An individual shall not be the technical manager of more than one accredited environmental laboratory without authorization from the ORELAP Administrator.

A technical manager who is absent for a period of time exceeding 15 consecutive calendar days shall designate another full-time staff member, meeting the qualifications of technical director, to temporarily perform this function. If this absence exceeds 35 consecutive calendar days, the ORELAP administrator must be notified in writing.

The required qualifications of a technical manager are found in the TNI 2009 Standards, V1:M2, section 5.2.6.1 (a) through (f) and exemption language in section 5.2.6.2 (a) through (c).

Quality Systems

The laboratory shall have a named quality assurance officer or a person designated as accountable for data quality. See the 2009 TNI standard (or most current standard adopted by NELAP) V1:M2 section 4.1.7.1 (a) through (h) for specific duties and requirements.

The quality manual documents and the quality system of the laboratory must meet all the criteria as set forth in V1:M2 4.2.8.3 and 4.2.8.4 of the 2009 TNI Standards. The TNI Quality System Checklist contains the requirements for the Quality Manual. This can be used to ensure that the quality manual meets the requirements of the TNI Standards.

Proficiency Testing

Required participation

In addition to passing a review of the application and a biennial on-site assessment, the laboratory must participate in a Proficiency Testing (PT) program. The requirements are found in V1:M1, Proficiency Testing, in the 2009 TNI Standards and are summarized below:

- To be accredited and to maintain accreditation, a laboratory shall participate in two single-blind, single-concentration PT studies, where available, per year for each method it seeks accreditation. For all fields of testing, including those for which PT samples are not available, the laboratory shall ensure the reliability of its testing procedures by maintaining a total quality management system that meets all applicable requirements of V1:M2 of the 2009 TNI Standards.

The samples shall be analyzed and the results returned to the PT provider no later than 45 calendar days from the opening date. The laboratory's management and all analysts shall ensure that all PT samples are handled (i.e., managed, analyzed, and reported) in the same manner as real environmental samples utilizing the same staff and methods as used for routine analysis of that analyte.

The laboratories must pass 2 out of the last 3 PT studies for every matrix-technology/method-analyte for which they are requesting accreditation. These PT studies are to be done approximately each six months apart (No less than 5 months and no more than 7 months apart based on analyzed date).
Note: ORELAP will first evaluate studies based on closing dates and only evaluate the analysis dates if a potential problem is indicated. Failure to meet the semi-annual schedule is considered a failed study. Supplemental studies for failed analytes may be no closer than 15 calendar days between the analysis dates for each study.
Note: ORELAP will evaluate analysis if there is less than 15 calendar days between the closing date to the shipment date of the last study.

We recommend a spring/fall schedule but whatever schedule you choose, inform ORELAP. We will not remind you to run your PT samples. However, the laboratory must note that a failure to participate in routine biannual PT studies is considered grounds for suspension or revocation.

A laboratory may withdraw from a PT study for an analyte(s) or for the entire study if the laboratory notifies both the PT provider and ORELAP administrator before the closing date of the PT study. Withdrawal from a study does not relieve the laboratory from the 5-7 month requirement between studies.

Restrictions on exchanging information

Laboratories shall comply with the following restrictions on the transfer of PT samples and communication of PT sample results prior to the time the results of the study are released:

1. A laboratory shall not send any PT sample, or portion of sample, to another laboratory for any analysis for which it seeks accreditation, or is accredited.
2. A laboratory shall not knowingly receive any PT sample or portion of a PT sample from another laboratory for any analysis for which the sending laboratory seeks accreditation or is accredited.
3. Laboratory management or staff shall not communicate with any individual at another laboratory (including intra-company communication) concerning the PT sample.
4. Laboratory management or staff shall not attempt to obtain the assigned value of any PT sample from their PT provider prior to the end of the study.

Failed Studies

Whenever the laboratory fails a study, it shall determine the cause for failure and take necessary corrective action. You must document the action taken in your own records and provide the recorded documentation of the investigation and action taken at the request of the ORELAP administrator or the on-site assessment team.

If you fail a second study out of the most recent three, ORELAP will take action within no more than 60 calendar days to determine the accreditation status of the unacceptable analyte(s) for that matrix and technology/method (e.g. suspension of the analyte for that matrix and Technology/method).

Records

The laboratory shall maintain copies of all written, printed, and electronic records, including but not limited to bench sheets, instrument strip charts or printouts, data calculations, and data reports, resulting from the analysis of any PT sample for five years or longer if required by applicable regulatory program. These records must be made available to assessors during the on-site assessment.

On-site Assessment

For the initial assessment of a laboratory, the on-site assessment is scheduled in advance for a date mutually agreeable to ORELAP and the laboratory. Routine assessments are generally scheduled in advance for a date mutually agreeable to ORELAP and the laboratory, however, ORELAP retains the authority to select the date if a mutually agreeable date is not resolved or perform an unannounced assessment. Unannounced on-site assessments may be performed for any reason, normally for causes such as complaints or misrepresentation of accreditation. In order to maintain accreditation, the laboratory must allow the assessors access during any normal business hours.

Opening Conference

Upon arrival, the lead assessor will introduce him/herself and any team members. The assessors will meet with the facility's administrator or laboratory director (however named) and management staff. The purpose of the assessment and assessment process will be briefly explained. Plans for an exit interview shall be made known. During the Opening conference the assessors will:

- Review the purpose of the assessment and the schedule of activities
- Identify the Standards that will be used by the assessors in judging the compliance status of the laboratory operation
- Verify information on the ORELAP application
- Indicate which tests that will be examined
- Examine the roles and responsibilities of key managers and staff in the laboratory
- Identify any records and operating procedures to be examined during the assessment
- Address Confidential Business Information (CBI) concerns
- Review special requirements that the laboratory may have *(e.g*., requirements related to health and safety or security)
- Allow the laboratory staff to ask any questions necessary to understand the assessment process and events that will follow the assessment
- Provide the responsible laboratory official with an assessment appraisal form to be submitted to ORELAP
- Identify tentative time for the closing conference
- Request a general laboratory tour

Analytical Records and Data Review

The analytical records and data review includes all laboratory documents and the tracking of a particular sample from laboratory receipt to the final laboratory reporting of the sample testing results. The analytical records and data review will vary widely depending on the field of testing that is being assessed. Analytical records can vary from simple handwritten transcriptions by an analyst of observations in microbiology and wet chemistry analyses to more complex computer hardcopy of chemical absorption, chromatograms, or mass spectra. In general however, all data will be evaluated by an assessor from its rawest form to determine method compliance and scientific defensibility.

The minimum set of records and documents for review includes:

- Standard Operating Procedures and method protocols for each parameter for which accreditation is sought
- Maintenance and calibration records for specific equipment separate for those included in measurement records
- Records for the preparation and calibration of stock solutions and standard reagents
- Documentation of the origins, purities, assays, and expiration dates of primary standards, analytical reagents and standard reference materials
- Records associated with method specific quality control requirements
- Records associated with the MDL and IDC study associated with each method for which the laboratory seeks accreditation, to be examined in detail with the historical calibration data
- Records associated with the methods used to estimate precision and accuracy in general for specific analyses
- Sample receipt and sample handling documentation
- Records of any internal audits conducted or corrective actions taken by the laboratory
- The documentation of the laboratory's annual management review. An example of this review for organic chemistry analyses would include a review of:
    - Chain-of-custody documents
    - Extraction records (if applicable)
    - Sample analysis records
    - Sample holding times
    - Hard copy of the calibration, method and sample data packet records.
    - Any Manual Integrations, including identifications and deletions performed must have a record of the "before" chromatogram and "after" chromatogram with a reason for the manual integration.

- Traceability records of all reagents, equipment, standards and any other element of the method that contributes to the uncertainty of the result and are necessary for the historical reconstruction of that result.
- Data results through any data input system to the production of the final report.

Proficiency Testing (PT) review

- Evidence of treatment of PT samples as if they were routine samples
- Review of raw data associated with the PT sample analysis
- Documentation and corrective action of any unsatisfactory performance.
    - Note dates of these failures and select these dates for QC record review.
- Evidence or documentation that the laboratory technical director reviews all PT results.

Note: PT is monitored throughout the year by ORELAP.

Staff interview Qualifications:

Information on all laboratory personnel and their qualifications (education and laboratory experience) should be on file in the laboratory and made available to assessors for review. The assessors will verify through interviews with key staff personnel that the staff have the appropriate qualifications and are performing the duties as reported and are truly knowledgeable of the procedures for which they are responsible. Staff members should be:

- Qualified and competent to perform specific analyses
- Familiar with the laboratory quality manual and follow its guidelines
- Understand the laboratory SOP's and reference methods and have them immediately available
- Follow method and program specific QA\QC

Equipment and Testing Supplies:

Assessor will observe and confirm that appropriate equipment, reagents, media are available to perform tests reported.

- Equipment is in good working order, maintained on a regular basis and documentation of such is kept
- All reagents, media are within expiration date, labeled properly and stored according to manufacturer's instructions
- Procedure manuals are readily available to laboratory staff for all instruments including operation and troubleshooting instructions

Assessment Team Debriefing

At the conclusion of the assessment, the team members will meet in private to discuss and organize findings. The assessment team will develop a closing conference outline, listing findings and order of presentation.

Closing Conference

Upon completion of the assessment, the assessment team conducts a closing conference to inform the laboratory director of preliminary assessment results and provide the opportunity to the laboratory staff to ask questions about the preliminary findings, including nonconformities, if any, and their basis. Final determinations concerning the number, nature and extent of assessment findings shall be made by the ORELAP Administrator or designee after reviewing reported findings.

Before adjourning, the lead assessor will review items that have been claimed to be CBI, review the schedule for completing the assessment report, and inform the laboratory director of procedures for responding to the assessment findings, which include:

- Submitting a plan of corrective action, if needed.
- Timelines for the submittal of corrective action plans

The closing session will reflect the fact that the purpose of the assessment is to judge the extent to which the laboratory is in compliance with the TNI Standards, not to pass judgment on the overall quality of the operation.

Corrective Action

After being notified of deficiencies, the laboratory shall have 30 calendar days from the date of receipt of the finalized assessment report to provide a corrective action plan. The corrective action plan shall include the action that the laboratory will implement to correct each deficiency and the time period required to accomplish the corrective action.

ORELAP will respond to the action noted in the corrective action plan within 30 calendar days of receipt. If the corrective action plan (or a portion) is deemed unacceptable to remediate a deficiency, the laboratory shall have an additional 30 calendar days to submit a revised corrective action plan.

If the corrective action plan is not acceptable to ORELAP after the second submittal,

the laboratory shall have accreditation revoked or denied for all or any portion of its scope of accreditation for any or all of a field of testing, or a method, or analyte within a field of testing.

If the laboratory fails to implement the corrective actions as stated in their corrective action plan, accreditation for fields of testing, specific methods, or analytes within those fields of testing shall be denied or revoked.

Proprietary data and Confidential Business Information and classified national security information will be excluded from all public records. All other information included and documented in an assessment report and the corrective action plan are considered to be public information.

No laboratory will have their accreditation denied, suspended, or revoked without due process. Refer to SOP for Denial, Suspension, and Revocation.

Follow-up Assessment

Follow-up assessments may be necessary when a major change occurs at a laboratory in personnel, equipment, or in a laboratory's location that might alter or impair analytical capability and quality. Any major changes should be reported to ORELAP as soon as possible to determine the need for a Follow-up assessment. These assessments may be to determine whether a laboratory has corrected deficiencies or to determine the merit of a formal appeal by the laboratory. Any follow-up assessment that might warrant downgrading the laboratory's accreditation status shall be completed and reported within 45 calendar days after the follow-up assessment.

Determination of the need for a follow-up assessment will be decided on a case by case basis through discussion by the assessment team assigned to the laboratory. The final decision to perform a follow-up assessment will be made by the ORELAP administrator based on assessment team's recommendation.

Interim Accreditation for New Methods

Interim accreditation allows the laboratory to perform analyses and report results for similar technologies as currently accredited, with the same status as an accredited laboratory until the on-site requirements have been completed. Interim accreditation cannot exceed twelve months. The following must be met for interim accreditation:

- Already ORELAP accredited and in good standing (or previously NELAP-accredited by a different AB and changing accreditation to ORELAP)
- Completed application submitted

- Fees paid
- SOP's written and submitted
- DOC's completed and submitted
- Acceptable PT (2) completed
- Methods involve similar technologies for which the lab is already accredited

Oregon does not provide interim accreditation to new laboratories.
Revocation of interim accreditation may be initiated at any time for due cause.

Notification and Reporting Requirements

The laboratory shall notify the ORELAP administrator, in writing, of any changes in key accreditation criteria within 30 calendar days of the change. This written notification includes but is not limited to changes in the laboratory ownership, location, top management or key personnel, main policies, resources or premises, scope of accreditation, anything else that may affect the laboratory's ability to fulfill the requirements of accreditation such as changes in major instrumentation. All such updates are public record and any or all of the information may be placed in the national database.

Record Keeping and Retention

All laboratory records associated with accreditation parameters shall be maintained for a minimum of five years, unless otherwise designated for a longer period in another regulation or authority.