Oregon Environmental Laboratory Accreditation Program

Department of Agriculture, Laboratory Division
Department of Environmental Quality, Laboratory and Environmental Assessment Division
Oregon Health Authority, Oregon State Public Health Laboratory

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ORELAP Program, Policy, and Procedure Manual

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PART I. THE ORELAP PROGRAM

I.1. Introduction

In 1999 the Oregon State Legislature authorized the Oregon Health Authority (OHA), in concurrence with the accrediting authority made up of the Directors (or their designees) of OHA, Oregon Department of Environmental Quality (DEQ), and Oregon Department of Agriculture (ODA), to implement the Oregon Environmental Laboratory Accreditation Program (ORELAP). ORELAP has been a National Environmental Laboratory Accreditation Program (NELAP) recognized accreditation body since 1999. In 2014, the Oregon State Legislature directed ORELAP to provide accreditation to cannabis compliance testing laboratories. In 2021, the Oregon State Legislature directed ORELAP to provide accreditation to psilocybin compliance testing laboratories.

Laboratory accreditation by ORELAP is based on the 2016 TNI Standards and rules found in Oregon Administrative Rules (OAR) Chapter 333 Division 64. Additional rules for cannabis testing can be found in OAR Chapter 333 Division 7 while additional rules for psilocybin testing can be found in OAR Chapter 333 Division 333. The authority for the program comes from Oregon Revised Statutes (ORS) 438.605 to 438.620, 448.150 and the Oregon Drinking Water Quality Act of 1981, 475A.606, and 475C.560.

The authority for granting, maintaining, suspending, or revoking a laboratory's NELAP accreditation resides solely with ORELAP and may not be delegated.

I.2. Definitions

The following definitions apply to this manual and other ORELAP documents, unless context indicates otherwise. Where these definitions differ from federal or state regulations or the TNI Standards, the regulations or national standards take precedence.

Annually – occurring within twelve months not to exceed fourteen months between occurrences.

Biennially – occurring every other year and approximately twenty-four months apart, not to exceed thirty months between occurrences.

Daily – occurring once each working day and approximately twenty-four hours apart.

Monthly – occurring between the same calendar dates in consecutive months, not to exceed six weeks between occurrences.

Quarterly – occurring four times per year approximately three months apart, not to exceed four months between occurrences.

I.3. Program Policy

ORELAP is committed to following the 2016 TNI Standards. The NELAC Institute (TNI) will propose new standards as necessary and ORELAP will adopt new standards in rule and will implement them as soon as practicable. As with changes in the accreditation standards, due notice will be provided if there are any changes to ORELAP requirements for accreditation. Public comments must be taken into consideration before final rules are adopted.

ORELAP is administered by OHA's Public Health Division, Oregon State Public Health Laboratory (OSPHL) in an impartial and non-discriminatory manner, and as such, have no rules, regulations, procedures or practices that:

- Restrict the size, large or small, of any laboratory seeking accreditation
- Require membership or participation in any laboratory or other professional association
- Impose any financial conditions or restrictions for participation in the accreditation program other than the fees authorized by territorial, state, or federal law
- Conflict with any territorial, state, or federal laws governing discrimination
- Restrict the number of in-state laboratories applying for accreditation

ORELAP initiates the processing of laboratory applications for NELAP accreditation in the chronological order a complete application is received. Furthermore, ORELAP personnel, committees, or its contractors shall act objectively and shall not offer paid consultancy or other services that may compromise the impartiality of its accreditation process and decisions. ORELAP accredited laboratories must define key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory in order to identify potential conflicts of interest.
Technical assistance in answering accreditation questions is provided by ORELAP staff to any interested party without bias. ORELAP also encourages a cooperative program by encouraging laboratories in the program to work with each other to answer technical questions and raise quality in the Oregon laboratory community.
ORELAP's accreditation requirements, assessments and decision-making processes for an accredited laboratory are limited to those matters specifically related to the fields of accreditation being sought by a laboratory.

ORELAP will maintain as confidential laboratory assessments to the extent permissible under state public records laws.

The ORELAP Manager will notify the TNI Accreditation Council, in writing, within 30 calendar days of any of the following changes to:

- The authority to accredit laboratories as stated in the statutes, regulations, and promulgating instructions governing Oregon's environmental laboratory accreditation program
- The organizational structure, including key personnel
- The rules, regulations, policies, guidance documents, and standard operating procedures
- The mailing address and office location, telephone, and email address
- The contractual arrangements, including contractor's personnel, for laboratory accreditation activities

I.4. Program Structure

The organizational structure of ORELAP is illustrated in Figure 1. The role of each organizational unit is defined in Part II of this document.

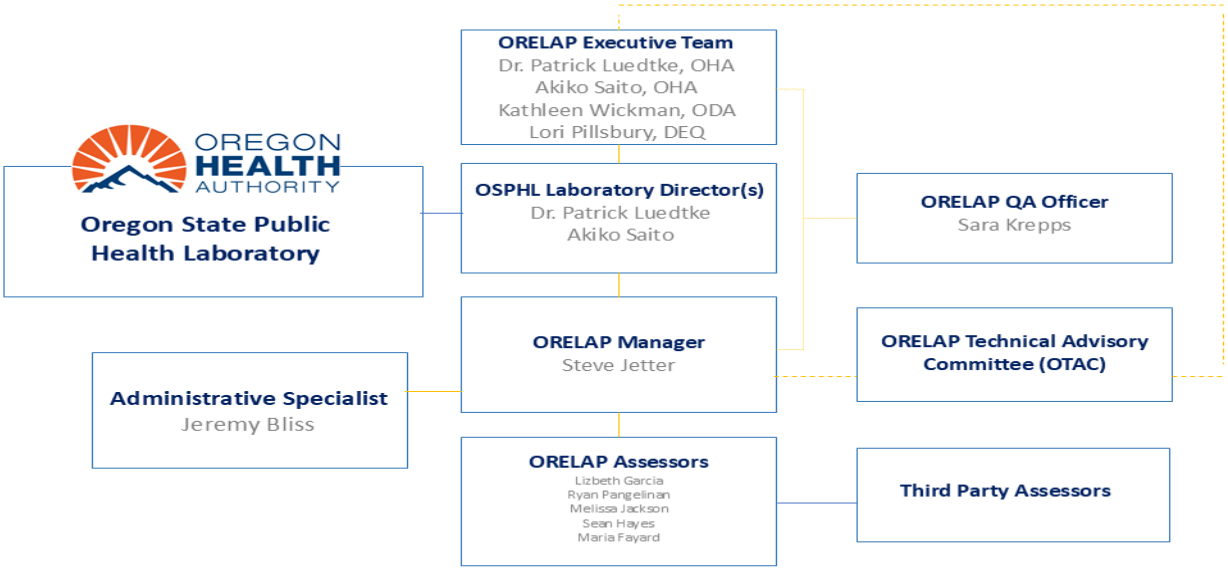

Figure 1. ORELAP organizational structure. Solid lines are primary lines of communication and authority; dashed lines are secondary paths of communication and authority.

I.5. Fees

Funding of ORELAP is accomplished using fees to reimburse the Program for the cost of performing the activities and to provide documentation necessary to comply with TNI/NELAP rules and criteria. See ORS 438.620. The fee schedule is found at OAR 333-064-0060. Fees include:

- Annual Application Fee: A non-refundable fee submitted to ORELAP with initial and annual renewal applications.
- Biennial Assessment Fee: Paid initially and every other year thereafter during renewal to cover the cost of performing the on-site assessment. The fee is dependent on categories of environmental analysis for which the laboratory chooses to be accredited. Assessment fees are only paid by laboratories with primary accreditation.
- Additional Fees: The laboratory will be responsible for additional application and assessment fees when the laboratory applies for additional parameters outside of the annual renewal window. There may also be additional assessment fees if unscheduled or unannounced assessments are conducted at the laboratory.
- Out-of-state laboratories seeking accreditation in Oregon shall also be billed for cost of travel, including wages during travel time, per diem, airfare, car rental, and other travel costs for ORELAP staff to perform on-site inspection. The laboratory is also responsible for fees incurred to gain access to the laboratory, such as National Security Clearance.

I.6. Display of ORELAP and NELAP Insignia

The ORELAP and NELAP insignia can be found on the cover page of this manual. The ORELAP insignia is the State Seal of Oregon with the text "ORELAP" wrapping over the top of the seal. The NELAP Accreditation Body insignia and the ORELAP insignia will appear on all accreditation certificates and scopes. The display of the NELAP Accreditation Body insignia will include at least the phrase "NELAP Recognized" on accreditation certificates. These insignia may also appear on ORELAP letterhead and other program documents. The ORELAP insignia is a distinctly different symbol from other government entities and related bodies. Laboratories which are currently accredited may use the ORELAP insignia on reports or certificates issued within the scope of their accreditation. ORELAP does not allow the use of the ORELAP insignia by unaccredited entities or by entities making inaccurate or misleading claims regarding ORELAP accreditation. ORELAP will protect the ORELAP insignia from misuse, such as at unaccredited premises, or for unaccredited tests.

I.7. Program Scope

See OAR 333-064-0010; these rules apply to laboratories seeking or currently holding accreditation for drinking water testing, environmental or agricultural laboratory testing, cannabis items testing, or psilocybin products testing.

The program accredits fixed base and mobile laboratories. See OAR 333-064-0025 and OAR 333-064-0050 for more information about mobile laboratories.

The program accredits laboratories performing the analyses of samples which fall under the air, drinking water, non-potable water, solid and chemical waste, and biological tissue matrices. These matrices may contain sub-matrices that ORELAP may define in memos or policy updates for the purposes of requiring appropriate matching sub-matrix quality control elements.

The program accredits all laboratories performing analysis for drinking water testing or residential wells associated with real estate transactions in Oregon under OAR Chapter 333 Division 61.

The program accredits all laboratories holding an Oregon Liquor & Cannabis Commission (OLCC) laboratory license and performing cannabis sampling or analysis in Oregon under OAR Chapter 333 Divisions 7 & 64.

The program accredits all laboratories holding an Oregon Psilocybin Services (OPS) laboratory license and performing psilocybin sampling or analysis in Oregon under OAR Chapter 333 Divisions 64 & 333.

Specific analytical methods and analytes are listed in the ORELAP Data Input and Edit (ODIE) database. There may come a need for ORELAP to expand the scope of the accreditation program. The following considerations are evaluated before expanding ORELAP's fields of accreditation:

- the program's present competence, suitability of extension, resources, etc. in the new field
- current employee expertise and that of contract third party assessors
- the need for application or guidance documents (checklists, method references, etc.)
- the impact to Public Health

I.8. Program Documentation

ORELAP's authority is documented in the statutes mentioned in the preceding sections of this manual. ORELAP's requirements are documented in the rules mentioned in the preceding sections of this manual. ORELAP's policies and procedures are documented in Parts II and III of this manual. ORELAP assesses laboratories to the requirements documented in the 2016 TNI Standard, Volume 1. ORELAP's quality system is based on the requirements documented in the 2016 TNI Standard, Volume 2. In addition, the ORELAP webpage contains more information about the program.

ORELAP and OSPHL maintain documents and records to demonstrate the program has the financial resources necessary for the operation of its activities.

ORELAP rules, policies and procedures are developed by committees or persons possessing the necessary competence and with the participation of interested parties, where appropriate.

ORELAP is a state governmental program and adheres to state policies regarding document and record generation, organization, storage, retention, and disposal. The Oregon State Public Health Laboratory maintains a current record retention schedule.

I.9. Public Availability of Information

ORELAP maintains confidentiality of laboratory documents and records to the extent allowed by state public information laws. Public access to records will be handled consistent with ORS Chapter 192 and current OHA policy. When a laboratory has made a claim of confidential business information in connection with on-site assessment records, ORELAP will share this claim with OHA public records coordinators for consideration during process of public records requests.

ORELAP will make the following information available to the public via the ORELAP website:

- through posting of this document, detailed information about assessment and accreditation processes, including arrangements for granting, maintaining, extending, reducing, suspending and withdrawing accreditation
- a document or reference documents containing the requirements for accreditation, including technical requirements specific to each field of accreditation, where applicable
- general information about the fees relating to the accreditation
- a description of the rights and obligations of laboratories
- information on the accredited laboratories is available through the ODIE search feature including the following:
    - name and address of each accredited laboratory
    - dates of granting accreditation and expiration dates
    - current scope of accreditation
- information on procedures for lodging and handling complaints and appeals
- information about the authority under which the accreditation program operates
- a description of its rights and duties
- general information about the means by which it obtains financial support
- information about its activities and stated limitations under which it operates

PART II. ORELAP QUALITY MANUAL

II.1. Introduction

This quality manual describes the policies to be used by ORELAP for the implementation, management, documentation, and measurement of success of the program. All ORELAP staff as well as third party assessors are responsible for, and attest to, understanding and following the policies and procedures outlined in this quality manual.

II.2. Quality Policy

II.2.1. ORELAP Mission

The mission of ORELAP is to establish and implement an environmental laboratory accreditation program with standards equivalent to standards adopted by national accreditation programs. In carrying out this mission, ORELAP staff act out a vision of all Oregonians working cooperatively to preserve, protect and promote public health. In all they do, ORELAP staff seek to remain true to values of quality laboratory testing, customer service, partnership, excellence, integrity, employee growth, teamwork, inter-laboratory program cooperation, diversity, and equity. ORELAP partners with NELAP and implements the consensus standards developed by TNI in its commitment to laboratory quality.

II.2.2. ORELAP Goal

The goal of ORELAP is to foster excellence in laboratory testing through the establishment of a premier accreditation program. We are committed to providing the tools, resources, and experiences necessary to help ORELAP staff develop new skills and build a quality work life. We support our team members through mutual respect and constructive feedback, celebrating our successes while learning from our mistakes. We encourage team participation and decision-making whenever appropriate and provide the tools necessary for the team to be successful.

II.2.3. ORELAP Objectives

The objectives of ORELAP are to:

- Ensure accreditation requirements are fair, achievable, and equivalent to national standards
- Complete work by established due dates and in a timely manner
- Accredit competent laboratories to protect public health
- Develop program staff into subject matter experts
- Maintain the highest quality standards
- Conduct program work in an impartial and objective manner

II.2.4. ORELAP Quality System

To meet its mission, ORELAP has implemented a quality system based on the 2016 TNI Standards, Volume 2. The ORELAP quality system consists primarily of the following:

- This quality manual
- Standard Operating Procedures
- Management Reviews

- Internal Audits
- Corrective & Preventive Action

II.3. Quality Management and Organization

II.3.1. Laboratory Accreditation Quality Assurance Policy

This Quality Manual is a management tool designed to meet the needs of the ORELAP by defining how the program objectives will be attained. The Quality Manual is reviewed every three years or as needed by ORELAP staff, with revisions approved by the ORELAP Executive Team.

The Program Manager is responsible for assuring that the Quality Manual is implemented. In implementing the Quality Manual and in accordance with ORELAP policies and procedures the Program Manager shall ensure:

- quality assurance is an identifiable activity with resources adequate to accomplish ORELAP goals in the development and execution of all projects and tasks involving laboratory accreditation
- appropriate quality assurance criteria for all projects and tasks are included in operating guidance
- an adequate degree of assessment is performed to determine compliance with quality assurance requirements
- deficiencies highlighted in assessments are appropriately addressed
- ORELAP specific quality assurance training needs are identified and provisions for training are made

The Quality Assurance (QA) Officer is responsible for monitoring the program's adherence to adopted quality management policies and procedures. The QA Officer shall ensure:

- That program operations are reviewed
- That deficiencies are reported to management for correction

II.3.2. Quality Management

All ORELAP personnel must understand the goals of the program and make contributions to the decision-making process that are pertinent to their roles. ORELAP quality management focuses on:

- Client Identification - All "clients" must be identified and brought into the process to articulate their requirements at each program level in terms of operations, resource needs and functions
- Standards and Performance - ORELAP uses standards and measures of performance that are proactive rather than reactive
- Management Commitment - ORELAP uses procedures and policies that foster a focus on quality as a commitment from management.

II.3.3. ORELAP Personnel

II.3.3.1. ORELAP Executive Team

The ORELAP Executive Team is comprised of the Directors (however named) from the Oregon State Public Health Laboratory, Oregon Department of Environmental Quality Laboratory, and Oregon Department of Agriculture Laboratory. The Executive Team is the Accrediting Authority.

The ORELAP Executive Team has overall responsibility for managing ORELAP and has final authority over the program. The ORELAP Executive Team is responsible for resolving QA issues that are identified through the ORELAP Program Manager or other members of the Program.

Major responsibilities of the ORELAP Executive Team, as related to QA, include:

- Management Team lead
- Approving the budget and planning processes
- Establishing policies to ensure that quality assurance requirements are incorporated in all quality assurance activities
- Annual review of the quality system and internal audits

The Executive Team delegates the responsibility of ORELAP development and implementation to the ORELAP Program Manager.

II.3.3.2. ORELAP Technical Advisory Committee (OTAC)

The ORELAP Technical Advisory Committee (OTAC) is comprised of interested parties affected by the ORELAP program including representatives from commercial environmental laboratories, commercial cannabis laboratories, commercial psilocybin laboratories, representatives from municipal and industrial facilities that are covered by the discharge regulations, drinking water supply organizations, representatives from agencies supporting the public health regulations relating to cannabis, psilocybin, and technical experts in laboratory analysis and regulation.

The members of OTAC will be appointed by the ORELAP Executive Team and will change as the needs of the program change. OTAC can make non-binding resolutions to the ORELAP Executive Team.

The responsibilities of OTAC are to meet regularly and discuss issues brought forward by the ORELAP Executive Team, the ORELAP personnel including the Program Manager and Assessors, the private and public facilities affected by the program and other interested parties including citizen groups and environmental groups. OTAC may serve in the capacity of ombudsperson by presenting concerns with the implementation of ORELAP as reported to OTAC by affected facilities. The responsibilities may include:

- Ensuring consistent and fair standards are used in all assessments
- Ensuring that all interested parties are heard by the ORELAP Executive team, Program Manager and Assessors

- Providing technical support and review of the quality assurance efforts if requested by the program staff
- Responding to the laboratories in a timely fashion to concerns brought forth to OTAC as ombudsperson

II.3.3.3. Regulatory Section Manager

The Regulatory Section Manager ensures that ORELAP operates within the rules, regulations, policies and procedures of Oregon Health Authority's Public Health Division (PHD) and that the ORELAP PHD staff have access to available resources to operate the program. The responsibilities may include:

- Providing information on PHD rules, regulations, policies and procedures as they apply to ORELAP
- Tracking the ORELAP budget
- Meet the training needs of the PHD staff
- Assessing performance of ORELAP PHD staff
- Providing technical support
- Reviewing (or appointing a designee to review) laboratory assessment reports

II.3.3.4. ORELAP Program Manager

The Program Manager is responsible for the day-to-day operation of ORELAP and ensures that ORELAP implements appropriate quality assurance policies. Quality assurance responsibilities of the Program Manager include but may not be limited to:

- Assuring that the ORELAP maintains a current Quality Manual and adheres to the document
- Taking corrective action that may be required when deficiencies are identified
- Ensuring appropriate quality assurance criteria for all projects and tasks are included in operating guidance for all assessment teams
- Reviewing and approving the ORELAP Program, Policy, and Procedure Manual
- Reports to the Executive Team on the performance of the management system and any need for improvement
- Ensuring that ORELAP personnel involved in laboratory accreditation have access to any training or quality assurance information needed to be knowledgeable in quality assurance requirements, protocols, and technologies
- Interpreting and developing the quality assurance policy for ORELAP in accordance with NELAP policies and direction from the ORELAP Executive Team
- Providing information to the laboratory community about the requirements necessary to become an ORELAP/NELAP accredited laboratory through mailings, presentations and the ORELAP website
- Performs evaluations of assessors performing laboratory assessments

- Ensuring that procedures needed for the management system are established
- Ensuring that routinely used accreditation activities are covered by standard operating procedures
- Ensuring that standard operating procedures for routinely used accreditation activities are reviewed and approved
- Ensuring that adequate follow-through actions are implemented in response to assessment/review findings
- Tracking and managing the status of the accreditation program
- Preparing the program's annual management review as required in the TNI Standards
- Making final accreditation decision. In instances where ORELAP Program Manager is lead or sole laboratory assessor, assessment report review and decision on accreditation will be made by the Regulatory Section Manager or their designee.

II.3.3.5. ORELAP Quality Assurance Officer

The Quality Assurance Officer (QAO) helps ensure that ORELAP adheres to its adopted policies and procedures. Quality Assurance Officer's responsibilities include, but may not be limited to:

- Reviewing and approving the ORELAP Quality Manual
- Reviewing and approving of ORELAP SOPs
- Performing internal audits (Management System Assessment and Technical System Assessment) to monitor ORELAP's conformance to established policies and procedures
- Reporting nonconformance discovered from the internal audits to the ORELAP management for corrective actions and tracking the results of corrective actions
- Reporting nonconformance discovered from either the ORELAP On-Site Assessment Appraisal forms or complaints received by the ORELAP Program Manager, to the ORELAP management for corrective actions and tracking the results of corrective actions
- Ensuring that ORELAP staff has read and understands the ORELAP quality documents as appropriate for the positions held by individuals within the program

II.3.3.6. Environmental and Cannabis Laboratory Assessor and Policy Developer

The Environmental and Cannabis Laboratory Assessor and Policy Developer works with the Program Manager and interagency/department program leadership. Responsibilities include but may not be limited to:

- Researching cannabis and psilocybin testing criteria, including contaminants of emerging concern, and naturally occurring & artificially derived cannabinoids
- Working closely with inter-agency partners and a state reference laboratory to create testing policies, methods, and other technical documents for accreditation of cannabis laboratories. Provide technical assistance to regulated entities
- Acting as program subject matter expert for the testing of all psychoactive substances, including cannabis and emerging psychedelics. Pursues training opportunities and professional memberships

- Expanding and improving the cannabis proficiency testing (PT) program
- Assisting the ORELAP Program Manager in developing new cannabis accreditation standards
- Leading ORELAP investigations into cannabis and psilocybin testing complaints

II.3.3.7. ORELAP Assessors / Assessment Team

ORELAP assessors make up the ORELAP assessment teams and are responsible for conducting the on-site assessments (OSA) of laboratories, as well as the review of laboratory's applications for accreditation. An assessment team may consist of a single (lead) assessor or a lead assessor and other technical or third-party assessors. Each assessor must have the appropriate training and experience, as specified in the TNI Standards, for those fields of testing for which they will be assessors. In order to be judged successful, the assessment team must produce accreditation reports that are comprehensive, accurate, complete, and timely. Technical advisors, who are not assessors, but are technical experts on the testing technology may accompany the assessment team to provide technical guidance. There are three categories of assessors: Lead Assessors, Technical Assessors, and Third-party Assessors. All members of the assessor team must:

- Be thoroughly knowledgeable of the various forms of required records
- Be thoroughly knowledgeable of data reporting, data analysis and data reduction techniques and procedures so they would be able to provide technical assistance
- Be technically conversant with the specific tests or type of tests for which accreditation is sought
- Be knowledgeable of associated sampling and preservation requirements
- Professional standards of conduct apply to all assessors. All members of the assessment team must certify in writing that they:
    - have no interest in play other than that of the accrediting authority and TNI during the entire accreditation process
    - act impartially and not give preferential treatment to any organization or individual
    - provide equal treatment to all persons and organizations regardless of race, color, religion, sex, sexual orientation, gender identity, national origin, age, and/or disability
    - not use their position for private gain
    - not solicit or accept any gift or other item of monetary value from any laboratory, laboratory representative, or any other affected individual or organization doing business with, or affected by, the action of the assessor's employer or accrediting authority
    - not hold financial interests that conflict with the conscientious performance of their duties
    - not engage in financial transaction using information gained through their positions as assessors to further any private interest

- not engage in employment activities (seeking or negotiating for employment) or attempt to arrange contractual agreement with a laboratory that would conflict with their duties and responsibilities as assessor
- not knowingly make unauthorized commitments or promises of any kind purporting to bind the affected accrediting authority
- attempt to avoid any actions that could create even the appearance that they are violating any of the standards of professional conduct outlined in this section

Assessors that fail to meet these professional rules of conduct may be subject to punitive action following the appropriate procedures.

II.3.3.8. Lead Assessors

The Lead Assessors are responsible for the performance and coordination of laboratory accreditation activities for laboratories assigned to them and for all information collection activities based on the ORELAP rules and regulations. Responsibilities include:

- Planning and leading the review of the laboratory's application, quality manual, Method Detection Limits (MDLs) and Initial Demonstration of Capabilities (IDOCs)
- Leading the on-site assessment team through the laboratory assessments according to ORELAP/NELAP requirements
- Summarizing the findings of the on-site assessments including itemizing any correct actions found necessary by the team
- Tracking the status of assigned laboratories
- Developing standard operating procedures for routine accreditation activities
- Reporting ORELAP quality problems to the Program Manager

II.3.3.9. Technical Assessors

The assessment team must consist of a lead assessor and may also contain one or more technical assessors. The lead assessor may also play the role of technical assessor. Technical assessors must be able to communicate effectively in appropriate fields of testing, both orally and in writing. Technical assessors responsibilities include but may not be limited to the following:

- Conduct technical assessments of laboratory procedures, equipment, and personnel qualifications
- Review documentation and records to verify compliance with applicable standards and regulations
- Collaborate with the lead assessor to prepare comprehensive assessment reports
- Participate in pre-assessment and post-assessment meetings and reviews
- Provide subject matter expertise during the assessment process, including identifying nonconformances
- Communicate findings clearly and professionally
- Maintain confidentiality and impartiality throughout the assessment process

II.3.3.10. Contractors or Third-party Assessors

When necessary, ORELAP may employ third-party assessors. Although these third-party assessors may be used to assist ORELAP, they may not make final accreditation decisions. That responsibility rests solely with ORELAP.

Because ORELAP takes full responsibility for contracted work, all third-party assessors must be experienced professionals, hold at least a Bachelor's degree or equivalent education/experience in the appropriate discipline, e.g. chemistry for chemistry assessors, and have relevant experience. All assessors must have successfully passed the TNI Basic Assessor's course and TNI Technical Training for Assessors. Additionally, if assessing potable water methods, the assessors must have passed the EPA Drinking Water Laboratory Certification Officer (LCO) course for the appropriate discipline. The assessors also must attend refresher training at least every five years. When assessing in Oregon, the assessors must review regulations pertinent to the analytical work being performed such as drinking water or cannabis. Each member of the third-party assessor team must present documentation covering education and training, as well as SOPs covering their on-site assessment process. Their responsibilities include adhering to the same ethical standards as those of assessors employed by the State of Oregon and adhering to contracts to perform assessments as requested by ORELAP.

II.3.3.11. Administrative Specialist

The Administrative Specialist provides administrative support for ORELAP. Responsibilities include but may not be limited to the following.

- Develop and maintain systems to assure prompt laboratory application and fee processes are in place to ensure timely issuance of laboratory certificates
- Reviews data input of laboratory applications and fees
- Ensure electronic and paper file management is accurate and organized
- Provide forms, packets, create and run reports
- Develop and maintain website record and material for ORELAP web pages

II.3.4. ORELAP Program Meetings

The ORELAP Program Manager, Policy Developer, Administrative Specialist, and Assessors meet as needed for coordination meetings. These meetings are used to discuss the status of on-site assessments, final reports, corrective action reports, and the overall health/status of ORELAP. Attendees discuss program and policy issues/changes as well as assessment concerns/problems and develop appropriate corrective actions. An agenda is created and attendance is recorded for the meetings.

II.4. Management System Reviews or Internal Audits

The ORELAP Executive Team will ensure that both internal program reviews and program systems and management reviews are performed at least annually. The ORELAP QA Officer will plan and organize a program review (internal audit) to verify that ORELAP is complying with its quality system utilizing the appropriate TNI Standards Checklist for Accreditation Bodies. The Program Manager will plan and organize a management review with the Executive

Team to ascertain the continuing suitability and effectiveness of the ORELAP policies and procedures. These reviews may be scheduled more frequently if major discrepancies are found. These internal audits will include, as appropriate, general reviews of ORELAP's compliance with, as applicable:

- The ORELAP Program, Policy, and Procedure Manual
- The organizational structure of the accrediting authority
- The application and fee schedule
- The accreditation personnel education and training
- Standard Operating Procedures for the accreditation process, including assessor's checklists
- The structure, comprehensiveness, and completeness of the accreditation database
- Actual record management and storage
- Timeliness of all reports, corrective action responses, and PT sample review
- Accreditation fee structure and budget analysis
- Annual report to the Executive Team that includes program highlights, training, continuing education efforts, number of on-site assessments performed, listing of laboratories accredited by matrix, and any accreditation status changes with reasons for those actions

The Program Manager must issue a corrective action report based upon the internal audit to the Executive Team and QA Officer within thirty calendar days. This reply will include action items and/or remedies for the documented discrepancies

The management review of the ORELAP will include the following topics:

- Results of audits
- Results of peer evaluation where relevant
- Participation in international activities, where relevant
- Feedback from interested parties
- New areas of accreditation
- Trends in nonconformities
- Status of preventive and corrective actions
- Follow-up actions from earlier management reviews
- Fulfillment of objectives
- Changes that could affect the management system
- Appeals
- Analysis of complaints

The management review of the ORELAP will include actions related to:

- Improvement of the management system and its processes
- Improvement of services and accreditation process in conformity with the relevant standards and expectations of interested parties

- Need for resources
- Defining or redefining of policies, goals and objectives

II.5. Conflict of Interest

ORELAP has the authority to issue certificates to environmental, cannabis, and psilocybin testing laboratories and to develop standards for the operation of these laboratories. Consequently, in an effort to assure laboratories that ORELAP and its staff do not have any Conflicts of Interest, as defined by ORS chapter 244, that may impact the performance of their statutory duties, the Program Manager, or their designee, reviews all assessment reports to ensure TNI Standards and analytical methods were enforced consistently and without bias. The ORELAP Program Manager where necessary will consult with technical or quality system experts available with ORELAP or with the NELAP community for assistance to ensure an unbiased decision is reached.

For the purpose of this section, the following definition applies:

Potential Conflict of Interest means when an employee is in a situation where the employee's action or decision could result in private pecuniary benefit or detriment.

Policy:

Financial Gain or Loss

- No employee shall use an official position to obtain financial gain for the employee or any member of the employee's household, nor any business which the employee or any member of the employee's household is associated with. Exceptions include the employee's official salary, honoraria and/or reimbursement of expenses.
- No employee shall receive personal gain using confidential information gained in any way during the course of or by reason of holding an official position or through official activities.

Employment Opportunities

- An employee has a potential conflict of interest when the employee is offered any pledge or promise of future employment with any business or government entity that the employee's official action, decision or recommendation affects.
- Employees are permitted to perform work for pay, other than their regular state job, if the work does not interfere with their efficiency on their state job, and the employee does not engage in unethical practices.

In the case where an assessor or ORELAP personnel has recent past employment experience with an accredited laboratory, they will not make assessment decisions on that laboratory for at least two years after the termination of employment. If the assessor is a contractor for other organizations, they will follow the organization's policy on how much time must lapse before performing an ORELAP assessment on a laboratory assessed for that organization.

Laboratories are provided with the names of the assessor(s) prior to the announced assessment for them to voice objections for legitimate reasons. The assessor shall declare any potential conflicts of interest on a form provided in the opening conference and the form will be signed by a laboratory person that is legally responsible if they accept the assessor despite the announced

potential conflict of interest. If a laboratory cites a reason deemed legitimate by ORELAP for not being satisfied with any member of the assessment team, they will be offered a replacement assessor or the option to use a third-party assessor at their own expense.

When an employee identifies a potential conflict of interest, that employee must notify the ORELAP Program Manager and the ORELAP Executive Team representative in writing of the potential conflict of interest, with distribution as follows:

- Original copy to the ORELAP Program Manager
- Copy to the ORELAP Executive Team Representative.
- A copy to the ORELAP staff member affected.

Upon receipt of the request for review of potential conflict of interest, the ORELAP Program Manager shall in writing, designate a resolution to the matter, such as removal from the assessment team, or direct the employee to manage the situation in a manner agreeable to the ORELAP Executive Team with distribution as follows:

- Original copy to the employee
- A copy to the ORELAP Executive Team
- A copy to the ORELAP staff member affected

Appeals of decisions made by ORELAP regarding conflict-of-interest matters shall be directed to the ORELAP Executive Team, who shall make the final decision as to the merit of such appeals.

II.6. Document Control

Laboratories seeking accreditation will be assigned a unique identifying number under which all appropriate accreditation documentation will be filed. Approval of application records are discussed in III.1.3. The master files will include (see OAR 333-064-0035(4)):

- The application and application amendments
- Proficiency testing results
- Corrective actions and responses
- On-site reports
- Appeals, complaints, and disputes, and their resolution(s)

Internal program documentation will also be kept and will be maintained by the ORELAP Program Manager. These master files will include:

- ORELAP Program, Policy, and Procedure
- Method checklists
- Forms and templates
- Assessment personnel training and qualifications
- ORELAP SOPs and Policies

Each document will be identified with a revision number. The controlled document is stored on ORELAP's shared drive. Printed copies are uncontrolled.

II.7. Implementation of the Accreditation Process

II.7.1. Notification of Program Implementation

Interested parties will receive information about ORELAP through a variety of media. These will include specific mailings to accredited laboratories and permitted municipal facilities, information posted on the ORELAP and TNI websites, and professional meetings. This documentation will briefly describe ORELAP and supply appropriate information about the application process and timeline.

II.7.2. Application Process

Applications and supporting documentation are submitted to ORELAP via the ODIE web application. Instructions for the process can be found under the Help tab in ODIE as well as on the ORELAP webpage. See OAR 333-064-0035(4)(a)(A). Once the application with all required documentation is submitted through ODIE, an email will be sent to the Program Manager. The Program Manager may assign application review to a member of the ORELAP technical staff. An invoice is generated and sent to the laboratory. When payment of the invoice has been received, a member of the ORELAP staff will schedule an on-site assessment if required. In the case of a laboratory seeking continued accreditation through a renewal application, an updated certificate and scope are generated and sent to the laboratory prior to expiration of the former certificate and/or when changes to the laboratory's scope require a new certificate and scope. The certificate and scope are emailed to the laboratory.

II.7.3. On-site Assessment Team

The Program Manager will develop a team comprised of a lead assessor and appropriate technical assessors. The assessment team will review the application, associated documentation and any pre-existing pertinent information. This team may request other documentation, more information, or clarification for the application. When the application is deemed complete and payment of the invoice is received, the on-site assessment can be scheduled and performed.

All members of the assessment team must:

- Be thoroughly familiar with the various forms of required records
- Be thoroughly aware of data reporting, analysis and reduction techniques and procedures so they would be able to provide technical assistance
- Be technically conversant with the specific tests or type of tests for which accreditation is sought
- Be familiar with associated sampling and preservation requirements
- Be able to communicate effectively, both orally and in writing

In addition, the lead assessor must:

- Be familiar with the relevant legal regulations, accreditation procedures, and accreditation requirements

- Have a thorough knowledge of the relevant assessment methods and assessment documents

All members of the assessment team must certify in writing that they are not directly involved with the laboratory seeking ORELAP/NELAP accreditation or have other affiliations that would compromise impartiality in the ORELAP/NELAP accreditation process. If any potential conflict of interest may exist, a report should be made as provided above in section II.5.

II.7.4. Final Report and Status

A final report noting any deficiencies and requesting necessary corrective action will be prepared by the lead assessor and assessment team and submitted to the Program Manager, or their designee(s), who will review the report prior to making the final accreditation decision. Resolution of any deficiencies or corrective actions will be determined based on the results and certification status will be assigned as described below.

The Program Manager or designee will provide updates to the NELAP national database with the required information specific to the laboratories for which ORELAP is the primary or secondary accrediting authority. The schedule for the updates includes submitting a report even if there were no changes to the database.

II.7.5. Accreditation Certificates

The Program Manager, or their designee, will review and determine whether the application and supplied information, PT scores, and assessment report(s) and corrective action(s) are deemed acceptable and in accordance with the TNI Standards. Laboratories will be granted accreditation (initial or continued) as soon as practicable after that determination has been made. The accreditation will be in effect for a period of one year from notice of accreditation.

Laboratories will be accredited by Matrix-Technology/Method-Analyte according to the following rating scheme:

II.7.5.1. Accredited

A laboratory that meets the minimum requirements of the ORELAP/NELAP and all applicable regulatory requirements will be accredited. “Accredited” status may not be granted to any laboratory that has not met the performance criteria specified in the program and within the policy required by their certification authority.

II.7.5.2. Interim Accreditation

This may be granted in certain limited circumstances on a case-by-case basis. This is considered a last resort option, normally reserved for cases when public health is at risk. An on-site assessment must be performed as soon as possible but no later than twelve months. ORELAP may revoke interim accreditation if the laboratory fails to meet accreditation requirements. See OAR 333-064-0035.

II.7.5.3. Not Accredited

A laboratory that demonstrates major deficiencies and, in the opinion of ORELAP, cannot consistently produce valid data within the acceptance limits specified by ORELAP/NELAP and within the policy described by the certification authority (See section III.4 Denial, Suspension, and Revocation of Laboratory Accreditation).

II.7.6. Signatures on Certificates and Correspondence

Certificates and correspondence may be signed physically or digitally on a PDF document. When an authorized person with delegated signature authority signs a letter for the Program Manager they must apply their own signature before the statement "for *First Name & Last Name*, ORELAP Program Manager". Electronic signatures are managed by secure computer login following OHA policies.

II.8. Complaints and Appeals

ORELAP uses the TNI Standards definition of a complaint for corrective action and tracking purposes:

"*Expression of dissatisfaction, other than appeal, by any person or organization, to an accreditation body, relating to the activities of that accreditation body or of an accredited CAB, where a response is expected*".

Complaints regarding an accredited laboratory or regarding ORELAP may be lodged to the Program Manager, Regulatory Section Manager, members of the Executive Team or the ORELAP QA Officer directly or through the ORELAP Technical Advisory Committee (OTAC). The Program Manager (or their designee) or QA Officer will then investigate and take appropriate action. Any complaints regarding a specific assessor should be made directly to the Program Manager.

Once the complaint is received, the Program Manager will assess the complaint and respond back to the complainant within seven days from the receipt that the complaint was received and provide an estimate as to when the investigation will be completed.

Records of the complaint must be saved in ODIE, on the server, and/or in hardcopy. Once the investigation has been completed, the Program Manager will take appropriate action and again respond back to the complainant. The Program Manager or the ORELAP QA Officer will follow-up on the actions, where applicable, within sixty days from implementation to assess the effectiveness of the actions taken. This follow-up will be recorded in the complaint database as well.

Complaints regarding an accredited laboratory, depending on the nature of the complaint, will result in contacting the laboratory directly and/or by a special assessment to evaluate the merits of the complaint. In these cases, the Program Manager or their designee will be part of the assessment team for complaint investigations. Decisions regarding disciplinary action must involve members of ORELAP Executive Team, and such will be taken in accordance with Section III.4 (Denial, Suspension, and Revocation of Laboratory Accreditation.)

Appeals related to accreditation decisions are handled in accordance with Oregon Revised Statutes and Oregon Administrative Rules. Written notice is provided to the laboratory of the intended action and provides the laboratory notice of their option to appeal the decision through the contested case hearing process.

PART III. ORELAP STANDARD OPERATING PROCEDURES

Standard Operating Procedures (SOPs) provide documentation on routine processes and procedures followed by the ORELAP. The following SOPs are documented as part of the ORELAP Program and Policy Manual:

- Application Receipt and Initial Review
- Laboratory Changes in Key Accreditation Criteria
- ORELAP Data Input and Edit (ODIE) Database
- Denial, Suspension, and Revocation of Laboratory Accreditation
- Dispute Resolution, Appeals, Contested Case Hearings, and ORS Chapter 183
- ORELAP Laboratory Assessor Requirements
- Internal Program Review
- Assessor Performance Appraisals
- Management Review
- Issuance of Accreditation Certificate
- Proficiency Testing
- Recognition (Secondary Accreditation)
- Document Control and Records
- Technical Review and On-site Assessment
- Third Party Assessor Requirements
- Nonconformance and Corrective Action

III.1. Application Receipt and Initial Review

III.1.1. Introduction

This document is designed to describe the procedures for receiving and processing applications for ORELAP accreditation. It is intended that initial review is a minimal review of the application to ensure all application criteria are met and required documentation and fees are received. The procedure for final review of the application is covered in the ORELAP On-site Assessment SOP. Applications are submitted electronically using ODIE following the instructions found on the ORELAP website and the ODIE database itself.

Each electronic application includes:

1. Completed application in ODIE with laboratory demographics, key personnel, contact information, and selected fields of testing
2. Quality Manual
3. MDL summary, when applicable (primary accreditation only)
4. Demonstration of Capability (DOC) (primary accreditation only)

5. Certification of Compliance: Certifying the laboratory will continually maintain compliance to the standard and adapt to future changes to accreditation requirements.
6. For secondary accreditations, the scope of accreditation must be submitted by the laboratory's primary accreditation body.

III.1.2. Request for Application

To access ODIE to apply for accreditation, or to find additional information, laboratories are to go to the Oregon Health Authority ORELAP website.

Laboratories that are unable to access ODIE on the website may request assistance from ORELAP by telephone, letter or email.

ORELAP Manager
Oregon Public Health Laboratory
7202 NE Evergreen Pkwy, Suite100
Hillsboro, OR 97124
Phone: (503) 693-4122
Email: ORELAP.INFO@odhsoha.oregon.gov

III.1.3. Application Receipt

When the laboratory has completed their application they click the "Submit" button in ODIE and an automatic notification is sent to ORELAP. Upon electronic receipt of the completed application from ODIE:

1) All application forms are date-stamped in ODIE.
2) If the application is for initial accreditation, a unique ORELAP identification code is assigned as follows:

   New laboratory applications are consecutively numbered starting with the number 4001.

   The previous numbering system worked as follows:

   a) From left to right, first two values indicate the state in which the laboratory is located, e.g. OR, WA, NY, etc. The exception is federal laboratories which are identified with US.

   b) The third value indicates whether the laboratory has applied for primary (1) or secondary accreditation (2). If a laboratory that has applied for secondary accreditation applies for primary accreditation for additional parameters not offered by its primary accrediting authority, this is indicated by a "3" rather than a "1".

   c) The remaining five values are assigned in ascending order as laboratories apply from each state and primary/secondary accreditation status, e.g., the second laboratory from New Jersey applying to ORELAP for secondary accreditation would be NJ200002.

3) The progress of the application is tracked in ODIE. There are blank fields to track each step of the process as follows:

a) The ORELAP Manager, or designee, initially reviews the application for completeness. Incomplete or unacceptable applications will be rejected, and the applicant will be notified that revisions are necessary. The completeness review consists of:

   i) Review of the adequacy of the information supplied by the laboratory in meeting elements necessary for accreditation set forth in OAR 333-064-0035(4). Confirm the following:

      (1) Key personnel (technical director(s) as applicable, quality assurance officer, primary lab contact)

      (2) Location is accurate

      (3) Fields of testing

      (4) Quality manual uploaded

      (5) Standard Operating Procedures uploaded

      (6) Certificate of Compliance uploaded

      (7) Laboratory's EPA ID, if available

      (8) Previous applications and on-site assessments (when applicable) are completed

   ii) Review ORELAP's ability to carry out the assessment based on ORELAP policies and availability of trained assessors for the requested fields of accreditation; and

   iii) Review of ORELAP's ability to perform the assessment within a timely fashion acceptable to the laboratory. If the assessment cannot be carried out in an acceptable time frame, the Program Manager may subcontract the assessment to a qualified third-party assessor(s).

b) When the application is deemed complete, the Program Manager, or designee, calculates the fees as described below in subsection (c). If deficiencies are not corrected, the application is denied. Nothing further happens to the laboratory application until such a time as the deficiencies are corrected (it remains idle in ODIE). If the application remains idle for more than six months, the ORELAP Program Manager may remove the application from ODIE after contacting the laboratory and a notation is made in the administration section of ODIE.

c) The fees are calculated using ODIE. An invoice for application and assessment fees is generated and sent to the laboratory. The invoice must include the program fund code, financial audit code, ORELAP ID#, date due. Checks must be made out to Oregon Health Authority Financial Services. A copy of the fee calculation sheet is available in ODIE.

d) Once all fees have been paid, the Program Manager, or designee, initials and dates the "Fees Rcvd" line in the application in ODIE. (Financial Services will send out regular reports describing the fees that have been paid). The invoice is filed, and ODIE is updated (see 3c above). The application is now considered complete. The application fee is considered non-refundable and will not be returned.

4) If required, the next step is scheduling a date(s) for the assessment.

III.1.4. Determination of Fees

A variety of applications will be submitted that affects the determination of application and on-site fees.

1. New application requiring on-site assessment
2. Annual renewal application not requiring on-site assessment
3. Annual renewal application requiring on-site assessment
4. Secondary (reciprocal) accreditation application
5. Application for re-certification (denial, suspension, revocation)
6. Additional parameters application
7. Miscellaneous applications (may require on-site assessment)

Fees are calculated in ODIE using the "Review Fees" button during application submission. The fees are automatically calculated based on the fees schedule in OAR 333-064-0060, available through the ORELAP web page.

III.1.5. Technical Review

If primary accreditation has been requested and an on-site assessment or a document review is needed, the application and supporting documents are made available to all assessors.

The Program Manager or designee reviews the application in order to determine the scope and staffing needed for the on-site assessment.

If secondary accreditation has been requested, the Program Manager or designee checks the laboratory's application against the laboratory's current certificate of primary accreditation and fields of accreditation (matching TNI method and analyte codes) which is sent directly to ORELAP from the primary accrediting authority. If minor discrepancies are found, the laboratory and/or the primary accrediting authority (as appropriate) is contacted by phone or email. Applications for parameters for which the laboratory has not been granted primary accreditation are denied. If all parameters are denied and/or there are major discrepancies that cannot be readily reconciled, the application is denied.

III.2. Laboratory Changes in Key Accreditation Criteria

III.2.1. Introduction

Because changes in key accreditation criteria, such as change in ownership, location, key personnel, and scope of accreditation, or policies may have a significant effect on data quality, laboratories are required to notify ORELAP of any changes within 35 calendar days for evaluation by ORELAP. Changes in key accreditation criteria may require an on-site assessment to verify effects of such changes on laboratory performance. Additionally, significant changes may result in revision to a laboratory's accreditation status.

Although notification of changes may require submitting an updated section of the ORELAP application, such notification is not to be considered as a re-application and no application fee will be charged. The laboratory's ORELAP identification number and, unless the laboratory's

accreditation is totally revoked, the expiration date of the current accreditation certificate will remain unchanged.

III.2.2. Change in Ownership

1. The laboratory must submit:
   - Completed Change of Ownership application in ODIE.
   - Written notification that, for primary ORELAP accredited laboratories, must include a list of any changes that may have occurred within the laboratory as a result of the change in ownership or, assurance that none have occurred.
   - Laboratories with secondary ORELAP accreditation, notification of any changes that may have resulted in its primary accreditation status as a result of the change in ownership. Laboratories must arrange to have the primary accrediting authority send a copy of the revised certificate and scope of accreditation, if applicable.
2. If, for a primary ORELAP accredited laboratory, the change in ownership has been determined to have no significant effect on laboratory operations or its commitment to adhere to policies and procedures in compliance with TNI Standards, no action will be taken.
3. If, for a primary ORELAP accredited laboratory, the change in ownership has resulted in other changes within the lab, an on-site assessment may be required.
4. Laboratories must keep records including those pertaining to analyses performed for a minimum of 5 years regardless of change in ownership, accountability or liability. See OAR 333-064-0035(4)(f). Such records shall also be subject to inspection by ORELAP during this period, with or without prior notification.
5. For secondary ORELAP accredited laboratories, appropriate changes are made to the laboratory's accreditation if required as indicated by changes in the laboratory's primary accreditation status.

III.2.3. Changes in Address or Location

1. The laboratory must submit a completed Change of Address application in ODIE. The Change of Address application must be approved before the laboratory may perform accredited testing at the new location.
2. Primary ORELAP accredited laboratories:
   - Laboratories must submit a description of the new facilities at its new location and provide assurance that the change has not impaired the laboratory's performance.
   - An on-site assessment will be scheduled and be conducted as soon as possible. Change of address assessments may be remote assessments.
   - New location's EPA Code / ID, if available.
3. Secondary ORELAP accredited laboratories must arrange to have its primary accrediting authority send a copy of the laboratory's certificate and scope of accreditation that indicates the address of the laboratory's new location, if applicable.

III.2.4. Change in Management and Key Personnel

1. The laboratory must submit a completed Change in Personnel application in ODIE for changes to primary laboratory contact, laboratory manager, technical director, quality manager, and other named positions.
2. Personnel changes for primary ORELAP accredited laboratories will be reviewed to ascertain whether such changes will affect the laboratory's accreditation status. Transcripts and credentials may be required for technical managers and must demonstrate compliance with the TNI Standards.
3. Secondary ORELAP accredited laboratories must arrange to have its primary accrediting authority send a copy of the authority's approval for the change in personnel. A copy of the laboratory's certificate and scope of accreditation may be required if changes in personnel have resulted in changes in the laboratory's accreditation status. Secondary ORELAP accreditation will be revised based on the changes in the laboratory's primary accreditation status.
4. ORELAP must ensure that at a minimum each laboratory has the following:
   - Primary Laboratory Contact
   - Technical Director(s) for applicable technical disciplines, with education transcript and work history
   - Quality Assurance Officer

III.2.5. Other Significant Changes

1. Other changes to a primary ORELAP accredited laboratory that may affect laboratory performance and their ability to fulfill the requirements for accreditation, which may include reduction in scope of accreditation, organizational changes, major policy changes, major laboratory remodeling, damage due to fire, flood, etc., must be reported to ORELAP within 35 calendar days. A request for further documentation and subsequent actions taken will be determined on a case-by-case basis.
2. Secondary ORELAP accredited laboratories must arrange to have its primary accrediting authority send a copy of the laboratory's certificate of and scope of accreditation if changes to the laboratory have resulted in changes in the laboratory's accreditation status. Secondary ORELAP accreditation will be revised based on the changes in the laboratory's primary accreditation status.

III.2.6. On-site Assessments

1. For laboratory changes that require an on-site assessment, the assessment will be scheduled and occur as soon as possible subsequent to payment of an assessment fee. However, there may be certain circumstances for which ORELAP may deem an unannounced on-site visit to be necessary. The Program Manager will assign an assessment team to go on-site prior to the next inspection if an unannounced assessment is necessary. To maintain accreditation, the laboratory must not prohibit entry of the assessors during routine business hours and must pay the specified on-site assessment fee.

2. An on-site assessment due to reported laboratory changes may include all or part of the laboratory's quality systems and/or a technical review as determined by ORELAP.
3. A subsequent assessment report and laboratory response shall be required according to the requirements for routine on-site assessments.
4. Remote assessments may be conducted remotely by electronic means during a period of time when the Governor has declared a state of emergency and on-site visit would jeopardize the health and safety of participants as defined in OAR 333-064-0025(33).

III.2.7. Notification of Evaluation

ORELAP will notify the laboratory requesting a change in key accreditation criteria of results of the evaluation of the reported changes.

III.2.8. Failure to Notify

Failure of a laboratory to notify ORELAP of changes to key accreditation criteria may result in partial or total suspension of accreditation to be determined by ORELAP for all parameters affected.

III.2.9. Record of Laboratory Changes

All original records of laboratory notification of changes and subsequent actions, if any, will be kept in the laboratory's file for the year in which it occurred. Records of the evaluation of the reported changes in key accreditation criteria will be kept in the laboratory's file for the year in which it occurred.

III.3. ORELAP Data Input and Edit (ODIE)

III.3.1. Introduction

ORELAP maintains data received and generated by the program using an electronic database called ODIE. The Program Manager and assessors record all data necessary for determining laboratory accreditation in ODIE, which includes: application receipt; invoicing; laboratory demographics; fields of accreditation requested; scheduling; assessment checklists; and pertinent dates. Accreditation certificates, assessment reports, responses to corrective action, invoices, and applications may be generated from ODIE.

Access to the administrative side of the database is restricted to persons that have been granted rights to ODIE by IT staff and/or designated ORELAP personnel. Approved laboratory personnel have access to ODIE with limited functionality, and can Search Labs, Analytes and view their Application and PT history. The subsequent sections are relevant to the administrative database. The Search Labs function is available to the general public.

III.3.2. Home Screen

The Home Screen section of ODIE is where the user can search for accredited laboratories and view laboratory applications, fields of accreditation, and assessment reports. This is where the majority of the ODIE content is accessed.

The user can search for an accredited laboratory using the laboratory name or the ORELAP ID. Clicking on a laboratory will populate the screen with the selected laboratory's current and past applications. Selecting an application will allow the user to view content of the applications, including assessment reports & corrective action plans, fields of accreditation, laboratory information, and past certificates and scopes. Past applications are normally locked to prevent changes unless ORELAP determines a change is required. New applications can be created by the laboratory and are unlocked and can be edited until submitted for review.

III.3.3. Lab Listing

This brings the user back to the Home Screen.

III.3.4. Reports

The Reports section of ODIE allows the ORELAP staff to produce demographics and specialty reports, similar to queries. These reports allow the user to generate lists of laboratories based on filters and allow the ORELAP assessors to keep track of the status of assessments and applications.

III.3.5. PT Upload

The PT Upload section of ODIE allows the user to upload the electronic files for PT samples. Upload of the electronic files allows ORELAP staff to review PT performance of laboratories.

III.3.6. Manage Users

The Manage Users section of ODIE allows the ORELAP staff to approve or deny new requests from outside users for access to ODIE. User profiles can be edited and inactivated as well.

III.3.7. Settings

The Settings section of ODIE allows the ORELAP staff several options such as: to add, remove, and edit analytes, methods, and technologies in ODIE; manage laboratories; update and review fees; create and edit PT libraries; helps new users navigate ODIE; and other settings.

III.3.8. Assessments

On-site assessments are documented in ODIE and are tied to an application, generally the renewal application where the assessment was paid. On-site assessors record their observations using checklists generated within ODIE. The assessors' observation may be classified in three categories: Deficiencies Requiring Immediate Attention "Immediate", Deficiencies to Be Addressed in the Corrective Action Plan "Corrective Action", and "Recommendations". Each of these categories corresponds to a unique section in the Laboratory On-site Assessment Report.

Findings in the "Immediate" section are either repeat deficiencies from previous assessments or deficiencies judged to critically affect data quality that must be addressed immediately by the laboratory. The laboratory must respond to these deficiencies in its corrective action plan (CAP) and provide evidence that the issue has been corrected prior to the closing of the assessment report. The "Corrective Action" section identifies deficiencies that must be addressed by the laboratory in its CAP, but the CAP is not required to be completed prior to the closing of the assessment report. If the CAP will not be completed prior to the closing of the assessment report, a reasonable timeframe for completion must be included. Finally, the "Recommendation" section

is used for observations that are aimed at helping the laboratory improve, but no response is required.

The assessment application in ODIE is also where corrective actions are submitted by the laboratory and reviewed by the assessors. The laboratory must upload applicable supporting documents as part of the corrective action plan. Assessors can close findings and can provide a review of the corrective action plan as well. The laboratory must respond to the findings in ODIE.

III.3.9. Data Integrity

Access to ODIE is limited to approved users and their level of access is carefully determined by the Program Manager, or their designee. ODIE also has the capability to produce an audit log of activity. ODIE exists on a server and is backed-up routinely. Each approved user logs in with a password and their session is automatically timed out after inactivity of approximately 15 minutes.

III.4. Denial, Suspension, and Revocation of Laboratory Accreditation

III.4.1. Introduction

ORELAP requires laboratories to meet the requirements of the TNI Standards. The consequence of not consistently adhering to the TNI Standards is loss of ORELAP accreditation for all or part of the laboratory's accredited analytical fields of testing, analyte or method. Accreditation can either be denied at the application step, temporarily suspended in part or in total for not more than six months or the period of accreditation, whichever is longer, or revoked in part or in total, consistent with Oregon Revised Statute (ORS) chapter 183. The Executive Committee will be informed of any total revocation of accreditation. The laboratory will be given an opportunity to voluntarily withdraw prior to denial, suspension, or revocation.

III.4.2. Denial

ORELAP may deny an application initially during the application (or renewal application) process or after the initial on-site assessment for ORELAP accreditation.

Reasons for denial can be found in ORELAP rules in OAR-333-064-035.

The ORELAP Manager will notify the primary lab contact in ODIE by certified mail or email, return receipt requested, of denial of accreditation and include the reason for denial. The application fee will not be refunded if accreditation is denied for any of the reasons stated above. Additionally, the fees associated with an on-site assessment will not be refunded if an on-site assessment has been performed. The laboratory will have the right to due process and may appeal the decision to deny accreditation according to ORS chapter 183.

III.4.3. Suspension

Suspension is a temporary removal of a laboratory's accreditation for a period not to exceed six months or the period of accreditation, whichever is longer. Suspension allows a laboratory time to correct deficiencies or areas of non-compliance with the TNI Standards. A suspended laboratory shall not continue to perform testing services for the affected scope of accreditation. The suspension shall apply to all or part of the fields of testing for which the laboratory is

currently accredited. A suspension will be lifted once the laboratory has corrected the non-compliance.

Reasons for suspension can be found in ORELAP rules at OAR 333-064-0035.

The ORELAP Manager will notify the primary lab contact in ODIE by certified mail or email, return receipt requested, of suspension of accreditation. The notification shall include the beginning date of the suspension, which elements are suspended and the reasons for the suspension. Accreditation status for the affected fields of testing will be restored after the laboratory successfully demonstrates it has complied with the TNI Standards and addressed the reasons for suspension within the time frame of the suspension. If the cause of the suspension has not been corrected within six months or the period of accreditation, whichever is longer, the affected fields of accreditation will be revoked. The laboratory has the right to due process and may appeal the decision to suspend accreditation according to ORS chapter 183.

III.4.4. Revocation

Revocation is the removal of a laboratory's accreditation for all or part of the current fields of accreditation.

Reasons for revocation can be found in ORELAP rules in OAR 333-064-035.

The Program Manager will notify the primary lab contact listed in ODIE by certified mail or email, return receipt requested, of revocation of accreditation and include the reason for the revocation. The letter will indicate the beginning date of revocation, whether the revocation is partial or total, and will cite the TNI Standards for the revocation. ORELAP may request that the laboratory return the accreditation certificate back to ORELAP.

With total revocation, the laboratory must refrain from using the NELAP logo or making any reference to either NELAP or ORELAP. Once the laboratory has made the appropriate correction(s), it may reapply for accreditation. A new application fee must accompany the new application.

The laboratory has the right to due process and may appeal the decision to revoke accreditation consistent with ORS chapter 183.

III.4.5. Appeals, Contested Case Hearings, and ORS Chapter 183

Denial, suspension, and revocation actions require ORELAP to send a Notice of Intent letter to the laboratory which describes the planned action and provides the laboratory a deadline to request a contested case hearing. This is in compliance with ORS chapter 183. If the laboratory responds by the deadline and requests a contested case hearing, this information is passed along to the Department of Justice staff attorney representing ORELAP and a pre-hearing is scheduled. ORELAP will refrain from taking the planned action against the laboratory pending the decision from the contested case hearing.

If the laboratory does not respond by the deadline in the Notice of Intent letter, the proposed action will be taken.

If the laboratory and ORELAP resolve any outstanding issues prior to the deadline in the Notice of Intent letter, the proposed action will be dropped, and a Withdrawal of Notice of Intent letter will be issued to the laboratory. In some instances, the laboratory and ORELAP may agree to

resolve the issues after the deadline but before the scheduled contested case hearing. This will also render the proposed action moot and the Withdrawal of Notice of Intent letter will be sent.

In the event of a public health emergency, or as a result of PT failures, a suspension or revocation may be issued to the laboratory without a Notice of Intent letter and without providing the option for a contested case hearing.

III.4.6. Voluntary Withdrawal

If a laboratory wishes to withdraw from ORELAP, in total or in part, it must submit a withdrawal application through ODIE. If the withdrawal is total, the laboratory must refrain from using the NELAP logo or making any reference to either NELAP or ORELAP.

III.5. Dispute Resolution

III.5.1. Introduction

Oregon Revised Statutes (ORS) chapter 183 governs the process by which the ORELAP handles disputes, complaints, and appeals concerning laboratory accreditation.

III.5.2. Complaints

Complaints must be made to ORELAP in writing (includes email), explaining the nature of the complaint. Any complaint filed directly by an ORELAP accredited laboratory or through the ORELAP Technical Advisory Committee (OTAC) will be investigated promptly by the Program manager and/or the ORELAP QA Officer. If a resolution has not been achieved, the Program Manager will forward the complaint to the ORELAP Executive Team who, working in conjunction with the Program Manager, will attempt to determine the cause and correct the problem. If the problem cannot be resolved informally, the process for appeals will be implemented.

III.5.3. Disputes

A dispute with a laboratory is the result of a formal complaint that was not resolvable informally. Any action taken by ORELAP will be taken consistent with ORS chapter 183. A notice of a hearing will be sent to all interested parties, which must be served personally or by registered mail. This notice shall include:

- A statement of the party's right to a hearing or a statement of the time and place of the hearing.
- A statement of ORELAP's authority and jurisdiction under which the hearing is being held.
- A reference to the particular sections of the statutes and rules involved.
- A short, plain statement of the matters asserted or charged.

All other rules under this statute will be followed as required by ORELAP.

III.5.4. Appeals

The Program Manager and the ORELAP Accrediting Authority will review all appeals of denials, suspensions or revocations. These appeals will be handled as described in ORS chapter 183.

III.6. ORELAP Laboratory Assessor Requirements

III.6.1. Introduction

Since the on-site assessment is an important part of the laboratory accreditation program, the ability and training of the assessors themselves is equally important to the success of the program. The requirements for the assessors are described in this document.

The ORELAP program follows the NELAP requirements for their laboratory inspectors, including passing required basic assessor training and receiving general and specialized technical training from third-party trainers. Laboratory assessors must have successfully completed EPA's drinking water laboratory certification officer training to assess drinking water testing laboratories.

III.6.2. Basic Qualifications

1. The assessors used by ORELAP must be an experienced professional with at least a minimum of a Bachelor's degree in a scientific discipline or have equivalent education and experience in laboratory assessment or related fields.
2. All assessors that assess laboratories for potable water FOAs must meet the education and training requirements set by EPA for assessing laboratories for drinking water compliance including successful completion of EPA's drinking water laboratory certification officer training.
3. Each new assessor must have successfully completed with a passing test score, a specific ORELAP approved assessor training course on assessing quality systems and take annual refresher training. Attending the most recent TNI Laboratory Forum may be considered as meeting the requirement for refresher training. Attending a presentation by an attendee to the conference also may be considered as meeting the requirement for refresher training. However, such a presentation must convey the most relevant changes to the TNI Standards and discuss arising issues that may affect the Standards. Records of attendance to such meetings will be maintained for each assessor in their ORELAP assessor qualification file.
4. In addition to basic training on quality systems assessments, each new assessor must have successfully completed with a passing test score a specific ORELAP approved technical assessor training course in the area of discipline they will assess. Technical training courses sponsored by EPA or TNI are automatically approved by ORELAP, DEQ laboratory section managers may also provide technical training to assessors. Technical disciplines are:
    - Microbiology
    - Toxicity Testing
    - Inorganics-Nonmetals

- Inorganics-Metals
- Organics-GC
- Organics-GCMS & MS/MS
- Organics-LC & LC-MS/MS
- Organics-GCHRMS
- Asbestos
- Radiochemistry

5. Each new assessor must also undergo on-site training with a qualified assessor during at least four actual assessments unless the qualified assessor has made the determination after at least two assessments that the new assessor is ready to perform independent assessments. Only one training assessment is required for assessors new to the ORELAP program but with prior assessment experience.
6. Each assessor must sign a statement that they will comply with the rules and policies of ORELAP.
7. In addition, all assessors must:
    a. Be familiar with the relevant legal regulations, accreditation procedures and accreditation requirements.
    b. Have a thorough knowledge of the relevant assessment methods and assessment documents.
    c. Be thoroughly familiar with the various forms of records discussed during the assessment planning which include but are not limited to; the application, IDOC/MDLs, PT testing results, organizational structure, Quality Manual submitted by the laboratory, SOPs for the methods of interest, procedures for preparing standards, reagents and other necessary solutions, the origin and expiration dates of standards, reagents and reference materials and the method's requirements for QA/QC.
    d. Be thoroughly cognizant of how the data is reported and the applicable data reduction methods employed.
    e. Be technically conversant with the specific fields of testing for which accreditation is sought.
    f. Be able to communicate effectively, both orally and in writing. Lead assessors must demonstrate writing and organization ability to meet the demands of managing the day-to-day assessment activities.
    g. Possess acceptable inter-personal relationship skills.

III.6.3. Assessor Responsibilities

1. All assessors are responsible for completing reports in a timely manner, meeting deadlines required under NELAP, ORELAP or individual EPA program.

2. The lead assessors and the Program Manager must maintain current checklists used during the assessments. These checklists must be reviewed and updated as the program requirements change.
3. The lead assessors are responsible for updating ODIE with current laboratory or program information as needed.
4. It is the responsibility of each individual assessor to aid in the identification of areas where training is needed.

III.6.4. New Assessor Training

1. New assessors must pass a NELAP approved basic assessor training course.
    a. After hire, until this course is available, a training on the most current standard offered by TNI and supplemental assessor training provided by a qualified member of ORELAP can be used as a replacement.
2. New assessors will receive basic orientation from the ORELAP staff that includes:
    a. Laboratory health and safety.
    b. Discussions of NELAC/TNI Standards, ORELAP OARs, SOPs, and ORELAP program requirements.
    c. Actual on-site assessments under the direct guidance of a qualified assessor. The supervising qualified assessor (Program Manager or ORELAP Lead Assessor) must document their observations and conclusions of the trainee assessor during an assessment. This information is used determine if the trainee assessor is ready to perform independent assessments.
    d. Familiarization of ORELAP forms and report formats.
3. A wide variety of training options are available and include:
    - TNI approved assessor training course
    - Workshops, seminars, meetings sponsored by the US Environmental Protection Agency (EPA)
    - Workshops, seminars, meetings sponsored by the State, instrument manufacturer, or professional organizations
    - Meetings with other state assessors
    - Specific college or university courses

III.6.5. ORELAP Assessor Personnel Qualification Records

The Program Manager shall maintain qualification records for each ORELAP assessor. These records will be kept filed by name for each assessor and by the name of the organization for third-party assessors. Each file will include:

1. Name and Address
2. Position held
3. Brief resume with education qualification and work experience

4. A completed ORELAP Assessor Training Form and Individual Training Record
5. Copies of any certificates or other documents received as evidence of completion of relevant training.
6. Experience in assessments and results of periodic monitoring

The Program Manager will also maintain a summary record that identifies the specific technical disciplines approved for each of the program assessors.

III.6.6. Assessor Review

1. The qualifications of all assessors will be reviewed by the Program Manager for their ability to meet the requirements set forth in this SOP.
2. The assessors will also be evaluated annually under the state required personnel review system.
3. The assessment appraisal forms given to the laboratories at the conclusion of the on-site assessments will be reviewed annually as part of the assessor evaluation. From the comments received from the laboratories, further training in conducting interviews, knowledge of specific EPA program requirements, the rules and regulations under the State of Oregon, NELAP rules or any other appropriate training will be planned for the assessor and completed within the following year.
4. Each assessor is observed by the Program Manager while performing an on-site assessment regularly, minimally every 3 years. This observation will be documented and placed in the Assessor's file. These observations will be taken into consideration as part of the assessor's annual review.
5. Required refresher courses will be planned in advance as part of an assessor development plan.

Conflict of interest statements, which are required from each assessor for each laboratory prior to the on-site assessment, will be maintained with the records of each specific assessment.

III.6.7. Ongoing Assessor Training

If there is a need for a new field of accreditation, arrangements will be made for additional training of assessors. Assessors with appropriate education, experience, and availability will receive the additional training. This training will be documented in the assessor's training files.

III.7. Internal Program Review

III.7.1. Introduction

ORELAP will, at least annually, conduct a program systems evaluation and a management review of its documents and activities to verify that its operations effectively comply with the requirements of the ORELAP quality system and the TNI Standards.

III.7.2. Program Systems Evaluation

III.7.2.1. Planning

The Quality Assurance Officer (QAO) will plan and organize an internal program evaluation at the request of the ORELAP Executive Team and/or Program Manager to verify that ORELAP is complying with its quality system. The TNI AB Evaluation checklist is used as the basis of the evaluation. This may be performed solely by the Quality Assurance Officer or with additional reviews carried out by trained and qualified personnel, who are, wherever resources permit, independent of the activity to be reviewed. The documents to be reviewed will include but are not limited to:

a. Applicable Oregon Administrative Rules (OARs)

b. ORELAP Program and Quality manual

c. Standard Operating Procedures (SOPs)

d. Assessor records

e. Laboratory records

f. Proficiency testing tracking records

g. Assessment appraisal forms

h. Third party assessor contracts

i. Previous audits and corrective actions

The appropriate personnel will be interviewed based on the determined scope of the evaluation. These may include the Program Manager, lead assessors and technical assessors.

III.7.2.2. Conducting the Review

The documents that were identified during the planning stage will be requested. When possible, a case study will be used as a tool to assess the program's effectiveness and accuracy relative to the current TNI and ORELAP Standards. The nature of the records and case study material is documented although additional material may be requested as the review proceeds.

III.7.2.3. Evaluating the Results

Results from the data gathering stage will include interview notes, summaries of documentation, results of the file reviews and results of any case studies that were pertinent to the scope of the review. As the information is sorted and organized, the initial plan will be reviewed so that the objectives of the audit remain in focus. The preliminary conclusions and recommendations will be as objective as possible. All reviewers will have an opportunity to comment on the preliminary conclusions, as this will help balance the final report.

III.7.2.4. Reporting the Findings

"Findings" are areas where the program does not meet the TNI Standards and identified with the specific relevant citation. "Comments" are added as opportunities for improvement and preventative action and may or may not include a standard citation.

A written draft of any findings and comments will be prepared. The written draft is sent to each reviewer for comments to ensure that the evidence from the review is accurate to the program. Differences between the reviewers should be resolved and the conclusions and recommendations added to the report at this time. A brief meeting with the staff with the finalized report including the conclusions and recommendations is scheduled and the report presented concludes the review process. The report is submitted to the Executive Team and Program Manager for review and response. The Executive team may request a meeting to discuss the findings. An electronic copy will remain in the ORELAP files.

III.7.2.5. Corrective action

In the context of the TNI Standards, the identification of cause and subsequent "Corrective Actions" refers to corrective actions, preventative actions, and other areas of improvement. The process is the same for all. A plan of corrective action including root cause analysis will be submitted to the QAO by the Program Manager and implemented according to a mutually acceptable predetermined schedule. Corrective actions shall be appropriate to the impact of the problems identified. The Program Manager will attempt to determine the root cause and correct findings from the program evaluation. The Program Manager will report all corrective actions taken to the Executive Team. The QAO will follow-up on the corrective actions periodically to monitor for effectiveness and progress against the schedule.

III.8. Assessor Performance Appraisal

The Program Manager will review each assessor's performance on a regular basis, usually annually as part of the review of the staff member's workplan evaluation. Review of the assessor's performance may include the following:

- Direct observation of the assessor while they perform an on-site assessment (observations should occur minimally once every three years unless there is sufficient supporting evidence that the assessor is continuing to perform competently).
- Review of ORELAP Assessor Evaluation forms completed by assessed laboratories.
- Review of the assessor's reports and findings to determine if they are timely and well written.
- Review of complaints, comments, and praise regarding the assessor's performance of their duties.
- A one-on-one interview with the assessor to discuss job performance, goals, and workplan development.

The outcome of this review will feed into the assessor's annual performance evaluation which includes career development plans and workplans. This evaluation is performed according to OHA policy and is conducted between the Regulatory Section Manager and the assessor. The Regulatory Section Manager will review the performance of the Program Manager.

III.9. Management Review

III.9.1. Planning

The Program Manager will plan and organize a management review to ensure the continuing suitability and effectiveness of ORELAP procedures and policies and to assess overall performance against goals and objectives. The annual review will take into account:

- Results of audits
- Results of peer evaluation where relevant
- Participation in international activities, where relevant
- Feedback from interested parties
- New areas of accreditation
- Trends in nonconformities
- Status of preventive and corrective actions
- Follow-up actions from earlier management reviews
- Fulfillment of objectives
- Changes that could affect the management system
- Appeals
- Analysis of complaints

III.9.2. Reporting the Findings

The findings and opportunities for improvement from the management review will be recorded as a draft along with a proposed plan of action, if needed. Outputs from the management review shall include actions related to:

a. Improvements of the management system and its processes
b. Improvement of services and accreditation process in conformity with the relevant standards and expectations of interested parties
c. Need for resources
d. Defining or redefining of policies, goals, and objectives

The action plan is comprised of those items related to the improvements in customer services, and improvements to the overall accreditation process for conformance to the TNI Standards, including any need for additional resources. A copy of the draft report will be given to each member of the ORELAP Assessor Team and discussed at the next ORELAP Assessor Team Meeting to ensure the accuracy of the report. The finalized report is then submitted to the Executive Team who may request a meeting to discuss the findings. An electronic copy of the management review will remain in the ORELAP files.

III.9.2.1. Proposed Plan of Action

A plan of action, which may be a corrective action plan and/or a plan for improvements, will be submitted to the Executive Team by the Program Manager. Any new/revised procedures or policies will be put in place, as required, and errors will be corrected when identified. Those documents requiring the Executive Team's approval will be sent to the Executive Team for authorization signature by each member. The ORELAP Program Manager will report all actions taken to the Executive Team.

III.10. Issuance of Accreditation Certificate

III.10.1. Introduction

This document describes the process for granting accreditation and issuing an accreditation certificate once an environmental laboratory has met all ORELAP standards for laboratory accreditation.

III.10.2. Procedure

Verify the laboratory has met all requirements for accreditation, which includes but may not be limited to:

- Fully paid application fees
- Key personnel (technical director(s) as applicable, quality assurance officer, primary lab contact) are correct and current
- Proficiency Testing status, if applicable
- Fields of testing status is correct
- Secondary accreditation laboratory's scope is verified against primary Accreditation Body's scope of testing
- Previous applications and on-site assessments (when applicable) are completed

Once a laboratory has met all the requirements for accreditation as indicated in the ORELAP database, the Program Manager or designee will issue the accreditation documents to the qualified laboratory. These documents, as described below, include a cover letter, the Certificate of Accreditation, and the ORELAP Fields of Accreditation describing the Matrices, Methods and Analytes for which the laboratory is receiving accreditation. Copies of these documents will be placed in the ORELAP files according to laboratory and year of issuance.

If a status change occurs during the accreditation year because of addition or loss of parameters, the Program Manager or designee will issue a new scope and a new certificate, if warranted. ORELAP may request that the laboratory return the old accreditation documents. Copies of the new documents will be placed in the ORELAP files according to laboratory and year of issuance.

III.10.3. Cover Letter

The cover letter will be sent electronically along with the laboratory's updated certificate and scope. This letter will include a description of the certificate and attached documentation. It includes requirements for posting the certificate, informing customers of all the certification documentation, and use of the accreditation in publications and advertisements.

It also describes the procedures required for change of key personnel, change of address, and change of ownership.

III.10.4. Certificate

The certificate will be generated by ODIE electronically, signed digitally and locked with password protection, and sent to the laboratory via e-mail. The certificate will contain the following information:

1. Laboratory name
2. Laboratory ORELAP Identification number

3. Laboratory address
4. Matrices and disciplines for which the laboratory has received accreditation (summary of scope of accreditation
5. Statement of conformity and identification of applicable standards and version.
6. Unique certificate number
7. Issue date
8. Expiration date
9. ORELAP name
10. NELAP Recognized Accreditation Body Logo
11. ORELAP state seal logo
12. Watermark
13. Program Manager's or acting ORELAP Assessor digital signature*

*The Program Manager may grant accreditation authority temporarily to a qualified individual within ORELAP.

III.10.5. ORELAP Fields of Accreditation

The ORELAP Fields of Accreditation (FOA) document is provided with each issuance of a certificate. It is identified with the laboratory name, ORELAP identification number, EPA code, date issued, and certificate number on each page. Each page will also display page x of y and the effective date.

The ORELAP Fields of Accreditation document will be generated from the ORELAP database (ODIE), locked with password protection to prevent change, and sent to the laboratory by email. The FOA lists all Matrices, Methods, and Analytes for which the laboratory has applied and meets ORELAP criteria. If status changes because of additional parameters, or loss of parameters, a new ORELAP Fields of Accreditation will be sent to the laboratory along with a new Certificate of Accreditation, if warranted.

III.10.6. Laboratory Representation of Accreditation

Once accredited, laboratories may use the ORELAP logo and/or statement of accreditation (e.g. ORELAP accreditation number) provided the following limitations are met. These items shall be evaluated during the on-site assessment process. Violations of any of these items will result in the need for corrective action up to and including suspension or revocation of their accreditation depending on the severity.

1. The accreditation certificate and FOA only apply to the facility at the address shown.
2. Laboratory reports shall clearly indicate the accreditation status of all parameters reported.
3. The laboratory shall not misrepresent, make misleading claims, or unauthorized claims regarding their accreditation status and scope of accreditation in any fashion. This includes, but is not limited to, in their advertising, web pages, brochures, media communications, laboratory reports (certificates of analysis), other documents, etc.

4. Discontinue use of logo or other statements that imply accreditation for a parameter when accreditation of that parameter is, in part or in full, suspended, revoked or withdrawn.
5. The accredited laboratory shall not use the fact of its accreditation to imply that any particular use of the analysis is approved by ORELAP. Acceptability of use of a particular analytical method is determined by client or specific state or federal agency program needs not simply based on accreditation.

III.11. Proficiency Testing

III.11.1. Introduction

Proficiency Testing (PT) provides a means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through the analysis of unknown samples provided by an external source. ORELAP recognizes the PT requirements and criteria for NELAP accredited laboratories as described in V1M1 of the TNI Standards. See also OAR 333-064-0035, 333-064-0025, and for additional cannabis matrix analyte guidelines, see OAR 333-064-0120.

ORELAP, as a primary NELAP accrediting authority, implements its requirement to monitor the PTs of ORELAP accredited laboratories according to V2M2 of the TNI Standards.

III.11.2. Laboratory Participation in PT Studies

ORELAP requires laboratories desiring ORELAP accreditation to participate in PT program(s) and obtain PT samples from any PT provider approved by a Proficiency Testing Oversight Body (PTOB) /Proficiency Testing Provider Accreditor (PTPA). The samples must be analyzed and the results returned to the PT provider prior to the closing date of the applicable study.

1. A laboratory seeking to obtain or maintain ORELAP accreditation shall successfully complete two initial or continuing PT studies for each field of accreditation (matrix-technology/method-analyte/analyte group) in which the laboratory has requested accreditation and for which approved PT samples are available within the most recent three rounds attempted. For initial accreditation, the most recent three rounds attempted shall have occurred within 18 months of the laboratory's application date with the most recent of the 3 rounds no more than 6 months from the initial application.
2. For initial accreditation, the laboratory must successfully analyze two PT studies; the closing dates of consecutive studies must be at least 7 calendar days apart for the same field of proficiency testing. Routine PT review in ODIE by ORELAP staff includes determining if this requirement is met by comparing the open and close dates of the two most recent studies.
3. Each laboratory seeking or maintaining accreditation shall be required to perform analysis of one PT sample at minimum twice per year, approximately six months apart (not to exceed 7 months from calendar date), in each field of accreditation (matrix-technology/method-analyte/ analyte group) for which it has applied for accreditation or for which it is currently accredited. A missed PT study shall be considered as a failed PT study for the affected field of proficiency testing.

4. When a laboratory fails an initial or continuing PT study (2 out of the last 3) and wishes to re-establish its history of successful performance or when an accredited laboratory wishes to add fields of accreditation to its scope of accreditation, a laboratory may elect to participate in supplemental PT studies.
    a. The PT sample used for corrective action shall be obtained from any PTPA recognized PT provider. A scheduled or a supplemental proficiency testing sample may be used for corrective action.
    b. The laboratory should notify the PT provider that the PT sample is for corrective action to ensure that the PTP provides a PT sample that meets the requirements for supplemental PT samples as specified in Volume 3 of the TNI Standards.
    c. The closing date of a supplemental study must be at least 7 calendar days before the opening date of a subsequent study for the same field of proficiency testing (see number 2 above).
    d. The laboratory shall report to the PT Provider results of all analytes for which the laboratory is demonstrating corrective action or requesting expansion of their existing accreditation.
    e. After the laboratory is granted accreditation for fields of testing for which the laboratory lost accreditation due to PT failure or upon initial accreditation for an expanded field of accreditation, the laboratory is required to participate in regular semiannual PT studies.
5. When PT samples are not available for the FoPT from any PTPA recognized PT provider at least twice per year, ORELAP shall only require the laboratory to analyze the PT samples in the minimum time frame in which the PT samples are available from any PTPA recognized PT provider.
6. ORELAP does not specify the months in which a laboratory is to participate in PT studies. Therefore, it is the responsibility of the laboratory to schedule PT studies to meet the TNI requirements for PT performance.
7. When participating in any PT studies, the laboratory shall inform the PT provider that the study is to be used for ORELAP accreditation purposes and that results are to be reported to ORELAP.
8. The laboratory shall comply with the following restrictions on analyzing and transferring PT samples and communicating PT results prior to release of the study (routine or supplemental) results.
    a. The laboratory's management and all analysts shall ensure that all PT samples are handled (i.e., managed, tracked, analyzed, and reported) in the same manner as routine environmental samples utilizing the same staff, methods, procedures, equipment, facilities, and frequency of analysis. This includes but is not limited to:
        i. PT samples are prepared according to the PT provider's instructions and subsequently handled as a routine sample

ii. PT samples are analyzed under the same analytical conditions and instrument calibrations as used for routine samples

iii. the type, composition, concentration, and frequency of quality control samples analyzed with the PT samples are the same as with routine samples

iv. PT samples are not analyzed multiple times unless routine samples are analyzed multiple times and results from multiple analyses are calculated in the same manner as routine samples

v. the laboratory has procedures in place for the analysis of environmental and PT samples when the concentration range of the samples is outside of its normal range of measurement

vi. the laboratory performs corrective action for any unacceptable evaluation received from the PT provider for any FoPT

b. The laboratory shall not send any PT sample, or a portion of a PT sample to another laboratory for which it seeks accreditation or is accredited;

c. The laboratory shall not knowingly receive any PT sample or portion thereof from another laboratory for any analysis for which the sending laboratory seeks accreditation or is accredited;

d. The laboratory's management or staff shall not communicate with any individual at another laboratory (including intra-company communication) concerning the PT sample; and,

e. The laboratory's management or staff shall not attempt to obtain the assigned value of any PT sample from their PT Provider.

f. The laboratory shall maintain copies of all written, printed and electronic records from the analysis (including the order form) of all PT samples for a minimum of five years. All of the records shall be made available to the ORELAP assessors during an on-site assessment of the laboratory.

9. A laboratory is allowed to analyze the same PT sample using different technologies and/or multiple test methods for FoPT (if they are accredited or seeking accreditation for the methods).

10. For matrices except drinking water, if a laboratory reports more than one test method per technology per FoPT, an unacceptable score for either test method shall result in an unacceptable score for both test methods for that FoPT.

11. If a laboratory wishes to withdraw from a PT study for an analyte(s) or for the entire study, the laboratory should notify both the PT Provider and ORELAP before the closing date of the PT study. Withdrawal does not exempt the laboratory from participating in the semiannual schedule.

III.11.3. PT Providers

For continuing accreditation, on or before the closing date of the study, the laboratory shall authorize the PTP to release the laboratory's final evaluation report directly to ORELAP.

ORELAP will not accept PT reports directly from the laboratory. ORELAP will not allow the laboratory to request the PTP to send the report after the study close date, unless there is evidence the laboratory requested to have the PT report sent to ORELAP when submitting the results, but it was not received or lost.

1. PT provider shall submit the following data to ORELAP:
    a. Name of provider
    b. Study identification/sample lot number
    c. Field of testing
    d. Analyte
    e. Method
    f. Sample matrix
    g. PT shipment date
    h. PT closing date
    i. True value
    j. Control range
    k. Laboratory identification
    l. Laboratory result(s)
    m. Date of report
2. The PT Provider shall report laboratory results to ORELAP as designated by the laboratory within the same 24-hour period that it reports the results to the laboratory.

III.11.4. Supplemental PT Studies

PT samples of supplemental PT studies that are used by laboratories for accreditation or corrective action must comply with all above requirements in this section and the PT sample cannot be one that has previously been sent to the laboratory.

III.11.5. Receipt of PT Results

As the primary accrediting authority, ORELAP shall be responsible for monitoring laboratory PT and act on unacceptable performance in accordance with the TNI Standards. The process for handling PT results is as follows:

1. Evaluation of the PT Results
    a. ORELAP considers the analytical result for a FoPT acceptable when the result reported by the laboratory for a FoPT is evaluated acceptable by the PT provider.
    b. PT results are to be evaluated for conformance to the TNI Standards to determine the accreditation status of a laboratory within 60 days of the receipt of the final report from the PT provider.
    c. ORELAP deems it acceptable for a laboratory to analyze the same PT sample using different technologies.

d. Except for drinking water analytes referenced in 40 CFR 141, a laboratory may choose to analyze and report a single method to represent a technology in a single PT study for a particular analyte. If the laboratory analyzes and reports PT studies "by technology" the score obtained for the reported method will be applied to all methods in that technology for which the laboratory seeks to obtain or maintain accreditation in that matrix.

e. If the laboratory reports more than one test method per technology per FoPT, an unacceptable score for either test method shall result in an unacceptable score for both test methods for that FoPT.

f. ORELAP will consider the analytical result for a FoPT not acceptable when:

i. the result reported by the laboratory does not meet the criteria for "acceptable" as specified in TNI V1M1 and associated subsections of the TNI Standard. If the criteria in the TNI Standard are met, and the result for the FoPT was scored "not acceptable" by the PTP, ORELAP may overturn the performance evaluation and score the analytical result "acceptable".

ii. the laboratory does not report results for an accredited FoPT within the time frames specified in the TNI Standards, this includes results from Discharge Monitoring Report Quality Assurance (DMRQA) studies.

iii. the laboratory makes any reporting error for the analytical result

iv. the laboratory submits analytical results for a FoPT from a PT provider that is not accredited by the PTPA or is not recognized by ORELAP or any other entity within TNI.

v. The laboratory reports results performed by another laboratory.

2. The PT provider supplies all PT results electronically to the ORELAP PT email inbox. The Program Manager or designee uploads the PT results into the ODIE software program and/or into the corresponding electronic laboratory folders found in the Shared (I:) drive. Information for a small PT study may be hand entered if needed, and the following PT information is captured:

a. Laboratory IDs

b. Receipt date

c. PT provider

d. PT provider study ID

e. PT study close date

f. PT sample analysis date

g. Method description and LAMS code

h. Analyte description and LAMS code

i. Sample matrix

j. Laboratory result

k. Evaluation

l. True value

m. Control range

n. Field of Accreditation (loaded from ODIE)

3. PT Upload and Review:

   a. After receiving a PT into the ORELAP.PT@odhsoha.oregon.gov inbox, they are manually stored into the Shared (I:) drive for storage and upload purposes. After the PT data has been uploaded into ODIE, The Program Manager or designee clicks on the Evaluate PT key and a report is generated that identifies the laboratory's accreditation status based on their PT performance.

   b. There may be some instances where the PT upload may not be successful due to a mismatch between the method and/or analyte code, or other issue. ORELAP personnel can attempt to resolve the problem by fixing the raw .CSV file or contacting IT and/or the PT provider.

   c. The accreditation status (from PT performance) is based on a laboratory maintaining a history of at least two (2) successful performances out of the most recent three (3) PT samples analyzed for the same accreditation FoPT.

   d. Once the accreditation status has been determined, the Program Manager will accredit those parameters with acceptable PT status if all of the other TNI criteria has been met. The PT tracking is maintained in the ODIE PT module for each laboratory and is reviewed when additional PT results are received as well as when the laboratory's accreditation status requires reevaluation.

   e. PT desk review - Laboratories that fail to achieve two (2) successful performances out of the most recent three (3) PT samples analyzed are notified with an e-mail from the Program Manager or designee confirming the PT status. The laboratory may choose to withdraw those FoAs prior to suspension or revocation due to PT failures.

   f. PT desk review - Laboratories seeking to reinstate after suspension and revocation must meet requirements in V1M1 section 8 of the TNI Standards. Laboratories are notified of the reinstatement by email from the Program Manager or designee stating the accreditation status.

   g. All past hardcopy PT results reports (prior to ODIE) are stored/filed according to laboratory.

4. Any change of accreditation status is recorded in the ORELAP database and shall be uploaded to the TNI LAMS database.

5. A copy of the ORELAP Fields of Accreditation and, if issued, a new certificate and cover letter is emailed to the laboratory. All actions taken which affect the status of a laboratory shall be uploaded to the national database.

6. Copies of all PT result reports and associated information and raw data shall be made available to the assessment team for use in evaluating laboratories as part of the on-site

assessment as per TNI Standard V2M2 Section 6. All assessors have access to PT information contained in ODIE. If an assessor suspects that there may be a problem with a particular PT study or PT study report, the assessor shall report the problem to the Program Manager for further investigation and possible action.

a. If during the review of the records it is discovered that a PTP has suggested or directed a laboratory to purchase QC standards that are specifically designed for a given PT sample or that the PT provider has given the laboratory analysis instructions beyond those specified in the TNI Standards, the Program Manager shall report the results of their findings to the PTP's PTPA.

7. As a secondary accreditation body, ORELAP shall accept the assessment decisions made by the Primary Accreditation Body (AB) regarding a laboratory's performance and compliance with the proficiency testing requirements set forth in the TNI Standards.
8. As a secondary accreditation body, ORELAP shall not impose additional requirements for proficiency testing that are not included in the TNI Standards as a requisite for initial or continued accreditation.

III.11.6. Failed PT Studies

Whenever a laboratory fails a study, the laboratory shall:

1. Determine the root cause(s) for the failure and take appropriate corrective action.
2. Document all corrective actions for failed PT studies.
3. Upon request by ORELAP, submit copies of completed corrective action documentation to ORELAP within 30 days. Corrective actions that have been deemed unacceptable by ORELAP shall be reported to the laboratory for further correction.

All documentation pertaining to each laboratory's corrective actions for failed PT shall be kept in each laboratory's file for the year in which the PT results were released.

Laboratory corrective actions for a failed PT result are reviewed during the laboratories renewal on-site assessment.

III.11.7. Failed PT and Accreditation Status

Although PT performance is not the sole criterion for determining accreditation status, repeated PT failure will affect a laboratory's accreditation status as follows:

1. If a laboratory seeking initial accreditation fails a second study out of the most recent three for a given analyte, ORELAP shall deny the laboratory accreditation for each affected field of accreditation.
2. If an ORELAP-accredited laboratory fails a second study out of the most recent three for a given analyte, ORELAP shall suspend accreditation for each affected field of accreditation.

a. Additionally, ORELAP may take action on a laboratory in the case where the laboratory does not provide a corrective action report to the Primary AB within thirty (30) calendar days of request of such report.

3. If an ORELAP-accredited laboratory fails a third consecutive PT study, ORELAP shall revoke the laboratory's accreditation for each affected field of accreditation.
    a. Additionally, as the primary AB, ORELAP shall revoke the accreditation of a laboratory for a FoPT when:
        i. the laboratory does not participate in the PT program as required by the TNI Standards, or
        ii. the laboratory submits results for PT samples that were generated by another laboratory.
    b. Accreditation bodies that hold secondary accreditation for the laboratory should also be notified in the case of suspension or revocation of accreditation based on PT failures.
4. To obtain accreditation after denial, suspension, or revocation due to PT failure, the laboratory may either wait until the next regularly scheduled PT testing round or obtain and analyze a supplemental sample. However, a laboratory will be not accredited until the PT requirements are met. Note: if accreditation is revoked, the laboratory must start over with the initial accreditation process.

III.11.8. Handling of Questionable PT Samples (Complaint Resolution)

In the event that a PT Provider has shipped one or more samples for ORELAP accreditation that do not meet quality control requirements (TNI, Volume 3) and the provider has not notified affected laboratories in a timely manner (TNI Volume 3), ORELAP shall:

1. Contact the PT Provider and try to resolve the situation.
2. Review the summary data or other relevant documentation and based on the findings, may choose not to use the results of the analytes/matrices to support the accreditation status of the laboratories. The data is reviewed and discussed by qualified assessors and the findings as well as recommended actions are reported to the Program Manager. Decision on use of PT data shall be made by consensus of assessors and the Program Manager who serves as point of contact for ORELAP.
3. If unable to resolve with the PTP, submit a complaint to the PTPA that accredits the PT Provider for the particular analyte(s) and matrices after notifying the PT Provider. ORELAP shall follow all complaint procedures as specified by the PTPA.
4. Submit a complaint to the TNI PT Executive Committee if not satisfied with the response received from PTPA to ORELAP's complaint. The PT Executive Committee will then evaluate the complaint and take appropriate action.

III.12. Recognition (Secondary Accreditation)

III.12.1. Introduction

This section describes the procedures for handling laboratories that already have a current NELAP accreditation from their primary accrediting authority and request recognition from Oregon.

ORELAP will grant secondary accreditation only to those laboratories that have already been accredited by a primary (state) accrediting authority and consider only the current certificate of accreditation issued by the NELAP-recognized primary accrediting authority. ORELAP will only grant secondary accreditation for those fields of testing (matching NELAP method and analyte codes) that have been accredited by the current primary accrediting authority and fall under ORELAP's recognized scope of accreditation. ORELAP will not require any additional proficiency testing, quality assurance, or on-site assessment requirements for the fields of testing for which the laboratory holds primary accreditation.

The laboratory seeking secondary accreditation must complete an application through ODIE. If the laboratory cannot access ODIE, the laboratory may request assistance by telephone or email to ORELAP.

III.12.2. Application

The laboratory must submit a completed application through ODIE. The laboratory must arrange to have its primary accrediting authority send the current certificate of accreditation with attached fields of accreditation describing accredited methods/technologies, matrices, and analytes.

III.12.3. Application Receipt

The receipt of applications for secondary accreditation is described in ORELAP SOP "Application Receipt and Initial Review".

III.12.4. Determination of Fees

The determination of fees for secondary accreditation is described in ORELAP SOP "Application Receipt and Initial Review".

III.12.5. Technical Review

Technical review for secondary accreditation is described in ORELAP SOP "Application Receipt and Initial Review".

III.12.6. Nonconformity

If the Program Manager or their designee notes any nonconformance with the TNI Standards by a laboratory during the initial application process for secondary recognition, or for a laboratory that has already been granted NELAP accreditation through recognition, the Program Manager or designee will immediately notify the laboratory in writing. The primary accrediting body may be notified depending on the type of nonconformance found.

The notification must cite the applicable sections within the TNI Standards for which nonconformance by the laboratory has been noted.

- If the alleged nonconformance is noted during the initial application process for secondary recognition, final action on the application for NELAP accreditation will not be taken until the alleged nonconformance issue has been resolved.
- If the alleged nonconformance is noted after secondary NELAP recognition has been granted, the laboratory will maintain its current NELAP accreditation status until the alleged nonconformance issue has been resolved.

If the primary accrediting body does not take timely and appropriate action on the complaint, ORELAP will raise the issue to the TNI Accreditation Council of the dispute between the two accrediting bodies regarding proper disposition of the complaint.

If ORELAP is notified by a secondary accrediting body of alleged violations by a laboratory holding primary accreditation from ORELAP an assessor team will:

- Review and investigate the alleged nonconformance
- Take appropriate action on the laboratory as set forth by the applicable TNI Standards, including reporting changes in the accreditation status to the TNI Laboratory Accreditation Management System (LAMS).
- Respond to the NELAP-recognized secondary accrediting body and laboratory, in writing, of the nonconformance report and provide an initial report of the findings, a description of the actions taken, and a schedule for implementation of further action on the alleged nonconformance.

III.12.7. Accreditation

The issuance of the certificate of accreditation is described in ORELAP SOP "Issuance of Accreditation Certificate"

III.13. ORELAP Document Control and Records

III.13.1. Introduction

ORELAP is committed to maintaining its program records as required by NELAP. This section describes how documents are controlled.

1. The controlled electronic copies are stored in the "Controlled Documents" folder in the ORELAP shared (I:) drive. These files are accessible only to the Program Manager, ORELAP Assessors, and the Administrative Specialist.

III.13.2. ORELAP Program, Policy, and Procedure Manual

The quality systems document maintained by ORELAP is under documentation control. ORELAP Program, Policy, and Procedure Manual must have a front cover title page that includes:

- Title
- Revision number
- Revision date
- Authorization signatures
    - Executive Team
    - Program Manager
    - Quality Assurance Officer

Each additional page must include:

- Title

- Revision number
- Page number of total pages

III.13.3. Laboratory Records

Laboratory technical records may be found in both the ODIE profile for the laboratory or in the laboratory's folder. Laboratory records include but may not be limited to:

- Laboratory ID number
- Legal name of laboratory
- Physical address of the laboratory
- Laboratory mailing address
- Billing address
- Front door latitude and longitude
- Mobile laboratories
    - Vehicle identification number (VIN)
    - Make and model of vehicle
    - License number
    - State of registration
- Name of owner
- Address of owner
- Name and phone number of Technical Director(s)
- Name and phone number of Quality Assurance Officer
- Name and phone number of laboratory contact person(s)
- FAX number
- Laboratory hours of operation
- Primary Accreditation Body
- Fields of Testing for which the laboratory is requesting accreditation
- Fields of Testing for which the laboratory is currently accredited
- Description of laboratory type
- Proficiency testing results
- Laboratory accreditation status and history
- Completed applications
- Copies of certificates of accreditation and Fields of Accreditation as issued by ORELAP
- Copy of current Quality Manual (primary accredited laboratories)
- Communications
- For primary accredited laboratories: On-site assessment documents: electronic copy of assessment reports; corrective action; Conflict of Interest forms; assessment notes; checklists used; NELAP Assessment Confidentiality Notice; On-site Assessment (OSA) Conference Checklist; ORELAP opening/closing conference roster
- For secondary accredited laboratories: Copies of certificates of accreditation and Fields of Accreditation as issued by the laboratory's primary accrediting authority

Hardcopy laboratory documents are scanned and stored in the designated laboratory folder in the ORELAP shared drive. Once a record has been scanned and stored on the I:Drive, the record is shredded. Historical hardcopy laboratory files are stored in off-site storage until appropriate record retention time ends. Laboratory information collected from the initial or annual applications, on-site reports, and PT results will be maintained in the ODIE database and/or as electronic documents in secure folders

III.13.4. ORELAP Assessor qualification and training files

These records are stored in the Program Manager's office in a file cabinet, or on shared server.

- Assessor Training and Qualification records on assessors, including contractual assessors, who meet the education, experience and training requirements will be maintained as secure electronic files, and include but may not be limited to:
    - Name and address.
    - Organization affiliation and position held.
    - Educational qualification and professional status.
    - Work experience.
    - Training applicable to laboratory accreditation.
    - Experience in laboratory assessment, together with field of competence.
    - Any records of external assessor audits or client feedback.
    - Date of most recent updating of record.
    - Annual performance as part of the specific Agency's Annual Personnel Evaluation Report.
    - Results from annual ORELAP internal audits.
    - Results from assessment feedback evaluations.
- Third Party contracts are stored in the Program Manager's office in a file cabinet, or on the shared server
- Third Party Assessor qualification and training files are stored in the Program Manager's office in a file cabinet, or on the shared server

III.13.5. Other Records

- Performance Testing study results reports are emailed to the ORELAP PT inbox, uploaded into ODIE, and stored on the shared server
- Completed assessment appraisal forms are stored in the Program Manager's office in a file cabinet, or on the shared server
- Accrediting Authority Status and NELAP Recognition Certificate are stored in the Program Manager's office in a file cabinet, or on the shared server
- Current list of ORELAP accredited laboratories is available in ODIE, through TNI LAMS, and provided upon request

III.13.6. Electronic Records

When possible, any changes made to documents will be tracked. In addition, limited access to electronic documents will be maintained. ORELAP utilizes Microsoft Word and Excel formats to create "working" documents. In order to facilitate distribution over a wide variety of platforms, all final ORELAP documentation will be made available in pdf format.

III.13.7. Document Control Revisions

Revisions to quality system documents are performed using Excel files or "Track Changes" feature in Microsoft Word. If multiple people are working on a draft, draft versions are maintained on Shared (I:) drive and/or SharePoint. The final version is assigned a document number and revision date. Documents are then saved to pdf. Obsolete versions are removed from circulation and the new version is made accessible to staff and third-party assessors (as needed).

III.13.8. Record Archiving

Records are stored for 10 years according to ODHS and OHA policy 010-018: Records Retention and Management Policy. An archive files log is maintained.

Electronic files will be put in an archive folder on the Shared (I:) drive and deleted after ten years. All deleted files are documented in accordance with OAR 166-030-0026 and 166-300-0015. To retrieve hardcopy archive records, a request is made for one or more specific boxes to the Program Manager who will arrange for their retrieval.

III.13.9. Records Retention

ORELAP will keep all records for 10 years or longer as required by OSPHL 23 Quality 2.0: Records Retention Schedule and under the NELAP standards. All rules and regulations concerning the procedures for custody, access, storage, management, and retention are published in the Oregon Revised Statutes Chapter 192 and Oregon Administrative Rules, chapter 166, divisions 1-40.

III.13.10. Records Access

The Program Manager or designee will maintain and control access to all files. Electronic files are maintained on a shared directory where only authorized staff can access the files.

Completed applications, corrective actions, current laboratory quality assurance manual, proficiency testing results, on-site checklists and assessment reports will be filed by laboratory and must be retained by ORELAP in accordance with retention schedule required by the State of Oregon, or as set by NELAP, whichever period is longer.

Completed written and electronic records, if any, of internal ORELAP audits including findings, discrepancies and corrective actions, and revisions to program documents must be retained by ORELAP in accordance with retention schedule required by the State of Oregon, or as set by NELAP, whichever period is longer. ORELAP shall comply with Oregon Public Records Act in production of such records, if requested.

Access to program records is limited to personnel who have access to the building entrance and shared drive. Archived records are stored off-site according to OSPHL 92 Quality 4.0: Quality Records Management Policy.

III.14. Technical Review and On-site Assessment

III.14.1. Introduction

This document is designed to describe the procedures used to perform a technical review of the application, supporting documentation, the on-site assessment, the laboratory corrective action plan, and the completion of the final assessment report.

A laboratory assessment must review the ability of the laboratory to conduct accredited testing. The examination of the systems, processes and procedures of the laboratory should give a general sense of its past and present capabilities to perform work of known and documented quality. During a laboratory assessment, the assessment team may identify a number of samples or a recently completed or ongoing project and evaluate to what extent the tests are being conducted according to TNI Standards.

The purpose of a records review is to determine whether the testing laboratory has maintained necessary documentation of data and other information to technically substantiate reports previously issued. During a records review, the assessment team will conduct an overall audit of data and will compare data with submitted reports to determine whether the data were collected, generated, and reported following the TNI Standards. The lead assessor may recommend stopping the assessment based on the nonconformities found during records review. The recommendation is made to the Program Manager and, if the assessment is stopped, the Program Manager will notify the laboratory and identify the nonconformities in writing.

III.14.2. Assessment Frequency

After an initial assessment for accreditation, ORELAP performs reassessments at intervals of two years plus or minus six months. Once a laboratory is accredited, ORELAP reserves the right to assess a laboratory at any time during the accreditation period (follow-up assessments). The routine on-site re-assessment is scheduled in advance for a date mutually agreeable to ORELAP and the laboratory. Unannounced on-site assessments may be performed for cause, such as complaints, changes in key personnel or facility, to verify corrective action implementation, or misrepresentation of accreditation. Laboratories must be advised of this possibility. In order to maintain accreditation, the laboratory must allow the assessors access during any normal business hours.

III.14.3. Laboratory Assessment

The processes for planning and conducting an on-site assessment presented in this procedure are designed for an analytical laboratory seeking accreditation in multiple fields of testing involving analytical methods from several different disciplines. Such assessments are likely to require a team of assessors. In many cases, the scope of the application for accreditation or staffing limitations will dictate that an assessment be conducted by a single assessor. In these cases, all of the functions identified for the assessment team will be the responsibility of the lead assessor.

Reassessments are similar to initial assessments except that the experience gained from previous assessments is considered and enables the assessors to better focus the assessment. The on-site reassessment frequency should be sufficient to monitor a laboratory's conformance to the TNI Standards, however additional on-site presence may be warranted based on ongoing follow-up activities (e.g. PT evaluation, review of laboratory internal audits, corrective action follow-up,

complaint follow-up, etc.). Follow-up on-site assessments are less comprehensive but focus on specific areas. Follow-up assessments are only performed when there is an indicated need.

III.14.4. Pre-Assessment Procedures

Thorough planning and preparation prior to conducting any on-site assessment ensures that the assessment will be as efficient and effective as possible. In general, planning activities will be the responsibility of the lead assessor assigned by the Program Manager. All members of the assessment team must be involved in planning the assessment to ensure that they are well prepared and can function independently while at the laboratory.

The pre-assessment planning process consists of four principal steps:

1. Scoping
2. Staffing
3. Scheduling, and
4. Work plan development.

Table 1 identifies the parties responsible for each step in the process, the information needed to complete the step, and the outcome of each step. The final outcome of pre-assessment planning is a work plan for the assessment that identifies the assignments for all members of the assessment team; lays out a complete schedule of activities for milestones; and sets target dates for all activities through finalization of the assessment report and archiving of the assessment records.

Table 1. Summary of the Pre-Assessment Planning Activities

Step	***Responsible Party***	***Information Required***	***Outcome***
1. Scoping	Lead Assessor	Application for accreditation	Lists of Fields of Testing and methods for which the laboratory seeks or has previously attained accreditation
2. Staffing	Lead Assessor	Scope of assessment Conflict of Interest certification	Selection of the assessment team based on availability of qualified assessors for the requested FOAs.
3. Scheduling	Lead Assessor Assessment Team	Scope of assessment Staffing plan Pre-assessment report	Agreement on dates of assessment Schedule of events
4. Work plan	Assessment team	Report from last on-site assessment. Results from last 3 performance evaluation studies	Team assignments Assessment work plan

III.14.5. Define the Scope of the Assessment

For all routine assessments, the lead assessor begins the planning process by creating a file for the assessment records and reviewing a copy of the laboratory's application for accreditation or renewal of accreditation from ODIE. The application identifies the fields of testing and analytical methods for which accreditation is sought. This information allows the lead assessor to obtain the appropriate checklists for conducting the on-site assessment. The lead assessor verifies that the analytical methods are identified in the application and ensures that reference copies of all methods are available to the assessment team for use throughout planning, conducting, and reporting on the assessment. The lead assessor and the assessment team develop a plan to ensure a representative sample of the scope of accreditation are assessed on a regular basis. This means that all tests within a laboratory with a large scope of accreditation do not necessarily have to be assessed as long as enough of the tests have been analyzed to represent the entire laboratory. In most cases, laboratories with a small scope of accreditation will have all tests assessed. All compliance drinking water methods must be assessed during biennial assessments.

The scope of a non-routine assessment (follow-up) will depend on the purpose of the assessment. If it is to be comprehensive, a similar examination of the laboratory's most recent application or NELAP accreditation certificate should be made to identify the fields of testing and analytical methods for which the laboratory is certified. The scope of a non-routine assessment that is targeted to address a specific problem will be defined by the recent history of the laboratory and/or any agreements concerning corrective action that have been made.

The lead assessor may inquire as to the availability of recent reports of assessments on the lab-requested FOA performed by another AB based on the TNI Standards (e.g. DOD, DOE etc.). This may be done to reduce staffing needed to perform the on-site assessment. In some instances, a recent assessment report and associated corrective action response may be a useful tool is assessing specific portions of a laboratories ability to meet the TNI Standards. In these cases, the lead assessor must have assurances that the assessment was performed using the TNI Standards as the basis for the assessment.

III.14.6. Select the Assessment Team

The job of the assessment team is to review the documents collected from the lab, conduct the on-site assessment, summarize their findings and make recommendations to the Program Manager as to a laboratory's ability to meet the TNI Standards. Once the lead assessor has defined the scope of the assessment, a decision can be made concerning the need for additional assessors. In general, assessments will be conducted by at least two qualified assessors. This will ensure that a second professional opinion is available to validate conclusions and will protect assessors from unwarranted allegations of bias. The number of assessors selected is determined by the scope of the applicant laboratory. In the case of a small laboratory seeking accreditation for only a limited number of analyses, assigning two assessors may not be necessary.

The assessment team is selected based on the scope of accreditation and availability of assessors qualified for the technical disciplines in the scope. The Program Manager or their designee will be part of the assessment team for all complaint related assessments. Technical support personnel who are not formally qualified as assessors but are approved by the ORELAP may be part of the assessment team. Technical support personnel must be accompanied by a qualified assessor and may not conduct interviews in the absence of a qualified assessor. Moreover, technical support

personnel may not cite deficiencies. Upon making initial staff selections, the lead assessor must obtain a signed Conflict of Interest (COI) certification from each assessor, including technical support personnel, to be included on the team. An assessor who has a potential or actual conflict of interest is ineligible to participate on the assessment team and must inform the lead assessor as soon as possible of the potential conflict.

Failure to provide this information will make the proposed assessor ineligible to participate in the assessment.

The lead assessor is responsible to provide the names of the assessment team members to the laboratory, by email, in advance with sufficient time to allow the laboratory to object to any particular assessor or technical support personnel. Email notification must be saved electronically in the laboratory file folder. Objections should follow the general process for complaints. The Program Manager will inform the laboratory of the decision prior to the onset of the on-site assessment. The reasons for objections must be clearly stated and there must be evidence of a potential or actual conflict of interest to honor the appeal.

In the case of unannounced assessments, the names of the assessment team are not provided to the laboratory in advance, however, past known conflicts or complaints will be taken into consideration during the assessment team selection process.

It is possible that during the on-site assessment, assessors or laboratory personnel may become aware of a previously unrecognized or acknowledged potential or actual conflict of interest. When this happens the lead assessor consults with the Program Manager, as soon as practicable, to determine how to proceed. The Program Manager is to take action to ensure that the assessment can proceed without compromising its integrity and impartiality or request that the assessment team terminate the assessment. If it is necessary to appoint a new assessment team member, ORELAP shall appoint it as soon as practicable without jeopardizing the laboratories request for accreditation.

III.14.7. Application Review

The application and all supporting documents supplied by the laboratory are made available for review to the assessment team members via ODIE and the shared server. The assessment team will review the IDOC and MDL summaries for completeness and agreement to program requirements.

The assessor team will notify the Program Manager who will, in turn, notify the laboratory, in writing, of any deficiencies found in the application. All deficiencies must be corrected before the application is considered complete.

III.14.8. Develop the Assessment Plan

Make the work plan development process efficient and ensure that work plans are complete and effective. At a minimum, the assessment work plan should:

1. Define the scope of the assessment in terms of testing, analytical methods, checklists or other terms as appropriate;
2. Identify the laboratory processes to be evaluated:
    a. Laboratory organization and management

b. Quality system
c. Personnel and staffing
d. Physical facility
e. Equipment maintenance
f. Reference materials
g. Proficiency testing sample analysis
h. Measurement traceability and calibration
i. Test Methods and standard operating procedures
j. Sample handling, acceptance and tracking
k. Records management
l. Reporting
m. Subcontracting
n. Procurement of supplies and services
o. Handling of customers' complaints

3. Identify the analytical procedures to be evaluated and assign team members according to expertise.
4. Identify the extent to which a records review will be conducted and assign team members according to their expertise.
5. Identify the background material reviewed by the assessment team.
6. Identify documents to be requested from the laboratory.
7. Define an agenda, including dates and times for all activities to be conducted during the assessment, and assign team members as appropriate.
8. Identify, to the extent possible, laboratory staff to be interviewed during the assessment and team members who will conduct the interviews.

In order to complete the work plan, members of the assessment team should review the following documents:

- The Application for Accreditation
- Copies of previous assessment reports including Statements of Deficiencies and Plans of Correction
- Complaint allegations and/or investigations
- Proficiency testing results
- General laboratory information such as self-assessment forms submitted by the laboratory, SOPs, and quality manuals
- Official laboratory communications with accrediting authority staff and associated records (e.g., previous corrective action plans)

- Available documents from recipients of laboratory reports
- Current program regulations and special requirements that apply to the fields of testing or analytical methods for which the laboratory seeks accreditation (e.g., security clearance requirements, radioactive exposure protocols, etc.)
- Current versions of the analytical methods used by the laboratory to conduct the tests covered by the accreditation

The assessment plan must be reviewed and approved by each member of the assessment team. Portions of the work plan may be provided to the Laboratory Director (however named) in advance of the assessment. At a minimum, the Laboratory Director should be provided with an agenda for the assessment and a list of documents or records, if any, to be produced for the assessment team. The assessment team may or may not choose to identify staff to be interviewed prior to arriving at the laboratory. Generally, the only record and output of the work plan development is the scheduling letter and any other records the lead assessor might find necessary to manage the assessment process.

III.14.9. Schedule the Assessment

Initial assessments, complaint and complaint follow-up assessments take precedence over routine assessments. Special complaint and follow-up assessments will be performed as needed.

Trips are arranged in such a manner as to maximize inspections, minimize cost and travel time. Trips are also arranged for the safety of the assessors by avoiding possible dangerous road conditions.

The on-site assessment of a mobile laboratory may be performed at any convenient location. It is not necessary for the laboratory to be assessed at the same location where the laboratory performs analyses. The lead assessor shall schedule the on-site assessment of a mobile laboratory at a mutually agreeable location.

For announced assessments, the lead assessor will email the laboratory's primary contact and inform them of the full names of the members of the assessment team and identify mutually acceptable dates for the assessment. The lead assessor and laboratory primary contact will discuss and agree on:

- The date and time at which the assessment team will arrive at the laboratory
- The date and tentative time at which the assessment team will leave the laboratory
- The composition of the assessment team
- The scope of the assessment

Following the conversation, the lead assessor will provide written verification of the agreement in the form of a letter that announces the assessment and the mutually accepted schedule.

In addition, the Lead Assessor must obtain copies of all the forms required for the assessment, including checklists, and provide information to the laboratory on how to obtain assessment information from the ORELAP.

III.14.10. Handling Confidential Business Information (CBI)

During on-site assessments, laboratory assessors may come into possession of information claimed as business confidential. ORELAP will handle confidential business information in accordance with Oregon Public Records law.

1. The lead assessor must provide a NELAP Assessment Confidentiality Notice to the responsible laboratory prior to or at the beginning of the assessment. This informs laboratory officials of their right to claim any portion of the information requested during the assessment data as CBI. The laboratory will also be provided a CBI claim form.
2. The assessment team must take custody of all CBI information before leaving the laboratory and must maintain them in custody, using all proper procedures and safeguards until they can be received by ORELAP who must also treat such information as CBI, until an official determination has been made in accordance with Federal and State laws.
3. Once CBI documents have been received by ORELAP, it is the responsibility of ORELAP to hold all CBI-claimed information in a secure manner throughout the holding period of assessment records and may not be reproduced or distributed inconsistent with Oregon Public Records law. If ORELAP questions the claim that certain information is CBI, the laboratory must be contacted and given 21 calendar days to:
    a. Provide justification of their claim to CBI
    b. Remove claim of CBI
    c. Resolve the issue in a manner agreeable to both the laboratory and ORELAP
    d. Engage legal assistance
    e. Appeal the action to NELAP, or
    f. Withdraw their NELAP accreditation application for the field of testing associated with the CBI information
4. CBI may be purged of references to client identity by the responsible laboratory official at the time of removal from the laboratory. However, sample identifiers may not be obscured from the information. If the information claims as CBI suggests the need for further action, the information may be forwarded to the appropriate agency, which may act outside the scope of the accreditation, to obtain the client's identity.
5. It is not the responsibility of the on-site assessor to make any determination with respect to the validity of a CBI claim.
6. If a business confidentiality claim is received after the on-site assessment, it is the responsibility of ORELAP to make such efforts as are administratively practical to associate the late claim with copies of the previously submitted information in its files.
7. In no instance may ORELAP declassify CBI-claimed information without notification of the laboratory. If the responsible laboratory official does not consent to declassification of the CBI-claimed information, the laboratory may pursue any of all the actions described above in the third bulleted section.

III.14.11. National Security Issues

Assessors performing assessments at facilities owned and/or operated by Federal departments/agencies/contractors may need security clearances, appropriate badges, and/or a security briefing before proceeding with the on-site inspection. Assessors shall be informed in writing of any information, including analytical data that is controlled for national security reasons and cannot be released to the public.

III.14.12. Opening Conference

Arrival at the facility for routine ORELAP assessments shall occur during established working hours unless special arrangements are made with the laboratory.

A laboratory's refusal to admit the assessment team for assessment results in an automatic failure of the laboratory to receive accreditation or loss of existing accreditation by the laboratory, unless there are extenuating circumstances that are accepted and documented by ORELAP. The assessment team leader must notify the Program Manager as soon as possible after refusal of entry.

Upon arrival, the lead assessor will introduce themself and any assessment team members. The assessors will meet with the facility's administrator or laboratory director (however named) and management staff. The assessors will indicate that the on-site assessment will be conducted with pertinent technical staff. The purpose of the assessment and assessment process will be briefly explained. Plans for an exit interview shall be made known. Inquire if the laboratory staff have any questions regarding the assessment process. An attendance sheet is circulated by the assessment team to document all parties in attendance at the opening conference.

During the opening conference the lead assessor 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 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
- Identify the individuals in the laboratory responsible for providing the assessment team with the necessary documentation.
- 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 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 general laboratory tour

III.14.13. Initial Tour

Request a tour of all sites where laboratory testing occurs including pre-analytic, analytic and post-analytic processes and storerooms. During the walk-through, observe space, ventilation, temperature, types of equipment, storage, glassware washing, media and solution preparation and disposal of waste, handling/labeling/storage of samples, and personnel performing tests. (In a small laboratory, a tour may not be necessary.). Note any problems or concerns for further evaluation during the assessment process.

III.14.14. Documentation of Assessment

The assessors must document the required elements of the records review using checklists or notes. The TNI Standards checklist and other assessment checklists as they are developed, may be used by assessors and are available to the laboratories. Assessors need to keep accurate records of each potential deficiency observed. Assessment records must be identifiable to the laboratory, date of assessment, and task assessed. Record information in specific terms such that any laboratory person, director, or lawyer may understand what criteria are not met. Point out deficiencies at the time of the inspections so the technical staff understands that data or lack of data supports your determination. This gives staff the opportunity to clarify any misunderstandings or produce records you require. When disagreements occur between the laboratory staff and the assessor(s), ask for additional reference materials or documents that support the laboratory's view. Reserve the right to discuss potential deficiencies with other ORELAP staff.

Maintenance of all assessment records is the responsibility of ORELAP even if assessments are performed by a third party.

Note: Assessors must document findings using current TNI Standards checklists. Electronic versions of the checklists are generated and documented in ODIE. The checklists used by the assessors during the assessment become a part of the permanent file kept by the accrediting authority for each laboratory.

III.14.15. Quality Manual, Analytical Records and Data Review

Although the assessors are expected to have reviewed the laboratory's quality manual as part of the laboratory's application review, the assessors shall determine that the document submitted by the laboratory is on-site at the facility, and that the authorized, current editions are understood by, available to, and implemented by appropriate personnel.

The assessors shall review laboratory records for accuracy, completeness, and the use of proper methodology. The analytical records and data review should include all laboratory documents tracking 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 hand-written 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 should be evaluated by an assessor as raw data to determine method compliance and scientific defensibility.

The minimum set of documents for review includes:

- Quality Manual and related quality documentation stating the laboratory's established policies and operational procedures
- 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, including any federal or state required detection limits, reporting limits, maximum contaminant levels or action levels
- Records associated with the initial method validation 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.
- Data results through any data input system to the production of the final report.

III.14.16. Proficiency Testing (PT) Review

Review the laboratory information associated with the analysis of PT samples for:

- Evidence of treatment of PT samples as if they were routine samples (e.g. sample handling, batching, analysts, preparations, calibrations, QC, data review etc.)

- Documentation and corrective action of any unsatisfactory performance (note dates of these failures and select these dates for QC record review)

Note: PT sample acceptability is monitored throughout the year by ORELAP.

III.14.17. Laboratory Personnel Qualifications

Laboratory personnel qualifications will be examined for compliance with the currently adopted TNI Standards. Assessors will review the education, experience, and training records for laboratory management including technical directors, as well as training and demonstrations of capability for all laboratory personnel.

III.14.18. Sample Integrity, Evaluation of Equipment and Testing Supplies

Sample Integrity:

As the quality of the sample can affect the accuracy of the test, sample collection and handling should be observed whenever possible. (Note: some laboratories do not collect samples.) Observe:

- Collection procedures to ascertain if staff follow written instructions and acceptable laboratory practices
- Labeling practices to assure correct identification of the sample
- Sample acceptability and rejection policies to determine if they are followed
- Test requisitions to determine if information is complete
- If the laboratory does not collect samples, check the method(s) by which the laboratory obtains assurance that the samples they receive for analysis were sampled and handled in the appropriate manner.

Equipment and Testing Supplies:

Observe and confirm that appropriate equipment, reagents, media are available to perform tests reported. Verify:

- 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

Equipment manuals are readily available to laboratory staff for all instruments including operation and troubleshooting instructions

III.14.19. Test Performance and Reporting of Test Results

Sample Selection and Size:

The selection of sample records is critical to the outcome of the inspection and should be representative of all laboratory functions in order to determine compliance. Select a sample of records that represent each instrument/method in use. Select records from the past six months. If no problems are found in this sample, no further record review is warranted. When problems are

found, expand the sample size and/or time period going back for a period of not more than two years or date of initial operation for new lab.

Consider the purpose of the assessment (i.e., initial, re-inspection, complaint, follow-up, change of owner, director or location). Complaints, follow-up inspections and changes in owner and/or director are focused on particular processes. If problems are found, the inspection and sample size may be expanded.

Test Performance:

Using the selected sample, review records of quality control (QC), calibration data and final reports. Observe test performance when possible. Records are usually kept on-site but instances may occur when records are stored off-site. Once the information is requested, the laboratory has a "reasonable" time to produce the records. Generally, this means within 4 hours, but in some circumstances, this could be several days.

Determine if personnel are following the laboratory's written policies and procedures for testing including the frequency and type of QC. Review QC data including system for tracking shifts and trends and outliers. Verify that corrective actions are taken when controls fall outside of acceptable limits and results are reported only when QC is acceptable. Verify that limits for controls are clearly stated and readily available to testing personnel.

Interview testing personnel regarding:

- Knowledge of new test/technologies
- Specific duties and responsibilities
- Supervision received or given
- Practices versus policies and procedures

Reporting of Test Results:

Review results by examining instrument printouts, worksheets, and final reports. Verify:

- Worksheets, printouts and final reports agree
- Reports identify the date of testing
- Pertinent information is included on the report to enable interpretation of test results (For example: date and time of collection)
- A system is in place for corrected reports
- A system is in place and followed to track tests
- A system is in place to assess accuracy of transcription if information/data is transferred to a final laboratory report

III.14.20. Analysis of Findings

Collect all necessary information before deciding if a potential deficiency exists and whether it is an "immediate and serious" finding. Analyze findings for degree of severity, frequency of occurrence, impact on delivery of services, and accuracy of test results.

One occurrence, which doesn't directly affect outcome, may not be a deficiency. Sporadic occurrences resulting in slight or no impact on quality of testing may not warrant a deficiency. Assess:

- frequency and patterns of occurrences which may indicate failure to be performed by a specific person
- Performance versus documentation
- Documentation of non-performance
- Seriousness of the finding and impact on testing accuracy
- If the finding is related to one test, multiple tests, or is laboratory wide

Consider the findings deficiencies if they limit the capacity of the laboratory to provide quality data and they are not in adherence to the TNI Standards, analytical methods, regulations, or to their own internal procedures.

If during an assessment, an assessor has sufficient information to believe that a particular person has violated an environmental law or regulation, this information must be carefully documented and presented to the lead assessor, who may take concerns to the Program Manager and/or the Executive Team for further consideration. At the discretion of the lead assessor, these issues may or may not be discussed during the closing conference.

III.14.21. Assessment Team Debriefing

At the conclusion of the assessment, the assessment team members may meet in private to discuss and organize findings and recommendations. The assessment team will develop a closing conference outline, listing findings and order of presentation. Care should be taken to identify any material that should not be discussed during the closing conference such as fraud or other potential litigation or enforcement.

III.14.22. Closing Conference

Upon completion of the assessment, the assessment team conducts a closing conference to inform the laboratory director, and other laboratory staff requested by the laboratory director, of preliminary assessment results. A daily debrief of findings during the assessment may also be performed. This information may be presented in writing or orally (or both). An attendance sheet is circulated by the assessment team to document all parties in attendance at the closing conference.

The lead assessor should thank the laboratory staff for their cooperation in the assessment process and point out some positive attributes of the laboratory prior to going through the findings.

The assessment team should endeavor to be as complete as possible in its identification of potential deficiencies. Any recommendations for improvement must be clearly stated as recommendations with no implication that it is a requirement.

It should be made clear that all findings presented at the closing conference are subject to review and change prior to the issuance of the final assessment report approved by the Program Manager. All deficiencies described must be described in the context of the applicable TNI Standards or appropriate test method or regulation.

The assessment team shall not provide instruction on preferred ways to correct the deficiencies. Providing this type of instruction constitute consultancy and is forbidden by ORELAP.

The lead assessor shall provide the laboratory an opportunity to ask questions about the findings and their basis. If the laboratory disagrees with the findings of the assessment team:

a) The lead assessor may remove the finding if they agree with the laboratory or

b) Where the assessment team cannot reach a conclusion regarding the laboratory's exception, the lead assessor shall document the laboratory's exception and consult with other ORELAP staff or the Program Manager as to the status prior to writing up the final assessment report.

c) The deficiencies to which the laboratory takes exception are to be included in the final report, it should be noted that the laboratory disagreed so the Program Manager may review more closely and add any other comments regarding the finding before approving the report.

Before adjourning, the lead assessor should 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 in ODIE.

The closing session should 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. Consequently, the closing session should always be conducted in a factual manner.

At the closing conference, the lead assessor shall also provide the laboratory with the assessment appraisal form and strongly encourage the laboratory to fill it out and submit to the Program Manager. Laboratory feedback is an important mechanism when assessing the performance of ORELAP.

If the assessors' findings indicate such an extreme degree of noncompliance to the TNI Standards or that public interest, safety or welfare are in jeopardy and emergency action is required, the lead assessor will notify the Program Manager immediately upon returning from the assessment. The Program Manager will notify the ORELAP Executive team and take actions towards immediate suspension of the laboratory's accreditation according to Oregon Administrative Procedures Act (Oregon Revised Statutes chapter 183).

III.14.23. Final Assessment Report

Although reporting begins during the closing conference when the lead assessor presents a summary of the assessment findings, the final product for the assessment is a formal, written report. The final report for an on-site assessment should include a summary and should describe existing conditions at the laboratory and identify and describe any deficiencies. At a minimum, the report must include:

- Identification of the laboratory (name, address, and ORELAP ID).
- Date or dates of the assessment.
- Identity and affiliation of each member of the assessment team.
- Identify participants in the opening and closing conferences.

- A statement of the objectives and scope of the assessment
- Documentation of the findings resulting from the assessment (including a description of all deficiencies found and a summary of the objective evidence supporting the findings).
- Comments and recommendations.

All deficiencies must be described in the context of the applicable TNI Standard or appropriate test method or regulation, and the specific standard (section number and text) must be cited. The final report must be completed and transmitted to the laboratory within 30 calendar days following completion of the on-site assessment.

The report must be reviewed by the Program Manager or their designee. If the Program Manager participated in the assessment the review must be performed by another staff member. The purpose of the review is to make sure the content of the report is of a suitable quality and professionally written, and also to determine if any accreditation decisions need to be made based on the outcome of the assessment. The Final Assessment Report is available in ODIE. An electronic copy of the final report can be generated as a PDF. ODIE sends a notification via email to the laboratory when the on-site assessment is complete.

The report deadline may be delayed in cases where ORELAP has cause to conduct further investigation of conditions or practices at the laboratory or is taking another action related to the accreditation status of the laboratory. In such cases, the accrediting authority must notify the laboratory of the proposed date for completion of the report and of the cause of the delay. All on-site assessment reports, whether internal or from third party assessors, are eventually made available to the public upon request. These must be obtained only from ORELAP, which has the sole responsibility for the distribution of the reports. However, reports will be made available first to the laboratory's named contact person. The laboratory must be allowed to request clarification regarding any aspect of the report and may take exception to any findings reported by notifying the ORELAP in writing. In accordance with Freedom of Information laws, any information judged to be proprietary, financial and/or trade information (Confidential Business Information), or relevant to an ongoing enforcement investigation is exempt from public disclosure requirements.

III.14.24. Corrective Action

After being notified of deficiencies, the laboratory shall have 30 calendar days from the date of receipt of the assessment report to provide a corrective action plan (CAP). The CAP shall describe the action(s) that the laboratory will implement to correct each finding and the time period required to accomplish the corrective action along with supporting evidence. Corrective actions are submitted through ODIE.

Note: Items identified as "Immediate" findings must be fully corrected prior to closure of the inspection report.

The lead assessor and the assessment team and/or the Program Manager review the laboratory's corrective action plan to ensure that all of the findings have been sufficiently addressed as to the proposed timeline for correction as well as the effectiveness and suitability of 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 of the plan, was deemed unacceptable to remediate a deficiency, the laboratory shall have an additional 30 calendar days to submit a revised corrective action plan. All responses and reviews of corrective action plans are in ODIE. There may be cases where information is submitted via email.

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, pending due process and opportunity for appeal.

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, pending due process and opportunity for appeal.

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 except in accordance with TNI Standards and applicable state law, including but not limited to the Oregon Administrative Procedures Act. Refer to SOP for Denial, Suspension, and Revocation.

III.14.25. Follow-up Assessments

Follow-up assessments may be necessary for numerous circumstances, including, but not limited to:

- following a previous on-site assessment with substantial or numerous deficiencies, or
- 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.

These assessments may be to determine whether a laboratory has corrected deficiencies or, to determine the merit of a formal appeal by the laboratory or, to determine the effects of a major change within the laboratory. Any follow-up assessment following a routine assessment that might warrant downgrading the laboratory's accreditation status shall be completed and reported within 30 calendar days after the receipt of the laboratory's plan of corrective action. The results of a follow-up assessment conducted for just cause other than prior reported deficiencies, e.g., a major change in personnel, shall be reported within 30 calendar days of the follow-up on-site 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 Program Manager based on assessment team's recommendation.

III.14.26. Assessment Records

Upon completion of the final report from each on-site assessment, the assessor or lead assessor should ensure that all of the original records of the assessment are compiled and saved to the shared server files. The assessment report and all corrective actions are handled through ODIE.

If for any reason the ODIE application cannot capture all of the report findings, corrective actions, or supporting documents for corrective actions, the alternative is to document this information in the laboratory folder on the shared server.

1. Upon completion of the on-site assessment, the lead assessor ascertains if all documents to be included in the assessment records are present. These documents include:
    - copies of paper assessment reports and location of electronic copy
    - original corrective actions from the laboratories, as required
    - completed paper checklists and location of any electronic checklist
    - completed Conflict of Interest forms for each participating assessment team member
    - CBI forms, if used
    - Opening and closing conference rosters
    - Opening and closing conference checklist
    - Letters, memos, e-mail
    - other documents relevant to the assessments, e.g., notes

III.14.27. Technical Review without an On-Site Assessment

Once a laboratory has been ORELAP accredited, the laboratory may add an analyte, method or matrix to its scope of accreditation without an on-site assessment providing the criteria listed below are met. If the criteria are not met, an on-site assessment may be required or the accreditation may be denied.

1. Addition of analyte(s). The laboratory must:
    a. be currently accredited for the matrix/method used to test for the analyte(s) requested;
    b. request the addition of the analyte by submitting an additional parameters application in ODIE and submit an LOD and/or LOQ summary as applicable;
    c. meet the TNI PT requirements for the matrix/method/analyte(s) requested.
2. Addition of a method(s). The laboratory must:
    a. be currently accredited for the matrix and a method of similar technology as the method requested;
    b. submit an application for additional methods in ODIE and pay appropriate application fee. Such a packet includes a completed application form, LOD (and/or LOQ) and DOC summaries;
    c. submit an acceptable method SOP;
    d. submit evidence of quality performance;
    e. meet the TNI PT requirements for the matrix/method/analyte(s) requested.

3. Addition of matrix (ices). The laboratory must:
    a. be currently accredited for the technology/method(s) for another matrix
    b. submit an application for additional methods in ODIE and pay appropriate application fee. Such a packet includes a completed application form, LOD (and/or LOQ) and DOC summaries;
    c. submit an acceptable method SOP;
    d. submit evidence of quality performance;
    e. meet the TNI PT requirements for the matrix/method/analyte(s) requested.

III.15. Third-party Assessor Requirements

III.15.1. Introduction

Because the on-site assessment is an important part of the laboratory accreditation program, the ability and training of the assessors themselves is equally important to the success of the program. The processes by which we obtain and evaluate third-party assessors are described here. The Program Manager will maintain all records on third-party assessors.

Third-party assessors will be used for evaluating laboratories that have requested parameters outside the scope of the ORELAP assessors (e.g., radiochemical analyses) and/or as travel or workload dictates.

ORELAP will take full responsibility for work performed by third-party assessors and retain all decision-making authority pertaining to the accreditation of a laboratory. Third-party assessors will meet the basic qualifications and additional qualifications set forth in the following sections. ORELAP will obtain written consent from the laboratory for the third-party assessment.

III.15.2. Procurement and Initial Review of Third-party Assessors

ORELAP may periodically, and in accordance with PHD policy, enter into agreements with third-party assessment providers. Those entities or individuals that wish to serve as third-party ORELAP assessors must submit the following for review:

1. Completed application form(s), as applicable.
2. Current copy of the third-party's Quality Manual.
3. Current copy of the third-party's Standard Operating Procedures (SOP) and checklists for conducting assessments according to TNI Standards adopted by ORELAP.
4. Current resumes of all assessors indicating level of education and relevant training as well as years of experience in their fields of expertise and as laboratory assessors.
5. Copies of certificates for all TNI/NELAC and relevant training (e.g. EPA) received by each assessor to demonstrate conformance to the training requirements in the TNI Standards.

Upon receipt, the application will be reviewed by the Program Manager and/or Lead Assessor.

1. The Quality Manual and SOP will be evaluated against the TNI Standards for conducting on-site assessments.

2. The quality documents must include acceptable policies for ethical practices and keeping all laboratory assessments reports and documents in confidence to ORELAP.
3. The resumes of the assessors will be checked to ascertain that they meet the ORELAP qualifications for laboratory assessors.

III.15.3. Assessor Qualifications

The qualifications of third-party assessors are as follows:

- Basic Qualifications
    1. The assessors used by ORELAP must be an experienced professional with at least a minimum of a Bachelor's degree in basic science or have equivalent education and experience in laboratory assessment or related fields.
    2. Each assessor must have successfully completed the TNI-specified basic assessor training course and take annual refresher training acceptable to ORELAP.
    3. Each assessor must also have successfully completed the TNI-specified technical assessor training course for the area in which they are performing assessments or an equivalent training course acceptable to ORELAP (e.g. EPA DW Laboratory Certification Officer training) and take annual refresher training acceptable to the ORELAP.
    4. Each new assessor must also undergo on-site training with a qualified assessor during at least four actual assessments, though this may be waived for legacy third-party assessors who can show prior experience conducting TNI assessments.
- Additional Qualifications
    1. Be familiar with the relevant legal regulations, accreditation procedures and accreditation requirements.
    2. Have a thorough knowledge of the relevant assessment methods and assessment documents.
    3. Be thoroughly familiar with the various forms of records discussed during the assessment planning which include but are not limited to; the application, DOC/LODs/LOQs, PT testing results, organizational structure, Quality Manual submitted by the laboratory, SOPs for the methods of interest, procedures for preparing standards, reagents and other necessary solutions, the origin and expiration dates of standards, reagents and reference materials and the method's requirements for QA/QC.
    4. Be thoroughly cognizant of how the data is reported and the applicable data reduction methods employed.
    5. Be technically conversant with the specific fields of testing for which accreditation is sought.
    6. Be able to communicate effectively, both orally and in writing.

III.15.4. Approval of Third-party Assessors

Once the application has been deemed acceptable, the applicant will receive a State of Oregon contract for services for PHD that includes the conditions to performing work that adheres to the TNI Standards (including confidentiality and conflict of interest requirements) and a description of the way in which payment for services will be obtained. Once the contract has been signed by all appropriate parties and returned, ORELAP may request their services as per the contract. This may also take the form of a memorandum of understanding (MOU).

III.15.5. Third-party Assessor Evaluation and Requirements for Contract Maintenance

1. Additionally, qualifications of the assessors may be initially evaluated by observation during an on-site assessment by an ORELAP Assessor or QA Officer.
2. The qualifications of the assessors will be evaluated at least every three years, or as needed, by the Program Manager for their ability to meet the requirements set forth in this SOP. The evaluation also will include a review of the completed assessment appraisal forms sent to ORELAP from the laboratories after on-site visits are completed. The Program Manager maintains a record of the evaluations.
3. If the third-party assessors are judged by the Program Manager to be lacking specific kinds of training, training will be requested. If the third-party assessors continue to fail to meet the expected standards of ORELAP, their contract will be terminated.
4. Contract assessors will be expected to maintain their ORELAP and NELAP/TNI training qualifications, including required refresher training and technical training, and supply this information to the Program Manager. If third-party assessors have not performed an ORELAP assessment within the past year, the Program Manager may request updated training records.
5. The Program Manager will review and maintain conflict of interest statements, which are required from each assessor before the on-site assessment, on file with each specific on-site assessment.
6. Third-party assessors must demonstrate writing and organization ability to meet the demands of managing the assessment activities. These include a clear writing style and timeliness when issuing reports. The contract of any third-party assessors who fail to meet these requirements will be terminated.
7. Third-party assessors must maintain current checklists used during the assessments. Third-party assessment checklists and notes used during the assessment must be submitted to ORELAP after each assessment. The Program Manager will review these checklists as the program requirements change.
8. When the third-party contractor has a change in personnel, the Program Manager must be notified before an on-site assessment can proceed so that the qualifications of the new assessor can be evaluated.
9. A contracted third-party assessor shall not offer consultancy or other services that may compromise the objectivity or impartiality of the assessments performed for ORELAP.
10. A failure of the third-party assessor to meet any of the qualifications and/or requirements listed above will result in the termination of the contract.

III.15.6. Third-party Assessor Conflict of Interest

1. ORELAP will obtain a written consent to use a particular subcontract assessor from the laboratory prior to the assessment or during the opening conference of the assessment.
2. ORELAP will exclude a third-party assessor from an assessment in the case where either the laboratory or assessor identifies a conflict of interest.

III.16. Nonconformance and Corrective Action Records

III.16.1. Scope and Application

A major component of the Quality Assurance program is the feedback mechanism designed to keep ORELAP staff informed on quality-related issues and to provide insight to problem resolution (corrective action) and identification of potential issues before they occur (preventative action).

The purpose of the ORELAP corrective action system is to provide a systematic and organized mechanism for reporting, analyzing, and correcting problems, discrepancies, and/or anomalies that occur during routine operations and to identify potential problem areas to help prevent future problems from occurring within the ORELAP program.

Among other things, the corrective action system attempts to: (1) collect information from which reports on the overall status of nonconformances can be made, (2) assign priorities, (3) assign responsibilities, (4) record the progress of the Corrective Action Plan, (5) notify the appropriate people of the nonconformance, and (6) produce management reports. In addition, the information gathered in the corrective action system provides a history of the various issues that may arise during ORELAP operations and helps identify general areas where additional resources may be required in order to maintain and improve laboratory operations.

In general, the corrective action system should be used to track nonconformances in any aspect of the ORELAP operations, including (but not limited to) IT problems, certification issues, program processes, invoicing, laboratory review, PT review, approval processes, management oversight, and/or QA oversight. Specific types of nonconformances documented by the corrective action system may include:

- Systematic problems (i.e., repeated problems or issues that fundamentally affect significant aspects of operations)
- Issues that potentially affect large amounts of data (e.g., ODIE)
- Audit/assessment findings
- Customer complaints

As a rule of thumb, use the corrective action plan for issues that require a true corrective action, e.g. changes in procedures, behaviors, other ‘fixes’ (e.g. computer fixes) or retraining (saying “don’t do that anymore” does not constitute retraining).

A nonconformance is identified and documented on an ORELAP Corrective Action Record (CAR) Form (see Attachment A). The form captures the necessary information and serves as a permanent record of all activities related to corrective and preventative actions. Any ORELAP staff member may initiate the corrective action process.

III.16.2. Attachment A: ORELAP Nonconformance Report Form

CAR #
Date CAR initiated:
Initiated by:
Verified on:
Verified by:

Oregon State Public Health Laboratory
Regulatory Section - **ORELAP**
7202 NE Evergreen Parkway Suite 100
Hillsboro, OR 97124-7251
Phone: (503) 693-4122
www.healthoregon.org/orelap

ORELAP *Corrective Action Record (CAR)*

Description of nonconformance
Has this occurred previously?

Source of nonconformance			
☐ Internal audit	☐ Public Agency	☐Staff	☐ Client
☐ Other			
If applicable: Complainant's name, address, email, and phone number:			
Name:			
Address:			
Phone:			
Email:			

Root Cause (RC) analysis
Corrective Action description
☐ Due date: ☐ No Action ☐ Other Action:
Corrective Action Plan (CAP)

Implemented Corrective Action		
Date:		
Actions taken:		
Status:	☐ Pending	☐ Completed
Verified and Date:	☐ Yes:	☐ No:
	☐ Other (specify):	
Signature:		Date Closed: ____/____/____

PART IV. ACRONYMS

Acronym	Definition
°C	Degrees Celsius
AA	Atomic Absorption
AB	Accreditation Body
ACM	Asbestos-containing Material
ACS	American Chemical Society
AF	Atomic Fluorescence
ASTM	American Society for Testing and Materials
BOD	Biochemical Oxygen Demand
BS	Blank Spike
BSD	Blank Spike Duplicate
C	Celsius
CAA	Clean Air Act
CAP	Corrective Action Plan
CBI	Confidential Business Information
CCB	Continuing Calibration Blank
CCV	Continuing Calibration Verification
CFR	United States Code of Federal Regulations
CFU	Colony-Forming Unit
COA	Certificate of Analysis
COC	Chain of Custody
COD	Chemical Oxygen Demand
CRM	Certified Reference Material
CV	Coefficient of Variation
CWA	Clean Water Act
DEQ	Department of Environmental Quality
DI	De-ionized

DL	Detection Limit
DMR-QA	Discharge Monitoring Report-Quality Assurance
DO	Dissolved Oxygen
DOC	Demonstration of Capability
DW	Drinking Water
DWS	Oregon Drinking Water Services program
EPA	United States Environmental Protection Agency
FOA	Field of Accreditation
FoPT	Fields of Proficiency Testing
GC	Gas Chromatography
GC-ECD	Gas Chromatography-Electron Capture Detector
GC-FID	Gas Chromatography-Flame Ionization Detector
GC-MS	Gas Chromatography-Mass Spectrometry
GC-MS/MS	Gas Chromatography-Mass Spectrometry-Mass Spectrometry
GC-NPD	Gas Chromatography-Nitrogen Phosphorus Detector
GC-PID	Gas Chromatography-Photoionization Detector
HPLC	High-Performance Liquid Chromatography
HPLC-FL	High-Performance Liquid Chromatography-Fluorescence Detection
HPLC-MS	High-Performance Liquid Chromatography-Mass Spectrometry
HPLC-MS/MS	High-Performance Liquid Chromatography-Mass Spectrometry-Mass Spectrometry
HPLC-UV-VIS	High-Performance Liquid Chromatography-Ultraviolet-Visual Spectroscopy
HRMS	High Resolution Mass Spectrometry
IC	Ion Chromatography
ICB	Initial Calibration Blank
ICP-AES	Inductively Coupled Plasma-Atomic Emission Spectroscopy
ICP-MS	Inductively Coupled Plasma-Atomic Mass Spectroscopy
ICV	Initial Calibration Verification
ID	Identification
iDOC	Initial Demonstration of Capability
IR	Infrared
ISE	Ion-Selective Electrode
IT	Information Technology
LAMS	Laboratory Accreditation Management System
L	Liter
LC	Liquid Chromatography
LCS	Laboratory Control Sample
LCSD	Laboratory Control Sample Duplicate
LFM	Laboratory Fortified Matrix
LFMD	Laboratory Fortified Matrix Duplicate
LIMS	Laboratory Information Management System
LOD	Limit of Detection
LOEC	Lowest Observed Effect Concentration
LOQ	Limit of Quantitation
MB	Method Blank
MCL	Maximum Contaminant Level

MDL	Method Detection Limit
MF	Membrane Filtration
MFL	Million Fibers per Liter
mg	milligram
MHW	Moderately Hard Water
MOU	Memorandum Of Understanding
MPN	Most Probable Number
MS	Matrix Spike
MSD	Matrix Spike Duplicate
MTF	Multiple Tube Fermentation
NCR	Nonconformance and Corrective Action Report
NELAC	National Environmental Laboratory Accreditation Conference
NELAP	National Environmental Laboratory Accreditation Program
NIST	National Institute of Standards and Technology
Non-ACM	Non-Asbestos-containing Material
NOEC	No Observed Effect Concentration
NP	Non-potable
NPDES	National Pollutant Discharge Elimination System
OAR	Oregon Administrative Rules
ODA	Oregon Department of Agriculture
ODIE	ORELAP Data Input and Edit
oDOC	Ongoing Demonstration of Capability
OHA	Oregon Health Authority
OLCC	Oregon Liquor and Cannabis Commission
OPS	Oregon Psilocybin Services
ORELAP	Oregon Environmental Laboratory Accreditation Program
ORS	Oregon Revised Statutes
OSA	On-site Assessment
OTAC	ORELAP Technical Advisory Committee
PCBs	Polychlorinated Biphenyls
PCM	Phase Contrast Microscopy
PCR	Polymerase Chain Reaction
PFAS	Per- and Polyfluoroalkyl Substances
PHD	Public Health Division
PLM	Polarized Light Microscopy
PMSD	Percent Minimum Significant Difference
ppb	Parts per Billion
ppm	Parts per Million
PT	Proficiency Test
PTPA	Proficiency Testing Provider Accreditor
PTRL	Proficiency Testing Reporting Limit
QA	Quality Assurance
QC	Quality Control
RCRA	Resource Conservation and Recovery Act
RI	Refractive Index

RL	Reporting Limit
RPD	Relative Percent Difference
RSD	Relative Standard Deviation
SDWA	Safe Drinking Water Act
SIE	Selective Ion Electrode
SIM	Selected Ion Monitoring
SM	Standard Methods
SVOC	Semi-Volatile Organic Compounds
SOP	Standard Operating Procedure
SRT	Standard Reference Toxicant
SW	Source Water
TAC	Test Acceptability Criteria
TCLP	Toxicity Characteristic Leaching Procedure
TDS	Total Dissolved Solids
TEM	Transmission Electron Microscopy
TIE	Toxicity Identification Evaluation
TNI	The NELAC Institute
TOC	Total Organic Carbon
TRE	Toxicity Reduction Evaluation
TS	Total Solids
TSS	Total Suspended Solids
TVS	Total Volatile Solids
UV	Ultraviolet
UV-Vis	Ultraviolet-Visual Spectroscopy
VOC	Volatile Organic Compounds
WET	Whole Effluent Toxicity
µg	microgram

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