



# Oregon

## Environmental Laboratory Accreditation Program



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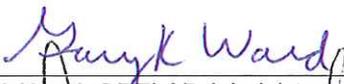
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# ORELAP Program, Policy, and Procedure Manual

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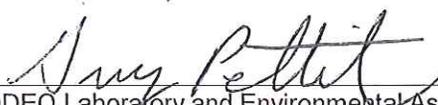
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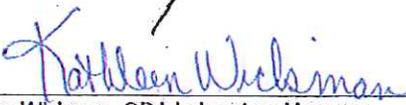
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## **PART I. THE ORELAP PROGRAM (V2M1: 4.0)**

### **I.1. Introduction**

The Oregon Public Health Laboratory of the State of Oregon Health Authority (OHA), Public Health Division (PHD), in concurrence with Oregon Department of Environmental Quality and Oregon Department of Agriculture was granted authority by the Oregon State Legislature to implement a Environmental Laboratory Accreditation Program. Approval of its program by the National Environmental Laboratory Accreditation Program (NELAP) to act as an Accrediting Authority established the Oregon Environmental Laboratory Accreditation Program (ORELAP). Subsequently ORELAP was recognized by the National Environmental Laboratory Accreditation (NELAP) Board of The NELAC Institute (TNI).

Accreditation of environmental laboratories by ORELAP is based on the 2009 TNI Standard (and any amendments) and as described in OAR 333-064-0005 through OAR 333-064-0070. These rules are for the purpose of implementing the National Environmental Laboratory Accreditation Program (NELAP). They establish requirements for accreditation of laboratories analyzing environmental sample matrices for environmental contaminants, hereafter referred to as ORELAP requirements for accreditation.

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

### **I.2. Program Policy**

ORELAP is committed to following the current TNI standards adopted at the Annual Conference in July 2009. TNI will propose new standards as necessary and since public notice is required to change the standards reference in the Oregon Administrative Rules (OARs), ORELAP will adopt the new rules by reference and implement them July 1st of the following year (The first TNI Standards will be implemented July 01, 2011). As with changes in the accreditation standards, due notice will be provided if there are any changes to ORELAP requirements for accreditation in general. Public comments will be taken into consideration before deciding and setting an effective date.

ORELAP is administered by the State of Oregon Health Authority's (OHA) Public Health Division, Public Health Laboratory 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.

In order that all laboratory applications for NELAP accreditation are treated equally, ORELAP initiates the processing of laboratory applications for NELAP accreditation in the chronological order that the applications are received. Furthermore, ORELAP personnel, committees, or its contractors shall act objectively and shall not offer consultancy or other services that may compromise the impartiality of its accreditation process and decisions. ORELAP holds the

accredited laboratories to this same requirement. ORELAP and its contractors confine their requirements, assessments and decision making processes for an accredited laboratory to those matters specifically related to the fields of testing of the accreditation being sought by a laboratory.

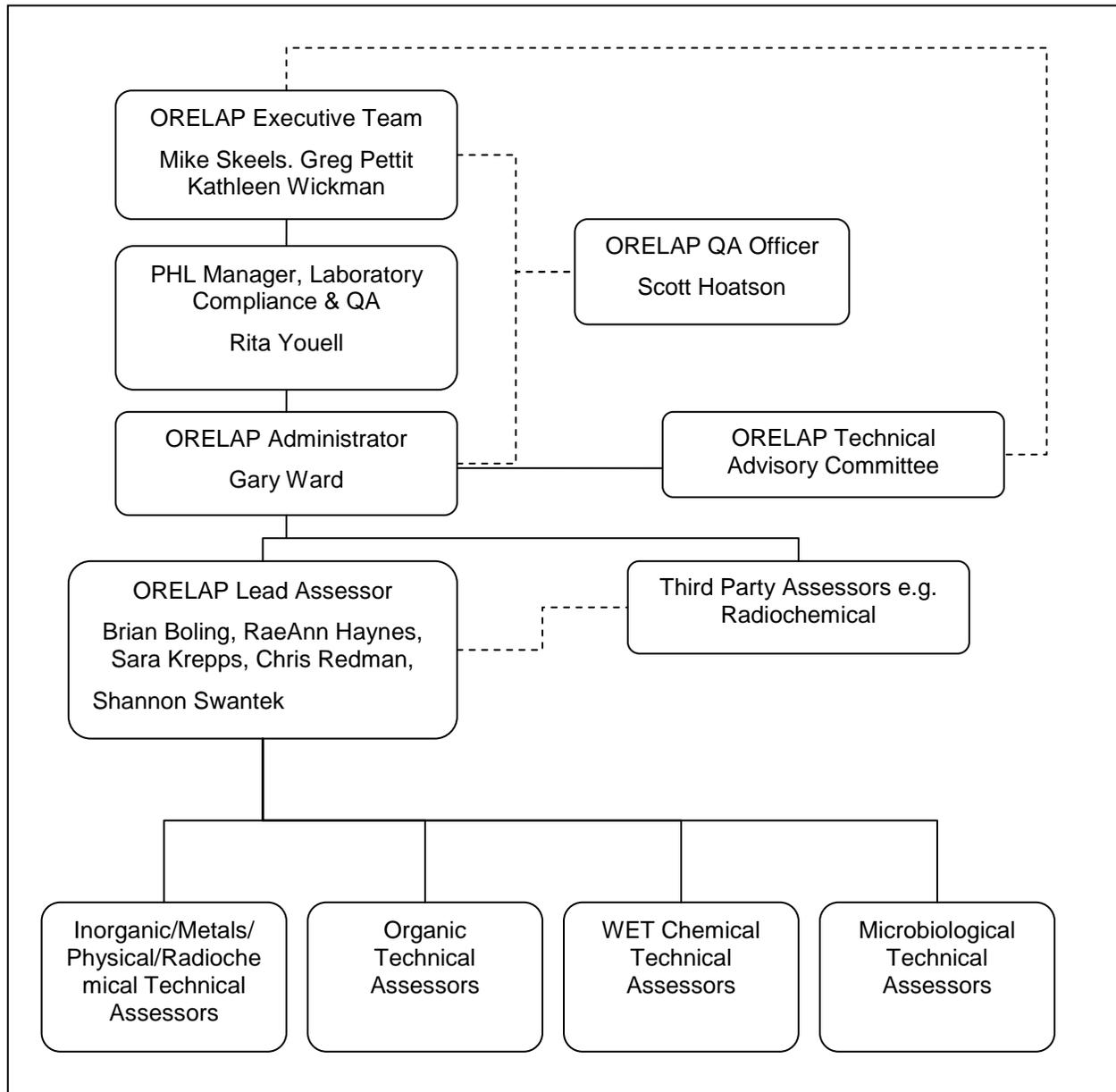
ORELAP and related bodies (DEQ) will maintain lab assessment confidential to the extent possible under state public records laws.

The ORELAP administrator will notify the TNI NELAP 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, FAX, and email address
- The contractual arrangements, including contractor's personnel, for laboratory accreditation activities.

### **I.3. Program Structure (V2M1: 4.2)**

The organizational structure of the ORELAP is illustrated in Figure 1.



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

### I.3.1.ORELAP Executive Team

The ORELAP Executive Team has overall responsibility for managing ORELAP and has final authority over the program. The Executive Team is responsible for resolving issues that are identified by the ORELAP Administrator, Assessors, or Environmental Laboratories.

The ORELAP Executive Team is comprised of the laboratory administrators from the Public Health Laboratory, Department of Environmental Quality Laboratory, and the Department of Agriculture Laboratory. Major responsibilities of the Executive Team include:

- Approving the budget and planning processes.
- Establishing policies and procedures to ensure that all program requirements are incorporated in activities.
- Delegating the responsibility of ORELAP development and implementation to the appropriate group.
- Delegate authority to committees or individuals to undertake activities on the behalf of ORELAP.
- Resolving internal program disputes.

#### I.3.2. ORELAP Technical Advisory Committee

An ORELAP Technical Advisory Committee (OTAC) is maintained to provide relevant competent technical support and impartiality through a balance of interests where no single interest predominates. OTAC has the responsibility for meeting regularly to discuss the issues brought forward by members of the regulated laboratories, including municipal and industrial laboratories, drinking water supply operators, citizen groups, environmental groups and members of the regulating community. Through the Administrator, this committee makes recommendations to the ORELAP Executive Team.

Also, OTAC, at the request of a laboratory serves as an ombudsman between ORELAP and the laboratory to help resolve specific disputes or contested issues.

The ORELAP Technical Advisory Committee is comprised of a total of eight members including a member from each of the affected communities and is chaired by one of the committee members. The committee seeks, as needed, the temporary involvement of other technical staff in order to take advantage of their specific technical expertise. Members of OTAC are nominated (or self-nominated); these nominations are reviewed by the ORELAP Administrator and the Lead Assessors, whose recommendations are forwarded to the ORELAP Executive Team for election to OTAC. The Executive Team elects members on a 2/3 majority.

The committee exists to provide assistance in the interpretation of requirements and to provide advice on the technical matters pertinent to the operation of ORELAP as well as a general forum for communication with stakeholders. Committee business, interpretations, and publications are distributed through the ORELAP web site:

<http://public.health.oregon.gov/LaboratoryServices/EnvironmentalLaboratoryAccreditation/Pages/otac.aspx>

#### I.3.3. PHL Manager, Laboratory Compliance and QA

The PHL Manager is responsible for ensuring that the ORELAP Administration Office operates within the rules, regulations, policies and procedures of Public Health Division (PHD) and has access to available resources to operate the program. The Manager must have a working knowledge of agency rules, regulations, policies and procedures in relation to ORELAP operations.

#### I.3.4. ORELAP Administrator

The ORELAP Administrator holds responsibility and authority for day-to-day operations and ensuring the appropriate implementation of ORELAP appropriate policies and procedures. The Administrator must be an employee of the State of Oregon and have the technical expertise necessary to:

- Plan and manage the laboratory accreditation program
- Develop and oversee the implementation of the policies and procedures of the program
- Coordinate various facets of the laboratory accreditation program with other territory state and federal accrediting authorities
- Coordinate development of environmental laboratory accreditation regulations
- Coordinate, monitor and assess the capabilities of any third party assessors used by ORELAP for on-site audits
- Developing standard operating procedures for routine accreditation activities
- Arrange for or conduct internal managerial audits as per Internal Review SOP
- Approve and authorize contracts with third party assessment contractors
- Make final decisions on accreditation
- Ensure corrective actions have been implemented

#### I.3.5.ORELAP Quality Assurance Officer

The ORELAP Quality Assurance Officer (QAO) is responsible for monitoring ORELAP operations to help ensure that the program is adhering to its adopted policies and procedures. The QAO must be an employee of the State of Oregon and have the expertise necessary to:

- Arrange for or conduct internal audits as per Internal Review SOP
- Developing standard operating procedures for routine accreditation activities
- Notify program management of deficiencies in program systems operations
- Provide an objective review of assessment findings when Administrator performs an assessment

#### I.3.6.ORELAP Lead Assessors

Lead Assessors must be employees of the State of Oregon or under contract with ORELAP to perform assessments, and 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:

- Performing on-site laboratory assessments according to NELAP requirements.
- Prepare laboratory assessment reports by collating individual technical assessors into one report document.
- Reporting ORELAP quality problems to the Administrator and QA Officer.
- Evaluate the technical competence and performance of applicant laboratory staff.

#### I.3.7.Third Party Assessors

Third Party Assessors must have successfully applied to ORELAP and hold a current contract with the Public Health Division to perform on-site assessments for ORELAP. Responsibilities include:

- Performing on-site laboratory assessments according to NELAP requirements.
- Performing document reviews at the request of ORELAP.
- Report all evaluation findings to the ORELAP Administrator within specified deadlines.

### **I.3.8. ORELAP Technical Assessors**

Technical Assessors must be qualified in the areas they are assessing and are responsible for the performance of laboratory accreditation activities for laboratories assigned to them.

Responsibilities include:

- Performing on-site assessments as assigned and according to TNI Standards.
- Performing document reviews as assigned.
- Preparing and submitting assessment reports to the Lead Assessor.

### **I.4. Fees**

Funding of the ORELAP will be accomplished using fees to reimburse the Program for cost of performing the activities and to provide documentation necessary to comply with TNI/NELAP rules and criteria. The fee schedule is found in [OAR 333-064-0060](#). Fees include:

- Annual Application Fee: Non-Refundable fee submitted to ORELAP with initial application.
- Biennial Assessment Fee: Biennial fee dependent on categories of environmental analysis (Fields of Testing and Programs) for which the lab chooses to be accredited.
- On-site Trip Fee: A fee dependent on the number of categories of environmental analysis for which the lab chooses to be accredited that will be assessed whenever a regular or unannounced on-site inspection is performed.
- Secondary Accreditation Fee: Includes a non-refundable application fee and a fee for secondary recognition.
- Out-of-state labs seeking accreditation in Oregon shall also be billed for cost of travel, including hourly wage, and per diem for ORELAP staff to perform on-site inspection. The lab is responsible for fees incurred to gain access to the laboratory, such as National Security Clearance.
- Out-of-state labs seeking accreditation in Oregon and using third party assessors shall also be billed by the third party for all costs associated with the on-site assessment, including actual cost of the on-site assessment and the cost of travel and per diem. The lab is responsible for fees incurred to gain access to the laboratory, such as National Security Clearance.

### **I.5. Display of ORELAP and NELAP Insignia**

ORELAP will accompany the display of the NELAP insignia with at least the phrase “NELAP-recognized”.

### **I.6. Supporting Agency Information**

The Oregon State Public Health Laboratory (PHL) is managed under the Oregon Health Authority (OHA), Public Health Division (PHD), the DEQ Laboratory and Environmental Assessment Division (LEAD) is managed under the Department of Environmental Quality, the ODA laboratory is managed under the Department of Agriculture. Each of these departments are agencies of the State of Oregon and are self-insured for liability insurance through the Dept of Administrative Services, Risk Management Division. They can be reached at 503-373-7475. Workman's compensation coverage for each agency is carried through the following policies:

- PHD's workman's compensation coverage is carried by SAIF Corporation under policy # 74530.
- DEQ's workman's compensation coverage is carried by SAIF Corporation under policy # 312157.
- DOA's workman's compensation coverage is carried by SAIF Corporation under policy # 266035.

## **I.7. Program Scope**

The scope of ORELAP is defined by the following:

- These rules apply to fixed base and mobile laboratories, performing analyses for environmental contaminants in environmental matrices in Oregon that request ORELAP accreditation. A mobile laboratory seeking ORELAP accreditation, whether or not owned and/or operated by an ORELAP-accredited fixed base laboratory requires independent ORELAP accreditation. The accreditation shall remain with the mobile laboratory and be site independent. Moving the configured mobile laboratory shall not require a new or separate accreditation.
- These rules apply to the analyses of air, drinking water, non-potable water, solid and chemical waste, and biological tissue.
- All laboratories performing analysis on Oregon samples for the Drinking Water Program or residential wells associated with real estate transactions are required to be accredited under this program. Analysis of samples for other programs does not require specific accreditation unless required by permit or contract.
- Analytical Technique and Matrices in which ORELAP will provide accreditation are listed in Table 1. The "X" indicates techniques for which laboratories are currently accredited by ORELAP.
- Specific analytical methods within a field of accreditation are listed on ODIE(ORELAP Data Input and Edit). Additional methods and analytes may be requested at the time of application. At that time, the ORELAP administrator will evaluate the request against the qualifications of the available assessors and PT requirements to determine if the additional methods/analytes may be accredited. The administrator will notify the laboratory as to whether or not ORELAP will be able to accredit the laboratory to the additional parameters.
  - The administrator will check the TNI website for valid Analyte and Method numbers and submit a request for any that are not currently available.
- Any new additions to methods and analytes will be added to the ODIE database to be available for all other laboratories.

**Table 1. Listing of the analytical technique and matrices for which the ORELAP provides accreditation.**

Name	Technology Description	Drinking Water	Non-Potable Water	Solids & Chemical	Air	Tissue
AMP	<b>Amperometric Titration</b>	<b>X</b>	<b>X</b>			
AS	<b>Alpha Spectrometry</b>	<b>X</b>	<b>X</b>	<b>X</b>		
ASC	<b>Alpha Scintillation Cell Counter</b>	<b>X</b>	<b>X</b>			
ASV	<b>Anodic Stripping Voltammetry</b>	<b>X</b>	<b>X</b>			
AUTO	<b>Auto Analyzer</b>	<b>X</b>	<b>X</b>	<b>X</b>		<b>X</b>
BETA	<b>Beta Spectrometry</b>	<b>X</b>	<b>X</b>	<b>X</b>		
BGCS	<b>Beta/Gamma Coincidence Scintillation Counter</b>	<b>X</b>	<b>X</b>			
BioTox	<b>Toxicity Testing</b>		<b>X</b>	<b>X</b>		
CAL	<b>Calorimetric Determination (Temperature, Flash Point, etc)</b>	<b>X</b>	<b>X</b>	<b>X</b>		
CALC	<b>Calculation</b>	<b>X</b>	<b>X</b>	<b>X</b>		
CE-UV	<b>Capillary Electrophoresis - UV</b>					
CF-QL	<b>Chromofluorogenic-Qualitative</b>	<b>X</b>	<b>X</b>			
CF-QN	<b>Chromofluorogenic-Quantitative</b>	<b>X</b>	<b>X</b>			
COND	<b>Conductance</b>	<b>X</b>	<b>X</b>	<b>X</b>		<b>X</b>
COUL	<b>Coulometric Titration</b>	<b>X</b>	<b>X</b>	<b>X</b>		<b>X</b>
C-QN	<b>Chromogenic/MPN-Quantitative</b>	<b>X</b>	<b>X</b>			
C-QT-QN	<b>Chromogenic/Quantitray</b>	<b>X</b>	<b>X</b>			
CRC-ICPMS	<b>Chemical Reaction Cell Inductively Coupled Plasma Mass Spectrometry</b>		<b>X</b>	<b>X</b>	<b>X</b>	
CVAAS	<b>Atomic Absorption-Cold Vapor</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
CVAFS	<b>Atomic Fluorescence - Cold Vapor Spectrometry</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
DCP-AES	<b>Atomic Emission - Direct Current Plasma Spectrometry</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
DPP	<b>Differential Pulse Polarography</b>	<b>X</b>	<b>X</b>			
FAAS	<b>Atomic Absorption - Flame Spectrometry</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
FAES	<b>Atomic Emission - Flame Spectrometry</b>		<b>X</b>	<b>X</b>	<b>X</b>	
FB-A1-QN	<b>Fermentation Broth(A-1)-Quantitative</b>	<b>X</b>	<b>X</b>	<b>X</b>		

Name	Technology Description	Drinking Water	Non-Potable Water	Solids & Chemical	Air	Tissue
FB-F-QL	<b>Fermentation Broth+Fluorogenic-Qualitative</b>	<b>X</b>	<b>X</b>			
FB-F-QN	<b>Fermentation Broth+Fluorogenic-Quantitative</b>	<b>X</b>	<b>X</b>			
FB-LE-QL	<b>Fermentation Broth-Qualitative</b>	<b>X</b>	<b>X</b>			
FB-PAE-QL	<b>Fermentation Broth(PA)-Qualitative</b>	<b>X</b>	<b>X</b>			
FB-PAF-QL	<b>Fermentation Broth(PA) + Fluorogenic-Qualitative</b>	<b>X</b>	<b>X</b>			
FB-QN	<b>Fermentation Broth-Quantitative</b>	<b>X</b>	<b>X</b>	<b>X</b>		
FFIFV	<b>Filtration/FA/IMS/FA/Viability</b>	<b>X</b>	<b>X</b>			
F-HPC-QN	<b>Fluorogenic (HPC)-Quantitative</b>	<b>X</b>	<b>X</b>			
FLUOR	<b>Ultraviolet or Visible Molecular Fluorescence Spectrometry</b>	<b>X</b>	<b>X</b>		<b>X</b>	
F-QN	<b>Fluorogenic/MPN-Quantitative</b>	<b>X</b>	<b>X</b>			
F-QT-QN	<b>Fluorogenic/Quantitray</b>	<b>X</b>	<b>X</b>			
GALV	<b>Galvanic Probe</b>		<b>X</b>	<b>X</b>		<b>X</b>
GC-AED	<b>Gas Chromatography - Atomic Emission Detection</b>					
GC-ECD	<b>Gas Chromatography - Electron Capture Detection</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
GC-ECD/FID	<b>Gas Chromatography - Electron Capture/Flame Ionization</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
GC-ELCD	<b>Gas Chromatography - Electrolytic Conductivity Detection</b>	<b>X</b>	<b>X</b>	<b>X</b>		<b>X</b>
GC-ELCD/PID	<b>Gas Chromatography - Electrolytic Conductivity/Photoionization Detection</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
GC-FID	<b>Gas Chromatography - Flame Ionization Detection</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
GC-FPD	<b>Gas Chromatography - Flame Photometric Detection</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
GC-FTIR	<b>Gas Chromatography - Fourier Transform Infrared Spectrometry</b>					

Name	Technology Description	Drinking Water	Non-Potable Water	Solids & Chemical	Air	Tissue
GC-HRMS	<b>Gas Chromatography - Mass Spectrometry - High Resolution</b>	X	X	X	X	X
GC-MS	<b>Gas Chromatography-Mass Spectrometry</b>	X	X	X	X	X
GC-MS-MS	<b>Gas Chromatography - Tandem Mass Spectrometry</b>	X	X	X	X	X
GC-NPD	<b>Gas Chromatography-Nitrogen/phosphorus Detection</b>	X	X	X	X	X
GC-PID	<b>Gas Chromatography-Photoionization Detection</b>	X	X	X	X	X
GFAAS	<b>Atomic Absorption-Graphite Furnace Spectrometry</b>	X	X	X	X	X
GRAV	<b>Gravimetry</b>	X	X	X	X	X
GS-HR	<b>Gamma Spectrometry-High Resolution</b>	X	X			
GS-LR	<b>Gamma Spectrometry- Low Resolution</b>	X	X			
HGAAS	<b>Atomic Absorption - Hydride Generation Spectrometry</b>	X	X	X	X	X
HPLC-ELEC	<b>High Performance Liquid Chromatography-Electrochemical</b>		X	X		X
HPLC-ELSC	<b>High Pressure Liquid Chromatography -Evaporative Light Scattering Detector</b>					
HPLC-ESMS	<b>High Pressure Liquid Chromatography - Electrospray Mass Spectrometry</b>		X	X		
HPLC-FLUOR	<b>High Performance Liquid Chromatography-Ultraviolet/visible Molecular Fluorescence</b>	X	X	X	X	X
HPLC-IR	<b>High Performance Liquid Chromatography-Infrared Molecular Absorption</b>					
HPLC-MS-MS	<b>High Performance Liquid Chromatography-Tandem Mass</b>	X	X	X	X	X
HPLC-PBMS	<b>High Performance Liquid Chromatography-Mass Spectrometry-Particle Beam</b>				X	

Name	Technology Description	Drinking Water	Non-Potable Water	Solids & Chemical	Air	Tissue
HPLC-PDAUV	<b>High Pressure Liquid Chromatography - Photodiode Array UV Spectroscopy</b>					
HPLC-TSMS	<b>High Performance Liquid Chromatography - Mass Spectrometry-Thermospray</b>		<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
HPLC-UV	<b>High Performance Liquid Chromatography - Ultraviolet/visible Molecular Absorption</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
IC-COND	<b>Ion Chromatography - Electroconductivity</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
IC-MS	<b>Ion Chromatography - Mass Spectrometry</b>	<b>X</b>	<b>X</b>	<b>X</b>		<b>X</b>
IC-MS-MS	<b>Ion Chromatography-Tandem Mass Spectrometry</b>	<b>X</b>	<b>X</b>	<b>X</b>		<b>X</b>
ICP-AES	<b>Atomic Emission - Inductively Coupled Plasma Spectrometry</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
ICP-MS	<b>Mass Spectrometry - Inductively Coupled Plasma</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
IC-UV	<b>Ion Chromatography - UV</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	
IMM	<b>Immunoassay</b>					
IMS-FA	<b>Filtration-Immunomagnetic Separation - Immunofluorescence Assay</b>	<b>X</b>	<b>X</b>			
IR	<b>Infrared Spectrometry</b>		<b>X</b>	<b>X</b>		<b>X</b>
ISE	<b>Ion Selective Electrode</b>	<b>X</b>	<b>X</b>	<b>X</b>		<b>X</b>
LP	<b>Lasar Phosphorimetry</b>					
LSC	<b>Liquid Scintillation Counter</b>	<b>X</b>	<b>X</b>			
LSP	<b>Luminescence-based Sensor Procedure</b>	<b>X</b>	<b>X</b>			
MF-2S-QN	<b>Membrane Filtration(2-Step)-Quantitative</b>	<b>X</b>	<b>X</b>			
MF-E-QL	<b>Membrane Filtration+Fermentation Broth-Qualitative</b>	<b>X</b>	<b>X</b>	<b>X</b>		
MF-E-QN	<b>Membrane Filtration+Fermentation Broth-Quantitative</b>	<b>X</b>	<b>X</b>	<b>X</b>		
MF-F-QL	<b>Membrane Filtration+Fluorogenic-Qualitative</b>	<b>X</b>	<b>X</b>	<b>X</b>		

Name	Technology Description	Drinking Water	Non-Potable Water	Solids & Chemical	Air	Tissue
MF-F-QN	<b>Membrane Filtration+Fluorogenic - Quantitative</b>	<b>X</b>	<b>X</b>	<b>X</b>		
MF-MEI-QN	<b>Membrane Filtration (Mei)- Quantitative</b>		<b>X</b>			
MF-MTEC-QN	<b>Membrane Filtration (m-TEC)-Quantitative</b>		<b>X</b>			
MF-QL	<b>Membrane Filtration- Qualitative</b>	<b>X</b>	<b>X</b>	<b>X</b>		
MF-QN	<b>Membrane Filtration- Quantitative</b>	<b>X</b>	<b>X</b>	<b>X</b>		<b>X</b>
NAA	<b>Neutron Activation Analysis</b>			<b>X</b>		<b>X</b>
Other	<b>Other</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
PHYS	<b>Physical Properties</b>	<b>X</b>	<b>X</b>	<b>X</b>		
PC	<b>Proportional Counter</b>	<b>X</b>	<b>X</b>	<b>X</b>		
PCM	<b>Phase Contrast Microscopy</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	
PLM	<b>Polarized Light Microscopy</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	
POL	<b>Polarographic Probe</b>					
PP-QN	<b>Pour Plate-Quantitative</b>	<b>X</b>	<b>X</b>			
PQ-2S-QN	<b>Plaque Counts(2-Step)- Quantitative</b>					
PQ-SL-QN	<b>Plaque Counts(Single Layer)- Quantitative</b>					
PREP	<b>Sampling/Digestion/Extraction</b>	<b>X</b>	<b>X</b>	<b>X</b>		<b>X</b>
SEM	<b>Scanning Electron Microscopy</b>					
SP-QN	<b>Spread Plate-Quantitative</b>	<b>X</b>	<b>X</b>			
TEM	<b>Transmission electron microscopy</b>	<b>X</b>	<b>X</b>			
TITR	<b>Titrimetry - Visual Indicator</b>	<b>X</b>	<b>X</b>	<b>X</b>		<b>X</b>
TOC-FID	<b>Total Organic Carbon - Flame Ionization Detector</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	
TOC-IR	<b>Total Organic Carbon - Nondispersive Infrared Detector</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
TOC-UV	<b>Total Organic Carbon - UV Spectrometer</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	
TOX	<b>Total Organic Halide</b>	<b>X</b>	<b>X</b>	<b>X</b>		<b>X</b>
TURB	<b>Turbidity</b>	<b>X</b>	<b>X</b>	<b>X</b>		
UV-VIS	<b>Ultraviolet or Visible Molecular Absorption Spectrometry</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>

Name	Technology Description	Drinking Water	Non-Potable Water	Solids & Chemical	Air	Tissue
XRF	<b>X-Ray Fluorescence Spectrometry</b>				<b>X</b>	
XRT	<b>X-Ray Transmission Spectrometry</b>					

**I.7.1 Process for expanding ORELAP’s Fields of Accreditation (V2M1 4.6.3)**

Based on external demands of laboratory customers, there may be a need for the ORELAP to expand the scope of the accreditation program. In order to expand the programs’ scope, the following is evaluated by the ORELAP Administrator:

- *the program’s present competence, suitability of extension, resources, etc. in the new field,*
- *current employee expertise and that of contract 3<sup>rd</sup> party assessors,*
- *the need for application or guidance documents (checklists, method references, etc.)*
  - *If checklists or methods references are unavailable they must be obtained or developed prior to performing assessments.,*

*If there are no current available resources, the Administrator will select an assessor to be initially trained to perform the assessments based on education, experience, and availability. If there is a need for additional assessors in the new field of accreditation, arrangements will be made for the training of additional assessors.*

**I.8. Program Documentation**

**I.8.1. Laboratory Information**

Laboratory accreditation information collected from the initial or annual application, on-site reports, and PT provider results (when program is developed for PT) will be maintained in the electronic ORELAP database and/or as paper documents in the Administrator’s Office and include, at a minimum, the following information:

- 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
  - 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
- FAX number

- Laboratory hours of operation
- Primary Accrediting Authority
- Fields of Testing for which the laboratory is requesting accreditation
- Fields of Testing for which the laboratory is currently accredited
- Methods employed including analytes
- Description of laboratory type (for example):
  - Commercial
  - Federal
  - Hospital or health care
  - State
  - Academic Institutes
  - Public water system
  - Public wastewater system
  - Industrial (an industry with discharge permits)
  - Mobile
  - Other (Describe)\_\_\_\_\_
- Proficiency testing results
- Laboratory accreditation status and history

#### I.8.2.Assessor Information

Assessor Training and Qualification records on assessors, including contractual assessors, who meet the education, experience and training requirements will be maintained in the assessor database and/or as paper documents in the Administrator's Office and will include:

- 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
- Date of most recent updating of record

#### I.8.3.Evaluation Records

Assessor Evaluation records will be maintained for ten years and include:

- Annual performance as part of the specific Agency's Annual Personnel Evaluation Report
- Results from annual ORELAP internal audits

#### I.8.4.Application and Assessment Records

Completed applications, corrective actions, current laboratory quality assurance manual, proficiency testing results, on-site checklists and assessment reports will be filed by laboratory and retained for ten years or longer, if required by policy or statute.

Completed written and/or electronic records of internal ORELAP audits including findings, discrepancies and corrective actions, and revisions to program documents will be maintained for ten years or longer, if required by policy or statute, and be readily available upon request.

## **I.9. Public Availability of Information**

Public access to records will be handled per ORS 192.

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

- a) detailed information about its assessment and accreditation processes, including arrangements for granting, maintaining, extending, reducing, suspending and withdrawing accreditation
- b) a document or reference documents containing the requirements for accreditation, including technical requirements specific to each field of accreditation, where applicable
- c) general information about the fees relating to the accreditation
- d) a description of the rights and obligations of laboratories
- e) information on the accredited laboratories
  - a. *name and address of each accredited laboratory*
  - b. *dates of granting accreditation and expiration dates*
  - c. *condensed scope of accreditation and information on how to obtain full scopes*
- f) information on procedures for lodging and handling complaints and appeals
- g) information about the authority under which the accreditation program operates
- h) a description of its rights and duties
- i) general information about the means by which it obtains financial support
- j) 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 and procedures to be used in the ORELAP for the implementation, management, documentation, and measurement of success of this program. All PHL, DEQ employees 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 Program Description and QA System**

The mission of the ORELAP is to be an active leader in the generation of environmental laboratory data of known and documented quality through the application of national performance standards for environmental laboratories and other entities involved in the environmental field measurement and sampling process. In carrying out this mission, ORELAP staff act out of a vision of all Oregonians working cooperatively to preserve, protect and promote the health of all of its people through the creation of a healthy, sustainable environment. In all that they do, ORELAP staff seek to remain true to values of environmental testing results, customer service, partnership, excellence, integrity, employee growth, teamwork and diversity. For this mission, and for these values to be implemented, it is critical that ORELAP support the NELAP association of state and federal agencies where the purpose is to establish performance standards for the operation of environmental laboratories.

The ORELAP mission is to accredit and issue certificates of competency to environmental laboratories that meet the minimum standards pursuant to the TNI Standards.

#### **II.2.2. ORELAP Goals**

The goal of the ORELAP is to assure to the public at large that the accredited laboratories meet the minimum quality standards, and are not only competent at generating data of known quality but strive for excellence.

We are committed to providing the tools, resources, and experiences necessary to help employees develop new skills and to enhance their quality of 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 teams to be successful.

#### **II.2.3. ORELAP Objectives**

The ORELAP is committed to operational excellence through implementation of a quality assurance program that adheres to TNI Standards for Accrediting Bodies. The objectives of the quality assurance program include:

- The data used to assess compliance with ORELAP regulations is obtained, reviewed, and acted upon in a predetermined uniform manner
- Documentation of ORELAP implementation (correspondence, reports, etc.) is handled in a predetermined uniform manner
- The personnel performing activities governed by the QM are appropriately trained

#### **II.2.4. ORELAP QA Program**

In order to meet its mission, ORELAP has implemented a QA program that assures that the information regarding accredited laboratories' operations can be used for its intended purpose. The ORELAP QA program consists primarily of the following:

- Quality Manual (QM)
- Management Systems Reviews
- Standard Operating Procedures
- Technical Systems Reviews

### **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 will be reviewed, annually, by the ORELAP Executive Team. The ORELAP Executive Team is described in the associated Program Manual and consists of a representative of each of the three agencies that are responsible for administering the program.

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

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

The Quality Assurance 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**

Total Quality Management is a process in which continuous improvement and innovation are integrated into management's planning and operating methodology. The ORELAP program uses principles to concentrate on improving the systems where work is performed. The primary goal is directed toward obtaining high quality data and customer satisfaction. The Total Quality Management philosophy is participatory in nature and is aimed at achieving total employee commitment to quality. This means that ORELAP personnel at every level must be committed to the management of all aspects of the quality of the Program.

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 Laboratory Administrators from the Oregon Public Health Laboratory, Oregon Department of Environmental Quality, and Oregon Department of Agriculture.

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 Administrator 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 QA 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 Administrator.

#### II.3.3.2. *ORELAP Technical Advisory Committee*

The ORELAP Technical Advisory Committee is comprised of interested parties affected by the ORELAP program including representatives from commercial environmental laboratories, representatives from municipal and industrial facilities that are covered by the discharge regulations, drinking water supply organizations and technical experts in environmental analysis and regulation.

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

The responsibilities of the Advisory Committee are to meet regularly and discuss issues brought forward by the ORELAP Executive Team, the ORELAP program personnel including the ORELAP Administrator and Lead Assessors, the private and public facilities affected by the program and other interested parties including citizen groups and environmental groups. The Advisory Committee may serve in the capacity of ombudsman by presenting concerns with the implementation of ORELAP as reported to the Advisory Committee 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, ORELAP Administrator and Lead 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 the Advisory Committee as ombudsman

#### II.3.3.3. *PHL Manager, Laboratory Compliance and QA*

The Manager of the PHL Laboratory Compliance and QA section ensures that ORELAP operates within the rules, regulations, policies and procedures of Oregon Health Authority and the policies of PHL and that the ORELAP PHD staff has 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

#### *II.3.3.4. ORELAP Administrator*

The ORELAP Administrator is responsible for the day-to-day operation of ORELAP and ensures that ORELAP implements appropriate QA policies. QA responsibilities of the Administrator include:

- Assuring that the ORELAP maintains a current Quality Manual and adheres to the document
- Taking corrective action that may be required by evaluation
- Ensuring appropriate QA criteria for all projects and tasks are included in operating guidance for all evaluation teams
- Reviewing and approving the ORELAP Program and Quality Manuals
- 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 QA information needed to be knowledgeable in QA requirements, protocols, and technologies
- Interpreting and developing the QA 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 Web site
- 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 audit/review findings
- Tracking and managing the status of the accreditation program
- Making final accreditation decision. In instances where ORELAP Administrator is lead or sole laboratory assessor, assessment report review and decision on accreditation will be made by a committee composed of the QAO, or their designee and the ORELAP Administrator.

#### *II.3.3.5. ORELAP Quality Assurance Officer*

The Quality Assurance Officer helps ensure that ORELAP adheres to its adopted policies and procedures. QA Officer responsibilities include:

- 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 non-conformance discovered from the internal audits to the ORELAP management for corrective actions and tracking the results of corrective actions
- Reporting non-conformance discovered from either the ORELAP On-Site Assessment Appraisal forms or complaints received by the ORELAP Administrator, 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
- Reviewing laboratory assessment reports where the ORELAP Administrator is lead or sole assessor in the laboratory on-site assessment

#### *II.3.3.6. 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 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 the assigned laboratories
- Developing standard operating procedures for routine accreditation activities
- Reporting ORELAP quality problems to the ORELAP Administrator

#### *II.3.3.7. Contractors or Third-Party Assessors*

ORELAP may employ third party assessors. Although these third parties 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 recent bench experience. All assessors must have successfully passed the TNI/NELAC Basic Assessor's course and TNI/NELAC Technical Training for Assessors. Also, if assessing potable water methods, the assessors shall have passed the EPA Drinking Water Accreditation course for the appropriate discipline. The assessors also must attend annual refresher training. 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.3.3.8. Assessment Team*

The Assessment Team generally must consist of a Lead Assessor, and may contain one or more Technical Assessors. The Lead Assessor may also play the role of Technical assessor for small laboratories. 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
- Be able to communicate effectively, both orally and in writing

In addition, the lead assessor must:

- Be knowledgeable of the relevant legal regulations, accreditation procedures, and accreditation requirements
- Have a thorough knowledge of the relevant assessment methods and assessment documents

Professional standards of conduct apply to all assessors. All members of the assessor 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, 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 affect 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.

Each assessor shall 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 accreditation team must produce accreditation reports that are comprehensive, accurate, complete, and timely.

### II.3.4. ORELAP Program Meetings

The ORELAP Administrator, QAO, Lead Assessors, and Technical Assessors meet monthly for regularly scheduled meetings. These meetings are used to discuss the status of on-site assessments, final reports, corrective-action reports, and the overall health/status of the ORELAP. Attendees discuss program and policy issues/changes as well as assessment concerns/problems and, when necessary, develop appropriate corrective actions. Minutes of the meetings are maintained by the ORELAP Administrator.

### II.4. Management System Reviews or Internal Audits

The ORELAP Executive Team will ensure that internal program reviews, a program systems and a management review 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 *TNI Checklist to Determine Accreditation Body Compliance*. The Program Administrator 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, reviews of:

- The ORELAP Program Manual
- The Quality 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 Administrator will issue a corrective action report to the internal audit to the Executive Team and QA Officer within 30 calendar days. This reply will include action items and/or remedies for the documented discrepancies

The management review of the ORELAP will include the results of the internal audit above and review of the programs policies and performance and areas for improvement. Action items where applicable, will be developed that cover the topics.

- 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 laboratories and to develop standards for the operation of environmental laboratories. Consequently, laboratories must be assured that the economic interests of the ORELAP and its staff will not impact on the execution of their authority. The applicable criteria that apply to accreditation officers are taken from ORS Chapter 244 and are referenced below:

DEQ provides assessors that work in the State environmental laboratory. This allows for ORELAP the unique position of having experts in the field performing technical assessments. However, because of this situation, there is a possible perception of a conflict of interest. To avoid this conflict:

The DEQ laboratory does not offer services to the general public and does not enter into bidding situations where commercial laboratories are involved.

In order to ensure that any perceived conflict of interest is removed, the ORELAP Administrator reviews all assessment reports to ensure the TNI standards and analytical methods were enforced consistently and without bias. The ORELAP Administrator 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.

In the case where an assessor or ORELAP officer has recent past employment experience with an accredited laboratory, they will not assess or make assessment decisions on that laboratory for at least 3 years after the termination of employment to ensure objectivity is maintained.

Laboratories are provided with the names of the assessor(s) prior to the announced assessment for them to voice objections for legitimate reasons. If a laboratory has a legitimate reason for not being satisfied with any member of the assessment team, they will be offered a replacement assessor or the option of a third party assessor at their expense.

### *Definitions:*

*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 through the use of 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.*

As per agency conflict of interest policy, when an employee identifies a potential conflict of interest, that employee must notify the ORELAP Administrator and the ORELAP Executive Team representative in writing of the potential conflict of interest, with distribution as follows:

- Original copy to the ORELAP Administrator
- 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 Administrator shall in writing, designate a resolution to the matter, such as removal from the assessment team, or direct the employee to dispose of the matter 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. The quality program, policies and procedures are all reviewed and approved by the ORELAP Administrator and Quality Assurance Officer prior to implementations. Once approved the documents are controlled and any previous versions are take out of service and archived.

Approval of application records are discussed in III.1.3. The master files will include:

- 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 as master file on the ORELAP database that will be maintained by the ORELAP Administrator. These master files will include:

- ORELAP Program, Policy, and Procedure
- Method checklists
- Assessment personnel training and qualifications

Each document will be identified with a revision number and a copy number so that distribution can be managed. A distribution list will be maintained by the ORELAP Administrator.

## **II.7.Implementation of the Accreditation Process**

### **II.7.1. Notification of Program Implementation**

Interested parties will receive information about the ORELAP through a variety of media. These will include specific mailings to accredited laboratories and permitted municipal facilities, presence on the Internet 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 application instructions can be downloaded from the ORELAP web site. Once the application, with all required documentation, and associated fees are received by the ORELAP Administrator, an email will be sent to the Lead Assessor to enter into the ORELAP database and to schedule an on-site assessment if required.

### II.7.3. On-Site Assessment

The Lead Assessor, will develop a team comprised of a Lead Assessor and appropriate technical support staff, will review the application, associated documentation and any preexisting pertinent information. This team may request other documentation, more information or clarification for the application. When the application is deemed complete, an on-site assessment will be scheduled.

All members of the assessor 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 assessor 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.

### 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 submitted to the Program Administrator who will review the report prior to making the final accreditation decisions. Resolution will be determined based on the results and certification status will be assigned.

The ORELAP administrator or designee will provide updates to TNI for 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

Once the application and supplied information, PT scores, and assessment report(s) and corrective action have been reviewed and deemed acceptable and in accordance with the TNI Standard by the ORELAP Program Administrator, laboratories will be granted accreditation (initial or continued) as soon as practicable after the determination has been made. The accreditation will be in effect for a period of 1 year.

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 circumstances (such as switching from secondary accreditation to primary accreditation) when it is impractical or unnecessary to perform an on-site visit providing a laboratory has the appropriate instrumentation, is using approved methods, has adequately trained personnel to perform the analysis, and has satisfactorily analyzed performance evaluation samples, if available, for the analytes of concern. An on-site assessment must be performed as soon as possible but no later than 12 months. ORELAP may revoke interim accreditation for due cause

#### *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.5 Denial, Suspension, and Revocation of Laboratory Accreditation).

#### **II.7.6. Signatures on Certificates and Correspondence**

Whenever a signature stamp is used, the authorized person using the stamp must initial below the stamp to indicate who applied the stamp. Additionally, when an authorized person writes a letter for the ORELAP Administrator to sign their own signature before the statement “for *First Name & Last Name*, ORELAP Administrator”

### **II.8. Complaints, Appeals and Disputes**

ORELAP uses the TNI 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 the ORELAP program may be lodged to the ORELAP Administrator, Laboratory Compliance Manager, members of the Executive Team or the ORELAP QA officer directly or through the ORELAP Technical Advisory Committee. The Administrator or QA Officer will then investigate and take appropriate action. Any complaints regarding a specific assessor must be made directly to the ORELAP Administrator.

Once the complaint is received, the ORELAP administrator will assess the validity of the complaint and respond back to the complainant within 7 days from the receipt that the complaint was received and provide an estimate as to when the investigation will be completed.

The complaint will be entered into an excel database for tracking purposes. Once the investigation has been completed, the ORELAP Administrator will take appropriate action and again respond back to the complainant. The ORELAP Administrator or the ORELAP QA Officer will follow-up on the actions, where applicable, within 60 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 ORELAP Administrator or his/her designee will be part of the assessment team for complaint investigations. Decisions regarding disciplinary action will involve members of ORELAP Executive Team.

Appeals and disputes must be formally filed in writing with the ORELAP Administrator. The Administrator, in consultation with the ORELAP Lead Assessors and/or QA Officer, will review these and decide on the validity

of the appeal or dispute and will respond in writing within 30 calendar days. If it appears that the program is in error, a training session or internal audit may be triggered.

## **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
- Assessor Performance Appraisals
- Laboratory Changes in Key Accreditation Criteria
- ORELAP Database
- Denial, Suspension, and Revocation of Laboratory Accreditation
- Dispute Resolution
- ORELAP Laboratory Assessor Requirements
- Internal Program Review
- Issuance of Accreditation Certificate
- Proficiency Testing
- Recognition (Secondary Accreditation)
- ORELAP Records
- Technical Review and On-site Assessment
- Third Party Assessor Requirements

### **III.1. Application Request and Initial Review**

#### **III.1.1. Introduction**

This document is designed to describe the procedures for answering requests for application under ORELAP and for processing them once received. It is intended that this is a minimal review of the application to ensure all application criteria are met and required documentation and fees are included. The procedure for complete review of the application is covered in the ORELAP On-site Assessment SOP. Applications are submitted electronically using the ODIE online following the online instructions found on the ORELAP website.

<http://public.health.oregon.gov/LaboratoryServices/EnvironmentalLaboratoryAccreditation/Documents/getmaintain.pdf>

Each application includes (paper and/or electronic):

1. ORELAP application to enter demographics and select fields of testing
2. Application instructions and list of methods
3. Fee calculation worksheet
4. Quality Manual (primary accreditation only)
5. MDL summary form (primary accreditation only)

6. Demonstration of Capability (DOC) (primary accreditation only)
7. Certification of Compliance: Certifying the laboratory will continually maintain compliance to the standard and adapt to future changes to accreditation requirements.
8. For secondary accreditations, the scope of accreditation submitted by the labs primary AB.

### III.1.2. Request for Application

To access ODIE to apply for accreditation or find additional information labs are to go to the ORELAP website:

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

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

ORELAP Administrator  
Oregon Public Health Laboratory  
3150 NW 229<sup>th</sup> Ave, STE100  
Hillsboro, OR 97124  
Phone: (503) 693-4122  
Email: [Gary.K.Ward@state.or.us](mailto:Gary.K.Ward@state.or.us)

### III.1.3. Application Receipt

When the laboratory applicant has completed their application they hit the Save key in ODIE and an automatic notification is sent to the ORELAP Administrator. Upon electronic receipt of notification of availability of the application from ODIE.:

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

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

Existing laboratories have a number assigned as follows

- a) From left to right, first two values indicates the state in which the lab 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 lab has applied for primary (1) or secondary accreditation (2). If a lab 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 labs apply from each state and primary/secondary accreditation status, e.g., the second lab from New Jersey applying to ORELAP for secondary accreditation would be NJ200002.
- 3) The progress of the application is tracked in ODIE. There are spaces for dates and initials or names for each step of the process as follows:

- a) The ORELAP administrator initially reviews the application for completeness. Incomplete or unacceptable applications will be rejected and the applicant is notified that revisions are necessary. The completeness review consists of
    - i) Review of the adequacy of the information supplied by the laboratory
    - ii) Review ORELAP's ability to carry out the assessment based on ORELAPS policies and availability of trained assessors for the requested fields of accreditation
    - iii) Review of ORELAP's ability to perform the assessment within a timely fashion acceptable to the laboratory. If the assessment cannot not be carried out in an acceptable time frame, the Administrator may subcontract the assessment to a qualified third party assessor(s).
  - b) When the application is deemed complete, Administrator initials and dates the "Reviewed" line in the application in ODIE and calculates the fees as described below in (4). 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 a year, the ORELAP Administrator may remove the application from ODIE after contacting the laboratory and a notation is made in the administration section of ODIE.
  - c) Once all fees have been paid, the Administrator initials and dates the "Fees Rcvd" line in the application in ODIE.
- 4) The fees are calculated using ODIE and entered into the Administrator's ORELAP database. 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 attached to a copy of the invoice.
  - 5) When the fees have been received (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.
  - 6) Once the information has been added to ODIE, when an assessment is required, an automatic email is sent to all appropriate parties within ORELAP including the DEQ Liaison to ORELAP so they can start the assessment process.

#### 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)

To calculate the fees

Open ODIE and click on the “Process Fees” key. The fees are automatically calculated based on the fees schedule in OAR 333-064 (Division 64 Accreditation of Laboratories), available through the ORELAP web page.

### III.1.5. Technical Review

Primary Accreditation. If primary accreditation has been requested and an on-site assessment or a document review is needed, the links to the applications are made available to all of the DEQ and PHL Assessors,

The Administrator and the DEQ Liaison review the application in order to determine the scope and staffing needs for the on site assessment.

Secondary Accreditation. If secondary accreditation has been requested, the Administrator checks the laboratory’s application form against the laboratory’s current certificate of primary accreditation and fields of accreditation that has been sent directly to ORELAP from the primary accrediting authority. If minor discrepancies are found, the lab and/or the primary accrediting authority (as appropriate) is contacted by phone, fax, mail or e-mail. Applications for parameters for which the lab has not been granted primary accreditation are denied. If all parameters are denied and there are major discrepancies that cannot be readily reconciled, the Administrator denies the application (see 3) b) in this section above)

## III.2. Assessor Performance Appraisals

### III.2.1. Introduction

A performance appraisal is a summary of feedback a manager has given an employee during the evaluation period. It is done after the Trial Period and at least annually thereafter. Assessor records are also reviewed and updated at that time. Performance appraisals affirm an understanding of how well the employee is performing the job through an open, two-way communication process.

The performance appraisal is a summary of past performance based on the employee’s current job description and/or work plan. These are designed to build agreement between the employee and manager about what the employee’s duties and assignments are. Job descriptions and/or workplans must be established within 30 days of employment and updated annually.

The appraisal should focus on goal setting and ways of enhancing future performance. The evaluation process must include any changes that may be occurring in the workplace or in the job. The eventual outcome should be an understanding and commitment to the success of program goals.

### III.2.2. Pre-Appraisal Interview

The employee and manager each bring a list of the employee’s accomplishments to the meeting.

The employee discusses changes that affect his/her duties, and how those may need to be reflected in the position description. The manager adds his/her perspective as well as any other information that might change the job description.

The manager and employee review all the ORELAP Assessment Appraisal forms from each assessment on which the employee was a member of the assessment team.

The employee and manager each present items from the current workplan that they believe could be improved.

The employee indicates areas that he/she would like to work on as both job improvement training and career development. The manager indicates areas he thinks should be part of the employee's career development plan.

All these items should be fully discussed and an agreement should be reached prior to the end of the meeting.

### III.2.3. Manager and Employee Meeting

The manager and employee meet to discuss the final revision of the performance appraisal. They also discuss an individual development plan for the employee for the next rating period.

The Performance Appraisal is then signed by the manager and the employee (acknowledging receipt and discussion of review with the manager). The form is then filed with a copy sent to the employee.

Performance evaluations cannot be appealed. However, an employee will be allowed to prepare a written rebuttal to the evaluation that will be attached to the form and become part of the official record.

## III.3. Laboratory Changes in Key Accreditation Criteria

### III.3.1. Introduction

Because changes in key accreditation criteria, such as change in ownership, location, key personnel and major equipment/instrumentation, scope of accreditation, or policies may have a significant effect on data quality, laboratories are required to notify ORELAP of any such changes within 30 calendar days for evaluation by ORELAP. Changes in key accreditation criteria may require an on-site assessment to verify affects 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 a completed section of the ORELAP application form, 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.3.2. Change in Ownership

#### 1. The laboratory must submit:

- Completed pages 1 through 3 of the application form.
- A written letter of notification that, for primary ORELAP accredited labs, must include a list of any changes that may have occurred within the lab 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. Labs must arrange to have the primary accrediting authority send a copy of the revised certificate and scope of accreditation

2. If, for a primary ORELAP accredited laboratory, the change in ownership has been determined to have no significant affect on lab 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 . If so, ORELAP will decide whether Interim accreditation will be granted until such an assessment can be performed. This will be determined on a case by case basis.
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. Such records shall also be subject to inspection by ORELAP during this period, with or without prior notification.
5. For secondary ORELAP accredited labs, appropriate changes are made to the laboratory's accreditation if required as indicated by changes in the lab's primary accreditation status.

### III.3.3. Change in Location

1. The laboratory must submit completed pages 1 through 4 of the application form.
2. Primary ORELAP accredited labs:
  - Labs must also submit a description of the new facilities at its new location and provide assurance that the change has not impaired the lab's performance.
  - The change will be evaluated, after consultation with the ORELAP assessors, as to whether another on-site assessment is required and, if so, whether Interim accreditation will be granted until such an assessment can be performed.
  - If an on-site assessment is required, one will be scheduled within 30 calendar days and be conducted as soon as possible after the lab has paid the on-site assessment fee.
3. Secondary ORELAP accredited labs must arrange to have its primary accrediting authority send a copy of the lab's certificate of and scope of accreditation that indicates the address of the lab's new location.

### III.3.4. Change in Management and Key Personnel

1. The lab must notify ORELAP in writing of all changes in key personnel such as lab manager, technical director, and quality assurance officer. For primary ORELAP accredited labs, this may include changes involving the analyst(s), if the change represents a change in the laboratory's analytical capability.
2. If the key personnel are the lab manager and/or technical director(s) and/or quality assurance officer, the laboratory must submit completed pages 1

through 6 of the application that includes the Certificate of Compliance signed by the new personnel.

3. Personnel changes for primary ORELAP accredited labs will be reviewed to ascertain whether such changes will affect the lab's accreditation status.
4. Secondary ORELAP accredited labs must arrange to have its primary accrediting authority send a copy of the lab's certificate of and scope of accreditation 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 lab's primary accreditation status.

### III.3.5. Changes in Major Equipment/Instrumentation

1. Primary ORELAP accredited labs must notify ORELAP of any changes in major instrumentation.
  - If the change represents the addition or replacement of a new instrument such as a gas chromatograph, the notification must include the proper identification of the instrument and notification of acceptable demonstration of capability.
  - If the change represents the loss of a major instrument that will affect the laboratory's analytical capability, the laboratory's accreditation status will be revised as required.
2. Secondary ORELAP accredited labs must arrange to have its primary accrediting authority send a copy of the lab's certificate of and scope of accreditation if changes in instrumentation have resulted in changes in the laboratory's accreditation status. Secondary ORELAP accreditation will be revised based on the changes in the lab's primary accreditation status.

### III.3.6. 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, includes but is not limited to reduction in scope of accreditation, organizational changes, major policy changes, major lab remodeling, damage due to fire, flood, etc., must be reported to ORELAP within 30 calendar days. A request for further documentation and subsequent actions taken will be determined on a case by case basis.
2. Secondary ORELAP accredited labs must arrange to have its primary accrediting authority send a copy of the lab'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 lab's primary accreditation status.

### III.3.7. On-Site Assessments

1. For most common laboratory changes that would require an on-site assessment, the assessment will be scheduled with the laboratory within 30 calendar days and occur as soon as possible subsequent to payment of an on-site fee. However, there may be certain circumstances for which ORELAP may deem an unannounced on-site visit to be 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.

#### III.3.8. Notification of Evaluation

ORELAP will notify all laboratories reporting a change in key accreditation criteria of results of the evaluation of the reported changes.

#### III.3.9. Failure to Notify

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

#### III.3.10. Record of Laboratory Changes

1. 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 the occurred.
2. Copies of laboratory notification of changes and subsequent actions, if any, will be submitted to the Lead Assessor for entry into the ORELAP and national database as appropriate.
3. 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 the occurred.

### III.4. ORELAP Database

#### III.4.1. Introduction

ORELAP maintains data received and generated by the program through the use of an electronic database that resides on DEQ's internal network. The ORELAP administrator and assessors record all data necessary for determining laboratory accreditation in the ORELAP database, which includes: application receipt; invoicing; laboratory demographics; FOT testing requested; scheduling; assessment check lists; and pertinent dates. Accreditation certificates, assessment reports, responses to corrective action, invoices, ORELAP's application, and various assessment status reports may be printer from the ORELAP database.

Please refer to the complete ORELAP Database operations manual for description and instruction for the use of the application. The ORELAP Database Administrator maintains documentation of the table definitions and relationships as well as documentation of the source code and queries.

The database is a Microsoft Access 2000 application, which permits flexibility in the design and use of the ORELAP database. Queries, tools, and reports can be customized to accommodate changes in the ORELAP. Development of the database is restricted to a database administrator; general users do not have access to the development portions of Microsoft Access.

Access to the database is restricted to persons that have been granted rights to the ORELAP directory on the DEQ network. Copies of the database are transferred to laptop computers for use by the assessors. The laptop data is synchronized with the master database by the database administrator following completion of on-site assessments.

The main menu of the database grants the user access to Laboratory Information, Database Maintenance tools, Reports, Assessments, and Import/Export functions.

#### III.4.2. Laboratory Information

The Laboratory Information section of the database is used to maintain basic laboratory information, application status, general laboratory notes, fields of accreditation, and history.

#### III.4.3. Maintenance

The Maintenance section of the database contains tools for maintaining various aspects of the database, such as assigning analyte/matrix combinations to specific analytical methods, maintaining lists of current analytical methods, and maintaining lists of analytes.

#### III.4.4. Reports

The ORELAP database facilitates the rapid production of Laboratory Summary Reports, Laboratory Field of Accreditation Reports, and Laboratory Certificates. In addition to producing final documents for laboratories, the reporting portion of the ORELAP database assists on-site assessors and the ORELAP administrator with specialized reports such as the Application Report and Laboratory Technology Report.

#### III.4.5. Assessments

On-site assessments are documented through the Assessments portion of the ORELAP database. On-site assessors record their observations using electronic checklists generated within the database. The checklist is specialized to the specific function of the assessor. Technical assessors use specialized checklists that are a combination of Quality Systems (NELAP Chapter 5) questions specific to technical assessors, the relevant aspects of NELAP Appendix C (Demonstration of Capability), and appropriate NELAP Appendix D questions. The checklist used by the Quality Systems assessor includes question specific to general laboratory operations. If systematic problems are identified by the technical assessors, specific questions may be added to the Quality Systems checklist. The Assessments portion of the database is designed so that questions may be grouped by functional groups. The assessors' observation may be classified in three categories: "Immediate", "Corrective Action Report", and "Recommendation". Each of these categories corresponds to a unique section in the Laboratory On-site Assessment Report. Findings in the "Immediate" section include problems that are considered to seriously compromise the laboratory's performance and quality of data. The "Corrective Action Report" section identifies findings that must be addressed in the laboratory's corrective action plan, but do not compromise the quality of the laboratory's data. Finally, the "Recommendation" section is used for observations that are not related to a laboratory's failure to meet the standard, but rather, may be helpful in improving laboratory operations.

The assessor also uses the Assessments portion of the database to document that the laboratory has addressed the identified deficiencies (i.e., implementation of acceptable corrective actions).

This is accomplished by filtering the checklist questions for all the "N" responses and checking the "CA Acceptable" checkbox.

#### III.4.6. Import/Export

The import/export functions of the ORELAP database allow the database to be exported to laptop computers and laptop data to be imported and synchronized with the master database.

#### III.4.7. Data Integrity

All data entry for laboratory demographics and laboratory Fields of Accreditation is performed by Technical Services of the DEQ laboratory. The ORELAP administrator performs 100% QA oversight for all data entry and reports errors or corrections for update.

Access to the official ORELAP database is protected by Microsoft Windows 2000 Advanced server user login with validated password designed to meet strict password policy (mixture of 8 or more alphanumeric or special characters, non-word, mixed upper and lower case). Passwords are required to be changed every 90 days.

The database security structure offers different level of security based on username and login.

Complete backups are made to digital tape weekly and incremental backups are performed nightly. Copies are rotated off site for emergency storage.

### **III.5. Denial, Suspension, and Revocation of Laboratory Accreditation**

#### III.5.1. Introduction

The ORELAP requires that environmental testing laboratories meet the TNI Standards. The consequence of not consistently adhering to the standards is loss of ORELAP accreditation for all or part of the laboratory's accredited analytical fields of testing, analyte or method. Accreditation can either be denied at the application step, temporarily suspended in part or in total for not more than six months or revoked in part or in total. 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.5.2. Denial (V2M1: 7.5.6)

Denial is applied during the application (or renewal application) or initial on-site assessment for ORELAP accreditation.

Reasons for denial include:

- failure to pay the required fees
- failure to submit an acceptable application
- failure to meet personnel qualifications
- failure to successfully analyze and report proficiency testing samples as required
- failure to respond to an on-site assessment report with a corrective action report within the required 30 calendar days

- failure to implement the corrective action described in the corrective action report in the agreed upon time frame
- failure to implement a quality system
- failure to pass the required on-site assessment
- misrepresentation of any fact pertinent to obtaining accreditation
- denial of entry of assessors during normal business hours for the purpose of an on-site assessment

The ORELAP Administrator will notify the laboratory's director by registered mail or email, return receipt, 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 section (III15.0 – Appeals Process)

### III.5.3. Suspension (V2M1: 7.9)

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.

Reasons for suspension include:

- failure to successfully (acceptable results) analyze and report at least two out of the last three PT samples
- failure to notify ORELAP of any key changes such as laboratory ownership, location, personnel, and/or major instrumentation
- failure to submit a corrective action report for PT failures within 30 days of a request for such report.
- a finding by an on-site team that public interest, safety or welfare is in jeopardy and requires emergency action
- failure to maintain a quality system
- failure to employ staff that meet the personnel qualifications for education, training, and experience as required by the TNI standards
- failure to meet customer requirements where there is potential for imminent harm to the public or environment (ie., failure to report compliance data exceeding regulatory limits to a public water system or state drinking water program in a timely manner).

The ORELAP Administrator will notify the laboratory's director by registered mail, return receipt, 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 will be restored after the laboratory successfully demonstrates that it has complied with the

TNI standards and addressed the reasons for suspension within the specified time period (no longer than 6 months). If the reasons for the suspension are not acted upon by the indicated time, the laboratory will lose its accreditation status (revocation). Upon reapplication, the laboratory will be required to submit an application fee along with the application.

If the cause of the suspension has not been corrected within six months or the period of accreditation, whichever is shorter, the status of the affected fields of testing will change to revoked. The laboratory has the right to due process and may appeal the decision to suspend accreditation according to section (III15.0 – Appeals Process).

#### III.5.4. Revocation (V2M1: 7.9)

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

Partial revocation shall include:

- failure to meet the required improvements as outlined in a letter of suspension
- failure to submit an acceptable corrective action report subsequent to an assessment report (the lab may submit two corrective action reports within the specified time limits)
- failure to implement corrective action(s) for deficiencies found during an assessment
- failure of three consecutive PT samples for any analyte

Reasons for total revocation shall include:

- Failure to pass an on-site assessment.
- failure to respond with a corrective action within 30 calendar days
- failure to participate in the required PT samples
- submittal of PT results generated by another laboratory
- misrepresentation of any material fact pertinent to receiving accreditation or accreditation status
- denial of entry of assessors during normal business hours for the purpose of an on-site assessment
- conviction of charges relating to the falsification of any report relating to laboratory analysis
- failure to remit any or all accreditation fees within the time limit established by ORELAP

The ORELAP administrator will notify the laboratory's director by registered mail, return receipt, 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 Standard(s) for the revocation and 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 according to section (III15.0 – Appeals Process).

### III.5.5. Voluntary Withdrawal

If an environmental laboratory wishes to withdraw from ORELAP, in total or in part, it must notify ORELAP in writing and return the accreditation certificate. If the withdrawal is total, the laboratory must refrain from using the NELAP logo or making any reference to either NELAP or ORELAP.

## III.6. Dispute Resolution

### III.6.1. Introduction

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

### III.6.2. 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 Administrator and/or the ORELAP QA Officer and a copy of ORS 183 will be sent to the laboratory notifying them of their rights under Oregon Statute. If a resolution has not been achieved, the Administrator will forward the complaint to the ORELAP Executive Team who, working in conjunction with the Administrator, will attempt to determine the cause and correct the problem. If the problem cannot be resolved informally, these statutes will be implemented.

### III.6.3. Disputes

A dispute with a laboratory is the result of a formal complaint that was not resolvable informally. In the case of a dispute, ORS 183.415 will be followed. A notice of a hearing will be sent to all interested parties and will 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.6.4. Appeals

The Program administrator and the ORELAP Accrediting Authority will review all appeals of denials, suspensions or revocations. These appeals will be handled as described in the ORELAP SOP "III-15.0 Appeals Process".

### **III.7. ORELAP Laboratory Assessor Requirements**

#### **III.7.1. 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. Laboratory assessors must have successfully completed EPA's drinking water certification training or received general and specialized technical training from third party trainers.

#### **III.7.2. Basic Qualifications**

1. The assessors used by ORELAP must be an experienced professional with at least a minimum of a Bachelors 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.
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 discipline area 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. If an assessor has recent laboratory experience (within 1 yr) in the discipline they are assessing, is also considered to have completed a test with a passing score. An assessor that has served as an expert witness for a technical discipline needs not to have additional technical assessor training for that discipline provided they have received training in assessing any technical discipline.

Technical disciplines are:

- Microbiology
- Toxicity Testing
- Inorganics-Nonmetals
- Inorganics-Metals
- Inorganics/Organics- IC/LC

- Organics-GC
  - Organics-GCMS,
  - Organics-GCMS/MS
  - Organics-LCMS
  - Organics-GCHRMS
  - Asbestos (bulk)
  - Asbestos (EM)
  - 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 (See III.7.4.below). Only one training assessment is required for assessors new to the ORELAP program but have prior assessment experience.
6. Additional Qualifications : each assessor must **sign a statement that they will comply with the rules and policies of ORELAP**

In addition, all assessors must:

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, IDC/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.
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. Lead assessors must demonstrate writing and organization ability to meet the demands of managing the day-to-day assessment activities.
7. Possess acceptable inter-personal relationship skills

### III.7.3. 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 ORELAP administrator must maintain current checklists used during the assessments. These checklists must be reviewed and updated as the program requirement change.
3. The lead assessors are responsible for updating the database weekly. All updates will be recorded in the database with date, time and identity of the user.
4. It is the responsibility of each individual assessor to aid in the identification of areas where training is needed.

#### III.7.4. New Assessor Training

1. New assessors must pass a NELAP approved basic assessor training course.
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 (DEQ Section Manager or ORELAP Administrator), 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:
  - a. TNI approved assessor training course
  - b. Workshops, seminars, meetings sponsored by the US Environmental Protection Agency (EPA)
  - c. Workshops, seminars, meetings sponsored by the State, instrument manufacturer, or society
  - d. Meetings with other state assessors
  - e. Specific college or university courses

#### III.7.5. ORELAP Assessor Personnel Qualification Records

The ORELAP Administrator shall maintain qualification records for each ORELAP assessor. These records will be kept filed by name for each state 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 record (Form 5D – ORELAP Assessor Training and form 5E – ORELAP Assessor Refresher Training ). Record to be updated annually.

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 ORELAP Administrator will also maintain a summary record that identifies the specific technical disciplines approved for each of the program assessors.

#### III.7.6. Assessor Review

1. The qualifications of all assessors will be reviewed by the ORELAP administrator 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. Their evaluation will include job performance as described in the Assessor Review SOP.
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 or 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 ORELAP administrator while performing an on-site assessment regularly, minimally every three (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 as maintained according to Technical Review and On-Site Assessments, III.13.25.

### **III.8. Internal Program Reviews (V2:M1 5.7)**

#### III.8.1. Introduction

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

#### III.8.2. Program Systems Evaluation.

##### *III.8.2.1. 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 Administrator 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 QAO 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 review will include but are not limited to:

- a. Appropriate Oregon Administrative Rules (OARs)
- b. ORELAP program document
- c. ORELAP Quality Manual
- d. Standard Operating Procedures (SOPs)

In addition to the program documents, the following program records will also be reviewed:

- e. Assessor records
- f. Laboratory records
- g. Proficiency testing tracking records
- h. Assessment appraisal forms
- i. Third party assessor contracts
- j. Previous audits and corrective actions

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

#### *III.8.2.2. 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.8.2.3. 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.8.2.4. Reporting the Findings*

Findings" are areas where the program does not meet the TNI standard 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 Administrator for review and response. The Executive team may request a meeting to discuss the findings. An electronic

copy as an Adobe® (pdf) file and a paper copy of the report will remain in the ORELAP files in the Administrator's Office.

#### *III.8.2.5. Corrective action*

In the context of the TNI standard, 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 cause analysis will be submitted to the Executive Team and the QAO by the Program Administrator and implemented according to a mutually acceptable predetermined schedule. Corrective actions shall be appropriate to the impact of the problems identified. The Administrator will attempt to determine the cause and correct findings from the program evaluation. The ORELAP Administrator 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.8.3. Management Review (V2:M1 5.8)

##### *III.8.3.1. Planning*

The Program Administrator 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:

- a. Report of Program Systems Review
- b. Corrective and preventative actions
- c. Program Manual
- d. Quality Manual
- e. SOPs
- f. Revisions to the TNI Standards
- g. NELAP Evaluations
- h. Client feedback (includes any issues brought forth by the ORELAP Technical Advisory Committee)
- i. Appeals and Complaints
- j. Participation with TNI
- k. New areas of accreditation
- l. Trends in non-conformances
- m. Status of preventive and corrective actions (including follow-up on action items from previous management reviews)
- n. Other relevant factors that may affect the overall quality system, such as volume of work, resources and staff training

### *III.8.3.2. 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. “Findings” are areas where the program does not meet the TNI standard 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.

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 as an Adobe® (pdf) file and a paper copy of the report will remain in the ORELAP files in the Administrator’s Office.

### *III.8.3.3. 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 Administrator. 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 Administrator will report all actions taken to the Executive Team.

## **III.9. Issuance of Accreditation Certificate**

### **III.9.1. Introduction**

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

### **III.9.2. Procedure**

Once a laboratory has met all the requirements for accreditation as indicated in the ORELAP database, the Program Administrator will issue the accreditation documents to the qualified laboratory. These documents, as described below, include the Letter of Accreditation, 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 additional or loss of parameters, the Administrator will issue a new Accreditation Report and a new Certificate, if warranted, with a 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.9.3. The Letter of Accreditation

This letter will be issued on official ORELAP stationary and 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.9.4. Certificate (V2:M1 7.5.4)

The certificate is printed on commercial certificate stock and contains the following information:

1. Unique Identification of the Laboratory
2. Laboratory name
3. Laboratory ORELAP Identification number
4. Laboratory address
5. Matrices and disciplines for which the laboratory has received accreditation (summary of scope of accreditation)
6. Statement of conformity and identification of applicable standards and version.
7. Unique certificate number
8. Issue date
9. Expiration date
10. ORELAP name
11. Gold seal (logo)
12. ORELAP Administrator's signature

The certificate will also contain a reference to the Accreditation Report

### III.9.5. ORELAP Fields of Accreditation

The ORELAP Fields of Accreditation is provided with each issuance of a certificate. It is identified with the Laboratory name, ORELAP identification number, 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 will be generated from the new ORELAP database and 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 lab along with a new Certificate of Accreditation. When necessary, the old Certificate is returned to ORELAP.

However, until such time the Administrator has direct access to the new ORELAP database, the Administrator will request changes to and the printing of Certificates of Accreditation and Fields of Accreditation from authorized DEQ staff.

### III.9.6. 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 and including suspension or revocation of their accreditation (see III.5.) 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 not limited to, in their advertising, web pages, brochures, media communications, lab reports (certificates of analysis), other documents, etc.
4. Discontinue use of logo or other statements that imply accreditation when accreditation 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.10. Proficiency Testing (V2M2: 4-10)

### III.10.1. 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. ORELAP, as a primary NELAP accrediting authority, implements its requirement to monitor the PT of ORELAP accredited labs according to V2:M2 of the TNI Standards.

### III.10.2. Laboratory Participation in PT Studies

ORELAP requires laboratories desiring ORELAP accreditation to participate in PT program and obtain PT samples from any PT provider approved by a Proficiency Testing Oversight Body (PTOB) /Proficiency Testing Provider Accreditor (PTPA) (e.g., The American Association of Laboratory Accreditation, A2LA) The samples must be analyzed and the results returned to the PT provider prior to the closing date of the 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 lab 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 sets of PT studies; the analyses are to be performed at least 15 calendar days apart for the same field of proficiency testing. In practice, ORELAP tracks dates from the closing day of one study to the shipment date of another study for the same field of proficiency testing, but verifies the actual analysis dates if there is a discrepancy.
3. Each laboratory seeking or maintaining accreditation shall be required to perform analysis of one PT sample twice per year, approximately six months apart (at least 5 months and no more than 7 months), 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 shall 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 Standard.
  - c. The analysis dates of supplemental studies must be at least 15 calendar days apart from the closing day of one study to the analysis date of another 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 lab is demonstrating corrective action or requesting expansion of their existing accreditation.
  - e. After the lab is granted accreditation for fields of testing for which the lab 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 (every 5-7 months).
5. When PT samples are not available for the FoPT from any PTPA recognized PT provider at least twice per year, the 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 any FoPT (if they are accredited or seeking accreditation for the methods). 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.

10. If a laboratory wishes to withdraw from a PT study for an analyte(s) or for the entire study, the laboratory shall 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.10.3. PT Providers

1. PT provider shall submit the following data for cross-referencing with other laboratories that participated in the same PT study.
  - 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 24hour period that it reports the results to the laboratory.

### III.10.4. Supplemental PT Studies

PT samples of supplemental PT studies that are used by laboratories for accreditation or corrective action must meet the following criteria:

1. The PT study must be obtained from a PT Provider that meets TNI accreditation requirements.
2. The laboratory must inform the PTP the PT sample is for accreditation purposes (specify for a corrective action or to obtain accreditation) to ensure the PTP provides a TNI compliant study.
3. The PT sample must meet be TNI Compliant for design, testing and verification.
4. PT samples from previously released TNI compliant PT studies may be used as long as they are within the stability period (e.g., expiration date) for that sample.
5. The PT sample cannot be one that has previously been sent to the laboratory.

6. The original sample tracking ID must be masked and the sample tracking shall be unique.
7. For corrective action studies, the assigned values for all analytes requested by the laboratory must not be equal to zero, except for qualitative PCB group or qualitative microbiology samples.

### III.10.5. Receipt of PT Results

As the primary accrediting authority, ORELAP shall be responsible for monitoring laboratory PT and take action 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 standard 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 and/or multiple test methods for any FoPT. However, 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.
  - d. 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 V3, Section 10.3 and associated subsections of this Standard. If the criteria in V3, Section 10.3 are met, and the result for the FoPT was scored “not acceptable” by the PTP, the ORELAP will overturn the performance evaluation and score the analytical result “acceptable”.
    - ii. the laboratory does not report results for an accredited FoPT within the timeframes specified in the TNI Standard.
    - iii. the laboratory makes any reporting error or omission that results in a non-specific match between the analytical result for the FoPT and any criterion that identifies the laboratory or the field of accreditation for which the PT sample was analyzed for the purpose of initial or continued accreditation.
    - 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 Administrator. The Administrator uploads the PT results into the Oregon AB Manager software

program. Information for a small PT study may be hand entered if needed, The following PT information is captured:

- a. Laboratory ID
  - b. Receipt date
  - c. PT provider
  - d. PT provider study ID
  - e. PT study close date
  - f. PT sample analysis date
  - g. Method
  - h. Analyte
  - i. Sample matrix
  - j. Laboratory result
  - k. True value
  - l. Control range
  - m. Field of Accreditation (loaded from ODIE)
3. PT Evaluation:
- a. After the PT data has been uploaded into AB Manager, The Administrator clicks on the Evaluate PT key and a report is generated that identifies the laboratories accreditation status based on their PT performance. The AB Manager uses the criteria from the 2009 TNI Standard Volumes 2 Module 2 section 7 and 3 for the determination of status (also See III.10.7).
  - b. 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.
  - c. Once the accreditation status has been determined, the Administrator, the Administrator will accredit those parameters with acceptable PT status if all of the other TNI criteria has been met.. The PT tracking is maintained in AB Manager and is reviewed when additional PT results are received as well as when the laboratory's accreditation status requires reevaluation.
  - d. All past hardcopy PT results reports (prior to AB Manager) are stored/filed in alphabetical order according to laboratory.
4. Any change of accreditation status is recorded in the ORELAP database and shall be transferred to the National database.
5. The Administrator shall review all changes in accreditation status. The Administrator shall then order the printing of and issue a new ORELAP Fields of Accreditation and certificate of accreditation, if required, to the appropriate laboratory. A cover letter shall be sent accompanying the accreditation documents that describes any changes to the laboratory's accreditation status. A copy of the ORELAP Fields of Accreditation and, if

issued, a new certificate, and cover letter is placed in the laboratory's file. All actions taken which affect the status of a laboratory shall be reported to the national database.

6. Copies of all PT result reports and associated information and raw data (see #8 in section above *Laboratory Participation in PT Studies*) shall be made available to the lead assessor for use in evaluating laboratories as part of the on-site assessment as per TNI V2M2 Section 6. (All assessors have access to PT information contained in AB Manager). 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 ORELAP Administrator for further investigation and possible action. (See III.10.8, Handling of Questionable PT Samples).
  - 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 this Standard, the ORELAP program administrator 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 AB regarding a laboratory's performance and compliance with the proficiency testing requirements set forth in the TNI Standard.
8. As a secondary accreditation body, ORELAP shall not impose additional requirements for proficiency testing that are not included in the TNI Standard as a requisite for initial or continued accreditation.

### III.10.6. Failed PT Studies

Whenever a laboratory fails a study, the lab shall:

1. Determine the cause for the failure and take appropriate corrective action.
2. Document all corrective actions for failed PT studies.
3. Submit copies of completed corrective action documentation to ORELAP within 30 days upon request by ORELAP. 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 onsite assessment. (See Section III.13.16)

### III.10.7. 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. (See III.5.2 )

2. If an ORELAP-accredited laboratory fails a second study out of the most recent three for a given analyte, ORELAP shall take action within 60 calendar days and suspend accreditation for each affected field of accreditation. (See III.5.3 )
  - a. Additionally, ORELAP shall suspend the accreditation of a laboratory for a FoPT 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 take action within 60 calendar days and revoke the laboratory's accreditation for each affected field of accreditation. (See III.5.4)
  - 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 Standard, 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 must also be notified in the case of revocation of accreditation based on PT failures.
4. To obtain accreditation after denial, suspension, or revocation due to PT failure, the lab may either wait until the next regularly scheduled PT testing round or obtain an analyze a supplemental sample. However, a laboratory will be not accredited until the PT requirements are met. Note: if accreditation is revoked, the lab must start over with the initial accreditation process.

#### III.10.8. 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 Administrator. Decision on use of PT data shall be made by consensus of assessors and the Administrator who serves as point of contact for ORELAP.
3. If unable to resolve with the PTP, submit a complaint to the PTPA that accredited 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 written 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.

Require the laboratories that failed one of the prior two PTs for the particular analyte(s) and matrices to obtain and analyze a supplemental sample and repeat the test. A laboratory that is initially seeking accreditation or has failed two out of three consecutive PT studies and subsequently has been suspended for particular analyte(s) and matrices, shall schedule additional PT studies to meet the PT requirements to order to obtain accreditation.

### **III.11. Recognition (Secondary Accreditation)**

#### III.11.1. Introduction

This document is designed to describe 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 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 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 onsite assessment requirements for the fields of testing for which the laboratory holds primary accreditation. This secondary accreditation shall be issued within 30 calendar days of the receipt of a completed application.

#### III.11.2. Request for Application

The application can be obtained from the ORELAP website: <http://public.health.oregon.gov/LaboratoryServices/EnvironmentalLaboratoryAccreditation/Pages/index.aspx> . If the laboratory cannot access the site, the laboratory may request assistance by telephone, letter or email to ORELAP.

ORELAP Administrator  
Oregon Public Health Laboratory  
3150 NW 229<sup>th</sup> Ave, Suite 100  
Portland, OR 97201  
Phone: (503) 693-4122  
FAX: (503) 693-5602  
Email: Gary.K.Ward@state.or.us

#### III.11.3. Application

The application must include a completed application form and include both the lab demographics and methodology sections. 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.11.4. Application Receipt

The receipt of applications for secondary accreditation is described in ORELAP SOP "Application Request and Initial Review" in section III.1.

#### III.11.5. Determination of Fees

The determination of fees for secondary accreditation is described in ORELAP SOP “Application Request and Initial Review” in section III.1.4.

#### III.11.6. Technical Review

Technical review for secondary accreditation is described in ORELAP SOP “Application Request and Initial Review” in section III.1.5.

#### III.11.7. Non-conformity

If the ORELAP Administrator 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 ORELAP Administrator will immediately notify, in writing, the laboratory and the primary accrediting authority.

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 authority does not take timely and appropriate action on the complaint, ORELAP will notify the TNI NELAP Board of the dispute between the two accrediting authorities regarding proper disposition of the complaint.

If ORELAP is notified by a secondary accrediting authority 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 National Database.
- Respond to the NELAP-recognized secondary accrediting authority, in writing, with a copy to the TNI NELAP Board, within 20 calendar days of the receipt 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.11.8. Accreditation

The issuance of the certificate of accreditation is described in ORELAP SOP “Issuance of Accreditation Certificate”.

### **III.12. ORELAP Records**

#### **III.12.1. Introduction**

The ORELAP program is committed to managing its records in a professional manner so that the program records are maintained legible, identifiable and controlled as required by NELAP. These records include:

1. ORELAP Program, Policy, and Procedure Manual
  - a. Program Manual
  - b. Quality Manual
  - c. SOPs
  - d. Forms

Location: A current, controlled hardcopy is on file in Administrator's Office with controlled electronic copies distributed to each member of the Executive Team, the Quality Assurance Officer and each state ORELAP assessor. Working electronic files are restricted to Administrator and Lead Assessor with all other electronic copies made available in Adobe Reader® (pdf) format.

2. Laboratory Files (may be electronic or paper)
  - a. Completed applications
  - b. Copies of certificates of accreditation and Fields of Accreditation as issued by ORELAP
  - c. Copy of current Quality Manual (primary accredited labs)
  - d. Communications
  - e. For primary accredited labs: On-site assessment documents: hardcopy and electronic copy of assessment reports; corrective action; conflict of interest forms; on-sites notes; any paper checklist used; NELAP Assessment Confidentiality Notice; entrance conference checklist; exit conference checklist
  - f. For primary accredited labs: PT tracking forms
  - g. For secondary accredited labs: Copies of certificates of accreditation and Fields of Accreditation as issued by the laboratory's primary accrediting authority

Hardcopy laboratory documents are placed in folders and filed according to laboratory ORELAP number, name and year except for current quality manuals that are placed in a separate laboratory "QA" folder that is placed in front of all folders for the laboratory. If a packet of documents, e.g., on-site assessment or application, is too large for the lab's folder for the year, it will be placed in a separate folder or folders and labeled by laboratory, contents, and year. If a lab's by-year folder becomes too large, it will be separated into multiple folders. Copies of all certificates and Fields of Accreditation (FOA) issued to each laboratory is clipped to the inside cover of the by-year folder with the most current on top.

Electronic records are maintained on a PHL shared file server and stored by Lab Name, Year, and category. The following file categories are used for each laboratory:

- Assessment Documents (reports, CA Plans)
- Certification
- FOA
- Lab Quality Documents (SOPs, QAMs, etc.)
- Invoices
- PTs
- Correspondence (letters and emails)

File Location: All hardcopy laboratory files are in file cabinets in the Laboratory Compliance File Room, against the wall on the immediate left. Files accredited labs are arranged by lab ORELAP number, names alphabetical order and year. Inactive files (labs no longer accredited) are archived in alphabetical order by name and year. Pre-11/1/2011 electronic on-site assessment reports are located in the ORELAP database at DEQ. Archives for Chemistry assessment reports are maintained in the DEQ compressed file storage room.

### 3. Miscellaneous program files/location

- a. ORELAP Assessor qualification and training files/ Administrator's Office, file cabinet
- b. Third Party contracts/ Administrator's Office, file cabinet
- c. Third Party Assessor qualification and training files/ Administrator's Office, file cabinet
- d. Performance Testing study results reports, pre-2012, are located on book case in the Lab Compliance file room: Oregon lab reports arranged by lab name in alphabetical order and matrix of PT samples with most recent studies first; Out-of-state lab reports arranged by lab name in alphabetical order and matrix of PT samples with most recent studies first.
- e. Completed assessment appraisal forms/ Administrator's Office, file cabinet
- f. Copies of communications are kept with laboratory file records
- g. Minutes of Oregon Technical Advisory Committee Meetings/ Administrator's Office, file cabinet Agendas & minutes from monthly ORELAP Program meetings/website.
- h. Accrediting Authority Status/ NELAP Recognition Certificate posted in the Administrator's Office
- i. Current list of ORELAP accredited laboratories/ PHD website:  
<http://public.health.oregon.gov/LaboratoryServices/EnvironmentalLaboratoryAccreditation/Documents/acclab.pdf>

### III.12.2. 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:

1. Title
2. Revision number
3. Revision date
4. Authorization signatures
5. Copy control number.

Each additional page must include:

1. Title
2. Revision number
3. Page number of total pages

### III.12.3. Electronic Records

Electronic documents are maintained in Microsoft® applications. When possible, any changes made to documents will be tracked by the application control features. In addition, limited access to electronic documents will be maintained. In order to facilitate distribution over a wide variety of platforms, all ORELAP documentation will be made available in Adobe Acrobat® (pdf) format. Hard copies of documents (where applicable) will be kept in the files as a reference and backup for the electronic versions. Records that are scanned to pdf require at least 400dpi to maintain legibility.

### III.12.4. Revisions to Documents

Revisions to quality system documents are performed with using the “Track Changes” feature in Microsoft word. If multiple people are working on a draft, a single draft version is maintained on Sharepoint and all edits are made to a single version and the authors of the edits are identified. The final version is assigned a document number and revision date and is printed, and approved by the ORELAP Administrator and Quality Assurance Officer, and then saved to Adobe pdf. Obsolete versions are removed from circulation and the new version is made accessible to staff and third party assessors (as needed).

### III.12.5. Archiving

For laboratories granted primary accreditation, all by-year files from the year of the last completed on-site assessment to the present are kept in the Laboratory Compliance Workroom. For laboratories granted secondary accreditation, the two most current years’ files are kept in the Laboratory Compliance Workroom. Older files may be archived by being placed in boxes and stored for 10 years according to PHL policy 00 10: Record Inventory and Retention. An archive files log is maintained in the ORELAP Log Book in the Laboratory Compliance Work Room.

For all other ORELAP files, records that are to be retained but are more than two years old and no longer current, may be archived in the same manner as laboratory files.

To retrieve archive records, a request is made for one or more specific boxes to ORELAP Administrator who will arrange for their retrieval.

#### III.12.6. Records Retention

ORELAP will keep all records for 10 years or longer as required by PHL policy 00 10: Record Inventory and Retention 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.12.7. Records Access

ORELAP administrator will maintain and control access to all files except the electronic files located in the ORELAP database at DEQ which will be maintained and have its access controlled by DEQ.

The Laboratory Compliance Workroom and the Administrator's Office are located in the Oregon State Public Health Laboratory which is a restricted access facility according to PHL Policy 00 03: OSPHL Facility Access. Archived records are stored in boxes according to PHL policy 00 10: Record Inventory and Retention and placed in the Laboratory Compliance Work Room.

### **III.13. Technical Review and On-site Assessment**

#### III.13.1. 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 lab to conduct environmental 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 on-going 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 to stop the assessment based on the non-conformities found during records review. The recommendation is made to the Administrator and, if the assessment is stopped, the Administrator will notify the laboratory in writing.

#### III.13.2. Assessment frequency

After an initial assessment for accreditation, ORELAP performs reassessments at intervals of two years plus or minus six months. Once a lab is accredited, ORELAP reserves the right to assess a lab 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.13.3. 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 of 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.

The Assessor Training Manual, from the latest NELAC/TNI-specified training course, will serve as a reference for all on-site personnel. Assessors must use current NELAC/TNI-specified checklists during inspection.

Reassessments are similar to initial assessments except that the experience gained from previous assessments is taken into account and enables the assessors to better focus the assessment. The onsite reassessment frequency should be sufficient to monitor a lab's conformance to the TNI standard, however addition onsite presence may be warranted based on on-going follow-up activities (e.g. PT evaluation, review of lab internal audits, corrective action follow-up, complaint follow-up, etc.). Follow-up onsite assessments are less comprehensive but focus on specific areas. Follow-up assessments are only performed when there is an indicated need.

### III.13.4. 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 ORELAP Administrator. All members of the assessment team must be involved in planning the assessment, however, to ensure that they are well prepared and can function independently while at the laboratory.

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

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

The following table 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 2. Summary of the Pre-Assessment Planning Activities**

<i>Step</i>	<i>Responsible Party</i>	<i>Information Required</i>	<i>Outcome</i>
1. Scoping	Lead Assessor	Application for accreditation or renewal of 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	Application for accreditation or application for renewal of accreditation. Report from most recent on-site assessment. Results from last 3 performance evaluation studies	Team assignments Assessment work plan

III.13.5. Define the Scope of the Assessment

For all routine assessments, the lead assessor begins the planning process by creating a master file for the assessment records and obtaining a copy of the laboratory's application for accreditation or renewal of accreditation from the ORELAP administrator. The application identifies the fields of testing and analytical methods for which accreditation are 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 samples 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.

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 in assessing specific portions of a laboratory's 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.13.6. Select the Assessment Team

The job of the assessment team is to review the documents collected from the lab, conduct the onsite assessment, summarize their findings and make recommendations to the Administrator as to a lab'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 ORELAP administrator or his/her 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 real or apparent 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 either electronically in the laboratory file folder or a paper copy must be retained with the assessment file. Objections should follow the general process for complaints outlined in Section II.8. The

ORELAP Administrator will inform the laboratory of the decision prior to the onset of the onsite assessment. The reasons for objections must be clearly stated and there must be evidence of a conflict of interest or a significant personality dispute 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 unforeseen conflict of interest. When this happens the lead assessor consults with the ORELAP Administrator, as soon as practicable, to determine how to proceed. The ORELAP Administrator 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, the accreditation body shall appoint it as soon as practicable without jeopardizing the laboratories request for accreditation.

#### III.13.7. Application Review

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

Each assessor will review the laboratory Quality Manual to get a general understanding of the laboratory operations. The assessor assigned to quality systems assessment will complete the TNI Quality Systems checklist for the Quality Manual.

The assessor team will notify the ORELAP administrator 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 to be complete.

#### III.13.8. Develop the Assessment Plan

Templates for assessment work plans 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. Schedule private meetings of the assessment team to occur during the assessment.
  9. 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.

### III.13.9. 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.

Assessor workload will depend on the number of laboratories requesting accreditation for any particular field of testing. ORELAP will assign workload priority in this order: Oregon laboratories, laboratories requesting secondary accreditation, laboratories located in USEPA Region X, and, finally, all other laboratories.

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 director (however named) 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 Director 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.

The schedule should cover the following elements:

1. Schedule for work plan completion:
  - a. Date for completion of draft work plan
  - b. Review/approval process and dates
  - c. Date for completion of final work plan
2. Dates of the on-site assessment.

3. Final report schedule.
  - a. Date for completion of first draft
  - b. Review/approval process and dates
  - c. Date for completion of revised draft
  - d. Target date for approval and release to laboratory
  - e. Target date for final report

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.13.10. Handling Confidential Business Information (CBI)

During on-site assessments, lab assessors may come into possession of information claimed as business confidential. The U.S. Environmental Protection Agency regulations for handling CBI are detailed in Title 40, Code of Federal Regulations, Part 2, Subpart B and will be followed by ORELAP assessors and personnel.

1. The lead assessor must provide a NELAP assessment confidentiality notice to the responsible laboratory 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 representative must place (or attach to) the information at the time it is submitted to the assessor, a cover sheet, stamped, or typed legend, or other suitable form of notice, employing language such as "trade secret", "proprietary" or "company confidential".
2. The lead assessor 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 40 CFR Part 2. If ORELAP questions the claim that certain information is CBI, the laboratory must be contacted and given twenty-one 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 take action 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.13.11. 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.13.12. 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 Administrator as soon as possible after refusal of entry.

Upon arrival, the lead assessor will introduce him/herself and any team members. The assessors will meet with the facility's administrator or laboratory director (however named) and management staff. The 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 assessors will:

- Review the purpose of the assessment and the schedule of activities
- Identify the standards that will be used by the assessors in judging the compliance status of the laboratory operation
- Verify information on the ORELAP application
- Indicate which tests that will be examined

- Examine the roles and responsibilities of key managers and staff in the laboratory
- Identify any records and operating procedures to be examined during the assessment
- 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 director (however named) 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

Note: The standards specifically state that an assessor should never, under any circumstances, sign a waiver of responsibility on the part of the laboratory for injuries incurred by a team member during an assignment in order to gain access to the laboratory.

#### III.13.13. 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 specimens, 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.13.14. Documentation of Assessment

The assessors must document the required elements of the records review on the TNI Assessment checklists. Additional questions are also included from the EPA Drinking Water manual. The questions from these checklists are arranged in the AB Manager database to simplify use by the assessors. The TNI Checklist, the Drinking water checklists, and other assessment checklists as they are developed, are made available to the laboratories through the ORELAP website. This documentation includes specifying the laboratory documents, equipment, procedures, or staff evaluated and the observations that contributed to the evaluation of “No” for each assessment checklist item. This information must be documented or referenced in the comments section of the checklist. Assessors need to keep accurate records of each potential deficiency observed. 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 checklists. Electronic versions of the checklists are generated and documented in the ORELAP database. 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.13.15. 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 lab 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 from its rawest form 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
- 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.13.16. 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.13.17. Staff Interview

##### *Qualifications:*

##### 1. General

Information on all laboratory personnel and their qualifications (education and laboratory experience) should be on file in the laboratory and made available to assessors for review. Additionally, the ORELAP assessors, including contracted third-party assessors, have the authority to conduct interviews with any and all laboratory staff as part of the required assessment process of laboratories requesting ORELAP accreditation (OAR 333-064-0035). The assessors shall verify through review of personnel qualifications and training records on file and interviews with key staff personnel (management, analytical staff, and support staff) that the staff have the appropriate qualifications and are performing the duties as reported and are truly knowledgeable of the procedures for which they are responsible. Verify that the appropriate staff members are:

- a. qualified and competent to perform specific analyses
- b. familiar with the laboratory quality manual and follow its guidelines
- c. understand the laboratory SOPs and have them immediately available
- d. follow method and program specific QA\QC

##### 2. Quality Manager

The lab shall have a member of the staff appointed as quality manager (however named) whose position is defined as having the responsibility and authority for ensuring that the quality system is implemented and followed at all times. The quality manager shall have direct access to the highest level of management at which decisions are made on laboratory

policy or resources and have functions independent fro laboratory operations for which they have quality assurance oversight. However, where staffing is limited, the quality manager may also be the technical director. The quality manager must serve as the focal point for quality assurance and quality control.

The quality manager (and/or his/her designees) must:

- have documented training or experience in quality assurance and quality control;
- be knowledgeable in the quality system as defined under TNI;
- have a general knowledge of the analytical test methods for which data review is performed;
- arrange or conduct internal annual audits;
- notify management of deficiencies in the quality system ;
- monitor corrective actions.

### 3. Technical Director(s)

Laboratories must have one or more technical director(s), however named by the laboratory, who is/are full-time member(s) of the laboratory's staff and exercises actual day-to-day supervision of laboratory operations for the appropriate fields of accrediting and reporting results. The duties of the technical director include but are not limited to: monitoring standards of performance in quality control and quality assurance; monitoring the validity of the analyses performed and data generated in the lab to assure reliable data. The lab must designate another full-time staff member meeting the qualifications of technical director if the technical director is absent for more than 15 consecutive calendar days.

Qualifications of the technical director(s)

a. Technical director for chemical analysis shall be a person with:

- Bachelor's degree in chemical, environmental, biological sciences, physical sciences or engineering;
- Minimum of 24 college semester credit hours in chemistry;
- Minimum of two years experience in environmental analysis of representative inorganic and organic analyte for which the lab seeks or maintains accreditation. A masters or doctoral degree on one of the disciplines listed above may be substituted for one year of experience.

b. Technical director for chemistry limited to non-metal, inorganic analysis shall be a person with:

- Associates degree in the chemical, physical or environmental sciences,

Or,

Two years equivalent and successful college education with a minimum of 16 college credit hours in chemistry;

- Two years of experience performing such analysis.
- c. Technical director for microbiological or biological analysis shall be a person with:
- Bachelor's degree in microbiology, biology, chemistry, environmental sciences, physical sciences or engineering;
  - A minimum of 16 college semester credit hours in microbiology and biology;
  - Two years of experience in the analysis of representative analytes for which the lab seeks or maintains accreditation. A masters or doctoral degree on one of the disciplines listed above may be substituted for one year of experience.
- d. Technical director for microbiological analysis limited to total and fecal coliform analysis and standard plate count shall be a person with:
- Associates degree in an appropriate field of sciences or applied sciences;
  - A Minimum of four college semester hours in general microbiology,
- Or,
- Two years equivalent and successful college education including the microbiology requirement may be substituted for the associates degree
  - One year experience in environmental analysis.
- e. Technical director for radiological analysis shall be a person with:
- Bachelors' degree in chemistry, physics or engineering;
  - Minimum of 24 college semester hours of chemistry;
  - Minimum of two years of experience in radiological analysis of environmental samples. A masters or doctoral degree on one of the disciplines listed above may be substituted for one year of experience.

Exceptions to the qualifications listed above are those persons who are:

- A full-time employee of a drinking water or sewage treatment facility who holds a valid treatment plant operator's certificate appropriate to the facility and for only those analyses of samples taken within the facility's system.
- A full-time employee of an industrial waste treatment facility with a minimum of one year of experience under supervision in environmental analysis and for only those analyses of samples taken within the facility's system.

Exceptions to the educational qualifications but not experience requisites listed above are those persons who were:

- A technical director at the lab continuously for 12 months prior to February 28, 2000 when ORELAP became a NELAP-recognized accrediting authority. However, the individual can serve as technical director for only for the same fields of accreditation.

- A technical director meeting the criteria listed immediately above but is currently employed in a different laboratory. However, the individual can serve as technical director for only for the same fields of accreditation.

Assessors who evaluate the qualifications of the technical director(s) of the laboratory, must record the name, title and evidence of qualifications observed during the on-site assessment for each technical director and submit this information to the Administrator who will include it in the laboratory's files. For those laboratories whose technical directors qualify because of the exception granted to those individuals who served in this capacity in Oregon certified drinking water testing laboratories for 12 months prior to the February 28, 2000, evidence of qualification may be a signed statement by the former Oregon Drinking Water Laboratory Certification Coordinator attesting to the individual's prior service as technical director.

#### 4. Analyst(s)

- Must have documented evidence of having completed an initial demonstration of capability for each field of accreditation the analysts performs.
- Must have documented evidence of performing annual demonstrations of continuing proficiency each field of accreditation the analysts performs.

#### *Responsibilities:*

Assess the written responsibilities of directors and supervisors by record review and overall participation in laboratory activities. Confirm that there is evidence of:

- Review of PT, QC, QA, equipment maintenance on a regular basis; ask for written delegation of responsibilities if the director has not reviewed this data
- Review policies and procedures by the laboratory directory
- Communication to staff through appropriate written policies and meetings

#### III.13.18. 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 lab does not collect samples, check the method(s) by which the lab 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
- Procedure manuals are readily available to laboratory staff for all instruments including operation and troubleshooting instructions

### III.13.19. 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 6 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 using the TNI checklists for the appropriate methodologies. 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 with 4 hours, but in some circumstances, this could be several days.

Determine if personnel are following the laboratory's written laboratory 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 in place for corrected reports
- A system is in place and followed to track tests
- A system in place to assess accuracy of transcription if information/data is transferred to a final lab report

### III.13.20. Analysis of Findings

Collect all necessary information before deciding if a potential deficiency exists and whether it is a "major" or "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 lab 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 ORELAP Administrator and/or the Executive Team for further consideration. At the discretion of the lead assessor, these issues may or may not be discussed during at the closing conference.

### III.13.21. Assessment Team Debriefing

At the conclusion of the assessment, the team members will 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.13.22. Closing Conference (V2M3: 6.11)

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. 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 ORELAP Administrator. All deficiencies described must be described in the context of the applicable TNI standard 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 assess 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 administrator as to the status prior to writing up the final assessment report.
- c) The deficiencies to which the laboratory takes exception is to be included in the final report, it should be noted that the laboratory disagreed so the ORELAP Administrator 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, which include:

- Submitting a plan of corrective action
- Requesting a review of the assessment in accordance with the provisions of V2M3: 6.11 of the TNI standards.

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 and positive 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 ORELAP Administrator. Laboratory feedback is an important mechanism when assessing the performance of the ORELAP program.

If the assessors' findings indicate that public interest, safety or welfare are in jeopardy and emergency action is required, the lead assessor will notify the Administrator immediately upon returning from the assessment. The Administrator will notify the ORELAP Executive team and take actions towards immediate suspension of the laboratory's accreditation according to Oregon regulations governing due process (Oregon Revised Statutes 183).

If the assessors' findings indicate such an extreme degree of non-compliance to the TNI Standards, e.g., no technical director, that suspension of accreditation is warranted, the lead assessor will notify the Administrator immediately upon returning from the assessment. The Administrator will notify the ORELAP Executive team and take actions towards suspension of the laboratory's accreditation according to Oregon regulations governing due process (Oregon Revised Statutes 183).

### III.13.23. Final Assessment Report

Although reporting actually 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 be written in narrative form 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 assessment process.
- A statement of the objectives and scope of the assessment, including correction of prior deficiencies, if applicable.
- A summary of conditions at the laboratory.
- 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 described 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. Information from the report concerning the results of the assessment and the laboratory's status must also be forwarded to NELAP for inclusion in the National database.

The Final Assessment Report is generated from the ORELAP database. An electronic copy of the final report is saved in a write-protected Portable Document Format (PDF). A copy of the report is generated, initialed by the assessors and given to the ORELAP Administrator to be

reviewed and approved. The report is sent electronically via email or the web with a return receipt (if mutually acceptable to ORELAP and the laboratory) to the laboratory within 30 calendar days following completion of the on-site assessment.

The report deadline may be delayed in cases where the 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 within 15 calendar days following receipt for the report. Once any issues are resolved, the on-site assessment report must be finalized and transmitted to the laboratory and NELAP. Reports cannot be released to the public until the assessment report and associated corrective actions have been finalized. 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 on-going enforcement investigation is exempt from public disclosure requirements.

#### III.13.24. Corrective Action

After being notified of deficiencies, the laboratory shall have 30 calendar days from the date of receipt of the finalized assessment report to provide a corrective action plan. The corrective action plan shall include the action that the laboratory will implement to correct each deficiency and the time period required to accomplish the corrective action. **Note:** Items identified as "Immediate" findings must be fully corrected in the 30 day period.

The lead assessor and the members of the assessment team and/or the Administrator 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. This response report will be given to the ORELAP Administrator to be mailed by UPS, 2-day delivery or by U.S. Mail, certified, return receipt, and/or electronically via email or the web with a return receipt (if mutually acceptable to ORELAP and the laboratory). 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.

If the corrective action plan is not acceptable to ORELAP after the second submittal, the laboratory shall have accreditation revoked or denied for all or any portion of its scope of accreditation for any or all of a field of testing, or a method, or analyte within a field of testing.

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

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

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

#### III.13.25. 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 ORELAP administrator based on assessment team's recommendation.

#### III.13.26. Records

Upon completion of the final report from each on-site assessment, the assessor or lead assessor should ensure that a complete packet containing all of the original records of the assessment is compiled and given to the ORELAP administrator.

Records of on-site assessments are maintained as follows:

1. Upon the receipt of the completed initial on-site assessment report, the Administrator shall make a copy of the report prior to mailing the original to the laboratory. An "On-Site Assessment Packet Index" (Part 4 – Forms 4.T) is generated and attached to the front of the report. This index is kept current by checking the appropriate box as additional documentation is received. The report copy then will be placed in the "response due" box for either in-state or out-of-state laboratories, as appropriate, and the date of mailing recorded on the monthly ORELAP Accreditation Process Status report.
2. Upon the receipt of a laboratory's corrective action plan, the Administrator shall record the date received on the monthly ORELAP Accreditation Process Status, make a copy of the plan and send it to the lead assessor for evaluation. The original shall be attached to the copy of the laboratory's initial on-site report along with a copy of the letter to the lead

assessor and placed in the “response due” box for the respective agency to which it was sent.

3. Upon the receipt of the report on the corrective action plan, the Administrator shall make a copy of the report prior to mailing the original to the laboratory. The copy is attached to the series of documents from the “response due” box for the lead assessor. If no response is required, the documents are to be placed in the laboratory’s file for the year in which the on-site assessment was completed. If the document pack is too large to be included in this file, it is to be placed in a separate lab file labeled as lab’s on-site assessment and the year. If a response is required, steps 1 and 2 above are to be repeated with subsequent action taken as described in III.13.23 above.
4. Upon receipt of any other documents pertaining to the assessment, the Administrator will include them with the reports packet. If the packet becomes too large for any of the boxes as they move through the document evaluation process, all but the most recent document is to be placed in a separate lab file labeled as lab’s on-site assessment and the year.

Upon completion of the on-site assessment, the Administrator ascertains if all documents to be included in the packet 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
- Letters, memos, e-mail
- other documents relevant to the assessments, e.g., notes

Once the packet is complete, it is so indicated on the On-Site Assessment Packet Index which is placed as the first page of the packet which is filed either in the laboratory file by year or, if too large, as a separate on-site assessment file for the lab and placed in the file cabinet with the current lab files.

### III.13.27. Technical Review without an On-Site Assessment

Once a laboratory has been ORELAP accredited, the lab 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 in writing 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 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 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.14. Third Party Assessors (V2M1:7.4 Subcontracting the Assessment)**

#### III.14.1. 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 in this document. The ORELAP administrator will maintain all records on third party assessors.

Third party assessors will be used for evaluating laboratory's 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.

#### III.14.2. Application Process

Those entities or individuals that wish to serve as third party ORELAP assessors must submit an acceptable application that includes:

1. Completed application form.
2. Current copy of the third party's Quality Manual.

3. Current copy of the third party's Standard Operating Procedures (SOP) 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 standard.

Upon receipt, the application will be reviewed by the ORELAP Administrator and Lead Assessor.

6. The Quality Manual and SOP will be evaluated against the Standards for conducting on-site assessments TNI V2:M3 On-site Assessment.
7. The quality documents must include acceptable policies for ethical practices and keeping all laboratory assessments reports and documents in confidence to ORELAP.
8. The resumes of the assessors will be checked to ascertain that they meet the ORELAP qualifications for laboratory assessors.

#### III.14.3. 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 Bachelors 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/NELAC-specified basic assessor training course and take annual refresher training acceptable to the ORELAP.
  3. Each assessor must also have successfully completed the TNI/NELAC-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 Certification Inspection 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.
- 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, IDC/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.14.4. Application Acceptance

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.

#### III.14.5. 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 annually by the ORELAP Administrator 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 ORELAP Administrator maintains a record of the evaluations.
3. If the third party assessors are judged by the Administrator 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 NELAP/TNI training qualifications and supply this information to the ORELAP administrator. The contracts with third party assessors whose certification lapse will be terminated.
5. The ORELAP administrator 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. The ORELAP administrator will review these checklists as the program requirements change.

8. When the third party contractor has a change in personnel, the ORELAP administrator 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.14.6. 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.15. Appeals Process

#### III.15.1. Introduction

This document is designed to describe procedures for handling appeals from laboratories that have applied to ORELAP for accreditation but disagree with actions taken by the program.

#### III.15.2. Appeal Submittal

Appeals to ORELAP can be made directly from laboratories or through the ORELAP Technical Advisory Committee (OTAC) acting as ombudsman. Appeals must be in writing describing a specific concern(s) or issue(s) and submitted to the ORELAP Administrator.

ORELAP Administrator  
Oregon State Public Health Laboratory  
3150 NW 229<sup>th</sup> Ave. Suite 100  
Hillsboro, OR 97124

#### III.15.3. Appeals Receipt and Review

All appeals are date stamped upon arrival and given to the ORELAP Administrator for review. The Administrator will forward the appeal to the ORELAP Assessors for review and comment. The Administrator may prepare a response to the appeal or delegate this task to an appropriate Assessor. The response will be sent to the laboratory or the Chair of OTAC, as appropriate, within 30 days of receipt. If the response is not acceptable, the appeal can be re-submitted for consideration.

#### III.15.4. Non-Resolution

If a resolution has not been achieved and the appeal is resubmitted, the Administrator will forward the appeal to the ORELAP Executive Team for consideration. The Team will prepare a response or delegate this task to an appropriate ORELAP Assessor. The response will be sent to the laboratory or the Chair of OTAC, as appropriate, within 30 days of receipt.

If a resolution is not achievable, the laboratory will be advised directly or through OTAC, as appropriate, of their further appeal options. These options are described in the ORELAP SOP, “Dispute Resolution” (III.6.0).

## **III.16 NON-CONFORMANCE AND CORRECTIVE ACTIONS**

### **SCOPE AND APPLICATION**

A major component of the Quality Assurance program is the feedback mechanism designed to keep the 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). This feedback mechanism starts with the Nonconformance and Corrective Action Report (NCR) system.

The purpose of the ORELAP NCR 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 NCR 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 Process, (5) notify the appropriate people of the nonconformance, and (6) produce management reports. In addition, the information gathered in the NCR 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 NCR System should be used to track non-conformances 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 non-conformances documented by the NCR 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 NCR 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).

### **SUMMARY**

A nonconformance is identified and documented on an ORELAP Non-Conformance Report Form (see Appendix A).. The non-conformance is assigned to a specific individual who is responsible for identifying and documenting the Root Cause of the problem as well as identifying and implementing the most appropriate Corrective Action. The Root Cause, Corrective Action taken, and evidence of successful implementation of the CA is documented. The ORELAP Administrator or the QAO reviews the Corrective Action and verifies that the issue has been resolved. A followup check on the effectiveness of the Corrective action provides final review of the nonconformance and closes the issue. A summary of laboratory NCRs is included in the annual management review.

## PERSONNEL/QUALIFICATIONS

Anyone in ORELAP may open a new NCR or be assigned to work on a NCR. However, only the ORELAP Administrator or QA Officer (or designee) may be close a NCR.

All staff have the responsibility and obligation to inform Management and Quality Assurance when there are situations where any aspect of the accreditation process does not conform to ORELAP's procedures or QAM requirements.

### Identify the Most Appropriate Corrective Action

1. Evaluate any corrective action(s) that may be taken to resolve the root cause of the problem. Whenever possible, consider multiple Corrective actions.
2. Select the most appropriate Corrective Action based upon the likelihood of correcting the issue and the feasibility of implementation.

### Implement the Corrective Action

1. Implement the Corrective Action that was identified; make any measurements needed to show the effectiveness of the Corrective Action
2. Document the success and/or failure of the corrective action.
3. When appropriate, verify that the Corrective Action has been successful with the person that opened the NCR.
4. If the Corrective Action was not successful, return to "Identify the Corrective Action" and reiterate the procedure. Document any successes or failures that may have occurred during the process. (It may be necessary to go back and reevaluate the root cause as well.)
5. If the Corrective Action was successful, report the date for Corrective Action Implemented" and notify the appropriate manager, preferably by email or other written method<sup>1</sup>that the NCR is ready for Final Review.

## Closing a CAR

### Manager Review

- The manager reviews the NCR and ensures that the correct Root Cause was identified, the most appropriate Corrective Action was taken, and that the nonconformance was adequately addressed. The Manager should also check that any "Associated Issues" that were opened as a result of the NCR have been addressed and/or have been appropriately assigned.
- The manager should date that the CAR was reviewed and closed.

## DEFINITIONS

**Nonconformance:** a deviation of any product or procedure from its requirements or standards as defined in the Quality Manual, a Standard Operating Procedure, or accepted field or laboratory practice that results in (or may result in) a significant decrease in the quality and/or usability of the accreditation process performed by ORELAP.

**Corrective Action:** the action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence. (ISO 8402).

---

**Root Cause Analysis** : A factor that caused a nonconformance and should be permanently eliminated through process improvement. (ASQ)

## Appendix A

# ORELAP

## Non-Conformance Report Form

Date Submitted:

Submitter:

Area of Problem:

Description of problem:

Suspected cause of problem:

Investigation Completed Date:

Root Cause Determination:

Responsible Person:

Corrective Action:

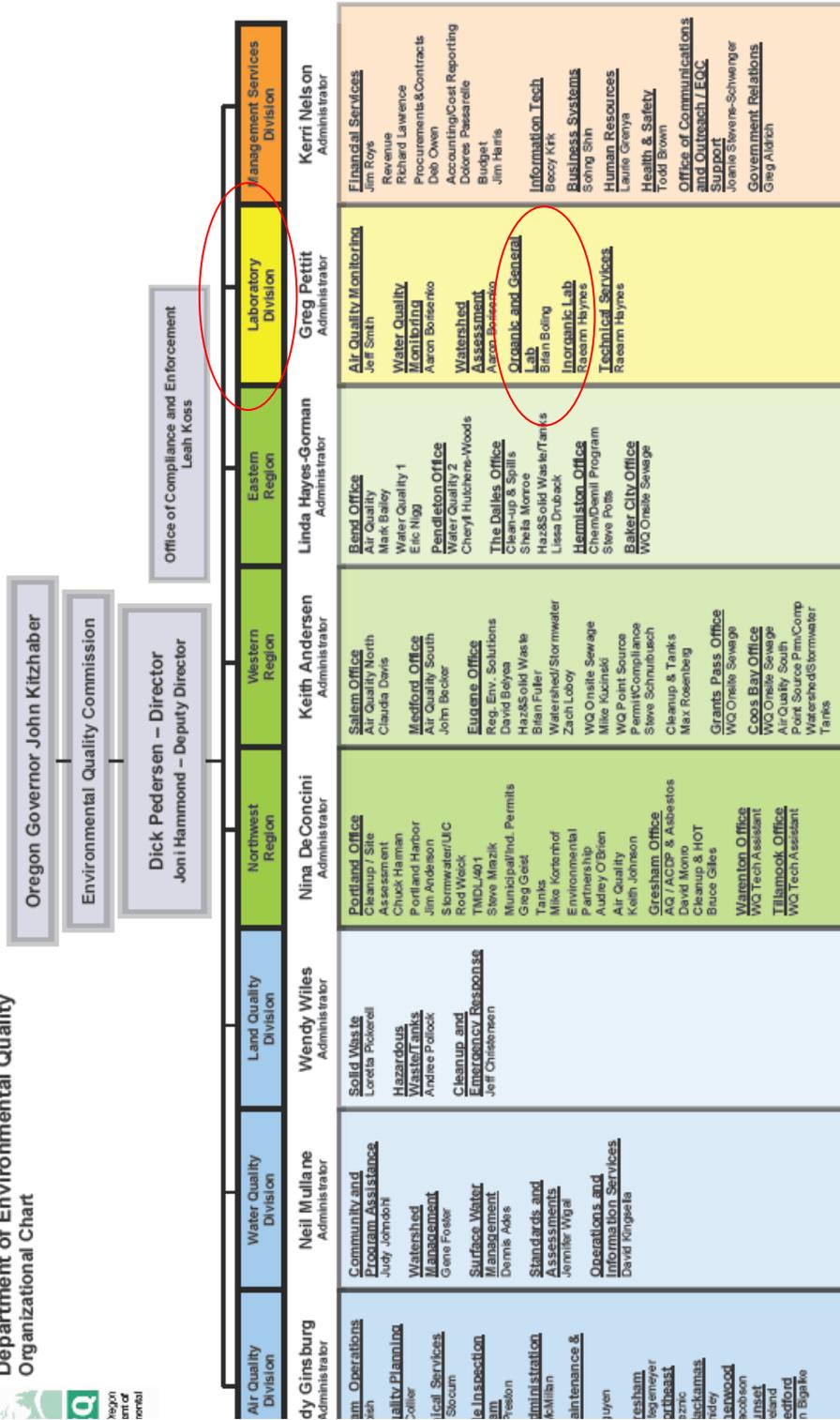
CA Implementation date:

CA Effectiveness Check Date:

Close Date:

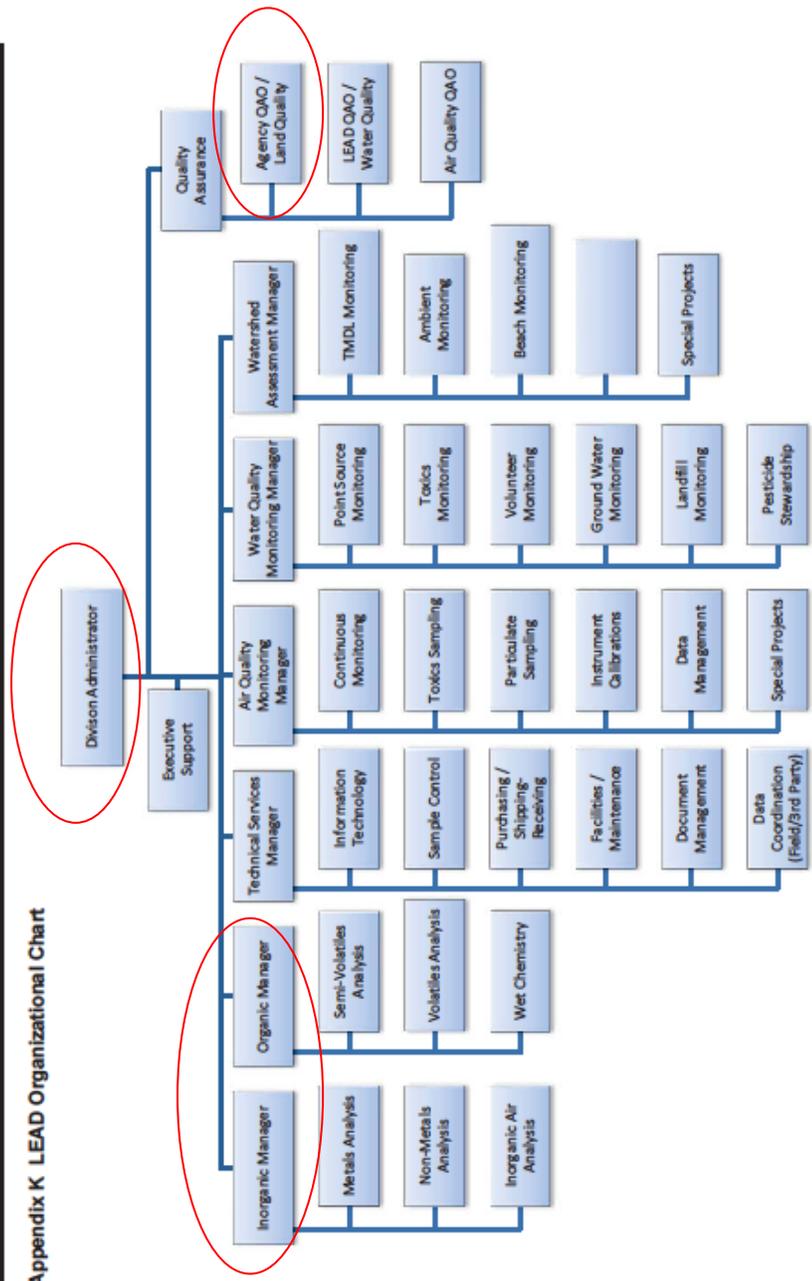
Attachment 1 Agency Organizational Charts

Department of Environmental Quality  
 Organizational Chart

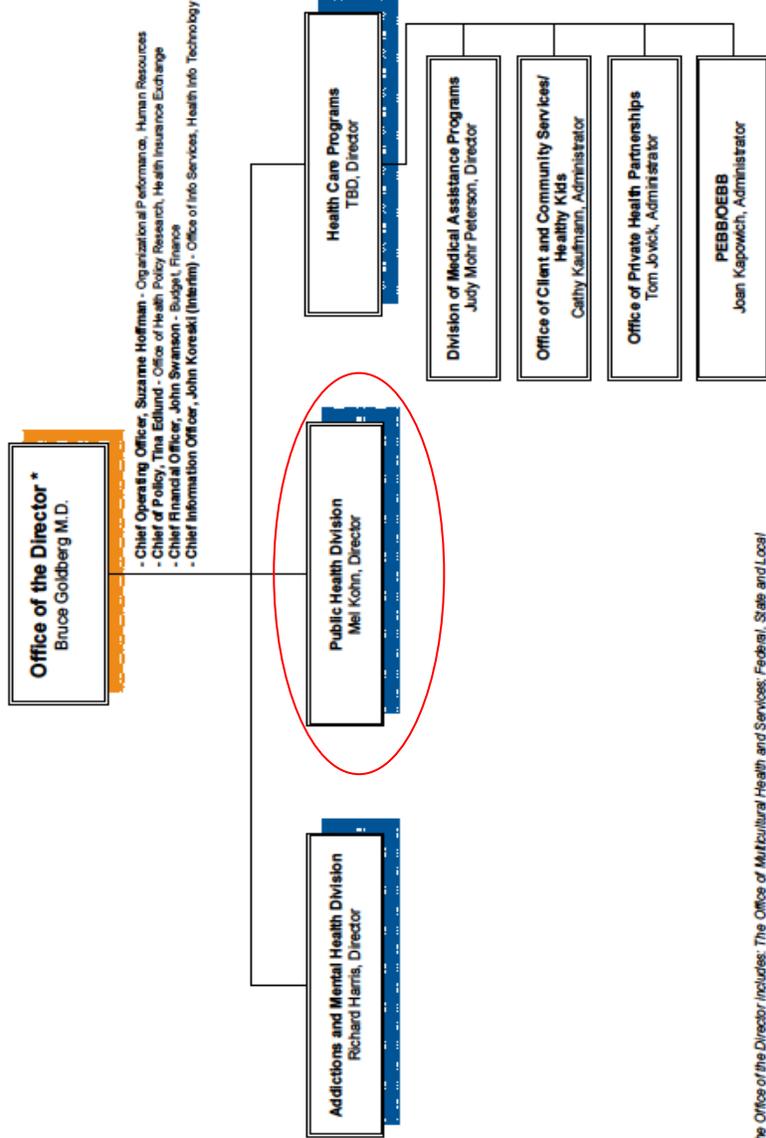


updated 6/22/2011

Appendix K LEAD Organizational Chart



# TRANSITIONAL ORGANIZATION CHART Oregon Health Authority



\* The Office of the Director includes: The Office of Multicultural Health and Services; Federal, State and Local Government Affairs; Tribal Relations; Communications; Ombudsman programs, and Legal Services

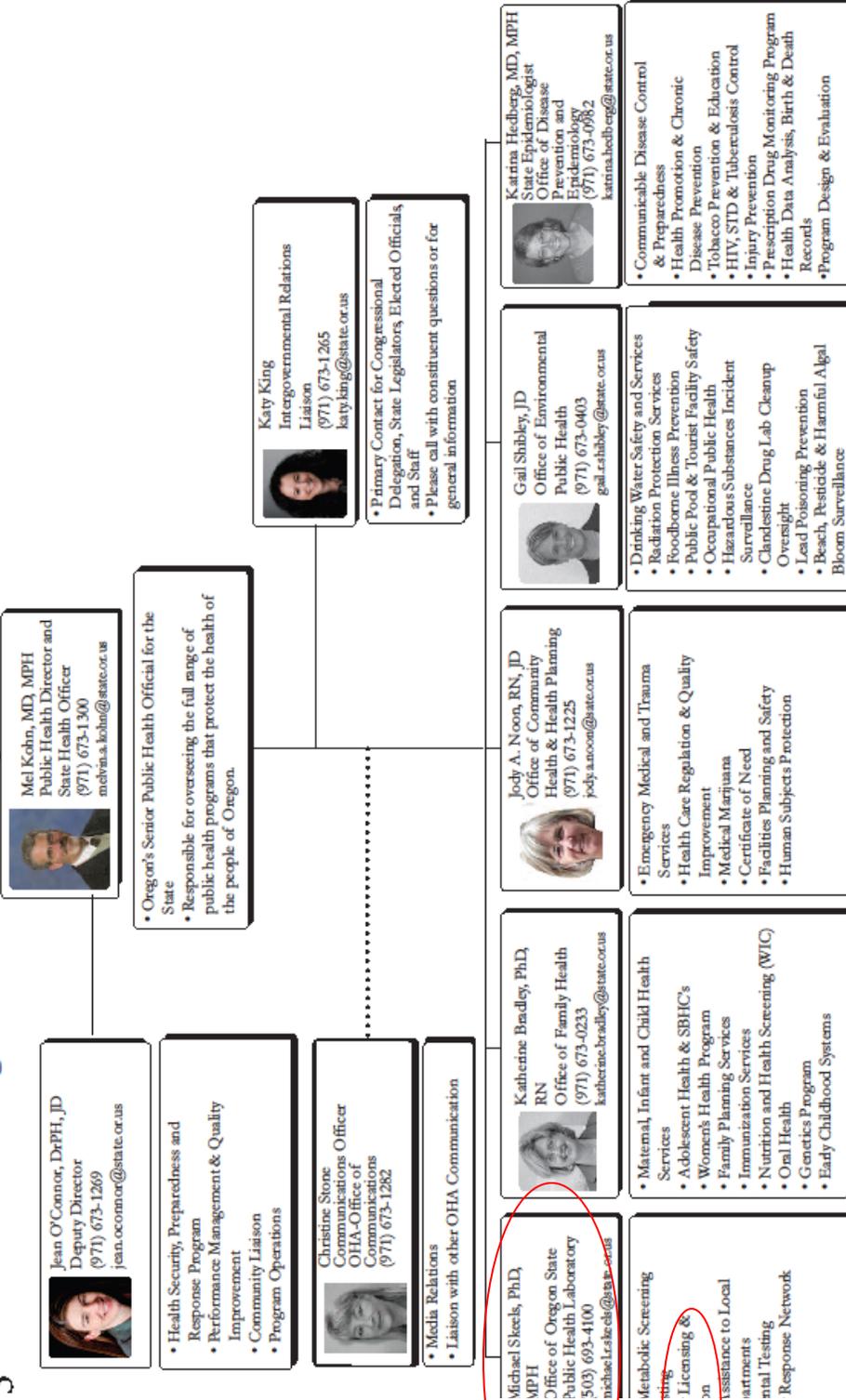
Prepared: 03/21/2011



December 2011

# Oregon Health Authority - Public Health Division

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Oregon Department of Agriculture – Organization Chart

