



# PROPOSED RULE MAKING

**CR-102 (July 2022)**  
**(Implements RCW 34.05.320)**  
Do **NOT** use for expedited rule making

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FILED

DATE: April 19, 2023

TIME: 8:23 AM

WSR 23-09-067

**Agency:** Department of Ecology AO# 22-07

- Original Notice**
- Supplemental Notice to WSR** \_\_\_\_\_
- Continuance of WSR**

- Preproposal Statement of Inquiry was filed as WSR 22-21-041 ; or**
- Expedited Rule Making--Proposed notice was filed as WSR \_\_\_\_\_; or**
- Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or**
- Proposal is exempt under RCW \_\_\_\_\_.**

**Title of rule and other identifying information:** (describe subject) Chapter 173-50 WAC Accreditation of Environmental Laboratories

For more information on this rulemaking, visit: <https://ecology.wa.gov/Regulations-Permits/Laws-rules-rulemaking/Rulemaking/WAC-173-50>

**Hearing location(s):**

Date:	Time:	Location: (be specific)	Comment:
May 25, 2023	9am-12pm	Webinar	Presentation, question and answer session followed by the hearing. We are holding this hearing via webinar. This is an online meeting that you can attend from any computer using internet access. Register here: <a href="https://waecy-wa.gov.zoom.us/meeting/register/tZYocOmurDojHtEDkylcpuhpCfliVJugpOPF">https://waecy-wa.gov.zoom.us/meeting/register/tZYocOmurDojHtEDkylcpuhpCfliVJugpOPF</a> Once registered, for audio call US Toll number 1-253-215-8782. Enter the meeting ID of 825 7062 1945, and enter passcode 174911.
May 31, 2023	1pm-4pm	Webinar	Presentation, question and answer session followed by the hearing. We are holding this hearing via webinar. This is an online meeting that you can attend from any computer using internet access. Register here: <a href="https://waecy-wa.gov.zoom.us/meeting/register/tZUvcuGorj8iE92rKsKIGMePhXKdBw34pJVO">https://waecy-wa.gov.zoom.us/meeting/register/tZUvcuGorj8iE92rKsKIGMePhXKdBw34pJVO</a> Once registered, for audio call US Toll number 1-253-215-8782. Enter the meeting ID of 812 5800 4899, and enter passcode 174911.

**Date of intended adoption:** August 28, 2023 (Note: This is **NOT** the effective date)

**Submit written comments to:**

Name: Ryan Zboralski  
Address:  
PO BOX 488  
Manchester, WA 98353-0488  
Email: ryan.zboralski@ecy.wa.gov  
Fax:  
Other:  
By (date) June 7, 2023

**Assistance for persons with disabilities:**

Contact Ecology's ADA Coordinator  
Phone: 360-407-6831  
Fax:  
TTY: 877-833-6341  
Email: ecyadacoordinator@ecy.wa.gov  
Other:  
By (date) May 22, 2023

**1. Purpose of the proposal and its anticipated effects, including any changes in existing rules:**

The proposed rule amendments would achieve the following goals:

**Amend wording in existing sections and add new sections to increase clarity and to 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 prior to a permanent laboratory move.
- Update reasons for suspension of accreditation to include: violation of federal law

**Amend the fee structure to meet current Ecology Laboratory Accreditation Unit implementation costs and address the need to increase fees to cover future cost increases.**

**Clarification of existing rule language and updating references.**

**Reasons supporting proposal:**

Ecology's Laboratory Accreditation Unit provides accreditation services and support to environmental labs across the state. These labs provide data that is necessary to support decisions made by regulatory bodies tasked with the protection of the people and resources within Washington State. The data produced by these labs requires a high level of precision and accuracy, which in turn requires a rigorous accreditation process by Ecology's Laboratory Accreditation Unit. Additionally, the emergence of contaminants of concern, such as 6-PPD Quinone, have added to the complexity of laboratory analysis and the accreditation process. The process required to accredit labs is a large part of the important work that Ecology does to ensure that the data that these labs produce is accurate and defensible.

- The existing rule is not clear what some of the required documentation and other requirements Ecology's Laboratory Accreditation Unit (LAU) expects. Specifically, it is critical that laboratories have a Standard Operating Procedure for each method they are seeking accreditation. This document ensures that the laboratories are adhering to the same procedures and quality control practices whenever they are performing that specific method and are being transparent in how they apply that method.
- Many non-drinking water laboratories have gone several years since their last audit. Audits are critical to provide the LAU with the ability to see the laboratory 'in action', and ensure that their SOPs accurately reflect the work done in the lab. The rule revision makes it clear all labs are to return to a triennial audit schedule.
- This rulemaking increases the LAU's ability to enforce necessary changes when the unit determines a laboratory is not meeting our standard. Laboratories occasionally require a codified standard for them to make an accreditation change requested by the LAU to prevent harm to the communities or environment of Washington State. The new sections in the rule accomplish this.
- With the current fee structure, the LAU is unable to recover its operating costs. The workload has steadily increased and gained complexity since the last rulemaking in 2010. This is due to additional labs seeking accreditation as well as emerging pollutants that require a more rigorous accreditation process. Not only is our fee structure insufficient with the current staff, more staff are necessary to return all laboratories to a triennial audit schedule. The proposed fee structure funds a LAU capable of supporting the current workload and added workload of returning to a triennial audit schedule. The structure also has the ability to grow over time using the state's Fiscal Growth Factor to minimize the need to return to rulemaking in the future to change the fee structure. The addition of the fiscal growth factor will also enable Ecology to implement fee increases on an annual basis, outside of a laboratory's yearly accreditation cycle or in association with and out-of-state audit. The fee structure also does not cover work performed in unsuccessful or prolonged accreditations. The new fee structure includes fees to cover costs in these instances.

**Statutory authority for adoption: Chapter 43.21A. Department of Ecology Section 230 Certification of environmental laboratories authorized—Fees—Use of certified laboratories by persons submitting data or results to department..**

**Statute being implemented: N/A**

**Is rule necessary because of a:**

Federal Law?  Yes  No

Federal Court Decision?  Yes  No

State Court Decision?  Yes  No

If yes, CITATION:

**Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:** N/A

**Type of proponent:**  Private  Public  Governmental  
**Name of proponent:** (person or organization) Department of Ecology

**Name of agency personnel responsible for:**

	Name	Office Location	Phone
Drafting:	Ryan Zboralski	Manchester	360-764-9364
Implementation:	Ryan Zboralski	Manchester	360-764-9364
Enforcement:	Rebecca Wood	Manchester	360-742-7022

**Is a school district fiscal impact statement required under [RCW 28A.305.135](#)?**  Yes  No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name:  
Address:  
Phone:  
Fax:  
TTY:  
Email:  
Other:

**Is a cost-benefit analysis required under [RCW 34.05.328](#)?**

Yes: A preliminary cost-benefit analysis may be obtained by contacting:  
Name: Ryan Zboralski  
Address: PO BOX 488  
Manchester, WA 98353-0488  
Phone: 360-764-9364  
Fax:  
TTY:  
Email: ryan.zboralski@ecy.wa.gov  
Other:

No: Please explain:

**Regulatory Fairness Act and Small Business Economic Impact Statement**  
Note: The [Governor's Office for Regulatory Innovation and Assistance \(ORIA\)](#) provides support in completing this part.

**(1) Identification of exemptions:**  
This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see [chapter 19.85 RCW](#)). For additional information on exemptions, consult the [exemption guide published by ORIA](#). Please check the box for any applicable exemption(s):

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.061](#) because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.  
Citation and description:

This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by [RCW 34.05.313](#) before filing the notice of this proposed rule.

This rule proposal, or portions of the proposal, is exempt under the provisions of [RCW 15.65.570\(2\)](#) because it was adopted by a referendum.

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(3\)](#). Check all that apply:

- |  |   |
|--|---|
| <input checked="" type="checkbox"/> <a href="#">RCW 34.05.310</a> (4)(b)<br>(Internal government operations) | <input checked="" type="checkbox"/> <a href="#">RCW 34.05.310</a> (4)(e)<br>(Dictated by statute)   |
| <input checked="" type="checkbox"/> <a href="#">RCW 34.05.310</a> (4)(c)<br>(Incorporation by reference)     | <input type="checkbox"/> <a href="#">RCW 34.05.310</a> (4)(f)<br>(Set or adjust fees)   |
| <input checked="" type="checkbox"/> <a href="#">RCW 34.05.310</a> (4)(d)<br>(Correct or clarify language)    | <input type="checkbox"/> <a href="#">RCW 34.05.310</a> (4)(g)<br>(i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit) |

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(4\)](#) (does not affect small businesses).

This rule proposal, or portions of the proposal, is exempt under RCW \_\_\_\_\_.

Explanation of how the above exemption(s) applies to the proposed rule:

**(2) Scope of exemptions:** *Check one.*

The rule proposal is fully exempt (*skip section 3*). Exemptions identified above apply to all portions of the rule proposal.

The rule proposal is partially exempt (*complete section 3*). The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using [this template from ORIA](#)): We analyzed the impacts of the proposed rule amendments relative to the existing rule, within the context of all existing requirements (federal and state laws and rules). This context for comparison is called the baseline and reflects the most likely regulatory circumstances that entities would face if the proposed rule was not adopted.

**2.2 Baseline**

The baseline for our analyses generally consists of existing rules and laws, and their requirements. This is what allows us to make a consistent comparison between the state of the world with and without the proposed rule amendments.

For this rulemaking, the baseline includes:

- The authorizing statute: RCW 43.21A.230, Certification of environmental laboratories authorized—Fees—Use of certified laboratories by persons submitting data or results to department. This statute:
  - Authorizes Ecology to certify environmental laboratories that conduct tests or prepare data for submittal to Ecology.
  - Authorizes Ecology to charge fees for certification to cover costs.
  - Allows certification to consider:
    - Protocols and procedures.
    - Accuracy and reliability of test results, including internal quality assurance and quality control procedures and proficiency at analyzing test samples.
    - Prior certification by another state or federal agency whose certification requirements are deemed satisfactory.
    - Other appropriate factors.
  - Authorizes Ecology to require that any person submitting laboratory data or test results use laboratories certified by Ecology or that participate in quality assurance programs administered by the Environmental Protection Agency (EPA).
  - Limits annual certification fees to the smaller of actual costs and \$4,000 for entities with a federal wastewater discharge permit that operate a laboratory solely for their own use, and who require certification for only conventional pollutants
- The existing rule: Chapter 173-50 WAC, Accreditation of Environmental Laboratories.
- Related Washington State requirements, including but not limited to:
  - RCW 43.21A.445, Departments authorized to participate in and administer federal Safe Drinking Water Act—Agreements with other departments
- Related federal requirements, including but not limited to:
  - 42 USC Sec. 300h et seq., Safe Drinking Water Act
  - 40 CFR Part 136, Guidelines Establishing Test Procedures for the Analysis of Pollutants
  - 40 CFR Part 141, National Primary Drinking Water Regulations

**2.3 Proposed rule amendments**

**2.3.1 Definitions**

**Baseline**

The baseline rule and law include multiple definitions to support implementation.

**Proposed**

The proposed rule amendments would add definitions or update existing ones. These changes would clarify definitions based on implementation experience, and update or add them to reflect current versions of documents or to support proposed new requirements.

### **2.3.2 Responsibilities of environmental laboratories**

#### **Baseline**

The baseline law and rule set requirements for laboratories when they apply for initial accreditation, including requirements for:

- Application.
- Quality assurance manual.
- Proficiency testing (PT) sample results.
- On-site audit.

#### **Proposed**

The proposed rule amendments would add or amend the following requirements for initial accreditation:

- Submission of standard operating procedures (SOPs).
- Some audits would no longer be on site. Audits could be remote unless Ecology determines an on-site audit is necessary.

### **2.3.3 Quality control practices**

#### **Baseline**

The baseline rule does not include explicit requirements for quality control (QC) practices.

#### **Proposed**

The proposed rule amendments would add the following requirements for quality control practices.

- Development and documentation of SOPs for each analytical method.
- Multi-level calibration requirements (if applicable).
- Limit of quantification requirements for analytical methods that do not already specify them.
- Matrix spike requirements as specified by analytical method.
- Requirements for laboratory control samples, including when high-biased sample data can be reported.
- Documentation of resolution of spectral interferences Inductively coupled plasma – optical emission spectrometry (ICP-OES).

### **2.3.4 Data and record traceability**

#### **Baseline**

The baseline rule does not include explicit requirements for data and record traceability.

#### **Proposed**

The proposed rule amendments would add the following requirements for data and record traceability. Laboratories must:

- Be able to recreate final sample results by means of records in entirety;
- Document proper storage of any chemical, reagent, and/or used by an analytical method;
- Document proper storage of samples as required by the specific analytical method and/or regulation;
- Document that all temperature-based equipment such as a refrigerator, oven, or incubator is both within control and checked manually as required by the relevant analytical method; and
- Keep logbooks for any and all instruments, including documentation of installation, setup, maintenance, and removal from service.
- Document proper preparation and QC of chemicals, reagents and media used in support of the analyses.
- Not use “erasable” handwritten records; requirement of traceable and secure format for electronic records.

### **2.3.5 Proficiency testing**

#### **Baseline**

The baseline law and rule include requirements for proficiency testing (PT), including, but not limited to:

- Acceptable use of previous PT studies.
- Minimum number and frequency of PT samples.
- Potential for raw data submission.
- Waivers for certain parameters if two or more PT samples do not exist or for other valid reasons.
- Approved PT sample vendors.

#### **Proposed**

The proposed rule amendments would add one PT sample per parameter per year, for microbiology parameters.

### **2.3.6 Audits**

#### **Baseline**

Under the baseline, all audits are on site. We note that this has been limited by Laboratory Accreditation Unit funding and resources, resulting in audits of only laboratories accredited for drinking water analyses undergoing audits every three years (per EPA requirement).

#### **Proposed**

Under the proposed rule amendments, audits would not automatically all be on site. Ecology would continue to audit laboratories accredited for drinking water analyses on site but would otherwise perform on-site audits only when necessary (laboratory does not have appropriate resources for remote audit; remote audit may not capture applicable concerns; etc.). Audits would occur at least every three years at all laboratories directly accredited by Ecology (i.e., not accredited by Ecology through third-party recognition), and any requested documentation – including at least SOPs and analytical data – would need to be submitted at least two weeks before the audit.

### **2.3.7 Interim accreditation**

#### **Baseline**

The baseline law and rule include requirements for interim accreditation, including submission of:

- Application and fees.
- Proficiency testing.
- Quality assurance manual.
- Potential analytical data package.

#### **Proposed**

The proposed rule amendments would add submission of applicable SOPs as a requirement for interim accreditation.

### **2.3.8 Maintaining accreditation status**

#### **Baseline**

The baseline law and rule include requirements for maintaining accreditation status, including:

- Definition of accreditation period (one year) and expiration.
- Renewal requirements.
- Three-year audit frequency for laboratories accredited for drinking water parameters (as required by the EPA).
- Audit frequency determined by Ecology for laboratories accredited for non-drinking-water parameters.

#### **Proposed**

The proposed rule amendments would:

- Clarify that laboratories that plan to permanently move are subject to the same accreditation requirements as new labs, since accreditation is inherently specific to the laboratory location.
- Require laboratories planning to permanently move to notify Ecology at least 60 days before new accreditation is needed.
- Add flexibility for temporary or emergency laboratory moves, identifying that they would be handled on a case-by-case basis.

### **2.3.9 Revoking or suspending accreditation**

#### **Baseline**

The baseline law and rule include requirements for revoking or suspending accreditation, including:

- Definitions of revocation and suspension.
- Reasons for suspension or revocation:
  - Failure to comply with audit standards.
  - Violation of state rules.
  - Misrepresentation.
  - Falsification of reports.
  - Unethical or fraudulent practices.
  - Deficiencies in accuracy and defensibility of data.
  - Refusal to permit enforcement entry.
  - Failure to pay fees.
  - Failure to maintain third-party accreditation.
  - Two consecutive unsatisfactory PT results.

#### **Proposed**

The proposed rule amendments would add violation of federal law to the baseline list of reasons for suspension or revocation.

### **2.3.10 Fee structure**

#### **Baseline**

The baseline law and rule include the fee structure and specific fees associated with laboratory accreditation. These fees and structure were developed during the last amendments made to this rule, in 2010, to reflect the program costs at that time. They include minimum (\$300) and maximum (variable by parameter) fees.

#### **Proposed**

The proposed rule amendments would:

- Remove maximum fees.
- Phase in fee increases beginning in FY 2024 (July 1, 2024).
- Increase fees beginning in FY 2026 according to the state's Fiscal Growth Factor.
- Increase minimum fees to \$500.
- Add a fee of \$300 for reaccreditation after 12 months of not being accredited.

### **2.3.11 Changes with no material impact**

#### **Baseline**

The baseline rule includes wording that Ecology identified – though over a decade of implementing the program since the last rule revision (2010) – as needing clarification to facilitate efficient compliance.

## Proposed

The proposed rule amendments would make changes to wording and structures in the rule, that would not affect rule requirements. These include, but are not limited to clarification that:

- Drinking water parameter accreditation must follow the Environmental Protection Agency (EPA) Manual for the Certification of Laboratories Analyzing Drinking Water (EPA).
- Appropriate basic laboratory and statistical methods must be used.
- PT samples must follow the same preparation and analytical processes as client samples.
- Audits for third-party accreditation are done by the relevant accrediting authority.
- Fees reflect costs of work done outside the normal application/renewal points of contact.

The rule proposal is not exempt (*complete section 3*). No exemptions were identified above.

### (3) Small business economic impact statement: *Complete this section if any portion is not exempt.*

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs. \_\_\_\_\_

Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

This Small Business Economic Impact Statement (SBEIS) presents the:

- Compliance requirements of the proposed rule.
- Results of the analysis of relative compliance cost burden.
- Consideration of lost sales or revenue.
- Cost-mitigating action taken by Ecology, if required.
- Small business and local government consultation.
- Industries likely impacted by the proposed rule.
- Expected net impact on jobs statewide.

A small business is defined by the Regulatory Fairness Act (chapter 19.85 RCW) as having 50 or fewer employees. Estimated costs are determined as compared to the existing regulatory environment—the regulations in the absence of the rule. The SBEIS only considers costs to “businesses in an industry” in Washington State. This means that impacts, for this document, are not evaluated for government agencies.

The existing regulatory environment is called the “baseline” in this document. It includes only existing laws and rules at federal and state levels.

This information is excerpted from Ecology's complete set of regulatory analyses for this rulemaking. For complete discussion of the likely costs, benefits, minimum compliance burden, and relative burden on small businesses, see the associated Regulatory Analyses document (**Ecology publication no. 23-03-010, April 2023**) We have retained section numbers here for easy cross-reference.

## COMPLIANCE REQUIREMENTS OF THE PROPOSED RULE, INCLUDING PROFESSIONAL SERVICES

### 2.3.1 Definitions

Definitions do not, in and of themselves, create regulatory requirements; definitions support requirements set elsewhere in the rule. Where definitions contribute to the impacts of rule requirements, the overall impacts of those requirements are discussed in the sections below.

We note also that the proposed rule amendments would update the date of the relevant Procedural Manual. As this manual is a living document that stays up to date with good practice and appropriate processes, maintenance of the external reference allows for timely updates to practice that do not necessitate repeated time-consuming rulemaking processes.

We expect the proposed rule amendments to result in costs of additional time to submit SOPs, as well as benefits of verified SOP documentation. They would also result in reduced costs associated with audits if they are remote rather than on-site.

### 2.3.3 Quality control practices

We expect these proposed amendments (new requirements) to result in labor costs associated with the additional time and effort necessary to perform these tasks or perform existing tasks using the required procedures. We expect them to result in benefits of ensuring a baseline of data quality across all laboratories accredited by Ecology, as they reflect both best practice and consistency with methods used, as well as consistency with other regulatory contexts.

### 2.3.4 Data and record traceability

We expect these proposed amendments (new requirements) to result in labor costs associated with the additional time and effort necessary to perform these tasks or perform existing tasks using the required procedures. We expect them to result in benefits of high-quality records that survive legal scrutiny, as could potentially be involved in noncompliance, penalties, lawsuits, and other regulatory or legal contexts that could be faced by the laboratory or its customers. This includes a shift from exclusive use of automated data loggers in lieu of manual checking, to reduce uncaught temperature errors for incubators, as there is a narrow range of acceptable temperatures to which the loggers are not sufficiently sensitive.

### **2.3.5 Proficiency testing**

We expect this proposed rule amendments to result in costs of additional PT analysis, as well as benefits of microbiology parameter PT consistent with chemistry parameter PT number and frequency under the baseline. The latter would result in increased confidence in the quality and reliability of microbiology analyses to be consistent with chemistry analyses.

### **2.3.6 Audits**

We expect these proposed rule amendments to result in additional time costs associated with the time and effort (at non-drinking-water labs) necessary to undergo audits at least every three years, mitigated by benefits (avoided costs) of those audits not necessarily being on-site. We also expect minor timing costs associated with when documentation is submitted to Ecology, and benefits of adequate preparation for audits and resulting audit effectiveness.

### **2.3.7 Interim accreditation**

We expect these proposed rule amendments to result in costs of additional time to submit SOPs in cases of interim accreditations, as well as benefits of verified SOP documentation in those cases.

### **2.3.8 Maintaining accreditation status**

We expect these proposed rule amendments to result in timing costs associated with notification of planned moves, and benefits of adequate time to complete necessary accreditation review without creating a gap in accreditation.

### **2.3.9 Revoking or suspending accreditation**

We do not expect this proposed rule amendment to result in significant costs or benefits, as it is in line with violation of state law as a reason for suspension or revocation.

### **2.3.10 Fee structure**

We expect these proposed rule amendments to result in costs of increased fees, as well as benefits of full funding of the Laboratory Accreditation Unit and the services it provides.

### **2.3.11 Changes with no material impact**

We do not expect these proposed rule amendments to result in costs or benefits beyond clarity.

### **COSTS OF COMPLIANCE: EQUIPMENT, PROFESSIONAL SERVICES**

Compliance with the proposed rule, compared to the baseline, is not likely to impose additional costs of equipment or professional services.

### **COSTS OF COMPLIANCE: SUPPLIES**

#### **3.2.5 Proficiency testing**

We expect this proposed rule amendment to result in costs of additional PT analysis.

We assumed laboratories with microbiology parameters would need to perform between one and five additional PT analyses per year. Based on Ecology accreditation records, there are currently 255 such labs. We surveyed product catalogs at PT sample providers that meet existing PT requirements, identifying an average cost per microbiology PT sample of \$105. This resulted in total annual costs of \$27,000 to \$134,000 across all impacted labs.

#### **COSTS OF COMPLIANCE: LABOR**

#### **3.2.2 Responsibilities of environmental laboratories**

We expect the proposed rule amendments to result in costs of additional time to submit SOPs. They would also result in reduced costs associated with audits if they are remote rather than on-site.

We assumed it would take two to four hours of laboratory management or quality assurance (QA) officer time to complete the additional work required under these amendments. At an hourly wage of \$41.90, at the 467 existing accredited labs, this would be \$39,000 to \$78,000.

Ecology reflects streams of costs over time as 20-year present values. A present value converts future costs to current values accounting for inflation as well as the opportunity cost of having funds later rather than now. Over 20 years, the present value equivalent of the annual costs above is \$0.7 to \$1.4 million.

#### **3.2.3 Quality control practices**

We expect these proposed amendments to result in labor costs associated with the additional time and effort necessary to perform these tasks or perform existing tasks using the required procedures.

We assumed it would take 40 to 120 hours of laboratory management or QA officer time to complete the additional work required under these amendments, if a lab does not already follow these procedures. At an hourly wage of \$41.90, if this cost was incurred at all 467 existing accredited labs, this would be \$0.8 million to \$2.3 million. We expect that many labs already follow the proposed quality control procedures, and so would not incur these additional costs, but we could not make a confident assumption about the percentage of labs for which this is the case. Given this uncertainty, we have taken a conservative approach (potentially overestimating costs), and identified that total annual costs would likely be less than this range.

#### **3.2.4 Data and record traceability**

We expect these proposed amendments to result in labor costs associated with the additional time and effort necessary to perform these tasks or perform existing tasks using the required procedures. This includes a shift from exclusive use of automated data loggers in lieu of manual checking.

We assumed it would take four to eight hours of laboratory analyst or technician time to complete the additional overall practice work required under these amendments. At an hourly wage of \$32.17, we assumed that 10 percent of the laboratories would need to improve these practices resulting in costs of \$5,000 to \$11,000. This is based on the acknowledgement and corresponding assumption that 90 percent of laboratories already follow the proposed data and record traceability procedures, and so would not incur additional costs.



In place of an automatic data logger, we assumed it would take 50 to 100 hours of laboratory analyst or technician time to complete additional work under these amendments. At an hourly wage of \$32.17, we assumed that 10 percent of the laboratories would need to improve these practices resulting in costs of \$67,000 to \$135,000. This is based on the understanding and corresponding assumption that most laboratories do not suffer issues with data quality due to use of automatic data loggers, and so would not incur additional costs. This element of the proposed rule intends to improve the quality of records and traceability at the relatively few labs for whom data loggers cause issues.

### 3.2.6 Audits

We expect these proposed rule amendments to result in additional time costs associated with the time and effort (at non-drinking-water labs) necessary to undergo audits at least every three years, mitigated by benefits (avoided costs) of those audits not necessarily being on-site. We also expect minor timing costs associated with when documentation is submitted to Ecology.

To reflect a shift to remote audits, we assumed the following levels of effort:

**Table 1: Assumed time spent on audits (remote)**

Emp category	Task	Hours
Ecology auditor	Preparation for audit	2-16
Ecology auditor	Travel to lab	0
Ecology auditor	Audit	3-16
Ecology auditor	Reporting and corrective action response	3-24
Management / QA Officer	Preparation for audit	2-8
Analyst / Technician	Audit	3-16
Management / QA Officer	Audit	3-16
Analyst / Technician	Corrective action response	2-16
Management / QA Officer	Corrective action response	2-16

We assumed that one-third of laboratories accredited only for non-drinking-water parameters (one-third: 114 labs) would be audited each year. These laboratories would incur the costs of remote audits, with associated staff wages of:

**Table 2: Staff wages**

Position	Wage
Ecology auditor	\$43.62 (\$80.39 including overhead)
Management / QA Officer	\$41.90 (\$77.38 including overhead)
Analyst / Technician	\$32.17 (\$54.52 including overhead)

The total estimated costs associated with these rule amendments was \$166,000 to \$1.1 million (including overhead costs), of which \$73,000 to \$0.5 million would be costs incurred by Ecology (funded by fees), and \$40,000 to \$0.5 million would be costs incurred directly by labs.

Note that by making audits no longer necessarily on-site, the proposed rule amendments could reduce costs associated with audits by \$9,000 to \$110,000 per year if all labs were remotely audited, compared to what the above costs would be if all audits remained on-site. (See Section 4.2.6 for discussion.)

### 3.2.7 Interim accreditation

We expect these proposed rule amendments to result in costs of additional time to submit SOPs in cases of interim accreditations. As these costs would be incurred as part of proposed amendments to regular accreditation, they are already reflected in the cost estimate discussed in Section 3.2.2.

### 3.2.8 Maintaining accreditation status

We expect these proposed rule amendments to result in timing costs associated with notification of planned moves. We note, however, these would not be significant additional costs, as compared to the baseline, but rather opportunity costs of expenditures at different times. The table below illustrates the opportunity costs associated with spending one dollar at various delayed times.

**Table 3: Difference in the present value of a dollar at different times**

Delay (weeks)	Present Value (cents)	Difference (cents)
0	100.00	0.00
1	99.98	0.02
2	99.97	0.03
3	99.95	0.05
4	99.93	0.07
5	99.91	0.09
6	99.90	0.10

**COSTS OF COMPLIANCE: ADMINISTRATIVE COSTS**

Where applicable, Ecology estimates administrative costs (“overhead”) as part of the cost of labor and professional services, above.

**COSTS OF COMPLIANCE: OTHER**

**3.2.10 Fee structure**

We expect these proposed rule amendments to result in costs of increased fees.

The tables below summarize baseline and proposed fees and fee structure, including elimination of maximum fees.

**Table 4. Baseline fees (and equivalent with inflation).**

Category	Fee per parameter	Fee per method	Max fee
General Chemistry	<b>\$80 (\$110)</b>	n/a	<b>\$1,600 (\$2,209)</b>
Trace Metals	n/a	<b>\$400 (\$552)</b>	n/a
Organics I	n/a	<b>\$200 (\$276)</b>	n/a
Organics II	n/a	<b>\$500 (\$690)</b>	n/a
Microbiology	<b>\$200 (\$276)</b>	n/a	n/a
Radiochemistry	<b>\$250 (\$345)</b>	n/a	n/a
Bioassay	<b>\$300 (\$414)</b>	n/a	<b>\$3,000 (\$4,142)</b>
Immunoassay	<b>\$80 (\$110)</b>	n/a	n/a
Physical	<b>\$80 (\$110)</b>	n/a	n/a

**Table 5. Proposed fees for Fiscal Year 2024.**

Category	Fee per Parameter	Per Parameter Add Fee to Existing Method	Fee Per Method
General Chemistry	<b>\$150</b>	—	—
Trace Metals	—	<b>\$30</b>	<b>\$745</b>
Organics I	—	<b>\$15</b>	<b>\$375</b>
Organics II	—	<b>\$35</b>	<b>\$930</b>
Microbiology	<b>\$375</b>	—	—
Radiochemistry	<b>\$555</b>	—	—
Bioassay	—	<b>\$15</b>	<b>\$375</b>
Immunoassay	<b>\$150</b>	—	—
Physical	<b>\$150</b>	—	—

**Table 6. Proposed fees for Fiscal Year 2025.**

Category	Fee per Parameter	Per Parameter Add Fee to Existing Method	Fee Per Method
General Chemistry	<b>\$220</b>	—	—
Trace Metals	—	<b>\$55</b>	<b>\$1,085</b>
Organics I	—	<b>\$30</b>	<b>\$545</b>
Organics II	—	<b>\$70</b>	<b>\$1,355</b>
Microbiology	<b>\$545</b>	—	—
Radiochemistry	<b>\$680</b>	—	—
Bioassay	—	<b>\$25</b>	<b>\$445</b>
Immunoassay	<b>\$220</b>	—	—
Physical	<b>\$220</b>	—	—

During the development of the proposed rule, we estimated the difference in fees at 15 representative types of laboratory, reflecting variable laboratory size, degree of direct versus third-party accreditation, and customer type. This difference was based on a set of fees per parameter, added parameter to an existing method, and method that were on average 33 percent higher than proposed FY 2024 fees, and 13 percent lower than proposed FY 2025 fees.

Baseline fees reflected FY 2022 estimated accreditation renewal costs or actual 2022 renewal invoices. The table below summarizes the descriptive statistics for the percentage increase in fees (estimated proposed fee minus baseline fee, as a proportion of baseline fee) under the proposed rule, for a representative laboratory. These estimates also accounted for fees charged on a method basis versus a parameter basis.

**Table 7. Percentage increase in representative fees, per laboratory.**

Statistic	2024 Increase from Baseline	2025 Increase from Baseline
Average	<b>136%</b>	<b>206%</b>
Minimum	<b>90%</b>	<b>137%</b>
Median	<b>122%</b>	<b>184%</b>
Maximum	<b>251%</b>	<b>381%</b>

Total laboratory accreditation fee revenues for FY 2022 were \$881,464. Using the average increase in estimated fees, and this baseline total fee value, the proposed rule would result in an average increase in total fees charged (across all laboratories) of \$1.2 million in FY 2024, and \$1.8 million in FY 2025. Considering the overall range of percentage increases estimated, the overall range of fee increases could be between \$0.8 million and \$3.4 million.

Fees beginning in FY 2026 would be based on the previous year's fees and the state's Fiscal Growth Factor, as determined by the Washington State Economic and Revenue Forecast Council (ERFC). The average nominal Fiscal Growth Factor in the ERFC's 2021 economic forecast was 5.88 percent. We applied this Fiscal Growth Factor to the estimated range of fee increases in FY 2025 and in subsequent years. The 20-year present value of fee increases under the proposed rule is a median of \$100.6 million.

We note that our estimation methodology holds the current number of labs, methods, and parameters constant for each year in the future. We were not able to confidently forecast future growth in laboratories, methods, or parameters, so holding this value constant was necessary to be able to estimate the costs of the proposed amendments to fees. While the endpoints of ranges reflect estimates based on implicit assumptions that all laboratories experience fee increases of the same percentage size as the smallest laboratories or the largest laboratories, this range also allows us to capture potential variance in laboratories and their accreditation attributes.

If there is an overall growth within or across the accredited laboratories beyond these assumptions and range, it is possible that total fee collections will ultimately fail to meet the funding needs of LAU workload. This is because fees are set in rule, and they would not be able to adapt in response to expanding needs and workload. This means the costs (fees charged) estimated above would not change over time, but LAU workload would increase nonetheless, potentially resulting once again in accreditation backlogs or other service limitations.

#### **COMPARISON OF COMPLIANCE COST FOR SMALL VERSUS LARGE BUSINESSES**

We calculated the estimated per-business costs to comply with the proposed rule amendments, based on the costs estimated in Chapter 3 of this document. In this section, we estimate compliance costs per employee.

The average affected small business likely to be covered by the proposed rule amendments employs approximately 11 people. The largest ten percent of affected businesses employ an average of 205,249 people at their highest ownership level. Based on cost estimates in Chapter 3, we estimated the following compliance costs per employee.

**Table 8: Compliance costs per employee**

Type of cost	Low	High
<i>Small business cost per employee</i>	<b>\$598</b>	<b>\$2,084</b>
<i>Largest business cost per employee</i>	<b>\$0.03</b>	<b>\$0.11</b>

We conclude that the proposed rule amendments are likely to have disproportionate impacts on small businesses. Therefore, Ecology is required to consider legal and feasible options to reduce this burden, as discussed in Section 7.4.

#### **CONSIDERATION OF LOST SALES OR REVENUE**

Businesses that would incur costs could experience reduced sales or revenues if the proposed rule amendments significantly affect the prices of the goods they sell. The degree to which this could happen is strongly related to each business's production and pricing model (whether additional lump-sum costs would significantly affect marginal costs), as well as the specific attributes of the markets in which they sell goods, including the degree of influence each firm has on market prices, as well as the relative responsiveness of market demand to price changes.

We used the REMI E3+ model for Washington State to estimate the impact of the proposed rule amendments on directly affected markets, accounting for dynamic adjustments throughout the economy. The model accounts for: inter-industry impacts; price, wage, and population changes; and dynamic adjustment of all economic variables over time.

The proposed rule amendment would primarily charge fees to businesses in the "Management, scientific, and technical consulting services" industry. The results of REMI E3+ model show that the rule amendments would impact a variety of businesses (see 7.6, below) and that they would cost an estimated \$3-37 million annually in output across all industries in the state. In 2023, Washington is estimated to have an output of \$1.06 trillion and \$1.53 trillion in 2043. Below are the industries that would have the highest estimated impact on their output. We note that the sector that captures laboratories – "Management, Scientific, and Technical Consulting Services" – would see the value of their output affected by less than one-tenth of one percent.

**Table 9: Modeled impacts to the value of output, percent of baseline**

Industry	Initial Output Impact	Output Impact in 10 years	Output Impact in 20 years
All industries	-0.001%	-0.002%	-0.002%
3259 - Other chemical product and preparation manufacturing	-0.002%	-0.014%	-0.017%
2213 - Water, sewage, and other systems	-0.002%	-0.012%	-0.016%
3222 - Converted paper product manufacturing	-0.001%	-0.005%	-0.006%
3221 – Pulp, paper, and paperboard mills	-0.001%	-0.004%	-0.006%
5416 - Management, scientific, and technical consulting services	-0.001%	-0.004%	-0.004%

**MITIGATION OF DISPROPORTIONATE IMPACT**

The RFA (19.85.030(2) RCW) states that:

“Based upon the extent of disproportionate impact on small business identified in the statement prepared under RCW 19.85.040, the agency shall, where legal and feasible in meeting the stated objectives of the statutes upon which the rule is based, reduce the costs imposed by the rule on small businesses. The agency must consider, without limitation, each of the following methods of reducing the impact of the proposed rule on small businesses:

- a) Reducing, modifying, or eliminating substantive regulatory requirements;
- b) Simplifying, reducing, or eliminating recordkeeping and reporting requirements;
- c) Reducing the frequency of inspections;
- d) Delaying compliance timetables;
- e) Reducing or modifying fine schedules for noncompliance; or
- f) Any other mitigation techniques including those suggested by small businesses or small business advocates.”

We considered all of the above options, the goals and objectives of the authorizing statutes (see Chapter 6), and the scope of this rulemaking. We limited compliance cost-reduction methods to those that:

- Are legal and feasible.
- Meet the goals and objectives of the authorizing statute.
- Are within the scope of this rulemaking.

Modifying regulatory requirements, changing reporting requirements, reducing the frequency of inspections, or delaying compliance timetables would not meet statutory objectives or are not feasible and within the scope of this rulemaking. While the scope and authorization for this rule limited Ecology’s options in reducing the disproportion of compliance cost burden, we note that the cost estimation (see Chapter 3) is based in part on a range of representative labs. This range is based on a sample of the overall laboratory population, and may overestimate the relative numbers or types of analytes (and thus, fees) for very small, independent labs. Some small laboratories are currently accredited for as few as one analyte, as necessary for their internal work, and this would naturally reduce their costs per employee even further than the costs estimated for a representative small laboratory in the table above.

**SMALL BUSINESS AND LOCAL GOVERNMENT CONSULTATION**

We involved small businesses and local governments in its development of the proposed rule amendments, using:

- Three stakeholder workshops were held in November and December 2022 with representatives from 39 different organizations and 64 different local governments or their departments.
- An informal public comment period was held from November 2, 2022 to January 4, 2023.
- E-mail communications to all permittees.

**NAICS CODES OF INDUSTRIES IMPACTED BY THE PROPOSED RULE**

The proposed rule amendments likely impact the following industries, with associated North American Industry Classification System (NAICS) codes. NAICS definitions and industry hierarchies are discussed at

<https://www.census.gov/cgi-bin/sssd/naics/naicsrch?chart=2017>.

**Table 10: NAICS codes of affected laboratories or their owners**

NAICS CodeDescription

- 1119 Other Crop Farming
- 1151 Support Activities for Crop Production
- 2211 Electric Power Generation, Transmission and Distribution
- 2213 Water, Sewage and Other Systems
- 2382 Building Equipment Contractors
- 2383 Building Finishing Contractors
- 2389 Other Specialty Trade Contractors
- 3114 Fruit and Vegetable Preserving and Specialty Food Manufacturing
- 3116 Animal Slaughtering and Processing
- 3219 Other Wood Product Manufacturing
- 3221 Pulp, Paper, and Paperboard Mills
- 3222 Converted Paper Product Manufacturing
- 3241 Petroleum and Coal Products Manufacturing
- 3251 Basic Chemical Manufacturing
- 3252 Resin, Synthetic Rubber, and Artificial and Synthetic Fibers and Filaments Manufacturing
- 3272 Glass and Glass Product Manufacturing
- 3313 Alumina and Aluminum Production and Processing
- 3314 Nonferrous Metal (except Aluminum) Production and Processing
- 3328 Coating, Engraving, Heat Treating, and Allied Activities
- 3331 Agriculture, Construction, and Mining Machinery Manufacturing
- 3364 Aerospace Product and Parts Manufacturing
- 4245 Farm Product Raw Material Merchant Wholesalers
- 4452 Specialty Food Retailers
- 4571 Gasoline Stations
- 5413 Architectural, Engineering, and Related Services
- 5416 Management, Scientific, and Technical Consulting Services
- 5417 Scientific Research and Development Services
- 5419 Other Professional, Scientific, and Technical Services
- 5617 Services to Buildings and Dwellings
- 5622 Waste Treatment and Disposal
- 5629 Remediation and Other Waste Management Services
- 6215 Medical and Diagnostic Laboratories
- 8133 Social Advocacy Organizations

**IMPACT ON JOBS**

We used the REMI E3+ model for Washington State to estimate the impact of the proposed rule amendments on jobs in the state, accounting for dynamic adjustments throughout the economy.

The proposed rule amendments would result in transfers of money within and between industries, as compared to the baseline. The modeled impacts on employment are the result of multiple small increases and decreases in employment, prices, and other economic variables across all industries in the state.

Employment modeling results of the REMI E3+ show a minor impact on jobs in the affected industries. All industries in the state would experience an estimated total initial job loss of 14 full-time employees (FTEs), increasing to a job loss of 45 FTEs by 2043. The industry with the highest jobs impact is construction with an estimated initial job loss of two FTEs. Construction is an industry highly sensitive to changes in economic activity in the state.

Direct cost estimates (inputs into the model) are based on the low end of the total cost ranges estimated in Chapter 3. We made this assumption based on the acknowledgement that most labs are already performing many, if not all, of the proposed requirements for quality control and data quality.


In terms of NAICS codes and sectors defined in the REMI model, laboratories are captured in the “Management, Scientific, and Technical Consulting Services” sector. The REMI model indicates that, in the aggregate, this sector would experience an equivalent loss of less than one full-time employee (FTE) total across all laboratories, increasing to a loss of two to three FTEs in 2027, and this loss would likely be permanent. To test the sensitivity of this result to our low-cost assumption, we also ran the model using high-cost inputs that reflect much broader or universal incurrence of the costs of additional quality control and data quality activities than is likely based on current lab practices and interpretations of the baseline rule. This resulted in the laboratory sector losing between two and fifteen FTEs annually through 2043.

We also heard from small laboratories that they were concerned about their ability to do additional work, pay more fees, or incur additional costs, in light of difficulties meeting their own workload and staffing needs. We note that our cost estimation (see Chapter 3) is based in part on a range of representative labs, and on conservative assumptions that likely overestimate costs. This means our estimates are likely to overestimate costs to many small laboratories – especially for small, independent laboratories. Some small laboratories are currently accredited for as few as one analyte, as necessary for their internal work, and this would naturally reduce their costs and any needs to hire additional staff or pay more in wages.

These attributes of small labs – likely incurring lower costs but having more difficulty adjusting to them work against one another to determine ultimate impacts of the proposed rule amendments. We note, however, that the employment impacts estimated in this section are therefore more likely to happen at small laboratories that have the most difficulty adjusting their overall business model and staffing.

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name: Ryan Zboralski  
Address: PO BOX 488  
          Manchester, WA 98353-0488  
Phone: 360-764-9364  
Fax:  
TTY:  
Email: ryan.zboralski@ecy.wa.gov  
Other:

<b>Date:</b> 4/19/2023	<b>Signature:</b> 
<b>Name:</b> Heather Bartlett	
<b>Title:</b> Deputy Director	