



DEPARTMENT OF
ECOLOGY
State of Washington

Rule Implementation Plan
Chapter 173-50 WAC, Accreditation of Environmental
Laboratories

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Implementation Plan
Chapter 173-50 WAC
Accreditation of Environmental Laboratories

Environmental Assessment Program
Washington State Department of Ecology
Olympia, Washington

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Purpose

The Washington State Department of Ecology (Ecology) provides the information in this implementation plan to meet agency and Administrative Procedure Act (RCW 34.05.328) requirements related to rule adoptions.

Introduction

On September 1, 2023, Ecology adopted amendments to Chapter 173-50 WAC Accreditation of Environmental Laboratories (AO # 22-07). The purpose of this rule implementation plan is to inform those who must comply with 173-50 about how Ecology intends to:

- Implement and enforce the rule.
- Inform and educate persons affected by the rule.
- Promote and assist voluntary compliance for the rule.
- Evaluate the rule.
- Train and inform Ecology staff about the amended rule.

Also included in this plan is information about:

- Supporting documents that may need to be written or revised because of the amended rule.
- Other resources where more information about the rule is available.
- Contact information for Ecology employees who can answer questions about the rule implementation.

Implementation and Enforcement

Chapter 173-050 WAC Accreditation of Environmental Laboratories establishes standards and fees for Ecology's Laboratory Accreditation Unit (LAU) to provide accreditation to laboratories that wish to report data to Ecology and the Department of Health (DOH).

The adopted rule amendments will be implemented to achieve the following goals:

- Amend wording in existing sections, add new sections to increase clarity, and incorporate existing best practices, quality control, and rules for participation in the lab accreditation program, including:
 - Updates and clarifications to definitions
 - Require laboratories to submit Standard Operating Procedures (SOPs)
 - Update and clarify quality control requirements
 - Add data management and record traceability requirements
 - Require additional proficiency testing (PT) sample per parameter per year for microbiology parameters
 - Clarify procedural requirements for PT
 - Clarify and update audit procedures and frequency
 - Clarify requirements for accreditation of drinking water laboratories
 - Clarify that laboratories must notify Ecology at least 30 days before a permanent laboratory move
 - Update reasons for suspension of accreditation to include: violation of federal law
- Amend the fee structure to meet current implementation costs and address future cost increases.
- Clarification of existing rule language and updating references.

On the effective date of the rule:

The implementation of the updated laboratory standards will begin upon the effective date of the rule, October 2, 2023. Laboratories are expected to identify areas where they may not meet the updated regulations and begin internal processes to gain compliance. LAU will update necessary documentation and provide technical support to the regulatory community to aid compliance. Laboratory audits that occur after the effective date will administer the updated rule.

Initially, the LAU works collaboratively with the laboratory to explain the nature of the non-compliance and provides guidance and technical support as needed. When laboratories are unable to gain compliance or decline to comply, their accreditation can be denied, suspended, or revoked, depending on the circumstances and nature of the deficiencies. The enforcement

process begins with the LAU issuing a notice of correction to the laboratory. This notice outlines the steps that must be taken in the next 30 days. If the laboratory remains unresponsive after 30 days from issuance of the notice, then Ecology may issue a formal suspension or revocation order.

Future steps

The fee section of the rule contains yearly increases designed to make sure the fees collected are sufficient to fund LAU in the future. These increases occur yearly on the same date starting July 1, 2024. The first two steps, on July 1, 2024, and 2025, are designed to provide LAU with sufficient resources to meet the existing needs of environmental and drinking water laboratories that make up the regulated community without a sudden and drastic economic shock. Starting July 1, 2026, the fees increase annually by the State's Fiscal Growth Factor (FGF), so the unit remains self-sustainable into the future. Fees invoiced are calculated using the Table or equation that is in effect on the date an accreditation action is effective.

After the updated fees are calculated, and no later than March 31 of the preceding year, the updated fees will be posted on LAU's website. Laboratories will be notified directly in their annual renewal notices, which are emailed to the laboratories 6 weeks prior to scope expiration. Additionally, the laboratory accreditation renewal portal has a fee calculation tool, which laboratories can use to calculate their fees.

Informing and Educating Persons Affected by the Rule

Throughout the rulemaking process, the rulemaking team communicated with the regulated laboratories, interested stakeholders, and the public through emails, phone calls, meetings, comment periods, news releases, and public hearings to inform them about the rule development and to capture input.

Staff will send notices of rule adoption immediately to entities subject to the rule after the rule is adopted: environmental and drinking water laboratories, Tribes, interested stakeholders, federal and state agencies, Ecology's mailing list of interested parties, and members of the public who provided contact information with their comments for the rule.

Additionally, the Environmental Assessment Program will use a combination of outreach materials and direct communication to educate persons affected by the rule, including:

- Updates to Ecology's website to notify users of the rule adoption and to direct them to published supporting documents and contact information.
- Inform and educate the regulated community and the public as we interact with them through the regular course of business.
- Respond to questions from the regulated community regarding the amended rule.

Promoting and Assisting Voluntary Compliance

This regulated community primarily consists of drinking water and environmental laboratories voluntarily choosing to become accredited. While working with the laboratories, LAU staff promote voluntary compliance. The staff uses detailed technical and audit reports to provide clear and specific next steps when a laboratory is not in compliance.

LAU staff also summarize key information in cover letters of accreditation documents that contain helpful guidance. LAU staff will provide training opportunities and technical assistance to help regulated entities and others to understand the changes in the amended rules and to clarify expectations for the new requirements. Staff will also answer questions and direct people to useful information and resources on our webpages during routine audits and technical support sessions.

Resources we have for regulated laboratories that promote and assist voluntary compliance (most are available on our website) include:

- *Procedural Manual for the Environmental Laboratory Accreditation Program*, Publication number 10-03-048
- *Model of a Quality Assurance Manual for a Small Wastewater Treatment Plant Laboratory*, Publication number 16-03-025
- *Writing Standard Operating Procedures, A Guide for Small Waste Water Treatment Plant Operators*, Publication Number 23-3-203
- Lab Action Sheet #1 *Prepare for the Next Renewal*

Evaluating the Rule

Ecology will evaluate areas directly affected by the updated rules: the updated accreditation standards and the revised fees.

Updated Accreditation Standards

The updated accreditation standards add new requirements and clarify existing requirements that laboratories need to meet to gain and maintain accreditation. We made these changes to improve the quality of data generated by laboratories in the regulated community. Improved data quality helps regulated facilities comply with other state and federal requirements, such as wastewater discharge permits, Safe Drinking Water Act, and Model Toxics Control Act.

It will be difficult to quantify the improved data quality since the accreditation staff is not the end user of data generated by accredited labs. However, we expect a reduction in the number and severity of concerns raised by these data users, both within other programs in the Department of Ecology and the Department of Health. As the accreditation requirements are implemented over the coming months and years, we expect the number of denied and provisional parameters to decline.

Revised Fees

In contrast to the updated accreditation standards, the efficacy of the revised fees will be much easier to quantify. The primary goal of the fee revision was to fully staff the accreditation unit to provide more-timely customer service and eliminate the audit backlog.

Over the coming years, we expect to see fewer concerns expressed by laboratories regarding the timeliness of accreditation actions and informal technical assistance. Laboratories have often leveled concerns that the accreditation staff's inability to respond quickly to their needs hurts their operations. With more accreditation staff available, we expect to see fewer delayed accreditation decisions.

Many labs have also requested technical assistance to help them comply with the current regulations. This assistance is difficult to provide due to the lack of available accreditation staff. With the improved timeliness and availability of technical assistance, we expect to see fewer audit findings and denied or provisional parameters.

Over the past several years, the accreditation staff have not had the availability to provide routine audits to many of the accredited laboratories. This is primarily because the fees were no longer sufficient to staff an accreditation unit capable of auditing all directly accredited labs on a routine basis.

Routine laboratory audits provide laboratories with formal technical assistance while ensuring compliance. This assistance is necessary to keep them in compliance as regulations or published methods change. When laboratories do not have this routine interaction with the accreditation staff, smaller technical issues can compound over time. Eventually, they become critical issues

that can lead to the loss of accreditation. With increased staff available to conduct more routine audits, we would expect to see a significant reduction in critical situations.

Our goal is to maintain adequate staff for the accreditation unit well into the future by using the fiscal growth factor in the fee structure. This will benefit the regulated laboratories and other regulators within the Department of Ecology and the Department of Health.

Training and Informing Ecology Staff

The Laboratory Accreditation Unit staff (LAU) are responsible for implementing and enforcing this rule. The LAU already works directly with the regulated community, including drinking water and environmental laboratories. LAU staff are responsible for assisting the laboratories in complying with the updated rule. The LAU will hold meetings and work-study sessions to become fully versed in the contents of the updated rule. The next steps will be to update the procedural manual and laboratory audit checklists. Auditors within the LAU perform laboratory audits and provide technical assistance, providing an opportunity to educate the regulated community on the rule.

Other units and programs within Ecology also work with the regulated community. However, they do not have a direct role in implementing this rule. The LAU will be an active resource to any other Ecology staff working with the regulated community to address any questions about laboratory accreditation.

List of Supporting Documents that May Need to be Written or Revised

The following supporting materials or systems may need to be updated because of the amended rules:

- Procedural Manual for the Environmental Laboratory Accreditation Program (Publication No. 10-03-048).
- Model of a Quality Assurance Manual for a Small Wastewater Treatment Plant Laboratory (Publication No. 16-03-025).
- Writing Standard Operating Procedures: A Guide for Small Waste Water Treatment Plant Operators (Publication No. 23-03-203).
- Technical Guidance for Laboratories Accredited for EPA Method 200.7 (Publication No. 16-03-028).
- Biochemical Oxygen Demand (BOD) and Carbonaceous BOD (CBOD) in Water and Wastewater (Publication No. 98-307).
- Audit checklists. When laboratories are audited, auditors utilize checklists to assist in audits and as record-keeping documents. These checklists may be available to audited laboratories upon request.
- Application for Environmental Laboratory Accreditation. (ECY 070-04) Laboratories new to the Washington laboratory accreditation program use this form to apply for initial accreditation.
- Laboratory Accreditation Renewal portal: <http://ecyapeap/labaccreditationrenewal/>. Laboratories use this online application to apply for their annual accreditation renewal and create invoices for laboratory accreditation work.
- eHub system. The accounting system is used to manage payments and track balances for accreditation fees.
- EcoEPay system. Laboratories use this website to pay their accreditation fees via electronic check or credit card.
- Website for the Laboratory Accreditation Unit: <https://ecology.wa.gov/Regulations-Permits/Permits-certifications/Laboratory-Accreditation>. This website provides a wide variety of accreditation information to laboratories of all sizes and types.

Other supporting materials and guidance documents may need to be developed as we receive feedback from program staff and the Regulated community on their needs.

No documents have been determined as obsolete due to the amended rules.

Other supporting materials and guidance documents may become obsolete as we receive feedback from program staff and the Regulated community on their needs.

More Information

For more information, please see the following Ecology Webpages:

- Website for the Laboratory Accreditation Unit: <https://ecology.wa.gov/Regulations-Permits/Permits-certifications/Laboratory-Accreditation>
- Chapter 173-50 rulemaking page: <https://ecology.wa.gov/Regulations-Permits/Laws-rules-rulemaking/Rulemaking/WAC-173-50>

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