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ECOLOGY
State of Washington

Preliminary Cost-Benefit and Least Burdensome Alternative Analysis

*Chapter 173-50 WAC
Accreditation of Environmental Laboratories*

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Preliminary Cost-Benefit and Least Burdensome Alternative Analysis

Chapter 173-50 WAC Accreditation of Environmental Laboratories

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Executive Summary

The proposed amendments to Chapter 173-50 make significant changes to elements of the rule concerning fees and timing in the lab accreditation process. Proposed changes to business practices reflect program reductions in the Lab Accreditation program, in response to cuts in the state budget, as well as equitable treatment across different types of accreditation. Ecology concluded that the qualitative and quantitative benefits of the proposed rule are likely to exceed its costs.

Specific changes under the proposed amendments include changes to:

- The general fee structure and maximum fees per category.
- Proficiency testing.
- Fees for acknowledgement of third-party accreditation.
- Organization names and references, updated to reflect current terminology.
- Limits on extensions to the time between on-site audits
- Causes of revocation or suspension of accreditation.
- Streamlining rule language.

The **benefits** of the proposed amendments over 20 years include:

- **\$167 thousand** in reduced accreditation fees for some labs.
- **\$1.2 – 4.9 million** in reduced on-site audit costs.
- Higher assurance of quality results from some labs, stemming from increased proficiency testing.
- Streamlined, clear, and uniform language facilitating compliance and equal treatment of tasks across labs.
- Full independent funding of the Environmental Lab Accreditation Program (ELAP) through fees, rather than from the state General Fund.

The **costs** of the proposed amendments over 20 years include:

- **\$3.5 million** in increased accreditation fees for some labs.
- **\$201 thousand** in increased proficiency testing costs.
- Lower assurance of quality results from some labs, stemming from decreased frequency of on-site inspections.

CHAPTER 1: Introduction

The Administrative Procedure Act (Chapter 34.05 RCW) requires that, before adopting a significant legislative rule, Ecology must, “Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.” [RCW 34.05.328(1)(c)]

For the proposed amendments to *Chapter 173-50 WAC – Accreditation of Environmental Laboratories* – this means Ecology must estimate the impacts of the amendments on individuals, businesses and the public, including increased or avoided costs, and changes in environmental quality in the state. Impacts are determined by comparing the current regulatory environment (the existing rule) to the way environmental lab accreditation would occur under the proposed rule.

This document provides the public with an overview of the methods Ecology used to perform its analysis, and the most likely impacts found. The associated Small Business Economic Impact Statement (SBEIS) discusses the impacts of the proposed amendments on small versus large businesses, and how ecology attempted to reduce or eliminate any disproportionate impacts in the proposed rule.

Background

Use of Accredited Labs

Ecology’s Executive Policy 1-22 requires that all environmental data is generated by laboratories capable of providing accurate and legally defensible data, shown by their successful participation in Ecology’s Lab Accreditation Program. Applicable environmental data include, but are not limited to, results from analysis of water, sediment, sludge, air, soil, plant and animal tissue, and hazardous waste.¹

The Lab Accreditation Unit within Ecology’s Environmental Assessment (EA) Program is responsible for determining whether a laboratory meets accreditation standards established in Chapter 173-50 of the Washington Administrative Code (WAC). Any laboratory, within or outside the state, may apply for accreditation. The Lab Accreditation Unit maintains a list of currently accredited labs and the analytical parameters and methods for which each lab is accredited.

In addition, use of accredited labs is required explicitly by rules pertaining to water supplies, MTCA (Model Toxics Control Act) hazardous substance analyses, NPDES (National Pollutant Discharge Elimination System) and other water and stormwater discharge permit programs, building codes, solid waste landfills, solid waste handling standards, and solid fuel burning devices.

¹ Paraphrasing taken from Ecology’s website: <http://www.ecy.wa.gov/programs/eap/labs/accred-require.htm>, which also lists and links to Ecology’s requirements for use of accredited labs.

Background of Proposed Rule Amendments

The existing lab accreditation rule (Chapter 173-50 WAC) and the included fee structure supporting the Environmental Lab Accreditation Program (ELAP) was last updated in 2002. Ecology has been collecting accreditation fees based on that structure since that time, generating revenues that increasingly fail to reflect or cover the costs of administering the ELAP. Over the last three biennia (2004 through 2009), the deficit has grown at an average rate of 20 percent per biennium. The percentage of costs in excess of revenue has grown at an average of 9.5 percentage points each biennium.²

In 2009, as part of fiscal appropriations for the coming biennium, the Legislature authorized fee increases to meet costs:

The department is authorized to increase the following fees in the 2009-2011 biennium as necessary to meet the actual costs of conducting business and the appropriation levels in this section: Environmental lab accreditation, dam safety and inspection, biosolids permitting, air emissions new source review, and manufacturer registration and renewal.³

Ecology also reduced program costs to meet the appropriation levels set by the Legislature's budget. This led to the elimination of one employee in the ELAP program. In turn, the reduction in employment constrained the viable amount of accreditation and audit work that can be performed by the program.

Using these lower projected costs, and other proposed amendments to the proficiency testing and auditing sections of the rule, Ecology then developed the proposed fee structure.

Existing Lab Accreditation Process⁴

Under the existing rule, to become accredited, a lab must:

- Submit a complete application and pay the appropriate fee.
- Submit an acceptable quality assurance manual.
- Successfully analyze required proficiency testing samples.
- Pass an on-site assessment by Ecology or another recognized assessor entity.

² The deficit grew from \$490 thousand in the 2004-2005 biennium, to \$588 thousand in 2006-2007, to \$704 thousand in 2008-2009. The percentage of costs over revenue grew from 47 percent, to 55 percent, to 66 percent in the respective biennia. Internal analysis. See communication with Stew Lombard and Gary Koshi dated October 20-21, 2009.

³ Engrossed Substitute House Bill 1244. Passed by the 61st Legislature during the 2009 regular session. Section 301(10). <http://apps.leg.wa.gov/documents/billdocs/2009-10/Pdf/Bills/House%20Passed%20Legislature/1244-S.PL.pdf>

⁴ These procedures are discussed in-depth in Ecology's lab accreditation guidance document: Procedural Manual for the Environmental Laboratory Accreditation Program, November 2002. Ecology publication no. 02-03-055.

To retain accreditation, a participating lab must:

- Submit results of performance testing sample analyses.
- Make required improvements in its quality assurance program.
- Report significant changes in facility, equipment, personnel, or quality assurance/control procedures.
- Submit a renewal application and pay annual fees.
- Submit to required on-site assessments and implement the required recommendations.

Application for Accreditation

Ecology's lab accreditation application process requires labs to provide information on the resources the lab may use to conduct the tests for which accreditation is requested.

This includes:

- General information about the lab.
- Participation in proficiency testing studies.
- Discussion of the matrices and testing methods for which a lab is requesting accreditation.

This may also include National Environmental Laboratory Accreditation Program (NELAP) accreditation, or accreditation in another state with which Ecology has a reciprocity agreement, to support third-party accreditation.

Quality Assurance Manual

The quality assurance (QA) manual outlines policies and procedures labs are required to follow to achieve reliable test results, and to support external confidence in those results.

This includes:

- The organizational structure of the lab and the personnel responsible for quality assurance.
- A policy with respect to objectives for data quality, including qualitative and quantitative goals, and how they are established.
- Policies regarding sampling procedures, to include the receipt, logging, storage, handling, and acceptance or rejection of samples.
- Analytic methods used for testing.
- Calibration and quality control (QC) procedures.
- Procedures for monitoring performance.
- Procedures for data recording, reduction, validation, entry, and reporting.
- Timing and responsibility for system assessments and proficiency testing.
- Requirements for QA/QC reporting to management and the frequency of those reports.

Proficiency Testing

Labs that apply to Ecology for accreditation by Ecology must submit one set of proficiency testing (PT) results, specific to the parameters for which the lab is seeking accreditation. Ecology has approved a set of providers of PT samples that labs may use for this purpose.⁵

Labs seeking to continue accreditation must submit PT study results to Ecology twice each year, except for drinking water microbiology parameters where only one set of PT study results is required.

On-Site Assessments

The on-site assessment involves a visit to the lab by Ecology's Lab Accreditation Unit. This is not required for some labs with third-party accreditation. Assessors examine documentation and other evidence demonstrating that the lab can produce accurate and defensible data. Assessors verify information provided in the lab's submitted application and quality assurance manual.

The existing lab accreditation rule requires that on-site assessments may be no longer than three years apart, unless a cause for delay is documented. For documented causes, on-site assessments may be four years apart, except for labs accredited to analyze drinking water, and NELAP-accredited labs.⁶

Existing Lab Accreditation Fees

The existing lab accreditation fee structure is summarized in WAC 173-50-190. It is broken down by both the matrix and test type. Fees owed, per parameter for which a lab applies to be accredited, range between \$60 and \$345. Similar tests for different matrices carry different fees in some cases – for example, the general chemistry and trace metals tests are \$5 more expensive for nonpotable water than for potable. Table 1 outlines the existing fee structure, including maximum fees per accreditation category.

Regulatory Baseline

The baseline for all analyses of the proposed rule amendments is the regulatory environment in the absence of any changes. Under the current regulatory framework, the process and fees for the accreditation of environmental laboratories would remain as described above. Without the adoption of the proposed rule amendments, the existing process would remain in place. In addition, ELAP would likely suffer cuts and reduced regulatory functionality under a low-revenue scenario.

⁵ This list is available from the Lab Accreditation Section at Ecology, and is also published in Appendix E of the Procedural Manual for the Environmental Laboratory Accreditation Program, November 2002. Ecology publication no. 02-03-055.

Ecology publication no. 02-03-055.

⁶ WAC 173-50-130.

Table 1: Existing Lab Accreditation Fee Schedule (WAC 173-51-190)			
Matrix	Category	Fee/ Parameter	Maximum Fee
Nonpotable Water	Chemistry I (General)	\$65	\$1,150
	Chemistry II (Trace Minerals)	\$65	\$975
	Organics I (GC/HPLC)	\$115	\$975
	Organics II (GC/MS)	\$345	\$1,035
	Radioactivity	\$145	\$1,380
	Microbiology	\$175	\$520
	Bioassay / Toxicity	\$230	\$1,435
	Immunoassay	\$65	\$390
Drinking Water	Physical	\$65	\$260
	Chemistry I	\$60	\$305
	Chemistry II	\$60	\$720
	Organics I	\$155	\$615
	Organics II	\$155	\$155
	Microbiology	\$155	\$460
Solid and Chemical Materials	Chemistry I	\$65	\$1,150
	Chemistry II	\$65	\$975
	Organics I	\$115	\$975
	Organics II	\$345	\$1,035
	Radioactivity	\$145	\$1,380
	Microbiology	\$175	\$520
	Immunoassay	\$65	\$390
	Physical	\$65	\$260
Air and Emissions	Chemistry I	\$65	\$1,150
	Chemistry II	\$65	\$97
	Organics I	\$115	\$975
	Organics II	\$345	\$1,035

Changes under the Proposed Rule Amendments

The proposed amendments to Chapter 173-50 make significant changes to elements of the rule concerning fees and timing in the lab accreditation process.⁷ Ecology's accreditation of environmental labs, and fee increases for accreditation, are authorized by:

- RCW 43.21A.230 – Certification of Environmental Laboratories
- Ecology's memorandum of understanding (MOU) with the Washington State Department of Health
- Engrossed Substitute House Bill (ESHB) 1244, Section 301

⁷ All proposed changes to rule language, and their significance in this analysis and the associated Small Business Economic Impact Statement (SBEIS) are described fully in Appendix A.

Proposed changes to business practices reflect program reductions in the Lab Accreditation program, in response to cuts in the state budget.

Specific changes under the proposed amendments include changes to:

- The general fee structure and maximum fees per category.
- Proficiency testing requirements.
- Fees for acknowledgement of third-party accreditation.
- Organization names and references, updated to reflect current terminology.
- Limits on extensions to the time between on-site audits
- Causes of revocation or suspension of accreditation.
- Streamlining rule language.

Each of these is described in detail, below.

Changes to the Fee Schedule

The proposed rule amendments change the fee schedule to:

- Create uniformity across fees for the same accreditation category.
- Streamline the fee structure to facilitate public understanding.
- Reflect current costs of funding the lab accreditation program.

This includes reorganization of some accreditation categories into new groups. The proposed fees and maxima are listed in Table 2, below. The proposed rule amendments also include a minimum fee for any accreditation (direct or indirect through third-party accreditation) of \$300.

Category	Fee / Parameter	Fee / Method	Maximum Fee / Category
General Chemistry	\$80		\$1,600
Trace Metals		\$400	
Organics I		\$200	
Organics II		\$500	
Microbiology	\$200		
Radiochemistry	\$250		
Bioassay	\$300		\$3,000
Immunoassay	\$80		
Physical	\$80		

Changes to Proficiency Testing Frequency

The proposed rule changes the frequency required for some proficiency testing (PT). Ecology proposed this change to create uniformity in PT requirements for microbiology across different types of labs. Under the baseline (existing) rule, one PT analysis is required annually for microbiology parameters for drinking water accredited labs. The proposed rule requires that labs submit results from one microbiology PT study each year for nonpotable water and solid samples as well.

Changes to Third-Party Accreditation Fees

Ecology's proposed rule revises the fees related to accrediting a lab in Washington State that has other accreditation accepted by Ecology. Ecology revised these fees to create uniformity across accreditation procedures, and updated them to represent the current costs of the ELAP, including recent cost and employment reductions.

Changes to third-party and NELAP accreditation fees include:

- In-state labs seeking accreditation in the state and holding NELAP accreditation no longer pay \$345, and instead pay 75 percent of the appropriate fee set by the rule for each accreditation category.
- Out of state labs with NELAP accreditation no longer pay fees from the baseline (existing) fee schedule, but pay 75 percent of fees based on the new fee schedule in the proposed rule.
- Labs with other third party (not NELAP) accreditation no longer pay a fee of \$345, but pay 75 percent of the appropriate fees set by the proposed fee schedule (see Table 2).
- Drinking water labs no longer pay an additional fee of \$115.

Changes to Names and Terminology

Since the last amendments to the lab accreditation rule, the names of some reference materials have changed. EPA has updated its Environmental Protection Agency Manual for the Certification of Laboratories Analyzing Drinking Water from the 4th edition to the 5th edition. These changes make no material change to regulatory requirements for lab accreditation.

Changes to Time between On-Site Audits and Length of Suspension

The proposed rule eliminates the three-year requirement for on-site audits for non-drinking water accredited facilities. This does not mean, however, that no supervision would occur, but rather that paper audits would still be performed under the proposed rule, and on-site investigation would occur as necessary.

The proposed rule also eliminates the six-month limit on the length of time a lab's accreditation may be suspended.

Changes to Causes of Revocation or Suspension

The proposed rule adds nonpayment of fees and failure to maintain third-party accreditation as causes for suspension or revocation of an accreditation. It states that an application for accreditation will not move forward unless the applicant has paid the appropriate fees to Ecology.

Streamlining Language

The proposed rule streamlines, reorganizes, and clarifies some language, to facilitate understanding and compliance of the rule. This includes updating and reorganization of definitions, without impact to their meaning in the regulation.

Organizational Outline for this Analysis

The rest of this analysis is organized into the following chapters:

- Qualitative Costs and Benefits ([Chapter 2](#)): Qualitative discussion of the likely benefits and costs of the proposed rule amendments, as compared to the regulatory baseline.
- Quantified Costs and Benefits ([Chapter 3](#)): Methodology and results of quantitative analysis, where possible.
- Observations and Conclusions ([Chapter 4](#)): Comments on results and sensitivity analysis, and analytic conclusions.
- Least Burdensome Alternative Analysis ([Chapter 5](#)): Analysis of the regulatory options considered during rulemaking, and determination that the proposed amendments are the least burdensome of these options.

CHAPTER 2: Qualitative Costs and Benefits

This chapter qualitatively describes the benefits and costs assessed by Ecology in its evaluation of the proposed rule amendments relative to the regulatory baseline. Each section also describes how the cost or benefit was included in the overall assessment.

Description of Benefits

The proposed rule amendments are likely to generate benefits to businesses, government, and the public, related to reduced costs of compliance for some environmental labs, and greater assurance of the quality of accredited lab results. Specific benefits are discussed in the sections below, and include:

- Reduced accreditation fees for some environmental labs.
- Reduced costs of compliance with on-site audits at some labs.
- Higher assurance of quality results from some labs, stemming from increased frequency of proficiency testing.
- Streamlined, clear, and uniform language facilitating compliance and equal treatment of tasks across labs.
- Full independent funding of the Environmental Lab Accreditation Program (ELAP) through fees, rather than from the state General Fund.

Reduced Accreditation Fees

Under the proposed rule, Ecology expects accreditation fees for some labs to decrease. New fees would be based on the proposed fee schedule. Whether a lab's accreditation fee decreases under the proposed rule would depend on the particular types of testing for which the lab is seeking to establish or maintain accreditation. Ecology expects approximately six percent of environmental laboratory firms or government agencies to experience a reduction in accreditation fees.⁸

Ecology included this benefit quantitatively in its analysis of the proposed rule.

Reduced On-Site Audits

Ecology expects that labs will incur lower compliance costs due to the proposed amendments to the rule's on-site audit requirements. The proposed rule maintains the three-year maximum time between on-site audits for labs accredited for drinking water testing, but extends the period between on-site audits to one determined by the accrediting body for all other labs. Ecology expects a cost-savings to manifest itself in

⁸ Ten percent reflects the combined fees of multiple environmental labs owned by the same firm or government entity. If each individual lab, regardless of ownership, is considered, Ecology expects over seven percent to experience a reduction in accreditation fees under the proposed rule.

terms of reduced laboratory staff and management time spent on on-site audit compliance.

This is not an elimination of all costs associated with audit compliance because labs would still need to prepare and provide appropriate materials to Ecology for a paper audit. Labs, however, already perform these tasks, and so the cost is not included in this analysis. Ecology did, however, estimate the cost reduction of delayed or eliminated on-site assessments.

Ecology included this benefit quantitatively in its analysis of the proposed rule.

Higher Quality Assurance

The proposed rule requires drinking water labs to perform one additional proficiency test , relative to the baseline, each year. While Ecology expects this new requirement to generate a compliance cost for those labs, it also expects this change will increase the confidence of the recipients who rely on the quality of environmental testing data to make decisions. This requirement would also establish a uniform standard across drinking water and non-drinking water accredited labs.

Ecology included this benefit qualitatively in its analysis of the proposed rule.

Streamlining, Clarification, and Uniformity

Ecology expects labs to benefit from the proposed rule's streamlining, clarification, and uniformity-related amendments. By simplifying fee structures and compliance requirements for accreditation, and making them uniform across labs seeking accreditation for similar testing, it will be easier for labs to comply with the rule. For example, the proposed rule eliminates unequal requirements and fees across labs performing functionally similar procedures requiring the same inputs, but applied to different matrices.

Ecology expects the proposed rule to generate more understanding of the rule requirements and how to comply with it, and in turn, a greater ability to establish or renew accreditation, or change accreditation to better suit demand and business decisions.

Ecology included this benefit qualitatively in its analysis of the proposed rule.

Independent Funding of ELAP

Ecology expects the proposed rule to create funding sufficient for the lab accreditation program's necessary actions. This accounts for a net increase in fee revenue, and a reduction in the size of the lab accreditation program.

Fee revenues would replace funding currently (under the baseline) taken from the state General Fund. Ecology expects higher General Fund availability to benefit other state programs, and those members of the public who use them. Ecology also expects the lab accreditation program to benefit through a consistent source of funding to perform its

duties. This is consistent with the legislative direction of RCW 43.21A.230 that Ecology should set fees as needed to cover costs of administering the program.

Under the baseline, ELAP has run an increasing deficit over the previous three biennia. The percentage of program costs over revenue has grown by approximately 20 percent (about ten percentage points) per biennium. The additional necessary funds have come from the state General Fund, which funds numerous state agency actions. Under the current economic climate, the General Fund is projected to fall nearly \$3 billion short of necessary expenditures across the state economy. Under the proposed rule, Ecology expects the retention of funds previously taken from the General Fund for ELAP activities to benefit other state programs, those that use them, and the Washington State public as a whole.

Ecology included this benefit quantitatively in its analysis of the proposed rule.

Description of Costs

The proposed rule amendments are likely to generate costs to some labs related to increased fees, and to labs seeking or maintaining drinking water accreditation related to increased proficiency testing. These include:

- Increased accreditation fees for some labs.
- Increased frequency of proficiency testing for some labs.

Increased Accreditation Fees

Under the proposed rule, Ecology expects accreditation fees for some labs to increase. New fees would be based on the proposed fee schedule. Whether a lab's fee rises under the proposed rule would depend on the particular types of testing for which the lab is seeking to establish or maintain accreditation. Ecology expects about 94 percent of environmental laboratory firms or government agencies to experience an increase in accreditation fees.⁹

Ecology included this cost quantitatively in its analysis of the proposed rule.

Increased Proficiency Testing

The proposed rule requires environmental labs seeking or maintaining non-drinking water accreditation to perform one additional proficiency test, for microbiology, per accreditation year. This brings drinking water-accredited labs and other labs under equal requirements for proficiency testing.

Ecology included this cost quantitatively in its analysis of the proposed rule.

⁹ 94 percent reflects the combined fees of multiple environmental labs owned by the same firm or government entity. If each individual lab, regardless of ownership, is considered, Ecology expects 92 percent to experience an increase in accreditation fees under the proposed rule.

CHAPTER 3: Quantifiable Costs and Benefits

For those benefits and costs discussed in Chapter 2 that are quantifiable, Ecology estimated the impacts of the proposed rule amendments.

The quantifiable benefits include:

- Reduced accreditation fees for some labs.
- Reduced costs of compliance with on-site audits at some labs.

The quantifiable costs include:

- Increased accreditation fees for some labs.
- Increased frequency of proficiency testing for some labs.

Model Inputs and Methods

Ecology used the following inputs to estimate the quantifiable benefits and costs of the proposed rule amendments.

Number of Environmental Labs

There are 455 existing accredited environmental labs operating in Washington State. Of these, 217 are public entities, and the remaining labs owned by 205 private firms.

Of the 455 existing labs, 113 are accredited for drinking water analysis, and 432 are accredited for non-drinking water parameters. 246 of the non-drinking water accredited labs carry accreditation for microbiology. As a subset, 68 of these are private labs impacted by the proposed rule.

Of the 455 existing labs, 404 are accredited by Ecology's ELAP, and therefore require on-site audits under the current rule.¹⁰

Fees by Lab

Ecology assigned the new accreditation fees under the proposed rule based on the proposed fee schedule (see Table 2).

Proficiency Testing Sample Cost

Ecology surveyed catalogs of businesses providing proficiency testing samples and services.¹¹ These samples are sold for individual testing methods or parameters, or

¹⁰ Washington State Department of Ecology ELAP list of accredited laboratories.

¹¹ Absolute Standards (www.absolutestandards.com), AccuStandard, Inc. (www.AccuStandard.com), Analytical Standards, Inc. (www.asipt.com), Environmental Resource Associates (www.eraqc.com), Microcheck, Inc. (www.microcheck.com), NSI Solutions (www.nsi-es.com), RTC (www.RT-Corp.com), and Wibby Environmental (www.wibby.com).

grouped for multiple methods or parameters. Ecology estimated the average cost of a sample per method or parameter, and rounded to \$50 each.

On-Site Audit Time Costs

Ecology estimated the time required for on-site audits, for various Ecology and lab personnel, based on a previous internal workload assessment.¹² Table 3 summarizes the assumed hours and tasks.

Table 3: Time Cost of On-Site Audits		
Employment Category	Task	Hours
Ecology Auditor	Preparation for audit	3.6
Ecology Auditor	Travel to lab	5.7
Ecology Auditor	On-site audit	5.7
Ecology Auditor	Reporting and corrective action response	7.8
Environmental Lab Management / Quality Assurance (QA) Officer	Preparation for audit	1.0
Analyst / Technician and Management / QA Officer	On-site audit	6.0
Management / QA Officer	Corrective action response	2.0

Ecology auditors include chemists, microbiologists, and environmental specialists.

Costs of Employment

For each employment category, Ecology estimated the costs of employment. The total cost of employment was the sum of wages and overhead/benefits costs.

The base wage for Ecology ELAP employees was based on the Washington State Department of Personnel Salary schedule, at the highest step (step L) of the relevant salary ranges. The average of these wages is \$35.80. Using the Washington State Office of Financial Management (OFM) methodology for estimating overhead and benefits costs,¹³ Ecology estimated additional costs of employment. Ecology calculated a total cost of employment for ELAP auditors of \$29.71 per hour.

For private sector employment, Ecology calculated the average wages of management and of technical and laboratory professions based on US Bureau of Labor Statistics wage estimates by profession.¹⁴ The average hourly wage for management was \$51.22, and the average wage for technical professions was \$25.04. Based on OFM methodology, Ecology calculated overhead and benefits costs of \$41.36 for management, and of \$21.58 for technical staff, per hour.

¹² See communication with Stew Lombard (Department of Ecology ELAP program), dated 23 February 2010.

¹³ WA Office of Financial Management, "Standard Cost Assumptions for 2010 Fiscal note Preparation", November 25, 2009.

¹⁴ http://www.bls.gov/oes/current/oes_nat.htm

Time Span and Discount Rate

Ecology estimated total quantifiable costs and benefits of the proposed rule amendments for a 20-year time span. This allowed Ecology to account for the flows of costs and benefits over time (e.g., on-site audits occurring less frequently). This time span is long enough to include costs and benefits far enough in the future that their value dissipates in current dollars.

From a current time-period perspective, costs and benefits incurred in the future do not carry the same value they would in current dollars because lesser amount of current funds could be invested now that would be equivalent to a future cost or benefit. This relationship is reflected in the discount rate Ecology used to calculate the present value of future flows of costs and benefits.

As the proposed rule impacts a variety of industries and spans public and private entities, Ecology based the discount rate on the inflation-adjusted risk-free rate of return on US Treasury I-Bonds over the last 11 years.¹⁵ The average rate was about 2 percent. Using the inflation-adjusted (or “real”) rate of return as the discount rate also accounts for both inflation over time, and returns on investment. This maintains a constant purchasing power equivalent of costs and benefits estimated in this analysis.

Quantifiable Results

Ecology calculated the change in accreditation fees for each lab under the proposed rule. In addition, Ecology estimated the cost of additional proficiency testing samples, based on the number of labs accredited for microbiology in non-drinking water matrices. Finally, Ecology estimated the cost savings of reducing the frequency of audits, from minor delay to full elimination for non-drinking water accredited labs.

Ecology calculated the present value of these costs and benefits based on the expected future flow of costs and benefits, at a discount rate of 2 percent. The results presented in this section are present values of costs and benefits over 20 years.

Reduced Accreditation Fees for Some Labs

Ecology expects the proposed rule amendments to benefit some labs under the new proposed fee schedule. The proposed schedule reflects the actual costs of accreditation, and balances the costs of similar or identical actions necessary for multiple forms of accreditation. For some labs, this resulted in a reduction in the annual accreditation fee. Ecology calculated the 20-year present value of these reduced annual fees as \$167 thousand, adjusted for inflation, and reported in 2010 dollars.

¹⁵ http://www.treasurydirect.gov/indiv/research/indepth/ibonds/res_ibonds_iratesandterms.htm

Reduced On-Site Audit Costs for Some Labs

Ecology expects the proposed rule to reduce the frequency of on-site audits, or nearly eliminate them, for some labs. The schedule for on-site assessment for non-drinking water labs is determined by Ecology under the proposed rule.

Ecology estimated, on average, the reduced costs of fewer on-site audits at these labs for 1 to 3 years, or eliminating them. Ecology expects this range to reflect the possible range of cost reductions experienced by Ecology and environmental labs, related to on-site assessment. Ecology estimated this benefit conservatively, relative to a baseline frequency of 3 years, although audits could occur more frequently under the existing rule. Ecology calculated this range as between \$1.2 million – \$1.9 million, for delay of the average on-site audit by 1 to 3 years (4 to 6-year frequency). Eliminating on-site audits for this set of labs would generate a cost savings of \$4.9 million, adjusted for inflation, and reported in 2010 dollars.

Increased Accreditation Fees for Some Labs

Ecology expects the proposed rule amendments to increase accreditation fees for some labs under the new proposed fee schedule. The proposed schedule reflects the actual costs of accreditation, and balances the costs of similar or identical actions necessary for multiple forms of accreditation. For some labs, this resulted in an increase in the annual accreditation fee.

Ecology calculated the 20-year present value of these reduced annual fees as \$4.6 million, adjusted for inflation, and reported in 2010 dollars.

Increased Proficiency Testing for Some Labs

The proposed rule includes an amendment that increases the number of proficiency tests for microbiology parameters to one per year, for labs accredited for matrices other than drinking water. At the average cost per method or parameter of \$50 per proficiency test, multiplied by the 246 labs carrying non-drinking water microbiology accreditation, This is an annual cost of \$12,300.

Ecology estimated the 20-year present value of these increased annual costs. The total cost Ecology estimated was \$205 thousand, adjusted for inflation, and reported in 2010 dollars.

Summary of Quantifiable Impacts

Ecology was able to quantitatively estimate the impacts of the proposed rule for two costs and two benefits. These include:

- \$167 thousand in reduced accreditation fees.
- \$1.2 – 4.9 million in reduced on-site audit costs.
- \$4.6 million in increased accreditation fees.
- \$205 thousand in increased proficiency testing costs.

CHAPTER 4: Observations and Conclusion

Conclusion

Taking the combination of quantifiable and qualitative benefits and costs expected to result from the proposed rule amendments, Ecology concluded the benefits of the rule amendments are likely to exceed the costs.

Ecology performed a sensitivity analysis of the results to examine the impact of variance in the number of labs used in the analysis, and further concluded the benefits of the proposed rule likely exceed the costs. The number of labs may be affected by the changes in compliance costs for third-party accreditation, resulting in some labs dropping out of the accreditation program.

Sensitivity Analysis – Dropout Labs

Ecology developed a list of environmental labs that may drop out of the accreditation program based on the increase in compliance costs for third-party accredited lab, under the proposed rule. While the decision to participate in the Washington state accreditation program is voluntary and based on internal business decisions, Ecology determined 16 labs were likely dropouts. All 16 labs dropping out would result in a reduction in the total fees paid under the proposed rule by a present value of \$987 thousand over 20 years.

As these labs are accredited by third parties, they are not subject to the proposed rule's on-site audits. The possible reduction in on-site audit frequency, and the resulting benefit, are not impacted by one or more of these labs dropping out of the Washington accreditation program.

These labs dropping out would result in a present value reduction in the costs of the proposed rule of \$114 thousand over 20 years.

Ecology concluded, based on up to 16 labs dropping out, that the costs of the proposed rule could fall by up to \$1.1 million dollars, in present value, over 20 years. Ecology does not believe the loss of these out of state labs is likely to affect the environmental laboratory market in either availability or prices.

Summary of Results

The **benefits** of the proposed amendments over 20 years include:

- \$167 thousand in reduced accreditation fees.
- \$1.2 – 4.9 million in reduced on-site audit costs.
- Higher assurance of quality results from some labs, stemming from increased frequency of proficiency testing.

- Streamlined, clear, and uniform language facilitating compliance and equal treatment of tasks across labs.
- Full independent funding of the Environmental Lab Accreditation Program (ELAP) through fees, rather than from the state General Fund.

The **costs** of the proposed amendments over 20 years include:

- \$4.6 million in increased accreditation fees.
- \$201 thousand in increased proficiency testing costs.
- Lower assurance of quality results from some labs, stemming from decreased frequency of on-site inspections.

This document describes Ecology’s preliminary analysis, as based on the best information available at the time of its publication. Ecology welcomes public comments on the analysis, and data that could improve the precision of results.

Summary of Results – Accounting for Dropout Labs

The **benefits** of the proposed amendments over 20 years include:

- \$167 thousand in reduced accreditation fees.
- \$1.2 – 4.9 million in reduced on-site audit costs.
- Higher assurance of quality results from some labs, stemming from increased frequency of proficiency testing.
- Streamlined, clear, and uniform language facilitating compliance and equal treatment of tasks across labs.
- Full independent funding of the Environmental Lab Accreditation Program (ELAP) through fees, rather than from the state General Fund.

The **costs** of the proposed amendments over 20 years include:

- \$3.5 million in increased accreditation fees.
- \$201 thousand in increased proficiency testing costs.
- Lower assurance of quality results from some labs, stemming from decreased frequency of on-site inspections.

This document describes Ecology’s preliminary analysis, as based on the best information available at the time of its publication. Ecology welcomes public comments on the analysis, and data that could improve the precision of results.

CHAPTER 5: Least Burdensome Alternative Analysis

RCW 34.05.328(1)(e) requires Ecology to “determine, after considering alternative versions of the rule and the analysis required under (b), (c), and (d) of this subsection, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated under (a) of this subsection.”

Conclusion

Based on research and analysis required by RCW 34.05.328(1)(e), the Department of Ecology determines:

There is sufficient evidence that the proposed rule is the least burdensome version of the rule for those who are required to comply, given the goals and objectives of the law for Ecology to propose the rule.

Alternate Fee Schedule

Ecology considered alternate fee schedules during the proposed rulemaking. These included:

- Alternate distributions of fees that would have created a sufficient fee surplus to fully fund ELAP under rising future cost scenarios.
- Alternate distributions of fees across accreditation categories and parameters.

Ecology did not choose these options, as the authorizing statute allows fee increases “as necessary to meet the actual costs of conducting business” under the appropriations discussed in the same bill.¹⁶ Instead, Ecology chose to include, in the proposed rule, a fee structure that reflects the typical costs incurred for different types of accreditation. This means that all labs, regardless of size or third-party accreditation, will pay fees in proportion to the work Ecology must do to grant or maintain their accreditation.

Compensating for Dropout Labs

Ecology acknowledges that some labs’ fees rise significantly under the proposed rule, to the degree that those labs may choose to leave the program. This is possibly or likely the case for 16 environmental labs accredited by third parties. Ecology considered alternate fee structures that would have either reduced the burden placed on third-party accredited labs (to reduce dropouts), or place higher burden directly on accredited labs to create a revenue surplus that would maintain full funding for ELAP in the event of labs dropping out of the program.

¹⁶ See: Washington State Legislature, Engrossed Substitute House Bill 1244.

Ecology did not choose these options, as the authorizing statute allows fee increases “as necessary to meet the actual costs of conducting business” under the appropriations discussed in the same bill.¹⁷ Instead, Ecology chose to include, in the proposed rule, a fee structure that reflects the typical costs incurred for different types of accreditation. This option neither overcharges, nor undercharges, labs for Ecology actions necessary for the accreditation process.

Flat Fees

Ecology had the option during rulemaking to create a flat fee across all types of accreditation. To cover aggregate ELAP costs in accreditation, this would have been an average fee of about \$1,800 per lab, per year. Ecology did not choose this option because it places identical burden across labs, regardless of size or accreditation types. In addition, the flat fee alternative would not have reflected the actual cost of services provided to all individual labs, but would have subsidized those labs with many types of accreditation through additional fees collected from small labs and others with more limited accreditation.

Maintain Existing Staff Levels and Raise Fees

As part of the relationship between this rulemaking and the budgeting process, Ecology considered the option of raising fees as necessary to meet previous staff levels and associated program costs. This would have entailed higher fee increases than would occur under the proposed rule. Instead, Ecology chose to eliminate one of seven positions in ELAP, and raise fees accordingly to reflect the costs of the now smaller program. Ecology expects newly acquired technology to help ELAP to maintain viable standards in spite of the staff reduction.

Separate ELAP Fund

Workshop comments suggested Ecology create a separate, dedicated fund for ELAP operations, distinct from the Washington State General Fund. The revenues generated from the fee program are too small, however, to justify the creation and ongoing operation of a separate fund.

Identical Fees for In-State and Out-of-State Labs

Workshop comments suggested Ecology charge third-party labs the same fees as directly-accredited labs. Ecology could not justify charging identical fees, however, as on-site inspections are not required for some third-party labs. The fee of 75 percent of directly-accredited equivalent fees more closely reflects the actual cost of accrediting these labs.

¹⁷ See: Washington State Legislature, Engrossed Substitute House Bill 1244. Operating Budget, Chapter 564, Laws of 2009. 61st Legislature, 2009 Regular Session.

Ecology is also proposing to terminate reciprocity agreements with other states in order to implement the more equitable fee structure for recognition of third-party accreditation.

One Proficiency Testing Sample per Year

Workshop comments suggested Ecology reduce proficiency testing requirements to one sample per parameter, per year. While Ecology agrees this would reduce burden on some labs, proficiency tests – especially in the case of reduced frequency of on-site audits – are the only ongoing indication of lab performance. Ecology does not believe reducing proficiency-testing requirements will meet the standards for ELAP to determine, on a consistent basis, which labs produce sufficiently sound results for use in compliance with environmental law.

References

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- Washington State Office of Financial Management (2009). Standard Cost Assumptions for 2010 Fiscal Note Preparation. November 25, 2009.
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APPENDIX A: Rule Amendments

EXISTING RULE LANGUAGE	NEW RULE LANGUAGE	CHANGE AND ANALYSIS?
173-50-020		
(1) The environmental laboratory accreditation program applies to laboratories which conduct tests for or prepare analytical data for submittal to any entity requiring the use of an accredited laboratory. This includes laboratories that analyze drinking water. This rule also describes how the department of ecology participates in the National Environmental Laboratory Accreditation Program (NELAP) as an accrediting authority once the department is certified by the National Environmental Laboratory Accreditation Conference (NELAC) Institute (TNI).	(1) The Washington State Environmental Laboratory Accreditation Program (WA ELAP) applies to laboratories which conduct tests for or prepare analytical data for submittal to any entity requiring the use of an accredited laboratory. This includes laboratories that analyze drinking water.	No significant change.
173-050-030		
Objectives of the accreditation program are to:	Objectives of the WA ELAP are to:	No significant change.
173-50-040		
(no previous definition)	“Analyte” – the constituent or property of a sample measured using an analytical method.	No significant change.
173-50-040		
(no previous definition)	“Analytical method” – a written procedure for acquiring analytical data.	No significant change.
173-50-040		

EXISTING RULE LANGUAGE	NEW RULE LANGUAGE	CHANGE AND ANALYSIS?
<p>“Drinking water certification manual” – the Environmental Protection Agency Manual for the Certification of Laboratories Analyzing Drinking Water, 4th Edition, March 1997.</p>	<p>“Drinking water certification manual” – the Environmental Protection Agency Manual for the Certification of Laboratories Analyzing Drinking Water, 5th Edition, January 2005.</p>	<p>Updates manual. Federal law applies in either case. No significant change.</p>
173-50-040		
<p>“Environmental laboratory” – a facility: Under the ownership and technical management of a single entity in a single geographical locale; Where scientific examinations are performed on samples taken from the environment, including drinking water samples;</p>	<p>“Environmental laboratory” or “Laboratory” – a facility: Under the ownership and technical management of a single entity in a single geographical location; Where scientific determinations are performed on samples taken from the environment, including drinking water samples;</p>	<p>No significant change.</p>
173-50-040		
<p>“Lab accreditation unit” – the lab accreditation unit of the environmental assessment program of the department of ecology.</p>	<p>“Lab accreditation unit” – the lab accreditation unity of the department of ecology.</p>	<p>No significant change.</p>
173-50-040		
<p>“Mandatory analytical method” – a recognized written procedure for acquiring analytical data which is required by law or a regulatory agency of the federal, state, or local government.</p>	<p>(deleted)</p>	<p>No significant change.</p>
173-50-040		
<p>“Matrix” means the substance from which a material to be analyzed is extracted, including, but not limited to... NELAP accreditations may include other matrices as designated in the NELAC TNI standards.</p>	<p>“Matrix” – the material to be analyzed, including, but not limited to...</p>	<p>No significant change.</p>
173-50-040		

EXISTING RULE LANGUAGE	NEW RULE LANGUAGE	CHANGE AND ANALYSIS?
<p>“NELAC” – the National Environmental Laboratory Accreditation Conference, a voluntary association of state and federal agencies. “NELAC standards” – the standards for laboratory accreditation published by NELAC, September 5, 2001. “NELAP” – the National Environmental Laboratory Accreditation Program governed by NELACTNI.</p>	<p>(deleted)</p>	<p>No significant change.</p>
173-50-040		
<p>(no previous definition)</p>	<p>“On-site Audit” – an on-site inspection and evaluation of laboratory facilities, equipment, records and staff.</p>	<p>No significant change.</p>
173-50-040		
<p>“Parameter” – a single determination or sampling procedure, or group of related determinations or sampling procedures using a specific written method.</p>	<p>“Parameter” – the combination of one or more analytes determined by a specific analytical method. Examples of parameters include: the analyte alkalinity by method SM 2320 B; the analyte zinc by method EPA 200.7; the set of analytes called Volatile Organic Compounds (VOCs) by method EPA 8260; and the analyte Total Coli/Ecoli-count by method SM 9222 B/9221 F.</p>	<p>No significant change.</p>
173-50-040		
<p>“Procedural manual” – the Procedural Manual for the Environmental Laboratory Accreditation Program dated November 2002.</p>	<p>“Procedural manual” – until October 1, 2010, the Department of Ecology Procedural Manual for the Environmental Laboratory Accreditation Program dated November 2002, and beginning October 1, 2010, the Department of Ecology Procedural Manual for the Environmental Laboratory Accreditation Program dated September 2010.</p>	<p>No significant change.</p>

EXISTING RULE LANGUAGE	NEW RULE LANGUAGE	CHANGE AND ANALYSIS?
173-50-040		
<p>“Quality control (QC)” – activities designed to assure analytical data produced by an environmental laboratory meet data quality objectives for accuracy and defensibility. These activities may include routine application of statistically based procedures to evaluate and control the accuracy of analytical results.</p>	(deleted)	No significant change.
173-50-040		
(no previous definition)	<p>“Quality control (QC)” – The routine application of statistically based procedures to evaluate and control the accuracy of analytical results.</p>	No significant change.
173-50-040		
<p>“Recognized analytical method” – a documented analytical procedure developed through collaborative studies by organizations or groups recognized by the users of the laboratory’s analytical data.</p>	(deleted)	No significant change.
173-50-040		
<p>“On site assessment” – an on-site inspection of laboratory capabilities. “Primary NELAP accreditation” – granting of NELAP accreditation by the ecology accrediting authority after having determined through direct evaluation that the laboratory is in conformance with the NELAC standards.</p>	(deleted)	No significant change.
173-50-040		

EXISTING RULE LANGUAGE	NEW RULE LANGUAGE	CHANGE AND ANALYSIS?
<p>“Secondary NELAP accreditation” – recognition by the ecology accrediting authority of a NELAP accreditation that was granted by another NELAP accrediting authority.</p>	<p>“Third-party accreditation” – recognition by the ecology accrediting authority of accreditation granted by another accrediting authority.</p>	<p>No significant change.</p>
173-50-040		
<p>(no previous definition)</p>	<p>“WA ELAP” – Washington State Environmental Laboratory Accreditation Program.</p>	<p>No significant change.</p>
173-50-050		
<p>Issuing, denying, suspending, and revoking accreditation;</p>	<p>Granting, denying, suspending, and revoking accreditation;</p>	<p>Streamlines terminology. No significant change.</p>
173-50-050		
<p>(2) Department personnel assigned to assess the capability of drinking water laboratories participating in the environmental accreditation program must meet the experience, education, and training requirements established in the Environmental Protection Agency drinking water certification manual.</p>	<p>(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.</p>	<p>No significant change.</p>
173-50-050		
<p>(3) When granting NELAP accreditations, the ecology accrediting authority is responsible for those actions designated in applicable chapters of the NELAC TNI standards. If a NELACTNI standard is more stringent than the corresponding standard in this chapter, the NELACTNI standard applies for laboratories seeking NELAP accreditation.</p>	<p>(deleted)</p>	<p>NELAP context and guidelines remain default regardless of being stated in rule. No significant change.</p>
173-50-067		

EXISTING RULE LANGUAGE	NEW RULE LANGUAGE	CHANGE AND ANALYSIS?
<p>(3) For laboratories applying for primary NELAP accreditation, QA requirements, including the conduct of specific QC tests, are those designated in the NELACTNI standards. If a NELACTNI standard is more stringent than the corresponding standard in this chapter, the NELAC standard applies for laboratories seeking NELAP accreditation.</p>	<p>(deleted)</p>	<p>NELAP context and guidelines remain default regardless of being stated in rule. No significant change.</p>
173-50-070		
<p>Performance audit. (1) The lab accreditation unit advises applying laboratories of specific requirements for proficiency tests. Such tests are completed for applicable parameters no more frequently than twice annually. Current proficiency tests conducted under the provisions of other recognized programs may be used to satisfy the accreditation program proficiency testing requirement. The lab accreditation unit determines the sufficiency of such audits.</p>	<p>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.</p>	<p>No significant change.</p>
173-50-070		
<p>(2) Drinking water laboratories must analyze a minimum of one PT sample per applicable microbiology parameter per year and two PT samples for applicable chemistry parameters per year.</p>	<p>(2) Accredited laboratories must analyze a minimum of one PT sample per applicable microbiology parameter per year and two PT samples for applicable chemistry parameters per year.</p>	<p>Significant. Ecology analyzed the costs and benefits of non-drinking water laboratories performing one additional PT sample for applicable microbiology parameters.</p>
173-50-070		

EXISTING RULE LANGUAGE	NEW RULE LANGUAGE	CHANGE AND ANALYSIS?
(5) Applying laboratories are responsible for obtaining PT samples for vendors certified by the National Institute of Standards and Technology (NIST) or otherwise approved by the lab accreditation unit. No fee shall be charged to the department for the purchase or analysis of PT samples.	(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.	No significant change.
173-50-070		
(6) For laboratories applying for NELAP accreditation, proficiency testing requirements are those designated in the NELACTNI standards. If the NELAC standard is more stringent than the corresponding standard in this chapter, the NELAC standard applies for laboratories seeking NELAP accreditation.	(deleted)	NELAP context and guidelines remain default regardless of being stated in rule. No significant change.
173-50-080		
(3) NELAC requirements. For laboratories applying for NELAP accreditation, on-site assessment requirements are those designated in the NELAC standards. If the NELAC standard is more stringent than the corresponding standard in this chapter, the NELAC standard applies.	(deleted)	NELAP context and guidelines remain default regardless of being stated in rule. No significant change.
173-50-090		
(1) After preliminary requirements (WAC 173-50-060 through 173-50-080) have been met, the lab accreditation unit submits a report to the affected laboratory concerning the results of the overall accreditation process. The report: Lists findings; Assesses the importance of each finding; and Makes recommendations concerning actions necessary to assure resolution of problems.	(1) ...The report may: List findings; Assess the importance of each finding; and Make recommendations concerning actions necessary to assure resolution of problems.	No significant change.

EXISTING RULE LANGUAGE	NEW RULE LANGUAGE	CHANGE AND ANALYSIS?
173-50-090		
(2) (a) ...The certificate remains the property of the department and must be surrendered to the department upon revocation of accreditation status.	(2) (a) ...The certificate remains the property of the department and must be surrendered to the department upon revocation or voluntary termination of accreditation status.	No significant change.
173-50-100		
(1) If for valid reasons resulting from a deficiency in the department and not the laboratory, interim accreditation may be granted.	(1) If the department is unable to complete the accreditation process through no fault of the laboratory, the accrediting authority may grant interim accreditation.	No significant change.
173-50-100		
(2) For NELAP accreditation, the only valid reason for granting interim accreditation is the delay of an on-site assessment for reasons beyond the control of the laboratory.	(deleted)	NELAP context and guidelines remain default regardless of being stated in rule. No significant change.
173-50-110		
(4) Provisional accreditation does not apply to NELAP accreditations.	(deleted)	NELAP context and guidelines remain default regardless of being stated in rule. No significant change.
173-50-120		

EXISTING RULE LANGUAGE	NEW RULE LANGUAGE	CHANGE AND ANALYSIS?
<p>(1)... Additionally, accreditation is granted within the following broad categories: Chemistry I (General); Chemistry II (Trace Metals); Organics I (Gas Chromatography (GC) and High Pressure Liquid Chromatography (HPLC) Methods); Organics II (Gas Chromatography/Mass Spectrometry (GC/MS) Methods); Radioactivity; Microbiology; Bioassay/Toxicity; Immunoassay; and Physical.</p>	<p>(1)... Within each matrix group, accreditation is granted within the following broad categories: General Chemistry; Trace Metals; Organics I; Organics II (Category II methods use mass spectrometer detectors); Microbiology; Radiochemistry; Bioassay; Immunoassay; and Physical.</p>	<p>Significant. Ecology analyzed costs and benefits of new categories and associated fee structure.</p>
173-50-120		
<p>(3) For laboratories granted NELAP accreditation, the scope of accreditation also indicates the matrix groups within which each parameter applies. Those matrix groups may include, but are not limited to; Nonpotable water; Drinking water; Solid and chemical materials; Biological tissue; and Air and emissions. For laboratories granted NELAP accreditation, the scope of accreditation may also indicate the technology, such as gas chromatography/electron capture detection (CC/ECD) or inductively coupled plasma/mass spectrometry (ICP/MS), associated with each parameter.</p>	<p>(3) The scope of accreditation also indicates the matrix groups within which each parameter applies. Those matrix groups may include, but are not limited to: Non-potable water; Drinking water; Solid and chemical materials; and Air and emissions.</p>	<p>No significant change.</p>
173-50-130		
<p>(1) Accreditation is granted for a one-year period and expires one year after the effective date of accreditation. Except for NELAP accreditation which is limited to one year, exceptions to the one year accreditation may be granted for a period up to two years.</p>	<p>(1) Accreditation is granted for a one-year period and expires one year after the effective date of accreditation.</p>	<p>No significant change.</p>
173-50-130		

EXISTING RULE LANGUAGE	NEW RULE LANGUAGE	CHANGE AND ANALYSIS?
(2) Renewal requires the laboratory to submit: An application and appropriate fees; An update of the laboratory's quality assurance manual if applicable; and Successful completion of proficiency testing requirements.	(2) Renewal requires the laboratory to submit: An application and appropriate fees; An update of the laboratory's QA manual if applicable; Evidence of accreditation by a third party when appropriate; and Successful completion of proficiency testing requirements.	No significant change.
173-50-130		
(2) ... On-site assessments are required at periods not to exceed three years from the previous on-site assessment.	(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.	No significant change.
173-50-130		
(2) ... For documented cause, on-site assessments may be extended up to four years from the previous assessment, except for laboratories accredited to analyze drinking water and NELAP accredited laboratories.	(4) For laboratories not accredited for drinking water parameters, the schedule of on-site audits will be determined by the Ecology accrediting authority.	Significant. Ecology analyzed the costs and benefits of possible reductions in the frequency of on-site audits for non-drinking water labs.
173-50-140		
(4) Reasons for denial of NELAP accreditation are as specified in the NELAC standards.	(deleted)	NELAP context and guidelines remain default regardless of being stated in rule. No significant change.
173-50-150		

EXISTING RULE LANGUAGE	NEW RULE LANGUAGE	CHANGE AND ANALYSIS?
... Suspension of accreditation is for a specified period not to exceed six months during which the affected laboratory corrects deficiencies that led to the suspension.	(2) Suspension of accreditation is for a specified period during which the affected laboratory corrects deficiencies that led to the suspension.	No significant change.
173-50-150		
...The ecology accrediting authority may suspend or revoke accreditation if the accredited laboratory: ...(no existing language on fees or third-party accreditation in this subsection)	(3) The ecology accrediting authority may suspend or revoke accreditation if the accredited laboratory: ... Fails to render applicable fees; or Fails to maintain third-party accreditation.	No significant change.
173-50-150		
(4) Reasons for revocation or suspension of NELAP accreditation are as specified in the NELAC standards.	(deleted)	
173-50-160		
Reciprocity. (1) The department may recognize accreditation (or certification, registration, licensure, approval) of an out-of-state laboratory by the laboratory's home state with which the department has established a reciprocity agreement. (2)The out-of-state laboratory must submit: An application and associated fee (WAC 173-50-190(8)); A copy of the other state's certificate; A copy of the other state's scope of accreditation; A copy of the other state's most recent on-site assessment report; A copy of the laboratory's corrective action report relative to the on-site assessment; and A complete set of the most recent PT results for applicable parameters.	(deleted)	Recognition of third-party accreditation is discussed in another section. No significant change.
173-50-160		

EXISTING RULE LANGUAGE	NEW RULE LANGUAGE	CHANGE AND ANALYSIS?
(3) In consideration of a requires to recognize a reciprocity agreements 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 favorable, a certificate and scope of accreditation are granted as in WAC 173-50-090.	(deleted)	Recognition of third-party accreditation is discussed in another section. No significant change.
173-50-160		
(4) In granting secondary NELAP accreditation, the ecology accrediting authority must recognize the accreditation of other NELAP accrediting authorities.	(deleted)	NELAP context and guidelines remain default regardless of being stated in rule. No significant change.
173-50-170		
(no previous language)	(4) Laboratories granted third-party accreditation must notify the laboratory accreditation unit immediately of changes in the status of their third-party accreditation.	No significant change.
173-50-180		

EXISTING RULE LANGUAGE	NEW RULE LANGUAGE	CHANGE AND ANALYSIS?
<p>Exemptions. (1) The application form provides for wastewater discharges whose laboratories meet the exemption qualifications of RCW 43.21A.230 to request exemption from the accreditation program. These laboratories shall be required to submit evidence that they are participating in a federal Environmental Protection Agency Administered Quality Assurance Program including as a minimum the following elements: Current QA program/project plans; performance evaluation audits; system audits; corrective action for audit deficiencies; quality control guidelines and records; and training in quality assurance for laboratory management personnel. The department shall grant exemption from accreditation requirements of this chapter upon receipt of confirmation from Region 10 of the federal Environmental Protection Agency of such participation by a laboratory.</p>	<p>(deleted)</p>	<p>No significant change.</p>
173-50-180		
<p>(2) Exemption is granted only for those analytical parameters included in the federal Environmental Protection Agency Quality Assurance Program. The exemption status shall be reviewed annually based upon submittal by the laboratory of a new application and updated evidence of continued participation in a sufficient quality assurance program.</p>	<p>(deleted)</p>	<p>No significant change.</p>
173-50-190		

EXISTING RULE LANGUAGE	NEW RULE LANGUAGE	CHANGE AND ANALYSIS?
<p>...The fee per parameter and maximum fee per category are identified in Table 1. These fees apply separately to each matrix group, except as noted in subsection (3) of this section.</p>	<p>...Fees shall be assessed for each parameter or method within each matrix, except as noted in subsection (3) of this section. The fee per parameter or method for each category, and the maximum fee per category where applicable, are identified in Table 1.</p>	<p>No significant change except categories and fees. Ecology analyzed costs and benefits of new fee categories and values.</p>
173-50-190		
<p>(3) A fee is assessed only once for a given parameter even though that specific parameter may be accredited under more than one matrix.</p>	<p>(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 non-potable water without paying an additional fee.</p>	<p>No significant change.</p>
173-50-190		
<p>(no previous language)</p>	<p>(4) The minimum fee for accreditation, either direct or through recognition of a third-party accreditation, is three hundred dollars.</p>	<p>Significant. Ecology analyzed the costs and benefits of the new fee structure.</p>
173-50-190		
<p>(6) The fee for recognition of a third party accreditation (WAC 173-50-170), other than NELAP accreditation (WAC 173-50-190(9)), is three hundred forty-five dollars.</p>	<p>(7) The fee for recognition of a third party accreditation (WAC 173-50-170) is three-fourths (75%) of the fee indicated in Table 1.</p>	<p>Significant. Ecology analyzed the costs and benefits of the new fee structure.</p>
173-50-190		
<p>(7) The fee for recognition of a laboratory under a reciprocity agreement (WAC 173-50-160) is three hundred forty-five dollars, or as specified in the reciprocity agreement, but not less than three hundred forty-five dollars.</p>	<p>(deleted)</p>	<p>Significant. Ecology analyzed the costs and benefits of the new fee structure.</p>

EXISTING RULE LANGUAGE	NEW RULE LANGUAGE	CHANGE AND ANALYSIS?
173-50-190		
(8) The fee for recognition by a NELAP accrediting authority for laboratories in Washington is three hundred forty-five dollars. For out-of-state laboratories, the fee for recognition of accreditation by a NELAP accrediting authority is the fee indicated in Table 1.	(deleted)	Significant. Ecology analyzed the costs and benefits of the new fee structure.
173-50-190		
(9) For drinking water laboratories, the base fee to defray the extra cost incurred by the department because of the need to coordinate directly with two regulatory agencies is one hundred fifteen dollars.	(deleted)	Significant. Ecology analyzed the costs and benefits of the new fee structure.
173-50-190		
(10) If a laboratory withdraws from the accreditation process after the application has been processed, but before accreditation is granted, the fee is nonrefundable up to an amount of two hundred thirty dollars...	(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...	Significant. Ecology analyzed the costs and benefits of the new fee structure and refunds.
173-50-210		
(1) For the purpose of conducting on-site assessments or otherwise enforcing this chapter, the department may enter any premises in which analytical data pertaining to accreditation under the provisions of this chapter are generated or stored.	(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.	No significant change.