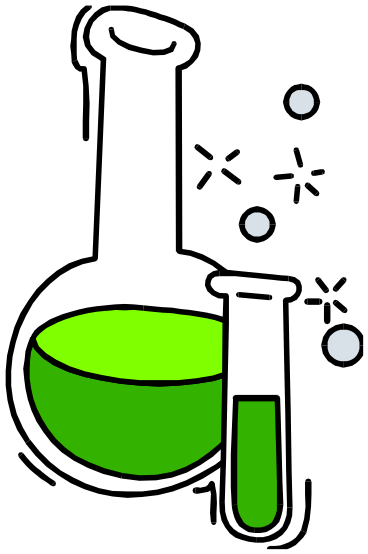

Procedural Manual for the Environmental Laboratory Accreditation Program

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Procedural Manual for the Environmental Laboratory Accreditation Program

by

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Table of Contents

Purpose of This Manual

This manual explains procedures for implementing the Washington State Environmental Laboratory Accreditation Program, administered by the Washington State Department of Ecology. The manual provides guidance to laboratories participating in the program and to users of data from these laboratories.

Chapter 173-50 WAC, *Accreditation of Environmental Laboratories*, establishes the state program for accreditation of environmental laboratories, including labs that analyze drinking water. The rule was last revised in 2002. Since then, the fee schedule established by the rule has lost ground to inflation, preventing the program from being revenue neutral as intended by the Washington State Legislature.

In 2010 we revised the rule to:

- Increase fees to meet the actual costs of conducting business. Our new fee structure aligns fees with the level of services required to accredit different types of labs.

- Clarify the grounds for revoking or suspending accreditation so that our rules expressly state that suspension or revocation can occur for failure to pay mandatory fees and for failure to maintain third-party accreditation.

- Eliminate reciprocity agreements with other states and the exemption provisions for certain wastewater discharge laboratories.

A revised rule addressing the above issues became effective on September 9, 2010. This version of the *Procedural Manual for the Environmental Laboratory Accreditation Program* recognizes those revisions.

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Introduction

This manual explains procedures for implementing the Washington State Environmental Laboratory Accreditation Program. The program was established under provisions of RCW 43.21A.230 and satisfies the intent of RCW 43.20.020.

Chapter 173-50 WAC, *Accreditation of Environmental Laboratories*, establishes the state program for accreditation of environmental laboratories, including labs that analyze drinking water. These laws and rule provide the legal basis for the program.

This manual is provided as an aid to labs affected by the Laboratory Accreditation Program and to users of data from those labs. The manual is not intended for enforcement purposes.

All enforcement actions are based on Chapter 173-50 WAC or on rules requiring the use of accredited laboratories. Chapter 173-50 WAC does not require labs to be accredited. This requirement is in other state, federal, or regulatory agency rules. Other documents such as permits, grants, or contracts also may stipulate that analytical data come from accredited labs. Requirements for use of accredited labs are summarized in Appendix B of this manual.

The Laboratory Accreditation Program is an important component of the effort to ensure the accuracy and defensibility of analytical data used by the Washington State Department of Ecology (Ecology), the Washington State Department of Health, and other data users. The process described in this manual ensures that accredited labs have the demonstrated capability to provide accurate, defensible data for the parameters specified in their Scope of Accreditation.

The Meaning of *Accreditation*

Accreditation means:

- The lab's quality system, staff, facilities and equipment, test methods, records, and reports have been evaluated.
- The evaluation indicates the lab has the capability to provide accurate, defensible data.

Accreditation does *not* authorize use of a specific method for any specific program or project. It is the responsibility of the laboratory to ensure that methods used to analyze client samples meet the requirements of the program or project for which the data are intended.

Accreditation does *not* mean that any specific report or set of data originating in an accredited lab is accurate or defensible. To ensure data quality, data users must require

labs to provide sufficient evidence, usually in the form of results of quality control (QC) tests, with each set of data.

Contents of This Manual

This procedural manual describes the following.

For environmental laboratories

- Procedures for applying for participation in Ecology's Laboratory Accreditation Program.
- Process for developing a quality assurance (QA) program of the type expected in an accredited lab and suggestions for preparing an effective QA manual.
- Requirements for participating in PT studies.
- Preparation for and conduct of the on-site audit.
- Special provisions for gaining accreditation for drinking water analyses.

For Ecology's Lab Accreditation Unit

- Criteria for recognizing third-party accreditation.
- Criteria for granting, denying, suspending, or revoking accreditation.
- Procedures for accrediting out-of-state laboratories.
- Mechanisms for notifying laboratories and data users of accreditation actions.
- Mandatory training requirements for Drinking Water Certification Officers.

Requirements for Participating in the Laboratory Accreditation Program

Initial Accreditation

To become accredited, a lab must:

- Submit a complete application and pay the appropriate fee.
- Submit an acceptable QA manual.
- Submit documentation of initial QC procedures required by the methods.
- Successfully analyze required PT samples.
- Pass an on-site audit by Ecology or another recognized accrediting authority.

Continuing Accreditation

To retain accreditation, a participating lab must:

- Submit results of PT sample analyses.
- Make required improvements in its QA program.
- Report significant changes in facility, equipment, personnel, or QA/QC procedures.
- Submit a renewal application and pay annual fees.
- Submit to required audits and implement any required corrective actions.

How to Apply for Accreditation and Pay Fees

A lab obtains an application by contacting the Lab Accreditation Unit (see Appendix C) or from the Lab Accreditation web site: https://ecology.wa.gov/Regulations-Permits/Permits-certifications/Laboratory-Accreditation

In addition to serving as a formal request for accreditation, the application provides information on personnel, equipment, and facilities available to conduct the tests requested by the lab. All information submitted in the application is subject to verification by the Lab Accreditation Unit during the on-site audit or through other means. The accreditation fee is determined by (1) the number and complexity of the requested tests and (2) whether accreditation is through recognition of accreditation by a third party.

For a large, multi-discipline laboratory, completing an application for initial accreditation can be a daunting exercise. Labs are encouraged to submit a draft for review prior to submitting the final application with payment of fee.

For out-of-state labs that require an on-site audit for initial accreditation, the Lab Accreditation Unit will send the lab an estimate of travel costs for the on-site audit. The out-of-state lab must sign and return the estimate prior to scheduling the on-site audit. After completion of the visit, Ecology will send an invoice to the lab for the actual travel costs.

Completed applications and the associated fee should be sent to the Ecology Cashiering Unit (see Appendix C). Payment may be made by check, money order, or purchase order.

A list of parameters with associated analyte and method codes and a fee calculator are available on our web site.

Quality Assurance Manual

When a lab submits an initial application and pays the fee to the Ecology Cashiering Unit, the lab must submit their QA manual to the Lab Accreditation Unit. The detail and scope of the QA manual should be commensurate with the size and mission of the lab. For example, a multi-discipline commercial lab may have a QA manual consisting of several volumes, while a small wastewater treatment plant lab or health district water lab may have a manual of only a few pages.

Why Is a QA Manual Required and Who Uses It?

The purpose of the QA manual is to identify policies, organization, objectives, functional activities, and QA and QC activities designed to achieve quality goals desired for operation of the lab. The manual is also intended to give confidence to users of the lab's reports by indicating specific methods and procedures by which the lab achieves its quality objectives.

The QA manual documents how the lab ensures the quality of results reported by the lab. QA is important during sampling and transport of samples to the lab, while samples are being analyzed, and when data are reported. Because this is a lab accreditation program, the emphasis in reviewing the QA manual is on the analysis of samples and reporting of results, but documentation regarding sample management and data management is also addressed.

The QA manual is primarily intended for use by lab personnel to ensure reliability of results, and the manual must be readily available to analysts. Secondarily, it is used by personnel outside the lab to gain insight and confidence in the overall QA measures used by the lab.

Formatting a QA Manual

A standard format is not required for QA manuals to meet the requirements of Ecology's Laboratory Accreditation Program. The only requirement is that the manual describes adequately the QA procedures followed by the lab.

An outline of a QA manual is presented on the following pages. While it is not necessary to follow this format, all applicable items in the outline should be addressed. As previously stated, the detail provided should be commensurate with the size of the lab and scope of analyses performed. A model QA manual for a typical, small wastewater treatment plant lab is available from our web site.

The U.S. Environmental Protection Agency (EPA) has not specified a format for a QA manual, but has specified requirements and content for a QA plan. Some labs have prepared QA program plans and/or QA facility plans according to EPA guidelines. These

plans often include standard operating procedures (SOPs), each of which instructs someone how to perform a specific task. A QA plan can fulfill the requirements of a QA manual, as long as it includes information on each of the elements described below.

Suggested Outline for a QA Manual

The following is an outline for a typical QA manual.

1. Title Page and Table of Contents

These are not required for short manuals.

2. Glossary

Because some QA/QC terms are not universally accepted, a list of frequently used QA/QC terms is a necessary part of a QA manual. Appendix A is a glossary of terms as used by Ecology's Laboratory Accreditation Program. The *Model QA Manual* available from our web site also includes an abbreviated glossary.

3. Organization and Responsibilities

This section identifies (1) managers who establish QA policy, (2) analysts/technicians who implement QA policy, and (3) the QA officer/coordinator if one exists.

Large labs should include an organization chart. If organization and responsibilities are already identified in a QA facility plan or other document, they need not be replicated in the QA manual, but the supplemental document should be submitted for review.

4. Policy for QA/QC

The overall policy and philosophy of the lab with respect to objectives for data quality should be included in the QA manual. Include a description of how data quality objectives are established for samples analyzed by the lab. Address both qualitative (e.g., completeness, representativeness, defensibility, accuracy) and quantitative (numerical objectives for precision and lack of bias) objectives. Include policy for training lab personnel in QA/QC.

5. Sample Management

This section (1) describes those aspects of sampling which relate to or are the responsibility of the lab, (2) specifies procedures for requesting sample analyses (needed by users of the lab) and receipt, logging, storage, and handling of samples, (3) includes

procedures for chain-of-custody (if not in a separate SOP or appendix to the QA manual), and (4) includes criteria for acceptance or rejection of samples submitted to the lab.

For compliance monitoring under the Safe Drinking Water Act or the Clean Water Act, required containers, preservation techniques, and holding times are specified in the Federal Register or Code of Federal Regulations (CFR).

6. Methods

This section lists all analytical methods used in the lab with references to published methods. For compliance monitoring under the Safe Drinking Water or the Clean Water Act, required methods are specified in the Federal Register or CFR.

7. Calibration and Quality Control Procedures

This section includes procedures for calibration, standardization, and QC for each analytical method used in the lab. Specify the QC samples included with each batch and the use of results to document the quality of the data. Common QC samples are:

- Blanks.
- Check standards (sometimes called blank spikes, fortified blanks, or laboratory control standards).
- Duplicate samples.
- Spiked samples (sometimes called matrix spikes).
- Positive and negative controls, sterility checks, and confirmations (for microbiology procedures).

8. Control Charts

SOPs should be written to describe the construction and use of control charts, especially for routine analyses of check standards. An Excel program that facilitates preparation of control charts, including instructions on its use, is available from our web site.

9. Corrective Actions

Describe the corrective actions to be taken by the analyst when QC results do not meet criteria in the method or SOP, or when the results exceed the warning or action limits of the control chart.

10. Data Management

The QA manual must address:

- *Data recording* procedures. How are data recorded – on bench sheets, bound notebooks, directly to computer software?
- *Data reduction.* How are computations done – by analyst, supervisor, computer?
- *Data validation*. How are data checked to ensure they are valid – by peer, supervisor?
- *Data entry.* How are final data entered into the system that will generate the final report?

  For small labs, data might be copied directly to the report after validation. Most wastewater treatment plant labs would, for example, transfer data directly from log books or bench sheets to the discharge monitoring report (DMR) after being validated by a supervisor.
- *Data reporting.* How is the final report generated – by analyst, supervisor, clerical staff?

10. Audits

This section specifies procedures for, and frequency of, system audits and proficiency testing. Other types of audits, such as management systems and data quality, may also be needed for large labs. As a minimum, the audits and PT required for participation in the Laboratory Accreditation Program should be addressed in this section.

11. Reports

This section describes the requirements for, and frequency of, reports on QA/QC to management. For labs to be accredited for drinking water, they must adhere to the report retention requirements found in the EPA *Manual for the Certification of Laboratories Analyzing Drinking Water*.

QA Manual Requirements for Drinking Water Labs

Labs applying for Drinking Water accreditation must comply with the requirements in EPA's *Drinking Water Certification Manual.*

Drinking water labs are required to address sampling in their QA manuals, if lab staff are involved in sampling.

Proficiency Testing

How Many Proficiency Testing (PT) Study Results Are Required?

When submitting their application, the lab seeking accreditation must submit results of PT studies from an approved PT provider. PT studies involve analysis of blind samples; true values are not known to the lab.

A list of approved providers of PT samples is found at https://ecology.wa.gov/Regulations-Permits/Permits-certifications/Laboratory-Accreditation/Proficiency-testing-providers

Important: To receive credit for satisfactory PT results, labs must report method and analyte codes to the PT provider with each result. A list of parameters with associated analyte and method codes are available on our web site.

For initial accreditation

One recent set of satisfactory PT study results must be submitted. This must be done before the Lab Accreditation Unit will schedule the on-site assessment. The study report(s) can be sent with the application/fee to the Cashiering Unit, or they can be sent directly to the Lab Accreditation Unit to save time.

- For accreditation in the *Drinking Water* category, the PT studies must be designated by the vendors as water supply (WS) studies.
- For accreditation in the *Non-Potable Water* category, the PT studies will normally be water pollution (WP**)** studies. However, if a lab is requesting accreditation for the same parameter (analyte and method) in both drinking water and non-potable water, a result from a WS study will satisfy the PT requirement for both matrices. If a vendor does not include all analytes in a WS study that would be of interest to a lab seeking accreditation for non-potable water, the lab might need to supplement the WS study by ordering specific WP analytes.
- For accreditation in the *Solids and Chemical Materials* category, the PT samples must be solids (e.g., Soil, Underground Storage Tank, and Resource Conservation and Recovery Act /Hazardous Waste studies).
- For accreditation in the *Air and Emissions* category, the PT studies must be designated for air samples.

Accreditation for *radiochemistry* tests, regardless of matrix, requires participation in approved radiochemistry PT studies.

For continuing accreditation

The lab must participate in two PT studies for each applicable parameter each accreditation year, except for microbiology and bioassay parameters where one study per year is required. The Lab Accreditation Unit decides the availability of PTs for specific parameters. The lab must ensure required PT samples are analyzed and that the results are reported to the Lab Accreditation Unit.

For chemistry parameters, after an accredited lab submits two satisfactory PT sample results and no unsatisfactory results in an accreditation year, the laboratory is required to submit only one satisfactory PT sample result in subsequent accreditation years. This applies as long as there are no intervening unsatisfactory PT sample results.

If the lab requests updates or changes to its Scope of Accreditation between renewals, processing will include review of all PT results available at that time.

Other Allowed Proficiency Testing Studies

PT studies identified below may be used to satisfy accreditation requirements. When study results are submitted, the entire study report must be submitted and is subject to review by the Lab Accreditation Unit. This may result in accreditation decisions made concerning analytes/methods other than those for which the study report was specifically submitted.

Allowed studies include:

- Make-up studies from one of the approved PT sample providers – i.e., studies in addition to the routine WP or WS studies.
- Quarterly National Council of the Paper Industry for Air and Stream Improvement (NCASI) studies.
- DMR-QA studies for National Pollutant Discharge Elimination System (NPDES) dischargers.
- Various PT studies administered by other state laboratory accreditation programs, such as the New York State Environmental Laboratory Accreditation Program. (But check with the Lab Accreditation Unit to determine if the state program's PT samples are acceptable.)
- Other PT studies if approved by the Lab Accreditation Unit.

Labs should not wait until contacted by the Lab Accreditation Unit, or until they must apply for accreditation, to request participation in PT studies. Early participation in PT studies will avoid delays in meeting the PT requirement for the Laboratory Accreditation Program. Furthermore, participation in PT studies is a good idea, even for labs that are not participating in the Laboratory Accreditation Program.

Can water supply studies be used for accreditation of non-potable water?

For accreditation in the non-potable water category, PT samples from WP studies should be analyzed. For accreditation in the drinking water category, PT samples from WS studies must be analyzed. However, if a lab is accredited for the same parameter (analyte and method) in both drinking water and non-potable water, a result from a WS study will satisfy the PT requirement for non-potable water as well.

Questions About Proficiency Testing Studies

Can a lab analyze one sample using several methods?

Portions of the same PT sample may be analyzed by two or more methods (e.g., volatile organics by both GC and GC/MS, or trace metals by both ICP and ICP-MS). PT providers may accommodate the reporting of results by more than one method for a given parameter. Alternatively, whichever results are not reported to the PT sample providers can be reported to the Lab Accreditation Unit *before the sample supplier announces the study results.*

What if a given study does not include all parameters of interest?

If a PT study does not include one or more of the parameters for which the lab has requested or will request accreditation, the Lab Accreditation Unit may be contacted for recommendations on other sources. The lab may choose its own source for PT samples, but the Lab Accreditation Unit must approve the source.

What if a lab's parent corporation runs its own PT studies?

PT samples are acceptable only if (1) the source provides blind samples (i.e., true values are not released until the lab has completed the analyses and submitted the results), and (2) the samples are part of a study in which a statistically significant number of labs participate. Samples provided by the parent company of the lab submitting the results are not considered blind for the purposes of this program.

Must the PT study report sent to Ecology come from the PT vendor?

No. The Lab Accreditation Unit accepts copies of PT study evaluation reports from the lab. However, most PT vendors will send evaluation reports to the Lab Accreditation Unit as well as to the lab.

Should PT samples be analyzed just like routine samples?

Special procedures (i.e., procedures other than those used for routine sample analyses) must not be used when analyzing PT samples. For example, no special calibration should be done, and results should be calculated from a single analysis, not as the mean of replicate analyses. Records for PT sample analyses, including raw data, are examined during on-site audits.

How are PT study results scored?

The Lab Accreditation Unit determines whether results of PT sample analyses are satisfactory. PT sample results may be classified as follows:

1. **Acceptable or Pass.** Results rated *Acceptable* or *Pass* are satisfactory. For PT samples involving an analyte group, such as volatile halocarbons by EPA Method 601, *satisfactory* performance means at least 80% of the analytes in a given study are within acceptance limits.
2. **Not Acceptable or Fail.** Results rated *Not Acceptable* or *Fail* are not satisfactory, and the lab must investigate causes for the failure and take corrective action. For all unsatisfactory WS PT results, a corrective action report must be submitted to the Lab Accreditation Unit, and the lab must participate in the next available PT study.
3. **Check for Error.** Results rated *Check for Error* are generally considered satisfactory.
4. **Unusable.** Results rated *Unusable* are unsatisfactory.

How are accreditation decisions made based on PT results?

In considering PT results, accreditation decisions for a given parameter are based on the following:

- When current results are satisfactory, full accreditation is granted, assuming other requirements are met.
- If the most recent PT result is unsatisfactory, or only one result was reported in an accreditation year when two were required, provisional accreditation will usually be granted. Provisional status may be upgraded to full accreditation upon receipt of satisfactory PT results.

  Provisional accreditation does not prevent the lab from reporting data to a regulatory agency. However, unsatisfactory results on a subsequent study could result in suspension of accreditation.
- If the two most recent PT results for the accreditation year are unsatisfactory, accreditation will be suspended, and the lab must submit satisfactory results before accreditation can be restored. For PT samples involving an analyte group, such as volatile halocarbons by EPA Method 601, accreditation may be withheld for specific analytes if *unsatisfactory* results are obtained repeatedly for those analytes.

On-Site Audit

The final requirement in the accreditation process is the on-site audit by the Lab Accreditation Unit. Unit staff may be assisted by auditors from other programs or agencies when special expertise is required.

No on-site audit by the Lab Accreditation Unit is required when accreditation is granted through recognition of a third-party accrediting authority such as one of the National Environmental Laboratory Accreditation Program (NELAP) states or the American Association for Laboratory Accreditation (A2LA).

The Lab Accreditation Unit makes advance arrangements with the lab for the on-site audit. Routine on-site audits are scheduled for dates and times that are mutually agreeable with the lab. The lab should be prepared to receive the auditor, or audit team for large labs, at the arranged date and time. The audit team attempts to minimize disruption to the normal working routine in the lab. On-site audits of a large commercial lab may involve three (and seldom more) auditors over a period of one or two days. Assessment of a small wastewater treatment plant lab may involve only one auditor for a portion of a day.

Emphasis in the audit is on documentation and other evidence demonstrating the lab is producing accurate and defensible data. Auditors examine documents to verify that all information provided in the application and QA manual is correct. Specifically, they verify:

- Personnel training and experience status.
- Facility features.
- Sample handling procedures.
- QA/QC procedures.
- Analytical procedures.
- Data management procedures.

Normally, the analysis of PT samples is not done as part of the on-site audit. However, if analysis of PT samples has been identified as a problem prior to the on-site audit, the lab may be required to analyze a PT sample during the assessment as part of the corrective action to identify and eliminate the cause(s) of the problem.

Auditors use checklists in either printed or electronic format to document lab procedures. These checklists aid the auditor in assuring complete and uniform evaluation of the labs. Checklists may be sent to the lab before the on-site visit, with a request that the lab complete the checklists and return them to the Lab Accreditation Unit. Auditors may also request to review electronic data before the audit. If completed before the audit, checklists are reviewed by Unit staff and used as a basis for further discussion and clarification as necessary during the audit. This helps to minimize disruption of lab activities during the on-site visit and saves time for all concerned.

Typical Agenda

The agenda for a typical on-site audit is as follows:

1. The auditor(s) conduct(s) an entry briefing with the lab manager to discuss the purpose and schedule for the audit. The lab's QA officer should attend the briefing. If the lab manager chooses, additional lab personnel may attend the briefing.

2. The auditor carries out the audit accompanied by appropriate lab personnel. The lab manager or any other personnel are not expected to accompany auditor during the visit, but may if they wish. The auditor requires access to all parts of the lab and to all staff members having anything to do with the analytical procedures for which accreditation is sought.

3. The auditor reviews lab records, which should be provided as requested. Records requested may include those corresponding to:
   - Samples including PT samples (e.g., records pertaining to identification, chain-of-custody, preservation, storage, holding times, tracking).
   - Analyses (e.g., methods, calibration, calculations).
   - QC (e.g., blanks, check standards, duplicates, spikes, certified reference materials, control charts).
   - Data management (reduction, validation, reporting, entry, assessment).

   The auditor evaluates the entire process of documentation from the time the samples are received by the lab until the results are reported. Sampling procedures are evaluated only if lab personnel are responsible for sampling.

4. The auditor physically examines lab equipment and facilities to determine if they are adequate to perform the analyses requested in the application.

5. Lab personnel may be observed performing analyses. They are expected to be able to explain what they are doing and why, as well as answer other pertinent questions.

6. If time permits and the lab so requests prior to the assessment, the auditor may provide a training session on a QA/QC or analytical topic of interest to the lab. This training should be arranged with the Lab Accreditation Unit when the on-site audit is first scheduled.

7. An exit briefing is held with the lab manager and selected staff to discuss the observations and preliminary findings of the audit. Preliminary recommendations for resolution of problems are discussed as appropriate. For large labs, a tentative time for the exit briefing is scheduled during the entry briefing to allow maximum flexibility in scheduling attendance by appropriate lab personnel. The scheduled time for the exit briefing is adjusted as necessary as the audit proceeds.

8. After the audit, a formal report of the findings is sent to the lab. Problems are identified, and formal recommendations for resolution made. Actions that must be completed before accreditation can be granted are identified. If appropriate, the lab is required to report corrective actions within a reasonable period following receipt of the assessment report.

9. Under certain circumstances where the Lab Accreditation Unit has sufficient evidence of a lab's capability, accreditation may be granted before an on-site assessment is completed. (See the *Interim Accreditation s*ection of this manual.*)*

Critical Elements for Accreditation

Certain laboratory operations are critical elements for consistent generation of accurate and defensible data. These elements are the subject of intense scrutiny throughout the accreditation process. Deficiencies in critical elements can be the basis for denial, suspension, or revocation of accreditation status.

For labs to be accredited for drinking water, they must adhere to the critical elements found in the latest edition of the EPA *Manual for the Certification of Laboratories Analyzing Drinking Water*. Some of those elements have been included in this manual for the convenience of lab personnel.

Analytical Methods

An analytical method is a set of written instructions completely describing the procedure to be followed by the analyst to obtain the required analytical result. It is essential that the analytical method be available to, and used by, analysts at the bench level. The lab's capability to accurately and defensibly carry out the written method is the basis for accreditation.

Written methods may be procedures published by recognized authorities, such as EPA, the American Society for Testing and Materials (ASTM), or the organizations that publish *Standard Methods for the Examination of Water and Wastewater,* or they may be methods developed and documented by the lab.

- When the lab follows a published method exactly, the method must be present in the lab and referenced in the QA manual. If a published method is modified or augmented in any significant way, the changes must be documented, either in an SOP or in an appendix to the QA manual. The modifications can be recorded in a lab notebook if the modifications were made for analysis of a specific set of samples as opposed to being used for all analyses.

  Clean Water Act methods may be modified if the chemistry of the method or the determinative technique is not changed, but Drinking Water methods cannot be modified. A lab must apply to EPA directly for approval of an alternate test procedure to modify Drinking Water methods.

- SOPs are required for methods that have been developed in the lab or adapted from sources other than those described above, such as articles appearing in the literature.

While the Laboratory Accreditation Program does not establish requirements for the use of specific methods, auditors insist that certain methods are used when those methods are required by state or federal regulations. The Federal Register and 40 CFR Part 136 lists test procedures that are approved for monitoring effluents under the NPDES permit system. The Federal Register and 40 CFR Part 141 list test procedures approved for

monitoring under the Safe Drinking Water Act. EPA's SW-846, *Test Methods for Evaluating Solid Waste Physical/Chemical Methods*, suggests methods to be used for solids and hazardous waste. Approved Biosolids methods are listed in 40 CFR Part 503 and WAC 173-308. Accreditation for a given method does not imply that the method has been approved for use in any specific regulatory program.

A list of parameters with associated analyte and method codes are available on our web site.

Reports of analytical results must reference the method used for analyses. For standard methods, the reference must be clearly stated so that the client can find and read the method if necessary.

Modifications to standard methods must be clearly identified and explained in the report. Copies of the SOP or lab notebook detailing the modifications should be made available to the client on request. When in-house methods have been used, copies of SOPs describing these methods and any modifications documented in notebooks should be provided to the client if requested.

Equipment and Supplies

The application and on-site audit are used to determine if sufficient equipment and supplies are available and functioning properly to perform the methods specified in the application for accreditation. Presence, functionality, and maintenance of those items of equipment and supplies required by specific methods is critical to accreditation decisions. Preventive maintenance requirements must be established and documented for all lab equipment and critical facilities (such as hoods). Accredited labs must report to the Lab Accreditation Unit significant changes in equipment status (e.g., loss of a key instrument for an extended period for repair) when they occur.

Quality Assurance and Quality Control

QA and QC are basic concepts in the accreditation process. If the lab documents adequate procedures to assure the quality of reported data, and the on-site audit confirms these procedures are being implemented, there is a strong basis for accrediting the lab. Because accreditation signifies that the lab has demonstrated the ability to produce accurate and defensible data, it is essential that the lab routinely analyze QC samples.

Following are the basic types of QC tests and an explanation of how results of the tests are used by Ecology in making an accreditation decision. See the *Glossary* in Appendix A for a definition of each of the QC tests.

Blanks

A method blank should be analyzed in every batch of samples for most analyses. For some analyses (e.g., pH), there is no blank. The blank is usually considered to be a test for contamination, but it can also be used to determine that all aspects of the test have been done properly. In the total suspended solids test, for example, failure to completely dry the filter may lead to a positive blank which was not caused by contamination. Consistent failure of blank analyses can be grounds for a decision to withhold accreditation for a given test.

Check standards

A check standard should be analyzed in each batch of samples. When a check standard from a different source than the calibration standards is analyzed and the result agrees with the known value, the analytical system is "in control" and the analyst may proceed with confidence to analyze other samples.

When that check standard is analyzed repeatedly, either in a single batch, or over a period of weeks or months in several batches, the average result compared to the true value is a good indicator of data quality. The difference between the average and true value is an indication of bias**.** By calculating the standard deviation of those repeated analyses, the analyst can get an estimate of precision. Because it can give an indication of both bias and precision, the two components of accuracy, the check standard is arguably the most important QC test in an environmental laboratory.

Excessive bias and/or imprecision as indicated by the average and standard deviation of repeated analyses of a check standard can, and normally would be, grounds for a decision to withhold accreditation for a given test.

Standard reference materials (SRMs) and certified reference materials (CRMs) are useful in checking the entire analytical process including digestion of the sample.

Duplicates

Duplicates aliquots of samples (analytical duplicates) are analyzed to check the within-batch variability (precision) of the analytical system in the matrix of the samples. Analytical duplicates should be run in each batch of samples.

If duplicate samples are collected under essentially identical conditions (field duplicates), they can be used to estimate the total variability affecting the determination.

If the precision of the check standard results indicates that the analytical system is in control but the variability in the results for the analytical duplicates is too large, the sample matrix may be affecting the precision of the analysis. Because the lab has little influence over the matrix, it would be unlikely that a negative accreditation decision would be made because of the errant duplicate results in such a case.

Matrix spikes

Spiked samples should be analyzed to check for bias due to interference by the matrix. If check standard results indicate that the analytical system is in control, but the matrix spike results indicate significant bias, the matrix may be interfering with the determination. Accreditation decisions would normally not be made based on matrix spike results. This does not relieve the lab from attempting to find a process for overcoming the matrix interference (such as using a different method or different extraction technique). If a duplicate and a spiked sample are to be run in the same batch, it is best to duplicate the spiked sample if the sample does not contain quantifiable concentrations of the analyte. This would be done to assure the availability of two results as a check on precision.

Sample Management

Sample management is a key element in QA and must be documented in the QA manual. The lab is responsible for those elements of sample management over which it has direct control. The process that results in evidence that the integrity of samples has been maintained from the time of sampling until the analyses are completed must be documented in the QA manual or elsewhere. The documentation must include sample preservation and storage and complete chain-of-custody,

Data Management

Because a lab's only product is a report, and that report is generated from data that are based on observations made in the lab, it is essential that the data be managed properly. Without an effective data management program, a lab's data (and therefore its reports) are not defensible, either scientifically or legally.

The following guidelines will assist labs in ensuring the defensibility of data.

- Documentation pertaining to sample analysis must be maintained in bound logbooks, filed chronologically, or stored electronically with adequate backup. Small labs, such as those at wastewater treatment plants, may maintain bench sheets in three-ring binders. Commercial labs and drinking water labs, on the other hand, should maintain bound, paginated logbooks. Depending on the scope of the lab mission, separate files may be required for standards preparation, sample log-in, instrument-run sequence, instrument maintenance, and sample preparation.

- The following criteria apply for all lab records. Failure to comply with these criteria, because the defensibility of data is at risk, may be grounds for denial, suspension, or revocation of accreditation.

    - All logbooks must be paginated before use. This may be done by hand or with a stamping device, or by purchasing paginated logbooks.

- A permanent record of all analysts' names, initials, and signatures must be maintained. It may be maintained as a permanent file separate from logbooks or on a dedicated page in each logbook. Even after an analyst leaves the lab, the record of initial/signature must be maintained for at least as long as the lab is required by regulation to maintain data (e.g., three years for NPDES reporting).
- All entries must be dated and initialed.
- Entries must be made in indelible ink. Pencils are unacceptable because the data would not be legally defensible. (It is wise to remove all pencils from labs to discourage their use.) Felt tip and "roller-ball" pens are not advisable because entries may be obliterated by water or other solvents.
- All deletions and corrections must be crossed-out with a single line, accompanied with the date and initials of the person making the deletion or correction. No information can be written over or scratched out other than with a single line. "White-out," correction tapes, and other means of correction are not acceptable.
- All logbooks must have the dates of use clearly documented on the front of the log. When a logbook is completed, the ending date of the old log must be the starting date of the new replacement log to eliminate any gaps in the data record.
- Records of standards preparation must be maintained. All stock standard solutions, intermediate standard solutions, and working standard solutions must be documented. Requirements for the recorded information are:
  - All pertinent compound information must be recorded. This includes all compounds or elements in the solution, vendor and the vendor lot number, purity, concentration (if made from a solution), amount used, and date opened. Equations showing how calculations were made should be included. Results must be checked for accuracy by a peer who initials and dates each section checked. A supervisor or designated QA officer must check authenticity of data on a regular basis.
  - All solution information – such as the final volume, solvent, and final concentration – must be recorded. Include the brand, lot number, and grade of solvents. An expiration date for the standard must be recorded when applicable. Additional items that may be recorded are the lot number and vendor of the solvent. When the last of a stock standard is used, the date should be entered in the standards log.
  - If a standard certificate of analysis is provided by the vendor, it must be maintained as part of the standard's permanent record.
  - The date the solution (working standard) is prepared and the initials of the person preparing the standard must be recorded.
- Records of sample receipt must be maintained for all samples, including PT samples. Requirements for sample information are:
  - Pertinent sample information available to the lab must be recorded in the sample logbook. The lab must record the sampling date, type of sample

(i.e., grab or composite), matrix, and the requested analyses. A lab sample identification number must be assigned to the sample and, if applicable, recorded with the client identification number.

- The date and time of sample receipt must be recorded with the name or initials of the persons receiving and relinquishing the samples. For samples delivered by common carrier (e.g., UPS, FedEx), a copy of the bill-of-lading (shipping bill) should be maintained by the lab. If a bill-of-lading is not provided by the carrier (as it is not by UPS and other carriers who use an electronic record of delivery), the lab should ask the delivery person to sign a form stating that a given number of sample packages was delivered at a specified time.

  The temperature of the samples also must be recorded, or a record made that wet ice was still present in the cooler, to provide a defensible record that samples received were within or outside of a required temperature range. The condition of the sample containers (e.g., for commercial labs receiving samples in coolers) must be noted in the sample log.

  These requirements are absolute for labs supporting NPDES compliance monitoring. If samples which require chain-of-custody management are received from a remote location, the presence or lack of intact custody seals must be noted.

LIMS and electronic maintenance/reporting of data

The following applies to data management issues for labs using automated data processing equipment. Some of the information applies to any lab processing or storing data on a personal computer.

- In labs using a Laboratory Information Management System (LIMS), an individual should be given primary responsibility for the system. Additionally, all personnel should be adequately trained to allow each to perform his/her duties using the system.
- Equipment (hardware and software) should include a backup and recovery system to ensure data availability in the event of a system failure.
- Access to the LIMS should be limited to personnel with documented authorization, with each individual being given access only to those parts of the LIMS necessary to accomplish the mission.
- The LIMS must provide for archival of records for at least the period required by the regulatory program under which data were gathered (e.g., three years for NPDES monitoring).
- An SOP should be in place covering:
  - System security to include prevention of time travel (entering bogus dates).
  - Data entry, analysis, processing, storage, retrieval, backup, and recovery.

- Interpretation of LIMS error codes, if used, and corresponding corrective actions.
- Procedure for making authorized changes to correct errors in data entry.
- Maintenance of system hardware.
- Electronic reporting of data.

Confidential business information

During the accreditation process, Ecology staff may come into possession of information claimed by the lab to be confidential business information (CBI). That information must be protected from unauthorized disclosure. *Unauthorized disclosure*, as used here, would be any disclosure that is not directly related to the support of accreditation decisions. Title 40, CFR, Part 2, Subpart B, defines CBI as information that "is entitled to confidential treatment for reasons of business confidentiality."

Only the lab can identify CBI. When doing so, the lab must mark the document or section of a document such that there is no question concerning whether or not it is claimed to be CBI.

Recommended Practices

Some elements of lab operations affect efficiency, safety, and other administrative functions but would not normally adversely affect accuracy or defensibility of analytical data. Deficiencies in those non-critical areas are brought to the attention of lab management under the heading of recommended practices and, individually, are not the basis for denial of accreditation status.

Following is a discussion of recommended practices for labs seeking accreditation.

Personnel

The accreditation process seeks to determine if managerial, supervisory, and analytical personnel have adequate training and experience to allow satisfactory completion of analytical procedures and compilation of reliable, defensible, accurate data. Personnel requirements take into account both the size of the lab and the skill necessary to perform the tests.

A position or job description should be available for each lab employee. The job description is a detailed statement of the requirements of the position and should include the following information as a minimum:

- Title and grade.
- Organizational unit and/or location of position.
- Detailed description of position duties.
- Supervision and guidance received.

Recommended training and experience for lab personnel are addressed below. They are provided as an aid to labs in establishing criteria for hiring and training of personnel. Special personnel requirements for staff at accredited drinking water labs are given at the end of this section. Accredited labs must report significant changes in personnel status (e.g., loss of a key supervisor) to the Lab Accreditation Unit within 30 days of the changes.

Lab Director

There should be either a person in this position or a person available for consultation who meets the requirements described below. This requirement may not be necessary for small labs (e.g., a lab supporting a small wastewater treatment plant).

- Academic Training: Minimum of a bachelor's degree in chemistry or a biological science. Or, if the bachelor's degree is in a field other than chemistry or a biology science, the individual should have college-level credit hours sufficient to qualify for a minor in chemistry or biology.
- Experience: Minimum of two years experience in an environmental lab.

Supervisors

Minimum recommended requirements for supervisor positions are listed below. If the supervisor is also an instrument operator, the requirements for *Instrument Operators* (below) should also be met.

- Academic Training: Bachelor's degree in science that included the number of credit hours in chemistry or biology courses required for a major in one of those disciplines.
- Experience: Minimum of one year experience in an environmental lab.

Instrument operators

Personnel operating atomic absorption (AA) spectrometers, ion chromatographs (IC), gas chromatographs (GC), liquid chromatographs (LC), inductively coupled plasma (ICP) spectrometers, automated or robotic analyzers, or other instruments of comparable complexity should meet the following requirements:

- Academic Training: Bachelor's degree in chemistry or related field. This may not be necessary if the immediate supervisor has a bachelor's degree in chemistry or related field or if the analyst has the number of credit hours in chemistry courses required for a major in chemistry.
- Specialized Training: Satisfactory completion of a short course offered by the equipment manufacturer, a professional organization, university, or other qualified training facility.
- Experience: Minimum of six months experience in operation of the instrument (see *Trainees* below).
- Initial Qualification: After appropriate training, the analyst should demonstrate the ability to produce acceptable results in the analysis of an applicable QC or PT sample.

Other analysts

Other analysts (e.g., chemistry, biology, or microbiology technicians) should meet the following minimum requirements:

- Academic Training: High school diploma.
- Initial Qualification: After being trained in a methods training course or by a qualified analyst, the trainee should demonstrate acceptable results by analyzing applicable QC or PT samples.

Wastewater treatment plant operators

For wastewater treatment plants which do not have full-time analysts and where analyses are performed by plant operators, the operators must meet the requirements of Chapter 173-230 WAC, *Certification of Operators of Wastewater Treatment Plants*.

Drinking water lab staff

Requirements for personnel at laboratories certified for drinking water analyses are described in the current version of EPA's *Manual for the Certification of Laboratories Analyzing Drinking Water.*

Trainees

Data produced by analysts and instrument operators while in the process of obtaining training or experience are acceptable when reviewed and validated by a fully qualified analyst or the lab supervisor.

Facilities

Information provided on the application and obtained from the on-site audit is used to determine if lab facilities support efficient generation of accurate, defensible data. Lab facilities should be clean, have temperature and humidity adequately controlled in the instrument areas, and have adequate lighting at the bench top. The lab should have provisions for the proper storage and disposal of chemical wastes. Exhaust hoods with a verified airflow of 75-125 cubic feet per minute should be available for procedures that produce dangerous or offensive fumes.

For chemistry determinations, a minimum of 150 square feet of lab space and at least 15 linear feet of usable bench space per analyst is recommended. Workbench space should be convenient to sink, water, gas, vacuum, and electrical sources. Electrical sources should be free of surges and unanticipated outages. Inorganic and organic facilities should be in separate rooms. Facilities used for analysis of volatile organics should be at an overpressure relative to other lab areas. The analytical and sample storage area should be isolated from all potential sources of contamination. Standards requiring refrigeration (e.g., volatile organics) should be stored separately from samples.

For microbiology determinations, a minimum of 150 square feet of lab space and five linear feet of usable bench space per analyst is recommended. Lab facilities should include sufficient bench-top area for processing samples; storage space for media, glassware, and portable equipment; floor space for stationary equipment (e.g., incubators, water baths, refrigerators); and associated areas for cleaning glassware and sterilizing materials.

For bioassay determinations, facility requirements depend primarily on the type and number of tests to be performed. In general, space requirements are relatively large.

Safety

Generally, safety procedures are not critical elements of the on-site audit. This does not imply a lack of concern for safety but rather recognition that other regulatory agencies have primary responsibility in this area. Serious safety deficiencies observed during the on-site assessment are referred to the appropriate state or federal regulatory agencies for follow-up.

All labs should have fire extinguishers. Fume hoods should be available if dangerous fumes are likely to be present during lab operations. Safety glasses should be worn by analysts and readily available for visitors. Eye washes and overhead showers should be readily available if dangerous (e.g., caustic, acidic, otherwise corrosive) materials are used. Lab areas likely to be wet should have ground fault protection for electrical circuits. Material Safety Data Sheets (MSDS) should be readily available for all chemicals used in the lab.

Evaluation and Issuance of Certificate

Following completion of the initial on-site audit, the Lab Accreditation Unit prepares a report describing the results of the accreditation process: application, QA manual, PT, and on-site audit. The Unit maintains a copy of the report. The report lists findings and describes actions required in response, and, as appropriate, makes recommendations about resolution of problems.

- If results indicate accreditation of the lab is justified, the Lab Accreditation Unit issues a certificate authorizing the lab to submit data to Ecology, the Washington State Department of Health (DOH), or another data user, for those parameters included in the accompanying Scope of Accreditation.

- If results indicate the lab should not be accredited (see the *Denying, Suspending, or Revoking Accreditation Status* section of this manual), the lab is advised of:

    - The specific reasons for the decision and actions required of the lab to correct the deficiencies, or

    - Other specific action required as a basis for a subsequent accreditation decision.

If the accreditation is for a lab that reports drinking water data, the DOH Drinking Water Program is notified of accreditation actions.

List of Participating Labs

A list of accredited labs and a list of accredited drinking water labs are posted on the Lab Accreditation Unit web site at:
https://ecology.wa.gov/Regulations-Permits/Permits-certifications/Laboratory-Accreditation

Interim and Provisional Accreditation

Interim Accreditation

When the Lab Accreditation Unit initially is not able to complete the accreditation process for an applying lab in a timely manner, interim accreditation may be granted based on review of the application, QA manual, SOPs, and successful completion of PT studies where appropriate. The on-site audit is completed as soon as practical after which a decision on full accreditation would be made.

When the on-site audit does not include complete evaluation for a specific analyte and method (e.g., because the capability did not exist at the time of the on-site audit), the lab may be requested to submit to the Lab Accreditation Unit a technical data package for use in making an accreditation decision. Based on review of the data package and PT sample analysis results, if appropriate, a decision may be made to grant interim accreditation pending completion of the on-site audit.

The content of such data packages will vary depending on the type of data reported but generally will contain, as applicable, complete information on the following:

- **Sample preparation:** Includes sample collection dates, sample preparation dates, sample identification, sample size, matrix spike compounds and amounts used, surrogate compounds and amount used, and all data pertaining to sample cleanup.
- **Calibration:** All calibration data, including amounts and/or concentrations of external and internal standards used. The data should make clear which calibration curve or factor was used to calculate individual sample results.
- **Initial Demonstration of Performance,** a.k.a. Initial Demonstration of Laboratory Capability: Usually includes data for four replicate analysis of a mid-range standard, the mean, percent recovery, standard deviation, and relative standard deviation for each analyte. This is also referred to as Initial Precision and Recovery. The lab may also need to include a method detection limit study summary, and (for metals) a linear dynamic range study.

  The lab should consult with the appropriate Lab Accreditation Unit specialist for metals, organics, microbiology, or toxicology (bioassay) to determine what specifically is required. See our web site for contact information.
- **Sample analysis:** Method used, sample analysis dates, final volumes (dilutions, splits, or aliquots), sample raw data (chromatograms, spectra, absorbances, other instrument outputs).
- **Quality control:** Method blank data, check standard data (including checks on calibration), duplicate sample analysis data, matrix spike recovery data, and surrogate spike recovery data.

- **Reports:** Final report forms (e.g., data summary with reporting limits, blank summary, matrix spike summary, surrogate summary, and QC sample summary).

Provisional Accreditation

A lab having deficiencies indicating an analytical problem, but not a complete inability to provide reliable, accurate, and defensible data, may be given a provisional accreditation pending resolution of those deficiencies. Under some circumstances, the Lab Accreditation Unit will specify a date by which deficiencies must be corrected. Upon determining that the deficiencies have been corrected, the Lab Accreditation Unit takes action to award full accreditation. If a lab fails to correct the deficiencies within the time period allowed, accreditation may be revoked for the affected parameters. Refer to the *Denying or Revoking Accreditation Status* section of this manual.

For drinking water laboratories, specific conditions warranting provisional accreditation and specific actions required of the laboratory when provisional accreditation is granted are found in EPA's *Drinking Water Certification Manual*.

Accreditation Categories

Ecology's Laboratory Accreditation Program accredits by matrix, analyte, and analytical method.

The four matrices in which accreditation can be granted are:

1. **Drinking Water:** All analyses regulated under federal or state Safe Drinking Water Act requirements.
2. **Non-Potable Water:** All aqueous matrices other than drinking water.
3. **Solids and Chemical Materials:** Solids, semi-solids, and hazardous waste that may include aqueous materials.
4. **Air and Emissions.**

The four matrices above are those for which the NELAP accredits labs. NELAP accredits for a fifth matrix, tissue, which in Ecology's program is included in the *Solids and Chemical Materials* matrix.

For each matrix, environmental labs are accredited within broad technology categories. Not all of the following technology categories apply to each of the four matrices.

- General chemistry.
- Trace metals.
- Organics I: GC, high pressure liquid chromatography methods without a mass spectrometer.
- Organics II: mass spectrometry methods.
- Radiochemistry.
- Microbiology.
- Bioassay.
- Immunoassay.
- Physical.

Within those categories, labs are specifically accredited to analyze samples within well-defined parameters. For example, a lab may be accredited to analyze purgeable halocarbons using EPA Method 601 and phenols using EPA 604 under *Organics I,* and dioxin using EPA Method 613 under *Organics II.*

Accreditation for some methods can be requested in only one of the matrix groups. For example, all 500-series methods for organics can be requested only in *Drinking Water,* and SW-846 methods can be requested only in *Solids and Chemical Materials,* even though the lab may be using those methods exclusively for testing aqueous samples.

An important feature of Ecology's accreditation program is that a lab may be accredited for a specific parameter (analyte and method) in *Drinking Water* and not pay a second fee for that identical parameter in *Non-Potable Water*.

Requirements for Maintaining Accreditation

Accreditation is granted for a one-year period (the accreditation year) and expires one year after the effective date on the certificate. Approximately 60 days before the expiration date, accredited labs are sent information necessary to renew their accreditation. The laboratory should apply for renewal at least two weeks prior to the expiration of the current accreditation.

Renewal requires submission of an application which includes:

- Significant changes.
- Any updates to the lab's QA Manual.
- Evidence of accreditation by a third party, when appropriate.
- Payment of appropriate fees.
- Analysis of required PT samples.

On-site audits of drinking water labs are required every three years to maintain accreditation. For laboratories not accredited for drinking water parameters, the schedule of on-site audits will be determined in part by the workload in the Lab Accreditation Unit. We will attempt to conduct on-site audits every three to four years. In some cases, we may decide to review documentation of lab practices and capabilities in lieu of an on-site visit.

The purpose of these audits is to determine if the lab's capability has been adequately maintained and to evaluate any capabilities added since the last audit. These audits usually involve a more focused evaluation of selected analytical capabilities, based on review of the lab's performance since the last audit.

Denying, Suspending, or Revoking Accreditation

Denying Accreditation

A lab may be denied accreditation (WAC 173-50-140) if any of the following apply to the lab:

- Fails to comply with standards for critical elements of the on-site audit.
- Misrepresents itself to the department (Ecology).
- Fails to disclose pertinent information in the application.
- Falsifies reports of analysis including PT results.
- Engages in unethical or fraudulent practices concerning generation of analytical data.
- Is deficient in its ability to provide accurate and defensible analytical data.
- Fails to render applicable fees.

Additionally, accreditation may be denied for specific parameters based on unsatisfactory PT results. For some tests, a parameter includes an analyte group rather than a single analyte (e.g., volatile halocarbons by EPA Method 601). For these parameters, failure to achieve satisfactory results for 80% of the individual compounds constitutes an unsatisfactory result for that parameter.

Suspending or Revoking Accreditation

Accreditation status may be suspended or revoked (WAC 173-50-150) if any of the following apply to the lab:

- Fails to comply with standards for critical elements of an on-site audit.
- Violates a state rule relative to the analytical procedures for which it is accredited.
- Misrepresents itself to the department (Ecology).
- Falsifies reports of analysis including PT results.
- Engages in unethical or fraudulent practices concerning generation of analytical data.
- Is deficient in its ability to provide accurate and defensible analytical data.
- Refuses to permit entry to the lab for enforcement purposes.
- Fails to render applicable fees.
- Fails to maintain third-party accreditation.
- Reports two consecutive unsatisfactory PT sample results.

Revocation of accreditation is the withdrawal of a previously granted accreditation. Revocation may involve the entire laboratory or one or more individual parameters. Revocation is a permanent status requiring the lab to apply, pay a fee, and go through pertinent steps of the accreditation process including, if necessary, an on-site audit.

Suspension is a temporary withdrawal of accreditation for a specific period during which the lab takes corrective action directed toward regaining accreditation. If successful corrective action cannot be taken within the suspension period, accreditation for the applicable parameter(s) may be revoked.

Recognition of Accreditation by Third Party

Ecology may recognize accreditation by another accrediting authority of an environmental laboratory located in Washington or out-of-state.

Examples of third parties which have been recognized by Ecology's Laboratory Accreditation Program are (1) NELAP-accrediting authorities in other states and (2) A2LA.

Labs considering applying for recognition of accreditation by a third party should contact Ecology's Lab Accreditation Unit before submitting an application to ascertain whether the third party is or could be recognized by Ecology.

Labs applying for recognition of a third party's accreditation must provide copies of the following to the Lab Accreditation Unit:

- The Certificate and Scope of Accreditation issued by the third-party accrediting authority.
- The accrediting agency's most recent on-site audit report.
- The lab's corrective action report associated with that audit.
- Recent, satisfactory PT sample results.
- The lab's QA manual.

Results of PT studies are the primary means of monitoring lab performance on a continuing basis. To maintain third-party accreditation, labs must meet Washington's PT requirements regardless of the third-party accrediting authority's requirements.

Laboratories granted third-party accreditation must notify the Lab Accreditation Unit immediately of changes in the status of their third-party accreditation.

Washington laboratories accredited, or applying for accreditation, in recognition of a third-party accreditation must notify the Lab Accreditation Unit of on-site audits scheduled by that third party and allow a representative of the Lab Accreditation Unit to observe those audits.

Appeals

Managers of environmental labs may appeal final accreditation actions (awards, denials, suspensions, revocations) within 30 days of notification of that final action, in accordance with Chapter 43.21B RCW. The Water Pollution Control Board hears and makes decisions on such appeals. If an appeal does not result in action favorable to the laboratory, a laboratory having had its accreditation denied or revoked may reapply for accreditation to include payment of appropriate fees. A lab should reapply only after correcting any deficiencies.

Enforcement

For the purpose of conducting on-site audits or inspections to ensure compliance with the accreditation requirements, Ecology staff may enter business premises in which analytical data pertaining to accreditation are generated or stored. Ecology would take this action only during the lab's regular business hours.

Refusal to permit entry for such purposes may result in denial or revocation of accreditation.

Organizations or persons who submit analytical data originating from a lab that is not accredited for the procedures used to generate that data may be subject to penalty under provisions of Ecology or DOH regulations, permits, contractual agreements, or other regulatory instruments which require use of an accredited lab.

Ecology Assistance to Labs

Laboratories scheduled to undergo an on-site audit may request that Ecology conduct a training session for lab staff in conjunction with that audit. Accredited laboratories may also request on-site assistance at times other than the on-site audit. Whether requested as part of the on-site audit or otherwise, Ecology will provide such assistance to the extent allowed by staff resources available at the time.

Special Requirements for Drinking Water Certification Officers

Lab Accreditation Unit staff acting as auditors of drinking water labs must attend EPA's *Drinking Water Certification Officer* training course. Refresher training is required every five years. Additionally, auditors must maintain proficiency in major technologies for which they assess labs by actually performing analyses with those technologies each year.

The Unit will furnish an annual report to EPA Region 10 covering actions completed regarding drinking water labs in the past year, as well as actions planned for the coming year.

Selected Unit staff acting as drinking water lab auditors will attend an annual meeting of certification officers (auditors) sponsored by EPA.

Appendices

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Appendix A. Glossary and Acronyms

Glossary

Accreditation year: The one-year period as stated on the certificate of accreditation.

Accuracy: The difference between a measured value and the true value. Accuracy is affected by both random error (imprecision) and systematic error (bias). (See *Bias* and *Precision.)*

Action Limit: The limit on a control chart, which, if exceeded, requires corrective action to be taken. Action limits are usually placed at ±3 standard deviations from the expected or mean value.

Analyte: The constituent or property of a sample to be measured.

Analytical Data: The qualitative or quantitative results from a chemical, physical, microbiological, toxicological, radiochemical, or other scientific determination.

Analytical Response: The output of a measurement system in response to a sample (e.g., spectrophotometric measurement of the absorbance of a solution). The magnitude of the response is related to the quantity of the analyte in the sample by calibration of the measurement system.

Analytical Result: A numerical estimate of the quantity of an analyte in a sample, obtained by carrying out the procedure specified in the analytical method once (unless the method calls for the result to be the average of two or more responses). The result also can be thought of as the final value reported to the user.

Analytical System: A combination of the analyst, analytical method, equipment, reagents, standards, laboratory facilities, and other components involved in carrying out an analytical procedure.

Auditor: A person who evaluates laboratories for the purpose of accreditation.

Bachelor's Degree: A college degree certifying satisfactory completion of a curriculum including an equivalent of 30 semester hours in a specific discipline. "Equivalent" is at least four years of experience in a specific scientific discipline.

Batch: A set of samples analyzed together without interruption. Results are usually calculated from the same calibration curve or factor.

Bias: The difference between the population mean and the true value. Bias usually describes a systematic difference reproducible over time, and is characteristic of both the measurement system, and the analyte(s) being measured. (See *Systematic Errors.)*

Blank: A synthetic sample, free of the analyte(s) of interest. For example, in water analysis, pure water is used for the blank. In chemical analysis, a blank is used to estimate the analytical response to all factors other than the analyte in the sample. *Field blanks* are used to obtain information on contamination introduced during sample collection, transport, or storage. *Method blanks* are used to reveal contamination introduced by laboratory.

Calibration Standard: Solution of a known analyte concentration, used in the calibration procedure to determine the relationship between concentration and analytical response.

Certification Officer: An EPA term synonymous with "Auditor."

Certified Reference Material (CRM): A Standard Reference Material from the National Institute of Science and Technology (NIST).

Check Standard: A solution of known concentration used to indicate bias and the precision of an analytical system. When used in conjunction with a control chart, it becomes a *control standard*. Check standards are prepared from different sources than standards used for calibration.

Control Chart: A graphical presentation of QC results indicating whether the measurement system remains in statistical control. (See *Control Limits.*)

Control Limits: Statistical warning and action limits calculated for control charts, used to make decisions on acceptability of QC results. *Warning limits* are usually established at two standard deviations above and below the mean of repeated analyses of a standard. *Action limits* are established at three standard deviations.

Department: The Washington State Department of Ecology unless another agency is indicated.

Drinking Water Certification Manual: EPA's *Manual for the Certification of Laboratories Analyzing Drinking Water.*

Ecology Accrediting Authority: The supervisor of the Lab Accreditation Unit in the Washington State Department of Ecology.

Environmental Laboratory: A facility in a specific geographic location, owned or managed by a single entity where scientific determinations are performed on samples taken from the environment, including drinking water samples.

Holding Time: The allowed time from when a sample was taken or extracted until it must be analyzed. For composited samples, the holding time starts when the last composite aliquot is collected.

Initial Demonstration of Capability: Demonstration by a lab or an analyst of the ability to meet acceptable precision and bias objectives, and meet desired method detection limits.

Lab Accreditation Unit: The unit in the Environmental Assessment Program of the Washington State Department of Ecology that administers the Washington State Environmental Laboratory Accreditation Program.

Laboratory: (See *Environmental Laboratory.)*

Matrix: The substance from which a sample is collected, such as groundwater, ambient water, wastewater, air, solid, semisolid (such as tissue), or chemical compounds (such as oil).

Method: A formalized group of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, data analysis), systematically presented in the order in which they are to be executed.

On-site Audit: An on-site inspection of laboratory capabilities, usually conducted by an outside agency.

Parameter: The combination of one or more analytes determined by a specific analytical method. Examples of parameters include:

- The analyte alkalinity by method SM 2320 B.
- The analyte zinc by method EPA 200.7.
- The set of analytes called volatile organic compounds (VOCs) by method EPA 8260.
- The analyte Total Coli/Ecoli-count by method SM 9222 B/9221 F.

Precision: A measure of the variability in the results of replicate measurements caused by random error. Also referred to as *imprecision*. Precision is usually measured as standard deviation, relative standard deviation (RSD), or relative percent difference (RPD).

Quality Assurance (QA): A set of activities designed to establish and document the reliability and usability of measurement data.

QA Manual: A QA manual documents policies, organization, objectives, and specific QC and QA activities. Volume and scope of QA manuals vary with complexity of the laboratory mission.

Quality Control (QC): The routine application of statistically based procedures to assess the accuracy of measurement data.

Random Error: Variability in the results of replicate measurements. Random error is so named because the size and magnitude of the difference between replicate results vary at random and not in any systematic way.

Reference Material: A material or substance usually taken from a natural source (such as a sediment), one or more properties of which are sufficiently well established to be used as a check standard. Often called standard reference materials or certified reference materials when produced by NIST.

Relative Percent Difference (RPD): The difference between results of duplicate analyses divided by the mean and expressed as a percentage.

Relative Standard Deviation (RSD): The standard deviation of repeated measurement results divided by the mean expressed as a percentage.

Spike: A known amount of analyte added to a sample to reveal bias due to interference present in the sample. The magnitude of bias is estimated as percent recovery. If the spike is added to an environmental sample, the sample is called a *matrix spike*.

Standard: A solution of known and documented concentration, either a check or control standard, or a calibration standard that is used to prepare a calibration curve.

Standard Deviation: A statistic that describes the random variability in results of repeated measurements.

Standard Operating Procedure (SOP): A detailed written description of a procedure designed to systematize performance of the procedure.

Surrogate Standard: A type of spike added to each sample for certain types of analyses (e.g., trace organics), in a known amount, and at the start of the analytical process. A surrogate compound is similar to one or more of the target analytes in the method but is not expected to be present in environmental samples.

Systematic Errors: Errors that cause measurement results to be consistently greater or smaller than the true value. Usually bias can be considered to be equivalent to systematic error.

Target Compound (or Analyte): A compound or element which can be measured by the method selected for analysis.

Third-Party Accreditation: Recognition by the Washington State Department of Ecology of accreditation granted by another accrediting authority.

Warning Limit: A type of control limit specified by a value on a control chart, usually ±2 standard deviations from the mean. When a measurement result falls outside the warning limits, there is a high probability that the analytical system is out of control and the analyst should investigate the reason for the errant result.

Acronyms

A2LA	American Association for Laboratory Accreditation
CFR	Code of Federal Regulations
DMR	Discharge Monitoring Report
DOH	Washington State Department of Health
Ecology	Washington State Department of Ecology
EPA	U.S. Environmental Protection Agency
GC/MS	Gas Chromatography - Mass Spectrometry
ICP/MS	Inductively Coupled Plasma/Mass Spectrometry
NELAP	National Environmental Laboratory Accreditation Program
NIST	National Institute of Science and Technology
NPDES	National Pollutant Discharge Elimination System
QA	Quality Assurance
QC	Quality Control
RCW	Revised Code of Washington
SOP	Standard Operating Procedure
WAC	Washington Administrative Code
WP	Water Pollution
WS	Water Supply

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Appendix B. Summary of Requirements to Use Accredited Laboratories

Requirements for use of accredited labs are found in several documents. The oldest is Ecology Executive Policy 1-22 which requires use of accredited labs for all water matrix analyses other than those submitted in accordance with a wastewater discharge permit.

Ecology Executive Policy 1-22

After July 1, 1990, Ecology managers responsible for ordering lab services through regulations, permits (other than wastewater discharge permits), or contractual agreements will ensure that water quality analyses are performed by laboratories accredited by Ecology's Lab Accreditation Unit. Applicable water quality data include results of analyses of sediment, dredging, and sludge; point source and nonpoint source pollution samples; and surface, marine, and ground waters. Applicable analyses include chemical, physical, biological, microbiological, radiological, or other scientific determinations which provide recorded qualitative and/or quantitative results.

Wastewater Discharge Permit Programs

WAC 173-220-210 (NPDES Permit Program) requires use of accredited labs for all major NPDES permittees after July 1, 1992. That WAC, WAC 173-216-125 (State Discharge Permit Program), and WAC 173-226-090 require all other permitted dischargers to use accredited labs after July 1, 1994.

All monitoring data submitted to Ecology must come from accredited labs, with specific exceptions. Tests which need not be conducted by an accredited lab are:

- Those done for process control only.
- Flow, temperature, and settleable solids.
- Conductivity and pH, if a lab operated by a discharger is not required to be accredited for any other test.

Model Toxics Cleanup Program

WAC 173-340-830(2)(a) states that "all hazardous substance analyses shall be conducted by a laboratory accredited under Chapter 173-50 WAC, unless otherwise approved by the department." ("The department" refers to Ecology.) This requirement includes accreditation for the Northwest Total Petroleum Hydrocarbon methods commonly referred to as:

- NWTPH-Gx Gas-range organics
- NWTPH-Dx Diesel-range organics
- NWTPH-EPH Extractable petroleum hydrocarbons
- NWTPH-VPH Volatile petroleum hydrocarbons

Stormwater Permits

All monitoring data, except for flow, temperature, pH, total residual chlorine, and other exceptions approved by Ecology, must come from an accredited lab.

Puget Sound Estuary Program (PSEP)

In observation of Ecology's Executive Policy 1-22, PSEP advised all labs supporting Puget Sound Dredge Disposal Analysis projects, via a June 28, 1991 letter, that they would need to be accredited when using methods listed in Appendix D of the PSEP Protocols or in SW-846.

Washington State Department of Health (DOH) Drinking Water Program

DOH requires that labs analyzing drinking water samples be accredited according to the requirements of the federal Safe Drinking Water Act. In November 2002, Ecology assumed the mission of accrediting drinking water labs under a Memorandum of Agreement with DOH.

DOH Clandestine Drug Lab Program

DOH requires that labs analyzing methamphetamine be accredited for the specific compound. There are special requirements that must be met for accreditation. Labs considering applying for methamphetamine accreditation should consult with the Lab Accreditation Unit early in the process.

Appendix C. Contacts at the Washington State Department of Ecology

Lab Accreditation Unit

Phone: (360) 871-8840

Web Site: https://ecology.wa.gov/Regulations-Permits/Permits-Certifications/Laboratory-Accreditation

Staff: https://ecology.wa.gov/Regulations-Permits/Permits-certifications/Laboratory-Accreditation/Lab-accreditation-contacts

Staff Email: firstname.lastname@ecy.wa.gov

Fax: (360) 871-8849

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