Preliminary Regulatory Analyses:

Including the:

- Preliminary Cost-Benefit Analysis
- Least-Burdensome Alternative Analysis
- Administrative Procedure Act Determinations
- Regulatory Fairness Act Compliance

Chapter 173-50 WAC

Accreditation of Environmental Labs

By

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For the

Environmental Assessment Program

Washington State Department of Ecology
Olympia, Washington

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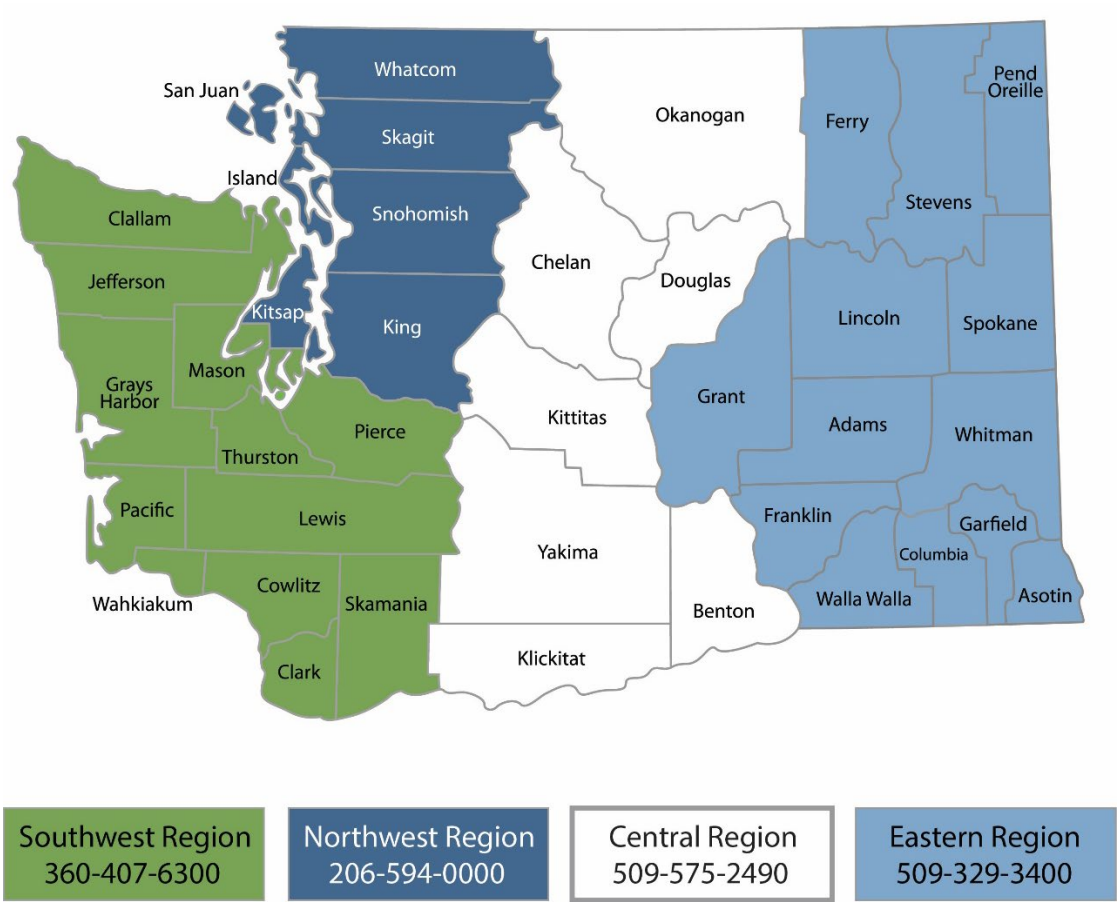

Region	Counties served	Mailing Address	Phone
Southwest	Clallam, Clark, Cowlitz, Grays Harbor, Jefferson, Mason, Lewis, Pacific, Pierce, Skamania, Thurston, Wahkiakum	P.O. Box 47775 Olympia, WA 98504	360-407-6300
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Abbreviations

APA	Administrative Procedure Act
CBA	Cost-Benefit Analysis
CFR	Code of Federal Regulations
DOH	WA Department of Health
EPA	Environmental Protection Agency
FTE	Full time employee
ICP-OES	Inductively coupled plasma – optical emission spectrometry
LAU	Lab Accreditation Unit
LBA	Least-Burdensome Alternative
LOQ	Limit of Quantitation
NAICS	North American Industry Classification System
PT	Proficiency testing
QC	Quality control
RCW	Revised Code of Washington
RFA	Regulatory Fairness Act
SBEIS	Small Business Economic Impact Statement
SOP	Standard Operating Procedure
USC	United States Code
WAC	Washington Administrative Code

Executive Summary

This report presents the determinations made by the Washington State Department of Ecology as required under Chapters 34.05 RCW and 19.85 RCW, for the proposed amendments to the Accreditation of Environmental Laboratories rule (Chapter 173-50 WAC; the "rule"). This includes the:

- Preliminary Cost-Benefit Analysis (CBA)
- Least-Burdensome Alternative Analysis (LBA)
- Administrative Procedure Act Determinations
- Regulatory Fairness Act Compliance

The Washington Administrative Procedure Act (APA; RCW 34.05.328(1)(d)) requires Ecology to evaluate significant legislative rules to "determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the law being implemented." Chapters 1 – 5 of this document describe that determination.

The APA also requires Ecology to "determine, after considering alternative versions of the rule…that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives" of the governing and authorizing statutes. Chapter 6 of this document describes that determination.

The APA also requires Ecology to make several other determinations (RCW 34.05.328(1)(a) – (c) and (f) – (h)) about the rule, including authorization, need, context, and coordination. Appendix A of this document provides the documentation for these determinations.

The Washington Regulatory Fairness Act (RFA; Chapter 19.85 RCW) requires Ecology to evaluate the relative impact of proposed rules that impose costs on businesses in an industry. It compares the relative compliance costs for small businesses to those of the largest businesses affected. Chapter 7 of this document documents that analysis, when applicable.

All determinations are based on the best available information at the time of publication. We encourage feedback (including specific data) that may improve the accuracy of this analysis.

Background

Ecology is proposing amendments to Chapter 173-50 WAC, Accreditation of Environmental Laboratories, for clarity and consistency across analytical approaches. We are also proposing amendments to the fee structure to reflect inflation and the increase in complexity and workload since the last rulemaking in 2010. The existing fees set in the rule do not provide sufficient funding to cover the costs of the Laboratory Accreditation Unit (LAU) processing complex, prolonged, or unsuccessful applications.

The proposed rule amendments are also necessary to allow for adaptation to new and emerging compounds and analytical processes. In the past 12 years, there has been an increase

in monitoring and laboratory analyses for novel compounds. Without updates to LAU funding, it will continue to be a challenge to provide the level of service our clients expect.

Proposed amendments

Definitions:

- Update or add definitions used to implement subsequent rule requirements.

Responsibilities of environmental laboratories:

- Require laboratories to submit Standard Operating Procedures (SOPs).

Quality control practices:

- Require laboratories to develop an SOP for each analytical method.
- Clarify appropriate statistical methods for multi-level calibration.
- Require laboratories to perform annual Limit of Quantification (LOQ) analysis.
- Require laboratories to conduct matrix spikes as specified by analytical method.
- Require laboratory control samples to include all analytes of interest in the respective analysis.
- Clarify when laboratories can report high-biased sample data.
- Require laboratories to document resolution of spectral interferences for ICP-OES even when the analytical methods are not clear in this.

Data and record traceability:

- Require laboratories to maintain appropriate data, records, and be able to demonstrate traceability.

Proficiency testing (PT):

- Require one additional proficiency testing (PT) sample per parameter per year for microbiology parameters.
- Clarify procedural requirements for PT.

Audits:

- Introduce and clarify the use of virtual audits.
- Clarify that audits for 3rd party accreditation are done by the relevant authority.
- Require audits at least every 3 years for Ecology accreditation.
- Clarify requirements related to federally required analytical methods.
- Require laboratories to submit documentation to Ecology at least 2 weeks before an audit.

Interim accreditation:

- Add applicable SOPs to be submitted for interim accreditation

Maintaining accreditation status:

- Drinking water clarifications:
    - Clarify that audits of laboratories for drinking water parameter accreditation are required to be on site.
    - Clarify that laboratories must follow the Department of Health's Drinking Water Laboratory Accreditation rule (Chapter 246-390 WAC).

- Clarify that laboratories must notify Ecology at least 30 days before new accreditation is needed for laboratories that have moved.
    - This section also clarifies expectations for laboratories that have moved.

Revoking or suspending accreditation:

- Add violation of federal law (as determined by a federal agency) to reasons for suspension of accreditation.

Fee structure:

- Remove the maximum fee.
- Update fees to match Ecology Laboratory Accreditation Unit implementation costs, using a phased-in approach and future Fiscal Growth Factor.
- Increase the minimum fee to $500.
- Add an application fee of $300 for initial accreditation or reinstatement of accreditation after 12 months of not being accredited.
- Clarify that fees must be sufficient to fund all of Ecology's laboratory accreditation costs, including those beyond of the activities of application or renewal.

Changes without material impact on rule requirements:

- Clarifications and references to baseline requirements.
- Restructuring.

Costs

We estimated the following annual costs of the proposed rule amendments. Recall that while we estimated ranges, the real costs likely incurred by labs are at (or below) the low end of these ranges, since most already follow the processes in the proposed rule amendments. This section therefore highlights those lower estimates where that was the case, as the high-end estimates are not likely to reflect actual outcomes. For full discussion and broadly conservative cost ranges, see Chapter 3.

- Responsibilities of environmental laboratories: $39,000 to $78,000
- Quality control practices: $0.8 million
- Data and record traceability: $73,000
- Proficiency testing: $27,000
- Audits: $166,000 to $1.1 million
- Interim accreditation: Costs are reflected in estimates for laboratory responsibilities, above.
- Maintaining accreditation status: $0 annual costs; minor timing costs of submitting information sooner.
- Fee structure: Average increase of $1.2 million in total fee collection in Fiscal Year (FY) 2024, and $1.8 million in FY 2025, growing by an average of 5.9 percent beginning in FY 2026.

The above costs result in average total costs of $3.9 million across all laboratories in FY 2024, increasing to $4.7 million in FY 2025. 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. Present values capture future increases in values stemming from factors like the Fiscal Growth Factor. Over 20 years, the present value equivalent of total cost is $100.6 million (median).

Benefits

We estimated the following benefits of the proposed rule amendments.

- Responsibilities of environmental laboratories:
    - Maintain certainty that the laboratories Ecology provides accreditation to have all the necessary procedures in place to ensure data quality.
    - Inadequate and undocumented SOPs that affect data quality, that in turn affects the ability of businesses, public entities, or other organizations to effectively comply with all environmental regulations that apply to them could not only result in eventual identification of noncompliance with regulations or permits, but in environmental and human health impacts.
- Quality control practices:
    - maintain certainty that the laboratories Ecology provides accreditation to have all the necessary procedures in place to ensure data quality. We acknowledge that most laboratories are already following the proposed quality control practices.
    - avoided corrective costs and liability, or even lawsuits for laboratories and their clients.
- Data and record traceability:
    - 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. We acknowledge that most laboratories are already following the proposed data and record traceability practices
- Proficiency testing:
    - increased confidence in the quality and reliability of microbiology analyses to be consistent with chemistry analyses.
    - Microbiology parameters include analytes such as fecal coliform, a type of bacteria that often sickens people at beaches or closes shellfish harvests.
- Audits:
    - $9,000 to $110,000 per year in avoided on-site audit costs (Ecology travel costs)
- Interim accreditation:
    - verified SOP documentation in cases of interim accreditations
- Maintaining accreditation status:
    - avoided Lost laboratory revenues
    - avoided Need for laboratory clients to seek out alternative laboratories for their analytical work, and associated costs.
- Fee structure:
    - full funding of the Laboratory Accreditation Unit and the services it provides

- Added values of LAU services:
    - Assurance that the laboratories analyzing data used for compliance provide accurate and reliable results for regulatory compliance and protection of the public and environment.
    - Assurance that the parties using those results to support their compliance with regulations are really meeting their obligations.
    - Reduced risk of liability for inadvertent damages to the environment or public health, or ability to provide full documentation in cases of legal action, for laboratories or their customers.
    - Reduced risk of repeated or duplicative work, or corrective action resulting from inaccurate analyses.

Uncertainty

We note that our discussion of these likely benefits holds the current workload faced by the LAU (whether the total number of laboratories, or the parameters and methods for which they are accredited) constant for each year in the future. We were not able to confidently forecast future growth in lab numbers, methods, and parameters, so holding this value constant was necessary to be able to estimate the impacts of the proposed amendments to fees.

It is possible that total fee collections will ultimately fail to meet the funding needs of LAU workload. This may happen if there is an overall growth in parameters beyond the assumption of the equivalent of an average lab each year or if accreditation grows in complexity beyond the current identified parameters. 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 LAU workload would increase nonetheless, potentially resulting once again in accreditation backlogs or other service limitations. This would, in turn, put each of the benefits listed above at risk.

Cost-Benefit Analysis Conclusion

We conclude, based on a reasonable understanding of the quantified and qualitative costs and benefits likely to arise from the proposed rule amendments, as compared to the baseline, that the benefits of the proposed rule amendments are greater than the costs.

Least-Burdensome Alternative

We considered the following alternative rule content, and did not include it in the proposed rule amendments because it did not meet the goals and objectives of the authorizing statute, would have increased compliance burden, or both.

- Changing the term “parameter” to “analyte”.
- Use of the Procedural Manual as an enforcement document.
- Broadening language used to refer to external documents and guidance.

After considering alternatives to the proposed rule’s contents, within the context of the goals and objectives of the authorizing statute, we determined that the proposed rule represents the least-burdensome alternative of possible rule contents meeting the goals and objectives.

Regulatory Fairness Act Compliance

The Regulatory Fairness Act (RFA; RCW 19.85.070) requires Ecology to perform a set of analyses and make certain determinations regarding the proposed rule amendments.

A small business is defined by the RFA as having 50 or fewer employees, at the highest ownership and operator level. Estimated compliance costs are determined as compared to the baseline (the regulatory environment in the absence of the proposed rule amendments, limited to existing federal and state requirements). Analyses under the RFA only apply to costs to "businesses in an industry" in Washington State. This means the impacts, for this part of our analyses, are not evaluated for government agencies.

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 1. Compliance costs per employee.

Type of cost	Low	High
Small business cost per employee	**$598**	**$2,084**
Largest business cost per employee	**$0.03**	**$0.11**

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.

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.[2] 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

[2] This impact persisted in model results through 2043.

the laboratory sector losing between two and fifteen FTEs annually through 2043.

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Chapter 1: Background and Introduction

1.1 Introduction

This report presents the determinations made by the Washington State Department of Ecology as required under Chapters 34.05 RCW and 19.85 RCW, for the proposed amendments to the Accreditation of Environmental Laboratories rule (Chapter 173-50 WAC; the "rule"). This includes the:

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The Washington Regulatory Fairness Act (RFA; Chapter 19.85 RCW) requires Ecology to evaluate the relative impact of proposed rules that impose costs on businesses in an industry. It compares the relative compliance costs for small businesses to those of the largest businesses affected. Chapter 7 of this document documents that analysis, when applicable.

All determinations are based on the best available information at the time of publication. We encourage feedback (including specific data) that may improve the accuracy of this analysis.

1.1.1 Background

Ecology is proposing amendments to Chapter 173-50 WAC, Accreditation of Environmental Laboratories, for clarity and consistency across analytical approaches. We are also proposing amendments to the fee structure to reflect inflation and the increase in complexity and workload since the last rulemaking in 2010. The existing fees set in the rule do not provide sufficient funding to cover the costs of the Laboratory Accreditation Unit (LAU) processing complex, prolonged, or unsuccessful applications.

The proposed rule amendments are also necessary to allow for adaptation to new and emerging compounds and analytical processes. In the past 12 years, there has been an increase

in monitoring and laboratory analyses for novel compounds. Without updates to LAU funding, it will continue to be a challenge to provide the level of service our clients expect.

1.2 Summary of the proposed rule amendments

The proposed rule amendments would:

Definitions

- Update or add definitions used to implement subsequent rule requirements.

Responsibilities of environmental laboratories

- Require laboratories to submit Standard Operating Procedures (SOPs).

Quality control practices

- Require laboratories to develop an SOP for each analytical method.
- Clarify appropriate statistical methods for multi-level calibration.
- Require laboratories to perform annual Limit of Quantification (LOQ) analysis.
- Require laboratories to conduct matrix spikes as specified by analytical method.
- Require laboratory control samples to include all analytes of interest in the respective analysis.
- Clarify when laboratories can report high-biased sample data.
- Require laboratories to document resolution of spectral interferences for ICP-OES even when the analytical methods are not clear in this.

Data and record traceability

- Require laboratories to maintain appropriate data, records, and be able to demonstrate traceability.

Proficiency testing (PT)

- Require one additional proficiency testing (PT) sample per parameter per year for microbiology parameters.
- Clarify procedural requirements for PT.

Audits

- Introduce and clarify the use of virtual audits.
- Clarify that audits for 3rd party accreditation are done by the relevant authority.
- Require audits at least every 3 years for Ecology accreditation.
- Clarify requirements related to federally required analytical methods.
- Require laboratories to submit documentation to Ecology at least 2 weeks before an audit.

Interim accreditation

- Add applicable SOPs to be submitted for interim accreditation

Maintaining accreditation status

- Drinking water clarifications:
    - Clarify that audits of laboratories for drinking water parameter accreditation are required to be on site.
    - Clarify that laboratories must follow the Department of Health's Drinking Water Laboratory Accreditation rule (Chapter 246-390 WAC).

- Clarify that laboratories must notify Ecology at least 30 days before new accreditation is needed for laboratories that have moved.
    - This section also clarifies expectations for laboratories that have moved.

Revoking or suspending accreditation

- Add violation of federal law to reasons for suspension of accreditation.

Fee structure

- Remove the maximum fee.
- Update fees to match Ecology Laboratory Accreditation Unit implementation costs, using a phased-in approach and future Fiscal Growth Factor.
- Increase the minimum fee to $500.
- Add an application fee of $300 for initial accreditation or reinstatement of accreditation after 12 months of not being accredited.
- Clarify that fees must be sufficient to fund all of Ecology's laboratory accreditation costs, including those beyond of the activities of application or renewal.

Changes without material impact on rule requirements

- Clarifications and references to baseline requirements.
- Restructuring.

1.3 Document organization

The remainder of this document is organized in the following chapters:

- **Baseline and the proposed rule amendments (Chapter 2):** Description and comparison of the baseline (what would occur in the absence of the proposed rule amendments) and the proposed rule requirements.
- **Likely costs of the proposed rule amendments (Chapter 3):** Analysis of the types and sizes of costs we expect impacted entities to incur as a result of the proposed rule amendments.
- **Likely benefits of the proposed rule amendments (Chapter 4):** Analysis of the types and sizes of benefits we expect to result from the proposed rule amendments.
- **Cost-benefit comparison and conclusions (Chapter 5):** Discussion of the complete implications of the CBA.
- **Least-Burdensome Alternative Analysis (Chapter 6):** Analysis of considered alternatives to the contents of the proposed rule amendments.
- **Regulatory Fairness Act Compliance (Chapter 7):** When applicable. Comparison of compliance costs for small and large businesses; mitigation; impact on jobs.
- **APA Determinations (Appendix A):** RCW 34.05.328 determinations not discussed in chapters 5 and 6.

Chapter 2: Baseline and Proposed Rule Amendments

2.1 Introduction

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. It is discussed in Section 2.2, below.

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

The proposed rule amendments would:

Definitions

- Update or add definitions used to implement subsequent rule requirements.

Responsibilities of environmental laboratories

- Require laboratories to submit Standard Operating Procedures (SOPs).

Quality control practices

- Require laboratories to develop an SOP for each analytical method.
- Clarify appropriate statistical methods for multi-level calibration.
- Require laboratories to perform annual Limit of Quantification (LOQ) analysis.
- Require laboratories to conduct matrix spikes as specified by analytical method.
- Require laboratory control samples to include all analytes of interest in the respective analysis.
- Clarify when laboratories can report high-biased sample data.
- Require laboratories to document resolution of spectral interferences for ICP-OES even when the analytical methods are not clear in this.

Data and record traceability

- Require laboratories to maintain appropriate data, records, and be able to demonstrate traceability.

Proficiency testing (PT)

- Require one additional proficiency testing (PT) sample per parameter per year for microbiology parameters.
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Interim accreditation

- Add applicable SOPs to be submitted for interim accreditation

Maintaining accreditation status

- Drinking water clarifications:
    - Clarify that audits of laboratories for drinking water parameter accreditation are required to be on site.
    - Clarify that laboratories must follow the Department of Health's Drinking Water Laboratory Accreditation rule (Chapter 246-390 WAC).
- Clarify that laboratories must notify Ecology at least 30 days before new accreditation is needed for laboratories that have moved.
    - This section also clarifies expectations for laboratories that have moved.

Revoking or suspending accreditation

- Add violation of federal law to reasons for suspension of accreditation.

Fee structure

- Remove the maximum fee.
- Update fees to match Ecology Laboratory Accreditation Unit implementation costs, using a phased-in approach and future Fiscal Growth Factor.
- Increase the minimum fee to $500.
- Add an application fee of $300 for initial accreditation or reinstatement of accreditation after 12 months of not being accredited.
- Clarify that fees must be sufficient to fund all of Ecology's laboratory accreditation costs, including those beyond of the activities of application or renewal.

Changes without material impact on rule requirements

- Clarifications and references to baseline requirements.
- Restructuring.

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.

Expected impact

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.

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.

Expected impact

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

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).

Expected impact

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

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.

Expected impact

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.[3]

[3] We note that most laboratories are likely using data loggers without issue, and the proposed rule intends to improve data quality at those that are not successfully doing so.

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.

Expected impact

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

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.

Expected impact

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

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.

Expected impact

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

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.[4]

[4] Note this includes the requirement for audits at least every three years. See section 2.3.6 for discussion.

- 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.

Expected impact

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

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.

Expected impact

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

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

Table 2. Proposed fees for Fiscal Year 2024.

Category	Fee per Parameter	Per Parameter Add Fee to Existing Method	Fee Per Method
General Chemistry	**$150**	**n/a**	**n/a**
Trace Metals	**n/a**	**$30**	**$745**
Organics I	**n/a**	**$15**	**$375**
Organics II	**n/a**	**$35**	**$930**
Microbiology	**$375**	**n/a**	**n/a**
Radiochemistry	**$555**	**n/a**	**n/a**
Bioassay	**n/a**	**$15**	**$375**
Immunoassay	**$150**	**n/a**	**n/a**
Physical	**$150**	**n/a**	**n/a**

Table 3. Proposed fees for Fiscal Year 2025.

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

Expected impact

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

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.

Expected impact

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

Chapter 3: Likely Costs of the Proposed Rule Amendments

3.1 Introduction

We analyzed the likely costs associated with the proposed rule amendments, as compared to the baseline. The proposed rule amendments and the baseline are discussed in detail in Chapter 2 of this document.

3.2 Cost analysis

The proposed rule amendments would:

Definitions

- Update or add definitions used to implement subsequent rule requirements.

Responsibilities of environmental laboratories

- Require laboratories to submit Standard Operating Procedures (SOPs).

Quality control practices

- Require laboratories to develop an SOP for each analytical method.
- Clarify appropriate statistical methods for multi-level calibration.
- Require laboratories to perform annual Limit of Quantification (LOQ) analysis.
- Require laboratories to conduct matrix spikes as specified by analytical method.
- Require laboratory control samples to include all analytes of interest in the respective analysis.
- Clarify when laboratories can report high-biased sample data.
- Require laboratories to document resolution of spectral interferences for ICP-OES even when the analytical methods are not clear in this.

Data and record traceability

- Require laboratories to maintain appropriate data, records, and be able to demonstrate traceability.

Proficiency testing (PT)

- Require one additional proficiency testing (PT) sample per parameter per year for microbiology parameters.
- Clarify procedural requirements for PT.

Audits

- Introduce and clarify the use of virtual audits.
- Clarify that audits for 3rd party accreditation are done by the relevant authority.
- Require audits at least every 3 years for Ecology accreditation.

- Clarify requirements related to federally required analytical methods.
- Require laboratories to submit documentation to Ecology at least 2 weeks before an audit.

Interim accreditation

- Add applicable SOPs to be submitted for interim accreditation

Maintaining accreditation status

- Drinking water clarifications:
    - Clarify that audits of laboratories for drinking water parameter accreditation are required to be on site.
    - Clarify that laboratories must follow the Department of Health's Drinking Water Laboratory Accreditation rule (Chapter 246-390 WAC).
- Clarify that laboratories must notify Ecology at least 30 days before new accreditation is needed for laboratories that have moved.
    - This section also clarifies expectations for laboratories that have moved.

Revoking or suspending accreditation

- Add violation of federal law to reasons for suspension of accreditation.

Fee structure

- Remove the maximum fee.
- Update fees to match Ecology Laboratory Accreditation Unit implementation costs, using a phased-in approach and future Fiscal Growth Factor.
- Increase the minimum fee to $500.
- Add an application fee of $300 for initial accreditation or reinstatement of accreditation after 12 months of not being accredited.
- Clarify that fees must be sufficient to fund all of Ecology's laboratory accreditation costs, including those beyond of the activities of application or renewal.

Changes without material impact on rule requirements

- Clarifications and references to baseline requirements.
- Restructuring.

3.2.1 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.

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[5], 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.[6] 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[7], 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.

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[5] US Bureau of Labor Statistics, 2022. May 2021 State Occupational Employment and Wage Estimates. Washington State. https://www.bls.gov/oes/current/oes_wa.htm

[6] US Treasury Department, 2022. I bond interest rates. Historic average September 1998 through November 2022. https://treasurydirect.gov/savings-bonds/i-bonds/i-bonds-interest-rates/#:~:text=The%20composite%20rate%20for%20I,through%20April%202023%20is%206.89%25 The current long-run average real risk-free rate of return is 0.89%, based on a 1998 to present averaging period.

[7] US Bureau of Labor Statistics, 2022. May 2021 State Occupational Employment and Wage Estimates. Washington State. https://www.bls.gov/oes/current/oes_wa.htm

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[8], 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[9], 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.

3.2.5 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.[10] We surveyed product catalogs at PT sample providers that meet existing PT requirements, identifying an average cost per microbiology PT sample of $105.[11] This resulted in total annual costs of $27,000 to $134,000 across all impacted labs.

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:

[8] Ibid.
[9] US Bureau of Labor Statistics, 2022. May 2021 State Occupational Employment and Wage Estimates. Washington State. https://www.bls.gov/oes/current/oes_wa.htm
[10] WA Department of Ecology, 2023. Lab Search. Database of accredited labs. https://apps.ecology.wa.gov/laboratorysearch/
[11] PT sample product catalogs for Advanced Analytical Solutions, LLC; NSI Solutions, Inc; MilliporeSigma; Phenova.

Table 4. Assumed time spent on audits (remote).

Employment 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 5. 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 6. 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**

3.2.9 Revoking or suspending accreditation

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

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 7. Baseline fees (and equivalent with inflation[12]).

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

[12] Fees adjusted for inflation using: US Bureau of Labor Statistics, 2023. Consumer Price Index, all urban consumers. https://www.bls.gov/cpi/data.htm. We estimate these fees, updated for inflation, would fund 80 to 85 percent of current program costs.

Table 8. Proposed fees for Fiscal Year 2024.

Category	Fee per Parameter	Per Parameter Add Fee to Existing Method	Fee Per Method
General Chemistry	**$150**	**n/a**	**n/a**
Trace Metals	**n/a**	**$30**	**$745**
Organics I	**n/a**	**$15**	**$375**
Organics II	**n/a**	**$35**	**$930**
Microbiology	**$375**	**n/a**	**n/a**
Radiochemistry	**$555**	**n/a**	**n/a**
Bioassay	**n/a**	**$15**	**$375**
Immunoassay	**$150**	**n/a**	**n/a**
Physical	**$150**	**n/a**	**n/a**

Table 9. Proposed fees for Fiscal Year 2025.

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

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 10. Percentage increase in representative fees, per laboratory.

Statistic	2024 Increase from Baseline	2025 Increase from Baseline
Average	**136%**	**206%**
Minimum	**90%**	**137%**
Median	**122%**	**184%**
Maximum	**251%**	**381%**

Total laboratory accreditation fee revenues for FY 2022 were $881,464.[13] 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.[14] 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.[15]

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.

[13] WA Department of Ecology, 2023. Budget Office communication. Via email with Gary Koshi, 3/1/23.
[14] WA Economic and Revenue Forecast Council, 2021. ERFC November 2021 forecast. https://erfc.wa.gov/fiscal-growth-factors
[15] Note that since the Fiscal Growth Factor is nominal, the calculated present value reflects a nominal discount rate based on historic real rates of return, as well as historic inflation rates.

3.2.11 Changes with no material impact

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

Chapter 4: Likely Benefits of the Proposed Rule Amendments

4.1 Introduction

We analyzed the likely benefits associated with the proposed rule amendments, as compared to the baseline. The proposed rule amendments and the baseline are discussed in detail in Chapter 2 of this document.

4.2 Benefits analysis

The proposed rule amendments would:

Definitions

- Update or add definitions used to implement subsequent rule requirements.

Responsibilities of environmental laboratories

- Require laboratories to submit Standard Operating Procedures (SOPs).

Quality control practices

- Require laboratories to develop an SOP for each analytical method.
- Clarify appropriate statistical methods for multi-level calibration.
- Require laboratories to perform annual Limit of Quantification (LOQ) analysis.
- Require laboratories to conduct matrix spikes as specified by analytical method.
- Require laboratory control samples to include all analytes of interest in the respective analysis.
- Clarify when laboratories can report high-biased sample data.
- Require laboratories to document resolution of spectral interferences for ICP-OES even when the analytical methods are not clear in this.

Data and record traceability

- Require laboratories to maintain appropriate data, records, and be able to demonstrate traceability.

Proficiency testing (PT)

- Require one additional proficiency testing (PT) sample per parameter per year for microbiology parameters.
- Clarify procedural requirements for PT.

Audits

- Introduce and clarify the use of virtual audits.
- Clarify that audits for third party accreditation are done by the relevant authority.
- Require audits at least every 3 years for Ecology accreditation.

- Clarify requirements related to federally required analytical methods.
- Require laboratories to submit documentation to Ecology at least 2 weeks before an audit.

Interim accreditation

- Add applicable SOPs to be submitted for interim accreditation

Maintaining accreditation status

- Drinking water clarifications:
    - Clarify that audits of laboratories for drinking water parameter accreditation are required to be on site.
    - Clarify that laboratories must follow the Department of Health's Drinking Water Laboratory Accreditation rule (Chapter 246-390 WAC).
- Clarify that laboratories must notify Ecology at least 30 days before new accreditation is needed for laboratories that have moved.
    - This section also clarifies expectations for laboratories that have moved.

Revoking or suspending accreditation

- Add violation of federal law to reasons for suspension of accreditation.

Fee structure

- Remove the maximum fee.
- Update fees to match Ecology Laboratory Accreditation Unit implementation costs, using a phased-in approach and future Fiscal Growth Factor.
- Increase the minimum fee to $500.
- Add an application fee of $300 for initial accreditation or reinstatement of accreditation after 12 months of not being accredited.
- Clarify that fees must be sufficient to fund all of Ecology's laboratory accreditation costs, including those beyond of the activities of application or renewal.

Changes without material impact on rule requirements

- Clarifications and references to baseline requirements.
- Restructuring

4.2.1 Definitions

Definitions do not, by 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.

4.2.2 Responsibilities of environmental laboratories

We expect the proposed rule amendments to result in benefits of verified SOP documentation. They would also result in reduced costs associated with audits if they are remote rather than on-site (see Section 4.2.6).

Verifying that laboratories have documented SOPs by having them submitted to Ecology would maintain certainty that the laboratories Ecology provides accreditation to have all the necessary procedures in place to ensure data quality. It is difficult to quantify this benefit, as it also depends on how often (and to what degree) insufficient SOPs may impact the quality of services provided by the lab, and any resulting impacts on laboratory clients and the environmental media they affect. Inadequate and undocumented SOPs that affect data quality, may in turn affects the ability of businesses, public entities, or other organizations to effectively comply with all environmental regulations that apply to them. This could not only result in eventual identification of noncompliance with regulations or permits, but in environmental and human health impacts. Documented and submitted (verified) SOPs eliminate this risk.

4.2.3 Quality control practices

We expect these proposed amendments to result in benefits of ensuring a baseline of data quality across all laboratories accredited by Ecology. They reflect both best practice and consistency with approaches used in individual analytical methods, as well as consistency with other regulatory contexts.

Ensuring that laboratories develop individual SOPs and use appropriate laboratory and statistical practices would maintain certainty that the laboratories Ecology provides accreditation to have all the necessary procedures in place to ensure data quality. As with the previous discussion of benefits, it is difficult to quantify, as it also depends on how often (and to what degree) inadequate QC practices could impact the quality of services provided by the lab, and any resulting impacts on laboratory clients and the environmental media they affect.

We acknowledge that most laboratories are already following the proposed quality control practices, and so benefits would not arise, as they would not need to change how they do their work. The proposed rule amendments intend to ensure that all laboratories follow these practices. As we could not confidently make an assumption about the proportion of labs for which this is the case, we conservatively assumed these proposed amendments would affect all labs (see corresponding approach to cost estimates in section 3.2.3). If fewer laboratories need to change their quality control practices under the proposed rule amendments (or change them to a lesser degree), both costs and benefits would scale down to the same degree.

Insufficiently precise or inconsistent laboratory practices affect data quality, that in turn affect the ability of businesses, public entities, or other organizations to effectively comply with all environmental regulations that apply to them. This could not only result in eventual identification of noncompliance with regulations or permits, but in environmental and human health impacts. Any of these impacts could additionally expose the laboratories and their

clients to corrective costs and liability, or even lawsuits. Appropriate and comprehensive QC procedures eliminate this risk.

4.2.4 Data and record traceability

We expect these proposed amendments 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 automated data loggers to 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.

The benefits of these proposed rule amendments are an extension of the benefits discussed in sections 4.2.2 and 4.2.3. Where data is necessary to support regulatory or legal arguments, it needs to be clear and traceable to meet legal standards. While Ecology supports automation where appropriate, the amendments also address the specific attributes of automatic data loggers related to data quality and rapid identification and correction of problems.

We acknowledge that most laboratories are already following the proposed data and record traceability practices, and so benefits would not arise, as they would not need to change how they do their work. The proposed rule amendments intend to ensure that all laboratories follow these practices. In estimating the costs of these proposed amendments, we assumed 10percent of laboratories would need to change how they do business (see corresponding approach to cost estimates in section 3.2.4). Similarly, expectations for this qualitatively discussed set of benefits should reflect that most laboratories would not be impacted by these amendments. If fewer laboratories need to change their quality control practices under the proposed rule amendments (or change them to a lesser degree), both costs and benefits would scale down to the same degree.

4.2.5 Proficiency testing

We expect this proposed rule amendments to result in benefits of microbiology parameter PT consistent with chemistry parameter PT number and frequency under the baseline. This would result in increased confidence in the quality and reliability of microbiology analyses to be consistent with chemistry analyses.

Microbiology parameters include analytes such as fecal coliform, a type of bacteria that often sickens people at beaches or closes shellfish harvests. Having the same level and frequency of PT for microbiology parameters as for chemistry parameters would bring uniform confidence in laboratory results for both categories of accreditation. If it, in turn, affects the actions of laboratory clients in prevention or remediation of microbiology parameters to which the public and environment would be exposed (as opposed to actions based on less-reliable data that may not be as protective in reality despite meeting regulatory requirements on the surface), benefits of this proposed amendment could include reduced impacts to public health and to cultures and economies that depend on shellfish harvest.

4.2.6 Audits

We expect these proposed rule amendments to result in benefits (avoided costs) of audits not necessarily being on-site. We also expect benefits of adequate preparation for audits and resulting audit effectiveness.

As discussed in section 3.2.6, we estimated the costs associated with increased frequency of remote audits. To estimate the underlying benefit mitigating the increased frequency of audits discussed in that section, we assumed between one and 12 hours of Ecology auditor time would be spent round trip, traveling to a lab. We multiplied this $80 to $965 cost by 114 (one third of non-drinking water laboratories) each year. This resulted in a total annual benefit offsetting the costs of increased audit frequency, of $9,000 to $110,000.

4.2.7 Interim accreditation

We expect these proposed rule amendments to result in benefits of verified SOP documentation in cases of interim accreditations. These benefits would be consistent with benefits discussed in section 4.2.2 and 4.2.3.

4.2.8 Maintaining accreditation status

We expect these proposed rule amendments to result benefits of adequate time to complete necessary accreditation review without creating a gap in accreditation. Gaps in accreditation could result in:

- Lost laboratory revenues.
- Need for laboratory clients to seek out alternative laboratories for their analytical work. This could result in increased costs if prices of other laboratories are not comparable. It could also affect expected timing of results if samples must be sent longer distances to other labs, or if clients with large sample quantities need to develop new contracts with a different lab.

4.2.9 Revoking or suspending accreditation

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

4.2.10 Fee structure

We expect these proposed rule amendments to result in benefits of full funding of the Laboratory Accreditation Unit and the services it provides. The labor and overhead costs of performing necessary laboratory accreditation work reflect a low-end proxy of the value of that work (based on economic theory of the marginal cost of providing a good being reflected in the marginal revenue received for that good). In reality, wages and salaries do not reflect the added value that the work provides (in economic terms, consumer surplus, or the willingness to pay for services and their results in excess of the price the market settles on).

In basic dollar terms, the proposed rule amendments to accreditation fees result in benefits precisely equaling the costs, by meeting the statutory goal that fees reflect actual workload costs and not exceed them. The services provided by the Laboratory Accreditation Unit provide value (benefits) beyond this in the form of:

- Assurance that the laboratories analyzing data used for compliance provide accurate and reliable results for regulatory compliance and protection of the public and environment.
- Assurance that the parties using those results to support their compliance with regulations are really meeting their obligations.
- Reduced risk of liability for inadvertent damages to the environment or public health, or ability to provide full documentation in cases of legal action, for laboratories or their customers.
- Reduced risk of repeated or duplicative work, or corrective action resulting from inaccurate analyses.

We note that our discussion of these likely benefits holds the current workload faced by the LAU (whether the total number of labs or the aggregate parameters for which all laboratories are accredited) constant for each year in the future. We were not able to confidently forecast future growth in lab numbers as well as their respective parameters, so holding this value constant was necessary to be able to estimate the impacts of the proposed amendments to fees.

If there is an overall growth in parameters beyond the assumption of the equivalent of an average lab each year, or growth in their complexity in accreditation beyond currently identified parameters, 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 LAU workload would increase nonetheless, potentially resulting once again in accreditation backlogs or other service limitations. This would, in turn, put each of the benefits listed above at risk.

4.2.11 Changes with no material impact

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

Chapter 5: Cost-Benefit Comparison and Conclusions

5.1 Summary of costs and benefits of the proposed rule amendments

Costs

We estimated the following annual costs of the proposed rule amendments. Recall that while we estimated ranges, the real costs likely incurred by labs are at (or below) the low end of these ranges, since most already follow the processes in the proposed rule amendments. This section therefore highlights those lower estimates where that was the case, as the high-end estimates are not likely to reflect actual outcomes. For full discussion and broadly conservative cost ranges, see Chapter 3.

- Responsibilities of environmental laboratories: $39,000 to $78,000
- Quality control practices: $0.8 million
- Data and record traceability: $73,000
- Proficiency testing: $27,000
- Audits: $166,000 to $1.1 million
- Interim accreditation: Costs are reflected in estimates for laboratory responsibilities, above.
- Maintaining accreditation status: $0 annual costs; minor timing costs of submitting information sooner.
- Fee structure: Average increase of $1.2 million in total fee collection in Fiscal Year (FY) 2024, and $1.8 million in FY 2025, growing by an average of 5.9 percent beginning in FY 2026.

The above costs result in average total costs of $3.9 million across all laboratories in FY 2024, increasing to $4.7 million in FY 2025. 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. Present values capture future increases in values stemming from factors like the Fiscal Growth Factor. Over 20 years, the present value equivalent of total cost is $100.6 million (median).

Benefits

We estimated the following benefits of the proposed rule amendments.

- Responsibilities of environmental laboratories:
    - Maintain certainty that the laboratories Ecology provides accreditation to have all the necessary procedures in place to ensure data quality.
    - Inadequate and undocumented SOPs that affect data quality, that in turn affects the ability of businesses, public entities, or other organizations to effectively comply with all environmental regulations that apply to them could not only

result in eventual identification of noncompliance with regulations or permits, but in environmental and human health impacts.

- Quality control practices:
  - maintain certainty that the laboratories Ecology provides accreditation to have all the necessary procedures in place to ensure data quality. We acknowledge that most laboratories are already following the proposed quality control practices.
  - avoided corrective costs and liability, or even lawsuits for laboratories and their clients.
- Data and record traceability:
  - 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. We acknowledge that most laboratories are already following the proposed data and record traceability practices
- Proficiency testing:
  - increased confidence in the quality and reliability of microbiology analyses to be consistent with chemistry analyses.
  - Microbiology parameters include analytes such as fecal coliform, a type of bacteria that often sickens people at beaches or closes shellfish harvests.
- Audits:
  - $9,000 to $110,000 per year in avoided on-site audit costs (Ecology travel costs)
- Interim accreditation:
  - verified SOP documentation in cases of interim accreditations
- Maintaining accreditation status:
  - avoided Lost laboratory revenues
  - avoided Need for laboratory clients to seek out alternative laboratories for their analytical work, and associated costs.
- Fee structure:
  - full funding of the Laboratory Accreditation Unit and the services it provides
  - Added values of LAU services:
    - Assurance that the laboratories analyzing data used for compliance provide accurate and reliable results for regulatory compliance and protection of the public and environment.
    - Assurance that the parties using those results to support their compliance with regulations are really meeting their obligations.
    - Reduced risk of liability for inadvertent damages to the environment or public health, or ability to provide full documentation in cases of legal action, for laboratories or their customers.
    - Reduced risk of repeated or duplicative work, or corrective action resulting from inaccurate analyses.

Uncertainty

We note that our discussion of these likely benefits holds the current workload faced by the LAU (whether the total number of labs or the aggregate parameters for which all laboratories are accredited) constant for each year in the future. We were not able to confidently forecast future growth in lab numbers as well as their respective parameters, so holding this value constant was necessary to be able to estimate the impacts of the proposed amendments to fees. We were also unable to forecast the degree to which laboratories will be directly accredited by Ecology versus by a third party in the future, as this depends on relative costs of the various accreditation choices and business decisions made by each laboratory.

If there is an overall growth in parameters beyond the assumption of the equivalent of an average lab each year, or growth in their complexity in accreditation beyond currently identified parameters, 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 LAU workload would increase nonetheless, potentially resulting once again in accreditation backlogs or other service limitations. This would, in turn, put each of the benefits listed above at risk.

5.2 Conclusion

We conclude, based on a reasonable understanding of the quantified and qualitative costs and benefits likely to arise from the proposed rule amendments, as compared to the baseline, that the benefits of the proposed rule amendments are greater than the costs.

Chapter 6: Least-Burdensome Alternative Analysis

6.1 Introduction

RCW 34.05.328(1)(c) requires Ecology to "…[d]etermine, after considering alternative versions of the rule and the analysis required under (b), (c), and (d) of this subsection, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated under (a) of this subsection." The referenced subsections are:

(a) Clearly state in detail the general goals and specific objectives of the statute that the rule implements;

(b) Determine that the rule is needed to achieve the general goals and specific objectives stated under (a) of this subsection, and analyze alternatives to rule making and the consequences of not adopting the rule;

(c) Provide notification in the notice of proposed rulemaking under RCW 34.05.320 that a preliminary cost-benefit analysis is available. The preliminary cost-benefit analysis must fulfill the requirements of the cost-benefit analysis under (d) of this subsection. If the agency files a supplemental notice under RCW 34.05.340, the supplemental notice must include notification that a revised preliminary cost-benefit analysis is available. A final cost-benefit analysis must be available when the rule is adopted under RCW 34.05.360;

(d) Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

In other words, to be able to adopt the rule, we are required to determine that the contents of the rule are the least burdensome set of requirements that achieve the goals and objectives of the authorizing statute(s).

We assessed alternative proposed rule content, and determined whether they met the goals and objectives of the authorizing statute(s). Of those that would meet the goals and objectives, we determined whether those chosen for inclusion in the proposed rule amendments were the least burdensome to those required to comply with them.

6.2 Goals and objectives of the authorizing statute

- The authorizing statute for this rule is Chapter 43.21A RCW, Department of Ecology. It is the statute that created the agency. Its goals and objectives include Ecology's protection of the environment and public health, as well as balancing the protective efforts undertaken with the state's economic needs.
- RCW 43.21A.230, Certification of environmental laboratories authorized—Fees—Use of certified laboratories by persons submitting data or results to department, specifically authorizes Ecology for laboratory accreditation and fees. Its goals and objectives are:

- Ecology certification (accreditation) of environmental laboratories that conduct tests or prepare data for submittal to Ecology.
- Ecology charging fees for certification to cover but not exceed costs of implementation of the program.

6.3 Alternatives considered and why they were excluded

We considered the following alternative rule content, and did not include it in the proposed rule amendments for the reasons discussed in each subsection below.

- Changing the term "parameter" to "analyte".
- Use of the Procedural Manual as an enforcement document.
- Broadening language used to refer to external documents and guidance.
- Not phasing in fee increases.

6.3.1 Changing "parameter" to "analyte"

During the rule development process, stakeholders suggested that the term "parameter" be changed to "analyte" throughout the rule, in order to be on par with the fee schedule and Ecology's ability to deny accreditation for one analyte within the rule's definition of "parameter". This alternative would not have met the goals and objectives of the authorizing statute because "parameter" as used in the rule encompasses analyte, method, and matrix combinations. A single analyte may be accredited under several methods or matrices which would not apply to a single proficiency test.

6.3.2 Use of the procedural manual as an enforcement document

Stakeholders also suggested that Ecology include specific examples of the types of additional documentation that laboratories might be required to provide, in the Procedural Manual. The reasoning provided suggested that having the examples in the Procedural Manual would allow them to be updated more frequently and as needed. This alternative would not have met the goals and objectives of the authorizing statute, and could have imposed additional burden through lack of immediate clarity. Making the procedural manual an enforcement document would necessitate the manual to follow the same or a similar public feedback process as a rulemaking, and would defeat the purpose of the manual, which is to be a guidance document rather than an enforceable document.

6.3.3 Broader reference language

Stakeholders suggested using generic language (similar to, "For laboratories to be accredited... must follow requirements designed in the drinking water certification manual.") throughout the rule when referencing documents. The rationale provided indicated that this type of language would not become stale with updates and name changes. This alternative would not have met the goals and objectives of the authorizing statute, as we are required to cite specific documents in a regulatory context. This maintains precise clarity about the document being

referenced, and is necessary practice in all rules to effectively implement their authorizing statutes.

6.3.4 Not phasing in fee increases

Ecology considered increasing fees all at once, and not phasing in increases over time. This would have increased burden on laboratories through larger immediate increases in fees. While fee increases are needed to fund the work of the LAU, it has been many years since fees were last updated, and larger fee increases could have posed difficulties for laboratories than phased-in fee increases (as well as future increases according to the Fiscal Growth Factor) that can be better planned for.

6.4 Conclusion

After considering alternatives to the proposed rule's contents, within the context of the goals and objectives of the authorizing statute, we determined that the proposed rule represents the least-burdensome alternative of possible rule contents meeting the goals and objectives.

Chapter 7: Regulatory Fairness Act Compliance

7.1 Introduction

The Regulatory Fairness Act (RFA; RCW 19.85.070) requires Ecology to perform a set of analyses and make certain determinations regarding the proposed rule amendments. This chapter presents the:

- Analysis of relative compliance cost burden.
- Consideration of lost sales or revenue.
- Cost-mitigating elements of the rule, if required.
- Small business and local government consultation.
- Industries likely impacted by the proposed rule.
- Expected impact on jobs.

A small business is defined by the RFA as having 50 or fewer employees, at the highest ownership and operator level. Estimated compliance costs are determined as compared to the baseline (the regulatory environment in the absence of the proposed rule amendments, limited to existing federal and state requirements). Analyses under the RFA only apply to costs to "businesses in an industry" in Washington State. This means the impacts, for this part of our analyses, are not evaluated for government agencies.

7.2 Analysis of relative compliance cost burden

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.[16] Based on cost estimates in Chapter 3, we estimated the following compliance costs per employee.

Table 11. Compliance costs per employee.

Type of cost	Low	High
Small business cost per employee	**$598**	**$2,084**
Largest business cost per employee	**$0.03**	**$0.11**

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 below in Section 7.4.

[16] Dun & Bradstreet, 2023. Market Insight. Database tool.

7.3 Loss of 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 12: 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%**

7.4 Action taken to reduce small business impacts

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[17]. The proposed rule amendments do, however, phase in changes to laboratory accreditation fees over FY 2024 and 2025.

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.

7.5 Small business and government involvement

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.

[17] The purpose and scope of the rulemaking can be found in the CR-101.

- E-mail communications to all permittees.

7.6 North American Industry Classification System codes of impacted industries

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 13. NAICS codes of affected laboratories or their owners.

NAICS Code	Description
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**

7.7 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.[18] 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.

Table 14. Estimated Impact on jobs, FTEs.

Industry	Initial Jobs Impact	Jobs Impact in 20 years
Whole state	**14**	**45**
Construction	**2**	**3**
State and Local Government	**1**	**5**
Management, Scientific, and Technical Consulting Services	**0**	**4**
Retail Trade	**1**	**3**
Food Services and Drinking Places	**1**	**3**

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

[18] This impact persisted in model results through 2043.

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.

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Appendix A: Administrative Procedure Act (RCW 34.05.328) Determinations

A. RCW 34.05.328(1)(a) – Clearly state in detail the general goals and specific objectives of the statute that this rule implements.

See Chapter 6.

B. RCW 34.05.328(1)(b) –

1. Determine that the rule is needed to achieve the general goals and specific objectives of the statute.

See chapters 1 and 2.

2. Analyze alternatives to rulemaking and the consequences of not adopting this rule.

There are 2 alternatives to rulemaking for the above concerns.

1. **<u>Continuing current fee schedule with supplemental funding</u>**
    - To continue with the current fee schedule without completing a rulemaking, the LAU must ask for additional supplemental resources from the Legislature to close the gap between the resources needed to process all accreditation actions and the resources made available through the current fee structure. This is currently the process the LAU relies upon. However, the outcome is highly dependent on the competing priorities presented to the Legislature. Over the years, this approach has failed to adequately close the gap between the LAU's cost and the LAU's revenue.
2. **<u>Continuing current fee schedule without supplemental funding</u>**
    - If Ecology does not move forward with this rulemaking and does not receive supplemental funding, the likely scenario is that the LAU will be forced to maximize the number of audits and renewals that can be done on the limited resources available. This will likely necessitate the auditors to perform less thorough reviews of laboratories to just maintain status quo. This could compromise the quality of the LAU's work which does not align with the Agency's mission to protect the State's air, land, and water.

Please see the Least Burdensome Alternative Analysis, Chapter 6 of this document, for discussion of alternative rule content considered.

C. RCW 34.05.328(1)(c) - A preliminary cost-benefit analysis was made available.
When filing a rule proposal (CR-102) under RCW 34.05.320, Ecology provides notice that a preliminary cost-benefit analysis is available. At adoption (CR-103 filing) under RCW 34.05.360, Ecology provides notice of the availability of the final cost-benefit analysis.

D. RCW 34.05.328(1)(d) – Determine that probable benefits of this rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.
See Chapters 1 – 5.

E. RCW 34.05.328 (1)(e) - Determine, after considering alternative versions of the analysis required under RCW 34.05.328 (b), (c) and (d) that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated in Chapter 6.
Please see Chapter 6.

F. RCW 34.05.328(1)(f) - Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.
This rule is a revision of exiting rule that previously did not contain any known violations of state or federal law. Also, during our rule development, we were in communication with colleagues from the Environmental Protection Agency and Washington Department of Health to help assure there are no new conflicts with state or federal laws. Finally, our rules have been reviewed by Ecology's Assistant Attorney General.

G. RCW 34.05.328 (1)(g) - Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.
The Environmental Protection Agency allows the Laboratory Accreditation Unit to provide the accreditation (the purpose of the existing rule) necessary to assure that public drinking water is safe to drink. The LAU does this by auditing to assure the drinking water laboratories are held to standards such as 40CFR 141, and other relevant federal and state regulations. Therefore, EPA does not need to accredit the laboratories directly, and this is called State Primacy. The EPA allows states to have more stringent requirements than the federal regulations if the state deems it necessary.

H. RCW 34.05.328 (1)(h) Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter.

Yes.

- If **yes**, the difference is justified because of the following:

☐ (i) A state statute explicitly allows Ecology to differ from federal standards.

☒ (ii) Substantial evidence that the difference is necessary to achieve the general goals and specific objectives stated in Chapter 6.

The granting of state primacy from the EPA implies that the state accreditation standards are either equal to, or more stringent than, the federal requirements.

I. RCW 34.05.328 (1)(i) – Coordinate the rule, to the maximum extent practicable, with other federal, state, and local laws applicable to the same subject matter.

During our rule development process, we were in communication with colleagues from the Environmental Protection Agency and Washington Department of Health on topics of:

- Suggested additional rule content.
- Concerns about proposed rule content.
- Suggested edits to existing rule content.