

Environmental Laboratory Accreditation Rule

Chapter 173-50 WAC Stakeholder Meetings Summary

Overview of rulemaking process

Ecology proposes to update Chapter 173-50 WAC, Accreditation of Environmental Laboratories. This rulemaking will update sections -040, -060, -070, -080, -130, and -190. We also propose to add new sections that are tentatively numbered -061, and -069. The Code Revisor may change these when the rule is filed.

Ecology proposes to update the rule, including the fee structure, to:

- Modify WAC language to improve clarity of laboratory accreditation requirements.
- Improve turnaround on accreditation decisions.
- Return to a triennial audit schedule.
- Improve capacity for technical assistance.
- Achieve full cost-recovery for the work of the Laboratory Accreditation Unit.

Ecology began this rulemaking process in 2022 and plans to complete it in 2024. The proposed dates for the rulemaking process are:

- Rulemaking announced – 10/10/2022
- Rulemaking proposal – 3/27/2023
- Public comment period – 3/28/2023-5/26/2023
- Public hearing – TBD
- Adoption – 8/21/2023
- Effective date – 1/1/2024

Stakeholder questions and feedback

Proposed rule-change clarification

Q: Would there be new data traceability rules?

A: Data traceability is an important part of our program. We are proposing to update the rule with language that defines data traceability and clarifies our expectations to help guide laboratories.

Q: In the strategies section of your presentation, you discussed quality-control practices, to make them comparable across labs. Please elaborate.

A: The new Quality Control Practices section is designed to help clarify quality control (QA/QC) requirements for accreditation. Some of the methods that we accredit do not clearly define QA/QC requirements, and we want to make it clear to labs what quality-control practices our auditors expect.

Q: I notice you have calibration requirements in your draft rule language. How will those effect [Federally mandated methods] SW-846?

A: While there is some flexibility built into the SW-846 program, basic QA/QC is still required. Calibrations and associated verifications need to be carefully implemented and checked to be accurate and sustainable.

Q: As per your Proposed Language at Chapter 173-50-130 WAC, regarding notification of a laboratory change, how should laboratories address sudden, temporary, or emergency laboratory moves?

A: In case of sudden moves, contact your auditor. The LAU will address laboratory moves on a case-by-case basis.

Remote Audits

Q: Will the new rule identify the elements of the triannual audit? Will these be on-site, or will there be provisions for an alternative audit, depending on the performance of the laboratory from their last audit?

A: The WAC will remain very high level in this regard. Currently, the WAC identifies some specific elements that will be present in all audits; however, each laboratory and audit presents its own unique challenges. We will continue to use virtual audits whenever they are appropriate. However, the WAC will not specify as to when an on-site or a virtual audit will be conducted. Drinking water audits and audits for new laboratories will be onsite. In other situations, we will determine whether virtual audits are a good fit on a case-by-case basis.

Q: Will there be more remote audits?

A: We will continue to use virtual audits whenever they are appropriate. However, there are cases where they are not an option.

Q: Will you continue to delay audits at your discretion?

A: We do our best not to delay audits. Although our goal is to provide timely audits, unfortunately we do not have the staff available to always maintain the audit schedule. We currently have five auditors and over 400 laboratories, so the workload is very challenging. The fee structure we are proposing should eliminate that circumstance by funding more auditors.

Q: How long is the current wait for drinking water laboratories seeking initial accreditation?

A: The time to process an initial application has been quite lengthy, due to the workload of the unit. Since there are a lot of variables specific to each accreditation request that can affect the turn-around time on an initial application, it is difficult to provide an estimate at this time. This can include the number of parameters requested, the types of parameters requested, and the supplemental documents submitted, or not submitted, with the application.

Q: Will there be separate or different guidelines for wastewater labs / small labs?

A: Accreditation guidelines are dependent upon the parameters requested, not the size of the laboratory.

Q: Have you considered using outside auditing organizations such as a class or A2LA for drinking water accreditation?

A: We are currently utilizing a third-party contractor to help us with our Drinking Water audit backlog. However, we do not intend on making this a long-term practice. There is value in the way the state accreditation program set up, with our own auditors having specific expertise.

Q: Is there any discussion of joining The NELAC Institute (TNI)?

A: Not at this time.

Q: Can you please distinguish between parameter, method, and category?

A: A parameter is a specific analyte, analyzed by a specific method, in a specific matrix. In the fee structure, categories are test groupings. For bioassay parameters, this is interpreted as a specific species, by a specific method, in a specific matrix.

These test groups are organized according to technology used and the type of analyte. For the Organic Chemistry and Trace Metals categories, we propose to charge a fee per method.

Q: Who audits Ecology's LAU or holds its auditors accountable?

A: The Department of Ecology Laboratory Accreditation Unit is assessed annually by EPA. That assessment includes certification of policies and procedures, records, and our responses to a detailed questionnaire. We are required to respond to any findings from that assessment. The assessments by EPA also include auditor interviews and shadowing during a laboratory audit.

Q: Is there a place to find current audit requirements or is that all individual per lab?

A: The [Procedure Manual for the Environmental Laboratory Accreditation Program](#) includes a detailed description of the audit process. Also, the rule contains requirements applicable to all audits. Of course, guidelines vary, depending on parameters.

Q: Will you be updating the [Procedure Manual](#) with the WAC? Can comments be submitted for the procedure manual?

A: The Procedure Manual will be updated once the rule is complete., as the last edition was revised with the last rulemaking in 2010. If you have questions regarding the procedural manual, please reach out to LAU Manager Rebecca Wood at Rebecca.Wood@ecy.wa.gov.

Q: Can the LAU change the way that they accredit labs for the SW-846 methods? Currently, all SW-846 methods are listed under the Solids and Chemical Materials matrix group. If a lab is accredited for an SW-846 method, such as 6020B, for both solids and for aqueous samples, the parameters and method 6020B should be listed under the Non-Potable water matrix group, in addition to Solids and Chemical Materials. The current practice of indicating accreditation for

SW-846 methods for a specific matrix is to add a footnote to the Scope of Accreditation certificate.

So, if the liquid piece is in the footnote, is there an additional charge? Those footnotes do not exist in the tables available on the LAUs Lab Search website, so customers and regulators can't determine the accreditation status for a particular matrix without getting a copy of the scope itself.

A: Our proposed rule does not include any changes for the way we list accreditations for SW-846 methods. Scope footnotes are for technical purposes only.

Q: Will you be adding an aquatic toxicologist to your auditing team?

A: Yes, we plan to refill our open toxicologist position.

Fees

Q: Any thoughts on how changes will impact small labs versus larger ones? I see an extreme increase that some smaller operations might not be able to shoulder.

A: We selected 12 labs that represent a diverse range of the sizes and types of laboratories we accredit. When we applied the proposed fee structure to these existing labs, we found the impact to be approximately the same proportional increase across all lab sizes. We understand that there are increased financial pressures for some laboratories, and we are still exploring options that might provide the funding for Ecology to meet its directives while avoiding burdening laboratories of all types and sizes.

Q: Are these fees coming into effect in March 2023?

A: No, we're currently targeting January 1, 2024.

Q: Will there no longer be a maximum fee per category?

A: That is correct. We are removing the maximum fee per category.

Q: Can you explain the current fee for recognition of a third-party accreditation and explain the proposed fee change, if any?

A: We are not proposing a change for third-party recognition at this time. Currently, recognition of a third-party for accreditation is 75 percent of the calculated fee from Table 1 in WAC 173-55-190.

Q: I see that accreditation fees are waived for Ecology's labs and for drinking water parameters certified by EPA Region 10 at "designated principal laboratories." Can you please explain what a designated principal laboratory would be?

A: Designated principal laboratories are selected by the Washington State Department of Health. Only parameters assessed directly by the EPA at those designated laboratories have their fees waived. Fees are charged for all other parameters on the principal labs' scopes.

Q: Why are Ecology and Department of Health not paying fees?

A: Ecology is not seeking a fee structure sufficient to fund the work of accrediting laboratories whose fees have been waived. There is not a practical accounting mechanism for Ecology to pay fees to itself for the work it performs.

Q: What does cost neutrality mean for Ecology/LAU?

A: Cost-neutrality means that revenues generated by accreditation fees are equivalent to the projected cost of the laboratory accreditation program. Currently, this means Ecology is seeking a fee structure that can generate revenue equal to approximately 98 percent of the total projected cost of a fully staffed laboratory accreditation unit capable of meeting all its directives.

Q: Are 14 new auditors adequate to operate at 100 percent efficiency and effectiveness?

[Note: We are proposing to add eight new auditors to our existing team of five auditors, for a new total of 13.]

A: Based on our current and projected workload, a unit of 13 auditors total would return all labs to a triennial audit schedule, while still keeping up with all the other work the unit conducts. Our goal is to have a fully staffed accreditation unit.

Q: Will there be separate fee for a full scan and the same parameter in SIM (Selected Ion Monitoring) mode?

A: The fee structure would be applied to parameters listed on the scope of accreditation. We have ongoing internal conversations about how we accredit and list for SIM.

Rulemaking Process and Timeline

Q: Did I miss the alternatives analysis?

A: No, we have not done this yet. We have built our proposed fee structure to staff an LAU that is cost-neutral while meeting all regulatory requirements, including the triennial audit schedule. We will explore alternatives as we move through the economics process.

Changes to draft rule language

- Chapter 173-50-060 (2)
 - Old: For laboratories to be accredited for drinking water parameters, the laboratory must be compliant with the current version of the EPA's Manual for the Certification of Laboratories Analyzing Drinking Water.
 - New: For laboratories to be accredited for drinking water parameters, the laboratory must follow requirements designated in the drinking water certification manual.

- Chapter 173-50-061 (3)
 - Old: Each calibration point must have its value re-calculated against the calibration curve. Unless specified in the method, each calibration point must have its percent error meet the calibration verification acceptance limits from the method; with the exception of the lowest point which is 50–15%.
 - New: Each calibration point must have its value re-calculated against the calibration curve. Unless specified in the method, each calibration point must have its percent error meet the calibration verification acceptance limits from the method; with the exception of points at or below the LOQ where the limit is 50–150%.
- Chapter 173-50-061
 - Inserted a new section (7): When Quality Control samples such as a Laboratory Control Sample or Matrix Spike are above their acceptance criteria for a parameter(s), the data for that parameter(s) can only be reported if the laboratory can demonstrate:
 - (a) no source of low bias of that parameter(s) is also present in the sample(s) and/or other related quality control samples and,
 - (b) the reported samples do not have a detection for the high biased parameter(s).
 - Old Section (7) became new section (8)
- Chapter 173-50-130
 - Added new section (7): For a laboratory to be accredited for Drinking Water parameters, the laboratory must comply with Chapters 246-390-055, 246-390-065, and 246-390-075 WAC.
- Chapter 173-50-190
 - Changing Bioassay parameters to a per-method cost matching trace metals and organics. The per-parameter cost will be \$925 with a per-parameter addition fee of \$45.

Public input and feedback

The public comment period for this rule will open when Ecology officially proposes the rule on March 27, 2023. At that time, we will post a link to the online comment form on the rulemaking web page at [WAC 173-50: Accreditation of Environmental Laboratories](#).