Washington State Register

WSR 23-09-067 PROPOSED RULES DEPARTMENT OF ECOLOGY

[Order 22-07—Filed April 19, 2023, 8:23 a.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 22-21-041. Title of Rule and Other Identifying Information: Chapter 173-50 WAC, Accreditation of environmental laboratories. For more information on this rule making, visit https://ecology.wa.gov/Regulations-Permits/ Laws-rules-rulemaking/Rulemaking/WAC-173-50.

Hearing Location(s): On May 25, 2023, at 9 a.m. - 12 p.m., webinar. Presentation and question and answer session followed by the hearing. We are holding this hearing via webinar. This is an online meeting that you can attend from any computer using internet access. Register here https://waecy-wa-gov.zoom.us/meeting/register/ tZYocOmurDojHtEDkyIcpuhpCfIiVJuqpOPF. Once registered, for audio call United States Toll number 1-253-215-8782. Enter the meeting ID of 825 7062 1945, and enter passcode 174911; and on May 31, 2023, at 1 p.m. -4 p.m., webinar. Presentation and question and answer session followed by the hearing. We are holding this hearing via webinar. This is an online meeting that you can attend from any computer using internet access. Register here https://waecy-wa-gov.zoom.us/meeting/register/ tZUvcuGorj8iE92rKsK1GMePhXKdBw34pJVO. Once registered, for audio call United States Toll number 1-253-215-8782. Enter the meeting ID of 812 5800 4899, and enter passcode 174911.

Date of Intended Adoption: August 28, 2023.

Submit Written Comments to: Ryan Zboralski, P.O. Box 488, Manchester, WA 98353-0488, email ryan.zboralski@ecy.wa.gov, by June 7, 2023.

Assistance for Persons with Disabilities: Contact the department of ecology's (ecology) ADA Coordinator, phone 360-407-6831, TTY 877-833-6341, email ecyadacoordinator@ecy.wa.gov, by May 22, 2023.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The proposed rule amendments would achieve the following goals:

Amend wording in existing sections and add new sections to increase clarity and to incorporate existing best practices, quality control, and rules for participation in the lab accreditation program, including:

- Updates and clarifications to definitions.
- Require laboratories to submit standard operating procedures (SOPs).
- Update and clarify quality control requirements.
- Add data management and record traceability requirements.
- Require additional proficiency testing (PT) sample per parameter per year for microbiology parameters.
- Clarify procedural requirements for PT.
- Clarify and update audit procedures and frequency.
- Clarify requirements for accreditation of drinking water laboratories.
- Clarify that laboratories must notify ecology at least 30 days prior to a permanent laboratory move.
- Update reasons for suspension of accreditation to include: violation of federal law.

Amend the fee structure to meet current ecology laboratory accreditation unit (LAU) implementation costs and address the need to increase fees to cover future cost increases.

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

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

Statutory Authority for Adoption: Chapter 43.21A.230 Certification of environmental laboratories authorized—Fees—Use of certified laboratories by persons submitting data or results to department.

Statute Being Implemented: Not applicable.

Rule is not necessitated by federal law, federal or state court decision.

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: Not applicable.

Name of Proponent: Ecology, governmental.

Name of Agency Personnel Responsible for Drafting and Implementation: Ryan Zboralski, Manchester, 360-764-9364; Enforcement: Rebecca Wood, Manchester, 360-742-7022.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Ryan Zboralski, P.O. Box 488, Manchester, WA 98353-0488, phone 360-764-9364, email ryan.zboralski@ecy.wa.gov.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(3) as the rules relate only to internal governmental operations that are not subject to violation by a nongovernment party; rules are adopting or incorporating by reference without material change federal statutes or regulations, Washington state statutes, rules of other Washington state agencies, shoreline master programs other than those programs governing shorelines of statewide significance, or, as referenced by Washington state law, national consensus codes that generally establish industry standards, if the material adopted or incorporated regulates the same subject matter and conduct as the adopting or incorporating rule; rules only correct typographical errors, make address or name changes, or clarify language of a rule without changing its effect; and rule content is explicitly and specifically dictated by statute.

Scope of exemption for rule proposal:

Is partially exempt:

Explanation of partial exemptions: We analyzed the impacts of the proposed rule amendments relative to the existing rule, within the context of all existing requirements (federal and state laws and rules). This context for comparison is called the baseline and reflects the most likely regulatory circumstances that entities would face if the proposed rule was not adopted.

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

For this rule making, 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:

- o Authorizes ecology to certify environmental laboratories that conduct tests or prepare data for submittal to ecology.
- o Authorizes ecology to charge fees for certification to cover costs.
- o 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.
- O 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).
- o 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:
 - o 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:
 - o 42 U.S.C. Sec. 300h et seq., Safe Drinking Water Act.
 - o 40 C.F.R. Part 136, Guidelines Establishing Test Procedures for the Analysis of Pollutants.
 - o 40 C.F.R. Part 141, National Primary Drinking Water Regulations.
- 2.3 Proposed rule amendments: 2.3.1 Definitions: Baseline: The baseline rule and law include multiple definitions to support implementation.

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

- 2.3.2 Responsibilities of environmental laboratories: Baseline: The baseline law and rule set requirements for laboratories when they apply for initial accreditation, including requirements for:
- Application.
- Quality assurance (QA) manual.
- PT sample results.
- On-site audit.

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

- Submission of SOPs.
- Some audits would no longer be on site. Audits could be remote unless ecology determines an on-site audit is necessary.

2.3.3 Quality control practices: Baseline: The baseline rule does not include explicit requirements for 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.
- Multilevel 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 highbiased sample data can be reported.
- Documentation of resolution of spectral interferences inductively coupled plasma optical emission spectrometry (ICP-OES).
- 2.3.4 Data and record traceability: Baseline: The baseline rule does not include explicit requirements for data and record traceability.

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

- Be able to recreate final sample results by means of records in entirety.
- Document proper storage of any chemical, reagent, and/or used by an analytical method.
- Document proper storage of samples as required by the specific analytical method and/or regulation.
- Document that all temperature-based equipment such as a refrigerator, oven, or incubator is both within control and checked manually as required by the relevant analytical method.
- Keep logbooks for any and all instruments, including documentation of installation, setup, maintenance, and removal from service.
- Document proper preparation and QC of chemicals, reagents, and media used in support of the analyses.
- Not use "erasable" handwritten records; requirement of traceable and secure format for electronic records.
- 2.3.5 Proficiency testing: Baseline: The baseline law and rule include requirements for PT, including, but not limited to:
- Acceptable use of previous PT studies.
- Minimum number and frequency of PT samples.
- Potential for raw data submission.
- Waivers for certain parameters if two or more PT samples do not exist or for other valid reasons.
- Approved PT sample vendors.

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

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

Proposed: Under the proposed rule amendments, audits would not automatically all be on site. Ecology would continue to audit laboratories accredited for drinking water analyses on site but would otherwise perform on-site audits only when necessary (laboratory does not have appropriate resources for remote audit; remote audit may not capture applicable concerns; etc.).

Audits would occur at least every three years at all laboratories directly accredited by ecology (i.e., not accredited by ecology through third-party recognition), and any requested documentation, including at least SOPs and analytical data, would need to be submitted at least two weeks before the audit.

- 2.3.7 Interim accreditation: Baseline: The baseline law and rule include requirements for interim accreditation, including submission of:
- Application and fees.
- PT.
- QA manual.
- Potential analytical data package.

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

- 2.3.8 Maintaining accreditation status: Baseline: The baseline law and rule include requirements for maintaining accreditation status, including:
- Definition of accreditation period (one year) and expiration.
- Renewal requirements.
- Three-year audit frequency for laboratories accredited for drinking water parameters (as required by EPA).
- Audit frequency determined by ecology for laboratories accredited for nondrinking water parameters.

Proposed: The proposed rule amendments would:

- Clarify that laboratories that plan to permanently move are subject to the same accreditation requirements as new labs, since accreditation is inherently specific to the laboratory location.
- Require laboratories planning to permanently move to notify ecology at least 60 days before new accreditation is needed.
- Add flexibility for temporary or emergency laboratory moves, identifying that they would be handled on a case-by-case basis.
- 2.3.9 Revoking or suspending accreditation: Baseline: The baseline law and rule include requirements for revoking or suspending accreditation, including:
- Definitions of revocation and suspension.
- Reasons for suspension or revocation:
 - o Failure to comply with audit standards.
 - o Violation of state rules.
 - o Misrepresentation.
 - o Falsification of reports.
 - o Unethical or fraudulent practices.
 - o Deficiencies in accuracy and defensibility of data.
 - o Refusal to permit enforcement entry.
 - o Failure to pay fees.
 - o Failure to maintain third-party accreditation.
 - o Two consecutive unsatisfactory PT results.

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

2.3.10 Fee structure: Baseline: The baseline law and rule include the fee structure and specific fees associated with laboratory accreditation. These fees and structure were developed during the last amendments made to this rule, in 2010, to reflect the program costs at

that time. They include minimum (\$300) and maximum (variable by parameter) fees.

Proposed: The proposed rule amendments would:

- Remove maximum fees.
- Phase in fee increases beginning in fiscal year (FY) 2024 (July
- Increase fees beginning in FY 2026 according to the state's fiscal growth factor.
- Increase minimum fees to \$500.
- Add a fee of \$300 for reaccreditation after 12 months of not being accredited.
- 2.3.11 Changes with no material impact: Baseline: The baseline rule includes wording that ecology identified, 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 EPA Manual for the certification of laboratories analyzing drinking water.
- Appropriate basic laboratory and statistical methods must be used.
- PT samples must follow the same preparation and analytical processes as client samples.
- Audits for third-party accreditation are done by the relevant accrediting authority.
- Fees reflect costs of work done outside the normal application/ renewal points of contact.

The proposed rule does impose more-than-minor costs on businesses.

Small Business Economic Impact Statement (SBEIS)

This SBEIS presents the:

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

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

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

This information is excerpted from ecology's complete set of regulatory analyses for this rule making. For complete discussion of the likely costs, benefits, minimum compliance burden, and relative burden on small businesses, see the associated regulatory analyses document

(Ecology publication no. 23-03-010, April 2023) We have retained section numbers here for easy cross-reference.

compliance requirements of the proposed rule, including professional services: 2.3.1 Definitions: Definitions do not, in and of themselves, create regulatory requirements; definitions support requirements set elsewhere in the rule. Where definitions contribute to the impacts of rule requirements, the overall impacts of those requirements are discussed in the sections below.

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

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

- 2.3.3 Quality control practices: We expect these proposed amendments (new requirements) to result in labor costs associated with the additional time and effort necessary to perform these tasks or perform existing tasks using the required procedures. We expect them to result in benefits of ensuring a baseline of data quality across all laboratories accredited by ecology, as they reflect both best practice and consistency with methods used, as well as consistency with other regulatory contexts.
- 2.3.4 Data and record traceability: We expect these proposed amendments (new requirements) to result in labor costs associated with the additional time and effort necessary to perform these tasks or perform existing tasks using the required procedures. We expect them to result in benefits of high-quality records that survive legal scrutiny, as could potentially be involved in noncompliance, penalties, lawsuits, and other regulatory or legal contexts that could be faced by the laboratory or its customers. This includes a shift from exclusive use of automated data loggers in lieu of manual checking, to reduce uncaught temperature errors for incubators, as there is a narrow range of acceptable temperatures to which the loggers are not sufficiently sensitive.
- 2.3.5 Proficiency testing: We expect these proposed rule amendments to result in costs of additional PT analysis, as well as benefits of microbiology parameter PT consistent with chemistry parameter PT number and frequency under the baseline. The latter would result in increased confidence in the quality and reliability of microbiology analyses to be consistent with chemistry analyses.
- 2.3.6 Audits: We expect these proposed rule amendments to result in additional time costs associated with the time and effort (at non-drinking water labs) necessary to undergo audits at least every three years, mitigated by benefits (avoided costs) of those audits not necessarily being on site. We also expect minor timing costs associated with when documentation is submitted to ecology, and benefits of adequate preparation for audits and resulting audit effectiveness.
- 2.3.7 Interim accreditation: We expect these proposed rule amendments to result in costs of additional time to submit SOPs in cases of interim accreditations, as well as benefits of verified SOP documentation in those cases.
- 2.3.8 Maintaining accreditation status: We expect these proposed rule amendments to result in timing costs associated with notification

of planned moves, and benefits of adequate time to complete necessary accreditation review without creating a gap in accreditation.

- 2.3.9 Revoking or suspending accreditation: We do not expect this proposed rule amendment to result in significant costs or benefits, as it is in line with violation of state law as a reason for suspension or revocation.
- 2.3.10 Fee structure: We expect these proposed rule amendments to result in costs of increased fees, as well as benefits of full funding of the LAU and the services it provides.
- 2.3.11 Changes with no material impact: We do not expect these proposed rule amendments to result in costs or benefits beyond clarity.

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

costs of compliance: supplies: 3.2.5 Proficiency testing: We expect this proposed rule amendment to result in costs of additional PT analyses.

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

COSTS OF COMPLIANCE: LABOR: 3.2.2 Responsibilities of environmental laboratories: We expect the proposed rule amendments to result in costs of additional time to submit SOPs. They would also result in reduced costs associated with audits if they are remote rather than on site.

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

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

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

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

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

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

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

3.2.6 Audits: We expect these proposed rule amendments to result in additional time costs associated with the time and effort (at nondrinking 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:

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

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

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

Table 2. Staff wages:

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

The total estimated costs associated with these rule amendments was \$166,000 to \$1.1 million (including overhead costs), of which

\$73,000 to \$0.5 million would be costs incurred by ecology (funded by fees), and \$40,000 to \$0.5 million would be costs incurred directly by labs.

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

- 3.2.7 Interim accreditation: We expect these proposed rule amendments to result in costs of additional time to submit SOPs in cases of interim accreditations. As these costs would be incurred as part of proposed amendments to regular accreditation, they are already reflected in the cost estimate discussed in Section 3.2.2.
- 3.2.8 Maintaining accreditation status: We expect these proposed rule amendments to result in timing costs associated with notification of planned moves. We note, however, these would not be significant additional costs, as compared to the baseline, but rather opportunity costs of expenditures at different times. The table below illustrates the opportunity costs associated with spending one dollar at various delayed times.

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

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

costs of compliance: administrative costs: Where applicable, ecology estimates administrative costs (overhead) as part of the cost of labor and professional services, above.

COSTS OF COMPLIANCE: OTHER: 3.2.10 Fee structure: We expect these proposed rule amendments to result in costs of increased fees.

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

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

Category	Fee Per Parameter	Fee Per Method	Max Fee
General chemistry	\$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

Table 5. Proposed fees for Fiscal Year 2024:

Category	Fee Per Parameter	Per Parameter Add Fee to Existing Method	Fee Per Method
General chemistry	\$150	_	
Trace metals		\$30	\$745
Organics I		\$15	\$375
Organics II	_	\$35	\$930
Microbiology	\$375	_	
Radiochemistry	\$555		
Bioassay	_	\$15	\$375
Immunoassay	\$150	_	
Physical	\$150		<u> </u>

Table 6. Proposed fees for Fiscal Year 2025:

Category	Fee Per Parameter	Per Parameter Add Fee to Existing Method	Fee Per Method
General chemistry	\$220	_	_
Trace metals	_	\$55	\$1,085
Organics I		\$30	\$545
Organics II		\$70	\$1,355
Microbiology	\$545	_	_
Radiochemistry	\$680	_	_
Bioassay		\$25	\$445
Immunoassay	\$220	_	_
Physical	\$220	_	_

During the development of the proposed rule, we estimated the difference in fees at 15 representative types of laboratories, 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 and added parameters to an existing method and methods that were on average 33 percent higher than proposed FY 2024 fees and 13 percent lower than proposed FY 2025 fees.

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

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

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

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

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

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

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

COMPARISON OF COMPLIANCE COST FOR SMALL VERSUS LARGE BUSINESSES: We calculated the estimated per-business costs to comply with the proposed rule amendments, based on the costs estimated in Chapter 3 of this document. In this section, we estimate compliance costs per employee.

The average affected small business likely to be covered by the proposed rule amendments employs approximately 11 people. The largest 10 percent of affected businesses employ an average of 205,249 people at their highest ownership level. Based on cost estimates in Chapter 3, we estimated the following compliance costs per employee.

Table 8. Compliance costs per employee:

Type of cost	Low	High
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 in Section 7.4.

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

We used the REMI E3+ model for Washington state to estimate the impact of the proposed rule amendments on directly affected markets, accounting for dynamic adjustments throughout the economy. The model accounts for: Interindustry 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 per-

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

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

MITIGATION OF DISPROPORTIONATE IMPACT: RFA 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 rule making. 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 rule making.

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 rule making.

While the scope and authorization for this rule limited ecology's options in reducing the disproportion of compliance cost burden, we note that the cost estimation (see Chapter 3) is based in part on a range of representative labs. This range is based on a sample of the overall laboratory population, and may overestimate the relative numbers or types of analytes (and thus, fees) for very small, independent labs. Some small laboratories are currently accredited for as few as one analyte, as necessary for their internal work, and this would naturally reduce their costs per employee even further than the costs estimated for a representative small laboratory in the table above.

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

- Three stakeholder workshops 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 held from November 2, 2022, to January 4, 2023.
- Email communications to all permittees.

NAICS CODES OF INDUSTRIES IMPACTED BY THE PROPOSED RULE: The proposed rule amendments likely impact the following industries, with associated North American Industry Classification System (NAICS) codes. NAICS definitions and industry hierarchies are discussed at https:// www.census.gov/cgi-bin/sssd/naics/naicsrch?chart=2017.

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

NAICS 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

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 acknowledgment 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 FTE total across all laboratories, increasing to a loss of two to three FTEs in 2027, and this loss would likely be permanent. To test the sensitivity of this result to our low-cost assumption, we also ran the model using high-cost inputs that reflect much broader or universal incurrence of the costs of additional quality control and data quality activities than is likely based on current lab practices and interpretations of the baseline rule. This resulted in the laboratory sector losing between two and 15 FTEs annually through 2043.

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

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

A copy of the statement may be obtained by contacting Ryan Zboralski, P.O. Box 488, Manchester, WA 98353-0488, phone 360-764-9364, email ryan.zboralski@ecy.wa.gov.

> April 19, 2023 Heather R. Bartlett Deputy Director

OTS-4306.5

AMENDATORY SECTION (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

WAC 173-50-040 Definitions. Definitions in this section apply throughout this chapter, unless context clearly indicates otherwise.

"Accreditation" - The formal recognition by the department that an environmental laboratory is capable of producing accurate and defensible analytical data. This recognition is signified by issuance of a written certificate accompanied by a scope of accreditation indicating the parameters for which the laboratory is accredited.

- The term "accredit" as used in this chapter is intended to have the same meaning as the term "certify" as used in RCW 43.21A.230.

 • Any laboratory accredited under this chapter shall be deemed to
- have been certified under RCW 43.21A.230.
- The department does not, by accrediting any laboratory pursuant to these rules, vouch for or warrant the accuracy of any particular work done or report issued by that laboratory.

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

"Accuracy" - The degree to which an analytical result corresponds to the true or accepted value for the sample being tested. Accuracy is affected by bias and precision.

"Analyte" - The constituent or property of a sample measured using an analytical method.

"Analytical data" - The recorded qualitative and/or quantitative results of a chemical, physical, biological, microbiological, radiochemical, or other scientific determination.

"Analytical method" - A written procedure for acquiring analytical data.

"Audit" - An inspection and evaluation of laboratory facilities, equipment, records, and staff. This may be on-site or virtual.

"Calibration curve" - A series of standards of known concentrations used to determine the relationship between concentration and analytical response.

"Data traceability" or "traceability" - The ability to recreate the final result by means of records. This must be an unbroken trail of accountability for verifying or validating the chain of custody of samples, the data, the documentation of a procedure, or the values of a standard.

"Department" - The state of Washington department of ecology when the term is not followed by another state designation.

"Drinking water certification manual" - The Environmental Protection Agency Manual for the Certification of Laboratories Analyzing Drinking Water, 5th Edition, January 2005.

"Ecology accrediting authority" - The supervisor of the lab accreditation unit of the environmental assessment program of the department of ecology.

"Environmental laboratory" or "laboratory" - A facility:

- Under the ownership and technical management of a single entity in a single geographical location or in a self-contained mobile unit;
- Where scientific determinations are performed on samples taken from the environment, including drinking water samples; and
- Where data is submitted to the department of ecology, department of health, or other entity requiring the use of an accredited laboratory under provisions of a regulation, permit, or contractual agreement.

"Instrument" or "instrumentation" - Equipment used to measure an analyte(s).

"Lab accreditation unit" - The lab accreditation unit of the department of ecology.

"Laboratory control sample" or "LCS" (also known as a "laboratory fortified blank" or "LFB") - An aliquot of analyte-free water or analyte-free solid (e.g., Ottawa sand, anhydrous sodium sulfate, or other purified solid) to which known amounts of the method analytes are add-<u>ed.</u>

"Limit of quantitation" or "LOQ" - Lowest amount of analyte that can be measured with acceptable precision and accuracy as required by data quality objectives.

"Matrix" - The material to be analyzed, including, but not limited to, ground or surface water, wastewater, drinking water, air, solid waste, soil, tissue, nuclear waste, and hazardous waste. For the purposes of establishing a fee structure (WAC 173-50-190(4)), matrices are grouped as follows:

- Nonpotable water;
- Drinking water;
- Solid and chemical materials; and
- Air and emissions.

(("On-site audit" - An on-site inspection and evaluation of laboratory facilities, equipment, records and staff.))

"Matrix spike" or "MS" - Matrix spikes are aliquots of environ-mental samples to which known concentrations of certain target analytes have been added before sample preparation, cleanup, and determinative procedures have been implemented.

"Method detection limit" or "MDL" - The minimum concentration of an analyte that can be measured and reported with a 99 percent confidence that the analyte concentration is distinguishable from the method blank results as determined by the procedure set forth in Appendix B of 40 C.F.R. Part 136.

"Out-of-state laboratory" - A laboratory that is not located in the state of Washington.

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

• The analyte alkalinity by method SM 2320 B in nonpotable water;

- The analyte ((zinc)) arsenic by method EPA ((200.7)) 200.8 in drinking water;
- The ((set of analytes called volatile organic compounds (VOCs))) analyte benzene by method EPA 8260 in solid and chemical materials; and
- The analyte ((Total Coli/Ecoli-count)) fecal coliform-count by method SM 9222 ((B/9221 F)) <u>D in nonpotable water</u>.

 "Principal laboratory" - A laboratory designated by the Washing-

ton department of health to support the drinking water certification program.

"Procedural manual" - The most recent version of the Department of Ecology's Procedural Manual for the Environmental Laboratory Accreditation Program ((dated September 2010)).

"Proficiency testing (PT)" - Evaluation of the results from the analysis of samples <u>in the accredited matrix</u>, the true values of which are known to the supplier of the samples but unknown to the laboratory conducting the analyses. PT samples are provided by a source external to the environmental laboratory.

"Quality assurance (QA)" - Activities intended to assure that a quality control program is effective. A QA program is a totally integrated program for assuring reliability of measurement data.

"Quality assurance (QA) manual" - A written record intended to assure the reliability of measurement data. A QA manual documents policies, organization, objectives, and specific QC and QA activities. Volume and scope of QA manuals vary with complexity of the laboratory mission.

"Quality control (QC)" - ((The routine application of statistically based procedures to evaluate and control the accuracy of analytical results.)) The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality.

"Regulatory program" - A program administered by a federal, state, or other regulatory agency.

"Standard operating procedure" or "SOP" - A detailed written description of a procedure designed to systematize performance of the procedure.

"Third-party accreditation" - Recognition by the ecology accrediting authority of accreditation granted by another accrediting authority.

"WA ELAP" - Washington state environmental laboratory accreditation program.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-040, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-040, filed 10/1/02, effective 11/1/02; WSR 93-20-011 (Order 92-53), § 173-50-040, filed 9/22/93, effective 10/23/93; WSR 90-21-090 (Order 90-21), § 173-50-040, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-040, filed 4/20/89 and 3/13/90, effective 4/13/90.]

AMENDATORY SECTION (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

- WAC 173-50-050 Responsibilities of the department. (1) The department maintains a procedural manual describing specifics of the accreditation process. As a minimum, the procedural manual describes the procedures for:
 - Submitting an application and fee;
 - Preparing a quality assurance manual;
 - Performing proficiency testing;
 - Conducting ((on-site)) audits;
 - Accrediting out-of-state laboratories;
 - Granting, denying, suspending, and revoking accreditation; and
- · Notifying laboratories and authorized government officials of accreditation actions.

The department will make the procedural manual available to all interested persons.

(2) Department personnel assigned to assess the capability of drinking water laboratories participating in the WA ELAP must meet the experience, education, and training requirements established in the drinking water certification manual.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-050, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-050, filed 10/1/02, effective 11/1/02; WSR 93-20-011 (Order 92-53), § 173-50-050, filed 9/22/93, effective 10/23/93; WSR 90-21-090 (Order 90-21), § 173-50-050, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-050, filed 4/20/89 and 3/13/90, effective 4/13/90.

AMENDATORY SECTION (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

- WAC 173-50-060 Responsibilities of environmental laboratories. (1) When applying for initial accreditation (see WAC 173-50-130 for maintaining an existing accreditation), managers of environmental laboratories must:
- ((+)) (a) Submit an environmental laboratory accreditation application (WAC 173-50-063) and required fees (WAC 173-50-190) to the department fiscal officer;
- ((*)) (b) Submit a copy of the laboratory's quality assurance manual (WAC 173-50-067);
- ((*)) (c) For laboratories seeking direct accreditation from the department, SOP's for all methods for which the laboratory is seeking accreditation must, at a minimum, be submitted;
- (d) Submit an initial set of satisfactory PT sample results (WAC 173-50-070); and
 - ((+)) <u>(e)</u> Undergo an ((on-site)) audit (WAC 173-50-080).
- (2) For laboratories to be accredited for drinking water parameters, the laboratory must follow requirements designated in the drinking water certification manual.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-060, filed 8/9/10, effective

9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-060, filed 10/1/02, effective 11/1/02; WSR 90-21-090 (Order 90-21), § 173-50-060, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-060, filed 4/20/89 and 3/13/90, effective 4/13/90.

NEW SECTION

- WAC 173-50-061 Required quality control practices. Laboratories must comply with the following quality control practices:
- (1) Have a dedicated SOP for each method listed on their current Washington scope of accreditation.
 - (2) For parameters where a multilevel calibration is necessary:
- (a) A laboratory must not remove any midpoints from a calibration curve with the exception of consecutive points at either end of the
- (b) Each calibration point must have its value recalculated against the calibration curve. Unless specified in the method, each calibration point must have its percent error or relative standard error meet the calibration verification acceptance limits from the method; with the exception points at or below the LOQ where the limit is 50 - 150 percent error, or percent relative standard error.
- (3) For parameters that require a limit of quantitation and the method does not specify any requirements, laboratories must analyze a standard at their limit of quantitation at least annually. This standard must meet 50 percent of the true value. This applies to the following instrumentation technologies:
 - (a) Atomic absorption;
 - (b) Flow-injection analysis;
 - (c) Gas and liquid chromatography;
 - (d) Inductively coupled plasma;
 - (e) Ion chromatography;
 - (f) Spectrometry;
 - (q) Total organic carbon analysis; and
- (h) Any other technology where method detection limits are applicable.
- (4) Matrix spikes are required as specified by the method. Observed matrix issues must be addressed for regulated parameters under the federal Safe Drinking Water Act and Clean Water Act.
- (5) Laboratory control samples must include all analytes of interest in the respective analysis. Matrix spikes should include all analytes of interest in the respective analysis.
- (6) When quality control samples for chemistry parameters such as a laboratory control sample are above their acceptance criteria for a parameter(s), the data for that parameter(s) can only be reported if the laboratory can demonstrate:
- (a) No source of low bias of that parameter(s) is also present in the sample(s) and/or other related quality control samples;
- (b) Instrument calibration have met method acceptance criteria; and
- (c) The reported samples do not have a detection for the high biased parameter(s).
- (7) Documented resolution of spectral interferences is required for ICP-OES.

AMENDATORY SECTION (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

- WAC 173-50-063 Application. (1) Through ((the)) a department environmental laboratory accreditation application, laboratory managers:
 - ((♠)) (a) Request accreditation for specific parameters;
 - ((*)) (b) Calculate fees due to the department; and
- ((-)) <u>(c)</u> Provide evidence that sufficient <u>and capable</u> personnel and equipment are available to successfully perform analytical methods as specified in the application.
- (2) Through review of the application submitted by the applicant laboratory, the lab accreditation unit determines if:
 - ((*)) (a) Requested parameters are eligible for accreditation;
- $((\bullet))$ The fee calculated by the applicant laboratory is correct; and
- ((-)) <u>(c)</u> Personnel and equipment are adequate to support successful performance of requested parameters.
- (3) Following the review, the lab accreditation unit advises the applicant laboratory of any required changes.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 \S 301. WSR 10-17-032 (Order 09-09), \S 173-50-063, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), \S 173-50-063, filed 10/1/02, effective 11/1/02.]

AMENDATORY SECTION (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

- WAC 173-50-067 Quality assurance manual. (1) The lab accreditation unit reviews and approves the laboratory's QA manual prior to the initial ((on-site)) audit. The QA manual submitted concurrently with ((the)) a department environmental laboratory accreditation application must be in detail and scope commensurate with the size and mission of the laboratory. Guidelines for contents of the QA manual are in the procedural manual.
- (2) The QA manual must address QA and QC requirements of applicable regulatory programs. For drinking water laboratories, such requirements ((are)) can be found in the drinking water certification manual and/or approved method.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-067, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-067, filed 10/1/02, effective 11/1/02.]

NEW SECTION

- WAC 173-50-069 Data and record traceability. (1) In order to demonstrate data traceability, laboratories must:
- (a) Be able to recreate final sample results by means of records in entirety;
- (b) Document proper storage of any chemical, reagent, and/or media used by an analytical method;
- (c) Document proper storage of samples as required by the specific analytical method and/or regulation;
- (d) 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;
- (e) Keep logbooks for any and all instruments, including documentation of installation, setup, maintenance, and removal from service; and
- (f) Document proper preparation and QC of chemicals, reagents, and media used in support of the analyses.
- (2) When records are handwritten, they must be in indelible ink and comply with the relevant method requirements. Incubator temperatures must be handwritten and include the date and time(s) of reading, temperature(s), and technician's initials.
- (3) When records are kept electronically, they must be recorded at the time of reading, using a fully traceable and secure format. Use of continuous data-loggers is not an acceptable substitute for method and/or regulatory required incubator temperature checks.

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AMENDATORY SECTION (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

- WAC 173-50-070 Proficiency testing (PT). (1) The lab accreditation unit advises applying laboratories of specific requirements for participation in proficiency testing (PT) studies for applicable parameters. Proficiency tests conducted under the provisions of other recognized programs may be used to satisfy these requirements. The lab accreditation unit determines the sufficiency of such proficiency tests.
- (2) Accredited laboratories must analyze a minimum of ((one)) two PT samples per applicable ((microbiology parameter per year and two PT samples for applicable chemistry)) parameters per year. ((For chemistry parameters,)) After an accredited laboratory submits two satisfactory PT sample results and no unsatisfactory results in an accreditation year, the laboratory is required to submit only one satisfactory PT sample result in subsequent accreditation years. This applies as long as there are no intervening unsatisfactory PT sample results.
- (3) The lab accreditation unit may require the laboratory to submit raw data along with the report of analysis of PT samples.
- (4) The lab accreditation unit may waive proficiency tests for certain parameters if PT samples are not readily available or for other valid reasons.
- (5) Applying laboratories are responsible for obtaining PT samples from vendors approved by the lab accreditation unit. No fee shall

be charged to the department for the purchase or analysis of PT samples.

- (6) PTs must undergo the identical preparation and analytical processes that are used for samples.
- (7) When two or more approved PTs exist for a parameter, the laboratory must analyze and pass a PT to gain or maintain accreditation, unless an exception is approved by the department.
- (8) Presence-absence microbiology parameters must pass all 10 replicates in their PTs to be considered acceptable.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-070, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-070, filed 10/1/02, effective 11/1/02; WSR 93-20-011 (Order 92-53), § 173-50-070, filed 9/22/93, effective 10/23/93; WSR 90-21-090 (Order 90-21), § 173-50-070, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-070, filed 4/20/89 and 3/13/90, effective 4/13/90.]

AMENDATORY SECTION (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

- WAC 173-50-080 ((Θ n-site)) <u>Audits</u>. The laboratory must undergo an ((Θ n-site)) audit by the department, or their primary accreditation authority (in cases of third party recognition), to assess critical elements and areas of recommended practices. All directly accredited laboratories will be audited on a triennial basis. The laboratory must assist/accommodate department of ecology personnel during ((on-site)) audits as required. The department will determine if the audit will be on-site.
- (1) Critical elements for accreditation. Elements of an environmental laboratory's operations which are critical to the consistent generation of accurate and defensible data are critical elements for accreditation. Critical elements are subject to intense scrutiny throughout the accreditation process. The ecology accrediting authority may deny, revoke, or suspend accreditation for deficiencies in critical elements. Functional areas including critical elements are:
- (a) Analytical methods. The ((on-site)) audit seeks to determine if documentation of analytical methods:
 - ((♠)) <u>(i)</u> Are present at the laboratory;
 - ((+)) (ii) Are approved for regulatory use, if applicable;
 - (iii) Readily available to analysts; and
- ((♠)) (iv) Being implemented. If the laboratory is using a locally developed method, the ((on-site)) audit may include an evaluation of the adequacy of that method.
- (b) **Equipment and supplies**. The ((on-site)) audit seeks to determine if sufficient equipment and supplies as required by analytical methods are:
 - ((♣)) <u>(i)</u> Available;
 - ((♠)) (ii) Being adequately maintained; and
- ((+)) (iii) In a condition to allow successful performance of applicable analytical procedures.

To gain and maintain accreditation, laboratories must demonstrate that equipment and supply requirements of applicable regulatory programs are being met.

- (c) QA and QC records. The ((on-site)) audit includes a review of QA and QC records for programs/projects within which the laboratory is generating analytical data for submission to the data user.
- (d) Sample management. The ((on-site)) audit includes a review of applicable procedures for receipt, preservation, transportation, and storage of samples. The laboratory is responsible only for those elements of sample management over which it has direct control. To gain and maintain accreditation, laboratories must demonstrate that sample management requirements of applicable regulatory programs are being met.
- (e) Data management. The ((on-site)) audit includes a review of activities necessary to assure accurate management of laboratory data including:
 - ((♣)) <u>(i)</u> Raw data;
 - ((-)) <u>(ii)</u> Calculations; and
- ((+)) (iii) Transcription, computer data entry, reports of analytical results.

To gain and maintain accreditation, laboratories must demonstrate that data management requirements of applicable regulatory programs are being met.

- (2) Recommended practices. Recommended practices are those elements of laboratory operations which might affect efficiency, safety, and other administrative functions, but do not normally affect quality of analytical data. Normally these practices would not be the basis for denial or revocation of accreditation status. Functional areas within which recommended practices may be noted are:
- (a) Personnel. The department seeks to determine if managerial, supervisory, and technical personnel have adequate training and experience to allow satisfactory completion of analytical procedures and compilation of reliable, accurate data. Minimum recommended education and experience criteria for laboratory personnel are specified in the procedural manual.
- (b) Facilities. The department seeks to determine if laboratory facilities allow efficient generation of reliable, accurate data in a safe environment.
- (c) Safety. The department may refer serious safety deficiencies to appropriate state or federal agencies.
- (3) Drinking water laboratory requirements. For laboratories applying for accreditation of drinking water parameters, ((on-site)) audit requirements are those designated in the drinking water certification manual. If such a standard is more stringent than the corresponding standard in this chapter, the drinking water certification manual applies.
- (4) Documentation requests. Laboratories must submit requested documentation to the department at least two weeks prior to the scheduled start date of an audit. At a minimum the documents submitted must include:
 - (a) Standard operating procedures for all methods being audited;
 - (b) Analytical data for each method being audited; and
- (c) Additional documentation deemed necessary by the department to conduct the audit.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-080, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-080, filed 10/1/02, effective 11/1/02; WSR 93-20-011 (Order 92-53), § 173-50-080, filed 9/22/93, effective 10/23/93; WSR

90-21-090 (Order 90-21), \$173-50-080, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), \$173-50-080, filed 4/20/89 and 3/13/90, effective 4/13/90.]

AMENDATORY SECTION (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

- WAC 173-50-100 Interim accreditation. (1) If the department is unable to complete the accreditation process through no fault of the laboratory, the ecology accrediting authority may grant interim accreditation. To be considered for interim accreditation, the laboratory must:
 - ((*)) (a) Submit an application and applicable fees;
 - $((\bullet))$ Successfully complete applicable proficiency tests; and
- $((\bullet))$ (c) Submit a QA manual <u>and applicable SOP's</u> that meet((s)) the requirements of WAC 173-050-067.
- $\underline{(2)}$ The lab accreditation unit may also require the laboratory to submit an analytical data package as evidence of analytical capability.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-100, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-100, filed 10/1/02, effective 11/1/02; WSR 93-20-011 (Order 92-53), § 173-50-100, filed 9/22/93, effective 10/23/93; WSR 90-21-090 (Order 90-21), § 173-50-100, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-100, filed 4/20/89 and 3/13/90, effective 4/13/90.]

AMENDATORY SECTION (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

- WAC 173-50-110 Provisional accreditation. (1) The ecology accrediting authority may grant provisional accreditation to laboratories which can consistently produce valid analytical data but have deficiencies requiring corrective action. When the laboratory has corrected such deficiencies, it must provide evidence of correction to the lab accreditation unit, or request a follow-up ((on-site)) audit, as appropriate. If the lab accreditation unit determines the deficiencies have been corrected, the ecology accrediting authority awards full accreditation as in WAC 173-50-090.
- (2) The ecology accrediting authority may renew a provisional accreditation for a subsequent accreditation period if laboratory management has demonstrated that all reasonable measures to correct deficiencies have been exhausted.
- (3) For drinking water laboratories, specific conditions warranting provisional accreditation and specific actions required of the laboratory when provisional accreditation is granted are found in the drinking water certification manual.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 \S 301. WSR 10-17-032 (Order 09-09), \S 173-50-110, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order

01-12), § 173-50-110, filed 10/1/02, effective 11/1/02; WSR 90-21-090 (Order 90-21), § 173-50-110, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-110, filed 4/20/89 and 3/13/90, effective 4/13/90.1

AMENDATORY SECTION (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

- WAC 173-50-130 Requirements for maintaining accreditation status. (1) Accreditation is granted for a one-year period (the accreditation year) and expires one year after the effective date of accreditation.
 - (2) Renewal requires the laboratory to submit:
 - ((*)) (a) An application and appropriate fees;
 - ((+)) (b) An update of the laboratory's QA manual if applicable;
- ((+)) <u>(c)</u> Evidence of accreditation by a third party when appropriate; ((and
- -)) (d) Successful completion of proficiency testing requirements; and
- (e) Any other documents specifically requested by the department needed to renew accreditation.
- (3) For laboratories accredited for drinking water parameters, on-site audits are required at periods not to exceed three years from the previous on-site audit.
- (4) For laboratories not accredited for drinking water parameters, the schedule of ((on-site)) audits will be determined by the ecology accrediting authority.
- (5) For a laboratory planning to permanently change their location, the laboratory must notify the department at least 30 days prior to the need for accreditation at the new location. At the time of the laboratory move, the department places all accredited parameters into interim status pending successful completion of an audit. For instrumental analysis methods laboratories must take the following actions after a move:
- (a) Conduct new MDL studies for all parameters at the new location;
 - (b) Pass a PT for all parameters at the new location;
- (c) Update SOPs for all changed parameters, if there are any revisions to the SOPs due to the laboratory move; and
 - (d) Update third-party scope(s), if applicable.
- (6) If the laboratory move includes a merger with another accredited laboratory, the laboratory must notify the department at least 60 days prior to the need for accreditation.
- (7) Temporary and/or emergency laboratory moves will be handled on a case-by-case basis. The laboratory must contact the department before any sample analysis can resume.
- (8) For a laboratory to be accredited for drinking water parameters, the laboratory must comply with requirements under WAC 246-390-055, 246-390-065, and 246-390-075 and 40 C.F.R. Part 141.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-130, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-130, filed 10/1/02, effective 11/1/02; WSR 93-20-011 (Order 92-53), § 173-50-130, filed 9/22/93, effective 10/23/93; WSR

90-21-090 (Order 90-21), § 173-50-130, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-130, filed 4/20/89 and 3/13/90, effective 4/13/90.]

AMENDATORY SECTION (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

- WAC 173-50-140 Denying accreditation. (1) The ecology accrediting authority may deny accreditation if the applicant laboratory:
- ((-)) <u>(a)</u> Fails to comply with standards for critical elements of the ((on-site)) audit;
 - ((♠)) (b) Misrepresents itself to the department;
- ((-)) (c) Fails to disclose pertinent information in ((the))their environmental laboratory accreditation application;
- ((+)) (d) Falsifies reports of analysis including proficiency testing results;
- ((-)) <u>(e)</u> Engages in unethical or fraudulent practices concerning generation of analytical data;
- ((+)) (f) Is deficient in its ability to provide accurate and defensible analytical data; or
 - ((-)) <u>(g)</u> Fails to render applicable fees.
- (2) A laboratory may be denied accreditation for a specific parameter for ((unsatisfactory)) unacceptable proficiency testing results.
- (3) Laboratories denied accreditation may appeal under the provisions of WAC 173-50-200. If an appeal does not result in action favorable to the laboratory, and following correction of deficiencies, laboratories denied accreditation may reapply for accreditation to include payment of appropriate fees as determined in WAC 173-50-190.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-140, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), \$ 173-50-140, filed 10/1/02, effective 11/1/02; WSR 90-21-090 (Order 90-21), \$ 173-50-140, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-140, filed 4/20/89 and 3/13/90, effective 4/13/90.

AMENDATORY SECTION (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

- WAC 173-50-150 Revoking or suspending accreditation. (1) Revocation of accreditation is the department's withdrawal of a previously granted accreditation. Revocation may involve the entire laboratory or one or more individual parameters.
- (2) Suspension of accreditation is for a specified period during which the affected laboratory corrects deficiencies that led to the suspension. Suspension may involve the entire laboratory, or one or more individual parameters.
- (3) The ecology accrediting authority may suspend or revoke accreditation if the accredited laboratory:
- ((+)) <u>(a)</u> Fails to comply with standards for critical elements of an ((on-site)) audit;

- ((+)) <u>(b)</u> Violates a state rule <u>and/or federal law</u> relative to the analytical procedures for which it is accredited;
- ((♠)) (c) Misrepresents itself to the department; ((♠)) (d) Falsifies reports of analysis including proficiency testing results;
- ((+)) (e) Engages in unethical or fraudulent practices concerning generation of analytical data;
- ((-)) Is deficient in its ability to provide accurate and defensible analytical data;
- ((*)) (g) Refuses to permit entry for enforcement purposes (WAC 173-50-210);
 - ((*)) (h) Fails to render applicable fees;
 - ((+)) <u>(i)</u> Fails to maintain third-party accreditation; or
- ((+)) (j) Reports two consecutive unsatisfactory PT sample results.
- (4) A laboratory having had its accreditation suspended or revoked may appeal under the provisions of WAC 173-50-200. If an appeal does not result in action favorable to the laboratory, and following correction of deficiencies, a laboratory having had its accreditation revoked may reapply for accreditation to include payment of appropriate fees as determined in WAC 173-50-190.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-150, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-150, filed 10/1/02, effective 11/1/02; WSR 90-21-090 (Order 90-21), § 173-50-150, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-150, filed 4/20/89 and 3/13/90, effective 4/13/90.

AMENDATORY SECTION (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

- WAC 173-50-170 Third-party accreditation. (1) The department may recognize accreditation (or certification, registration, licensure, approval) of a laboratory by a third party when the accreditation process is determined to be equivalent to that described in this chapter.
- (2) Laboratories applying for recognition of a third party's accreditation submit:
 - ((+)) <u>(a)</u> An application and associated fee (WAC 173-50-190(7));
 - ((♠)) (b) A copy of the third party's certificate;
 - ((-)) <u>(c)</u> A copy of the third party's scope of accreditation;
- $((\bullet))$ <u>(d)</u> A copy of the third party's most recent ((on-site)) audit report;
- ((♠)) (e) A copy of the laboratory's corrective action report relative to the ((on-site)) audit, if applicable; and
- ((+)) (f) Recent, satisfactory proficiency test results for the applicable parameters.
- (3) In consideration of a request to recognize a third party's accreditation as the basis for accreditation by the ecology accrediting authority, the lab accreditation unit reviews the application and supporting documentation to assure compliance with minimum accreditation requirements as stated in this chapter. If the review is favora-

ble, a certificate and scope of accreditation are granted as in WAC 173-50-090.

- (4) Laboratories granted third-party accreditation must notify the laboratory accreditation unit immediately of changes in the status of their third-party accreditation.
- (5) Washington laboratories accredited or applying for accreditation in recognition of a third party's accreditation must notify the lab accreditation unit of ((on-site)) audits scheduled by the third party and allow a department observer to attend such ((on-site)) audits.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-170, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-170, filed 10/1/02, effective 11/1/02; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-170, filed 4/20/89 and 3/13/90, effective 4/13/90.

AMENDATORY SECTION (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

WAC 173-50-190 Fee structure. (1) Fees in this chapter are in U.S. dollars and are established to cover costs of administering the WA ELAP. ((Fees shall be assessed)) The department shall assess fees for each parameter or method within each matrix, except as noted in subsection (3) of this section. Laboratories are charged using the fee structure of the fiscal year covering the effective date the department issues a determination on a laboratory's accreditation application, renewal of its accreditation, or a revision of a laboratory's scope of accreditation. The fee schedule per parameter or method for each category((, and the maximum fee per category where applicable,)) are identified in ((Table 1.)):

- (a) Table 1 Fee schedule through June 30, 2024.
- (b) Table 2 Fee schedule from July 1, 2024, through June 30, 2025.
- (c) Table 3 Fee schedule from July 1, 2025, through June 30, 2026.
- (2) Examples of parameters or methods for each category are published in the procedural manual. Accreditation may be requested for parameters in addition to those listed in the procedural manual.
- (3) When a fee is assessed for a specific drinking water parameter or method, the laboratory may be accredited for the same parameter or method in nonpotable water without paying an additional fee. ((TABLE 1 - FEE SCHEDULE

CATEGORY	FEE PER PARAMETER	FEE PER METHOD	MAX FEE PER CATEGORY
General Chemistry	\$80	_	\$1,600
Trace Metals	_	\$400	_
Organies I	_	\$200	_
Organies II	_	\$500	_
Microbiology	\$200	_	_
Radiochemistry	\$250	_	_
Bioassay	\$300	_	\$3,000
Immunoassay	\$80	_	_
Physical	\$80	_))

Table 1 - Fee Schedule through June 30, 2024

<u>Category</u>	Fee Per Parameter	Fee Per Method	Max Fee Per Category
General Chemistry	<u>\$80</u>	Ξ	<u>\$1,600</u>
Trace Metals	Ξ	<u>\$400</u>	Ξ
Organics I	Ξ	<u>\$200</u>	Ξ
Organics II	Ξ	<u>\$500</u>	Ξ
Microbiology	<u>\$200</u>	Ξ	Ξ
Radiochemistry	<u>\$250</u>	Ξ	Ξ
Bioassay	<u>\$300</u>	Ξ	<u>\$3,000</u>
<u>Immunoassay</u>	<u>\$80</u>	Ξ	Ξ
<u>Physical</u>	<u>\$80</u>	<u>=</u>	Ξ

Table 2 - Fee Schedule from July 1, 2024, through June 30, 2025

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

Table 3 - Fee Schedule from July 1, 2025, through June 30, 2026

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

(4) Starting July 1, 2026, Equation 1 below will be used to calculate the fees:

Equation 1

 $\underline{Fee_2} \equiv \underline{Fee_1} \times (1 + FGF)$

Where:

 $\underline{\text{Fee}}_1 \equiv \underline{\text{The current fiscal year fees for each category.}}$

 $\underline{\underline{Fee_2}} \equiv \underline{\underline{The fee for each category for the fiscal year following the fiscal year in which Fee_1 was in effect, rounded up to the$ nearest whole \$5 increment. The updated fee table is then posted on the department's website.

 $\overline{\text{FGF}} \equiv \frac{\text{An annual fiscal growth factor expressed as a percentage,}}{\text{as determined under chapter 43.135 RCW.}}$

- (a) Fiscal year begins July 1st and ends June 30th of the following calendar year. For example, fiscal year 2027 is July 1, 2026, through June 30, 2027.
- (b) Ecology will provide annual notice of the next fiscal year's fees by March 31st.
- (5) The minimum fee for accreditation, either direct or through recognition of a third-party accreditation, is ((three hundred dol-lars)) <u>\$500</u>.
- $((\frac{5}{1}))$ 1 In addition to paying the fee indicated in Table 1, Table 2, Table 3, or as updated by Equation 1: Out-of-state laboratories must pay the department for the actual cost of travel associated with on-site audits. The department invoices the laboratory for such costs after completion of the on-site audit.
- (((6) The laboratory must pay applicable fees before:)) (7) For laboratories that have not been accredited for any parameter by the department in the previous 12 months, the laboratory must pay a processing fee of \$300 before:
- ((+)) <u>(a)</u> Its quality assurance manual $((\frac{is}{s}))$ <u>and applicable</u> SOP's are reviewed by the department;
 - ((+)) (b) The ((on-site)) audit is conducted if applicable; and ((♠)) (c) Interim, provisional, or full accreditation is granted. The application fee is not refundable.
- $((\frac{7}{}))$ (8) Once accreditation is granted the laboratory will be invoiced annually by the department for the requested parameters.
- (9) When a laboratory applies for renewal of their accreditation, an application fee is not required. The applicable accreditation fees per Table 1, Table 2, Table 3, or as updated by Equation 1 do not need to be payed prior to processing of the application.
- (10) The fee for recognition of a third-party accreditation (WAC 173-50-170) is three-fourths (75((%))) percent) of the fee indicated in Table 1, Table 2, Table 3, or as updated by Equation 1.
- ((8) If a laboratory withdraws from the accreditation process after the application has been processed, but before accreditation is granted, the fee is refundable, less an amount up to three hundred dollars as reimbursement for costs of processing the application.))
- (11) If a laboratory requests to add or reinstate a parameter to their scope of accreditation outside of their initial application or renewal process, the laboratory will be invoiced a fee based on the type and number of requested parameters, per Table 1, Table 2, Table 3, or as updated by Equation 1.
- (12) If a laboratory withdraws from the accreditation process after the ((on-site)) audit has been completed, the department may retain the entire fee including reimbursement of travel costs if applicable.
- (((9) Dollar amounts listed in Table 1 and subsections (4) and (8) of this section may be decreased at any time the department determines they are higher than needed to meet accreditation program requirements. The department notifies affected parties of any fee adjustment at least thirty days prior to the effective date of the ad-justed fee.
- (10))) (13) Accreditation fees are waived for laboratories operated by the Washington state departments of ecology and health. Accreditation fees are also waived for drinking water parameters certified by EPA Region 10 at designated principal laboratories.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-190, filed 8/9/10, effective

9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-190, filed 10/1/02, effective 11/1/02; WSR 93-20-011 (Order 92-53), § 173-50-190, filed 9/22/93, effective 10/23/93; WSR 90-21-090 (Order 90-21), § 173-50-190, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-190, filed 4/20/89 and 3/13/90, effective 4/13/90.1

AMENDATORY SECTION (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

- WAC 173-50-210 ((Enforcement)) Compliance inspections and access. (1) For the purpose of conducting ((on-site)) audits or inspections to ensure compliance with this chapter, the department may, during regular business hours, enter business premises in which analytical data pertaining to accreditation under the provisions of this chapter are generated or stored.
- (2) Refusal to permit entry for such purposes may result in denial or revocation of accreditation.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-210, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-210, filed 10/1/02, effective 11/1/02; WSR 90-21-090 (Order 90-21), § 173-50-210, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-210, filed 4/20/89 and 3/13/90, effective 4/13/90.

AMENDATORY SECTION (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

WAC 173-50-220 Assistance to laboratories. Laboratories scheduled to undergo an ((on-site)) audit may request a training session be conducted by department staff in conjunction with that audit. Accredited laboratories may also request on-site assistance at times other than the ((on-site)) audit. Whether requested as part of the ((onsite)) audit or otherwise, the department will provide such assistance to the extent allowed by staff resources available at the time.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-220, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-220, filed 10/1/02, effective 11/1/02; WSR 90-21-090 (Order 90-21), § 173-50-220, filed 10/19/90, effective 11/19/90.]