



DEPARTMENT OF
ECOLOGY
State of Washington

Small Business Economic Impact Statement

*Chapter 173-50 WAC
Accreditation of Environmental Laboratories*

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Small Business Economic Impact Statement

Chapter 173-50 WAC Accreditation of Environmental Laboratories

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Note: Due to size limitations relating to the filing of documents with the Code Reviser, the SBEIS does not contain the appendices that further explain Ecology’s analysis. Additionally, it does not contain the raw data used in this analysis, or all of Ecology’s analysis of this data. However, this information is being placed in the rule-making file, and is available upon request.

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Executive Summary

Based on research and analysis required by the Regulatory Fairness Act – RCW 19.85.070 – Ecology has determined that the amendments to Chapter 173-50 have a disproportionate impact on small business. Therefore, we must include cost-minimizing features in the rule where it is legal and feasible to do so.

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. Applicable analyses include chemical, physical, biological, microbiological, radiological, or other scientific determinations which provide recorded qualitative and/or quantitative results.¹

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.
- Solid fuel burning devices.

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 lab accreditation program. 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

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.

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

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 of seven employees in the ELAP program. With one less person to do the work, Ecology is not able to audit and accredit as many labs as in the past.

With 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.

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.

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.

Application for Accreditation

Ecology's lab accreditation application process requires labs to provide information on the resources the lab may be 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 identifies policies and procedures designed to achieve reliable results at a lab, 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, as well as the receipt, logging, storage, handling, and acceptance or rejection of samples.
- Analytical 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 for lab 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 two sets of chemistry PT study results each year (semiannually), and one set of microbiology PT study results for drinking water accreditation.

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

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 Unit 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.

⁶ WAC 173-50-130.

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.

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
	Physical	\$65	\$260
Drinking Water	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

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.

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.

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.

Table 2: Proposed Lab Accreditation Fee Schedule			
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

The proposed rule changes the requirement for proficiency testing (PT). Ecology proposed this change to create uniformity in PT requirements for microbiology testing. Under the baseline (existing) rule, two PT studies are required annually for chemistry parameters, and one PT study is required annually for microbiology parameters in drinking water. The proposed rule adds one microbiology PT study annually for non-drinking water matrices.

Changes to Third-Party Accreditation Fees

Ecology’s proposed rule revises the fees related to accrediting a lab that has other accreditation accepted by Ecology. This includes NELAP accreditation, as well as other third party accreditation. 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 accreditation fees include:

- In-state labs seeking recognition of third-party accreditation no longer pay \$345, and instead pay 75 percent of the appropriate fee set by the rule for each parameter covered by third-party accreditation.
- Out of state labs with third-party 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.
- Drinking water labs no longer pay an additional fee of \$115.

Changes to Terminology

Since the last amendments to the lab accreditation rule, the names of some reference materials have changed. For example, 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 retains the three-year maximum time between on-site audits at labs accredited for analyzing drinking water.

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 the 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.

Compliance Costs for Washington Businesses

Ecology calculated, in the Cost-Benefit Analysis (Ecology Publication No. 10-03-25) for the proposed rule amendments, that the proposed rule would result in both quantifiable costs and benefits to Washington businesses. These impacts on Washington businesses are as follows.

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 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 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.

In this analysis, Ecology examined the degree of disproportionality in the increased costs of compliance, across small versus large businesses.

Quantification of Costs and Ratios

Using employment numbers by location where available,⁸ and otherwise by firm, Ecology divided each private entity's compliance costs by the number of employees to calculate cost per employee. New compliance costs resulting from the proposed rule language included net change in accreditation fees, and increased proficiency testing costs.

For the costs of compliance with accreditation fees as set by the proposed rule, as compared to the baseline, the average cost per employee, at the largest 10 percent of firms, was \$0.89. At small businesses, this average cost was \$93 per employee. For the costs of compliance with increased proficiency testing requirements at some labs, the average cost per employee, at the largest 10 percent of firms, was \$0.24. At small businesses, this average cost was \$51 per employee.⁹

These costs are mitigated by avoided costs associated with reduced on-site audits. Ecology could not confidently assign this benefit to particular businesses due to uncertainty, but expects the avoided costs to correlate with lab size at a declining rate. That is, larger labs would likely have higher costs of compliance with on-site audits, but

⁸ Washington State Department of Employment Security. www.workforceexplorer.com

⁹ Note that the reliability and precision of available employment data for impacted businesses is highly variable. Ecology used the best available data in its analyses, stemming from business sources, business databases, and public sources such as the WA Employment Security Department (see References for more information). For small businesses (especially those not publicly traded), employment data is more likely to be limited to a location, and may underestimate the true number of employees at a given firm. Large businesses are more likely to be publicly traded, exist in business information databases in their entirety, and offer information on employment to shareholders and in reports. This means that the employment data for large businesses is likely a better estimate of actual employment than for small businesses. Ecology chose to use this data because it was the best available, and provides a conservative view of the disproportionality of small versus large-business impacts. It is likely that the cost per employee reported for small businesses is an overestimate. All employment data was reported at the parent-company level to the extent available.

they would also have economies of scale in those costs. Ecology expects this reduced compliance cost to disproportionately benefit small businesses, on a per-employee basis.

Clearly, the proposed rule has disproportionate cost impact on small businesses, and so Ecology must include cost-reducing features in the proposed rule.

Action Taken to Reduce Small Business Impacts

Ecology's capacity to reduce the proposed rule's impact on small businesses was constrained by the scope of the rulemaking. However, Ecology does take actions under the rule that facilitate small business compliance. The Lab Accreditation Unit assists labs participating in Ecology's Laboratory Accreditation Program to the extent resources allow. Although they may be conducted in association with on-site assessments, assistance visits are not assessments, and a corrective action report is not required from the lab in response to deficiencies noted during the visit.¹⁰ This provides for a lower-cost way for labs to ensure their compliance with applicable requirements.

The proposed fee structure charges all labs, regardless of size, fees in proportion to the work Ecology must do to grant or maintain their accreditation. This makes the proposed fee more equitable than the existing fee, which subsidizes larger labs with many types of accreditation through additional fees collected from smaller labs with more limited accreditation. If we had retained the existing fee structure and increased fees across-the-board by 45% to recover program costs, this would have had a more disproportionate effect on small business. Also, the proposed fee structure eliminates maximum fees for several categories of testing, and increases the maximum fees in two remaining categories. Both of these changes benefit small business by decreasing subsidization of larger labs.

Small Business Involvement

In the rule development process for the proposed rule amendments, Ecology communicated with small businesses, and included input from the small business community in its decision making process. During November 17 – 19, 2009, Ecology held workshops in Olympia, Everett, and Moses Lake. During these workshops, Ecology presented material covering its intent in the rulemaking, possible options, and the interstate context of the Washington lab accreditation program relative to other states. Ecology collected and responded to comments received during these workshops.

¹⁰ WAC 173-50-220

NAICS Codes of Impacted Industries

Based on existing environmental labs subject to Ecology accreditation, Ecology determined which North American Industry Classification System (NAICS) codes reflect businesses likely impacted by the proposed rule amendments. The likely impacted NAICS codes are listed in Table 3. This list includes all likely affected private-sector industries.

Table 3: Impacted Industries									
1125	2371	3114	3221	3328	4239	4452	5413	5629	7211
1133	2372	3115	3222	3345	4241	4471	5416	6111	7212
1153	2373	3116	3241	3364	4244	4539	5417	6113	8139
2211	2389	3210	3259	3391	4246	4883	5419	6215	8731
2213	3110	3219	3313	4233	4441	5311	5614	6231	

Impact on Jobs

By creating additional compliance costs to some businesses, the proposed rule amendments create transfers of money within and across industries. These financial impacts can then filter through the economy (additional or reduced resources to employ individuals, purchase inputs, etc.). Ecology does not believe the compliance costs generated by the proposed rule will result in impacts to lab revenues or competition in the market.

Ecology used the 2002 Washington State Office of Financial Management Input-Output model to estimate the impacts of financial transfers created by the proposed rule amendments. Table 4 summarizes the distribution of job impacts across industries. The table includes only those industries in which more than 0.1 increase or decrease in jobs occurs per year. Ecology estimated that the proposed rule is likely to generate a small loss of 3.6 jobs in the state economy.¹¹ This job loss comes from the combined impacts of quantifiable fee and proficiency testing costs created by the proposed rule, as well as the reduced compliance costs of on-site inspections.¹²

¹¹ This annual loss does not indicate that nearly 4 positions would disappear each year, but rather that the equivalent of 3.6 positions would not exist over the full course of the 20 years.

¹² Ecology could not assign reductions in the cost of on-site audits to specific labs or entities, and so assumed all avoided costs would go to the Testing Laboratories industry (NAICS code 541380). In addition, job losses fall as on-site audits become less frequent. The estimate provided here reflects an average delay of one year in on-site audits.

Table 4: Significant Annual Job impacts Across the Washington Economy	
Industry	Change in Jobs*
Retail	-0.32414
Legal /Accounting and Bookkeeping /Management Services	-0.10611
Architectural, Engineering, and Computing Services	-0.20592
Educational Services	-1.40417
Ambulatory Health Care Services	-0.10186
Nursing and Residential Care Facilities, Social Assistance	-0.12333
Arts, Recreation, and Accommodation	-0.11665
Food Services and Drinking Places	-0.2087
Administrative/Employment Support Services	-0.18141
Waste Management/Other, and Agriculture Services	-0.18863
TOTAL CHANGE IN JOBS PER YEAR	-3.61450

* Industry impacts may not sum to the total due to smaller impacts in industries not listed, and to rounding.