DEPARTMENT OF
ECOLOGY
State of Washington

Concise Explanatory Statement

Chapter 173-50 WAC

Accreditation of Environmental Laboratories

Summary of rule making and response to comments

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Concise Explanatory Statement

Chapter 173-50 WAC
Accreditation of Environmental Laboratories

Environmental Assessment Program
Washington State Department of Ecology
Olympia, Washington 98504-7710

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CONCISE EXPLANATORY STATEMENT

I. Introduction

a) Identify the reasons for adopting this rule (RCW 34.05.325(6)(a)(i)):

Our current fee structure does not cover the cost of the State Environmental Laboratory Accreditation Program. In the 2009-11 budget, the legislature authorized The Department of Ecology (Ecology) to raise fees to cover the cost of the program. We have eliminated one FTE and need to raise fees by about 45% to fully fund the program. With the loss of one of our six auditors, we will also need to change some business practices specified in the rule. Without this amendment, we can not cover the cost of the program and will not meet the requirements of the current rule.

RCW 43.21A.230 allows Ecology to accredit environmental laboratories. The Department of Health has delegated to Ecology (in a MOU) their RCW 43.20.050 authority to certify drinking water laboratories.

b) Identify the adoption date of rule and effective date of rule.

Adoption date is August 9, 2010 and effective date is September 9, 2010.

II. Describe Differences Between Proposed and Final Rule

a) Describe the differences between the text of the proposed rule as published in the Washington State Register and the text of the rule as adopted, other than editing changes. State the reasons for the differences (RCW 34.05.325(6)(a)(ii)):

WAC 173-50-040 Definitions.

We added the following definitions:

- "Accreditation year" - the one year period as stated on the certificate of accreditation.
- "Principal laboratory" - a laboratory designated by Washington department of health to support the drinking water certification program.

These are terms added to the rule in response to comments in Appendix A.

We changed the following definition:

"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.

We plan to complete the revision of the procedural manual by the rule effective date.

WAC 173-50-060 Responsibilities of environmental laboratories.

We changed the third bullet:

- Submit an initial set of ~~acceptable~~satisfactory PT ((~~sample analysis~~)) sample results (WAC 173-50-070); and

This change aligns the terminology related to changes in proficiency testing requirements in response to comments 1.2 and 1.6.

WAC 173-50-070 ((Performance audit.)) Proficiency testing (PT).

We added the second sentence:

> (2) ((~~Drinking water~~)) 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. For chemistry parameters, after an accredited laboratory submits two satisfactory PT sample results and no unsatisfactory results in an accreditation year, the laboratory is required to submit only one satisfactory PT sample result in subsequent accreditation years. This applies as long as there are no intervening unsatisfactory PTs.

This is the change we agreed to make in response to comments 1.2 and 1.6.

WAC 173-50-130 Requirements for maintaining accreditation status.

We added the parenthetical phrase:

> (1) Accreditation is granted for a one-year period (the accreditation year) and expires one year after the effective date of accreditation.

This reiterates our definition of "accreditation year" added to WAC 173-50-040.

WAC 173-50-150 Revoking or suspending accreditation.

We added an additional condition to sub-section (3):

> Reports two consecutive unsatisfactory PT sample results.

This change is made in connection with our response to comments 1.2 and 1.6.

WAC 173-50-170 Third-party accreditation.

We changed this bullet:

- ~~A complete set of the most r~~Recent, satisfactory ((~~PT~~)) proficiency test results for the applicable parameters.

This change is made in connection with our response to comments 1.2 and 1.6.

WAC 173-50-190 Fee structure.

We deleted this sentence:

> (((~~(11)~~))) (9) ~~Dollar amounts listed in Table 1 and subsections (((6))) (4), (7), and (8)((, (9), and (10))) of this section may be adjusted every year based on inflation as indicated by the *Implicit Price Deflator for State and Local Government Services* as published by the economic and revenue forecast council.~~

This was done because the Implicit Price Deflator no longer exists.

We added this new sub-section:

> (10) Accreditation fees are waived for laboratories operated by the Washington state departments of ecology and health. Accreditation fees are also waived for drinking water parameters certified by EPA Region 10 at designated principal laboratories.

This was added in response to comments 1.1, 1.3, 1.5, 1.6, and 1.7.

III. Response to Comments

a) Summarize all comments received regarding the proposed rule and respond to comments by category or subject matter. You must indicate how the final rule reflects agency consideration of the comments or why it fails to do so (RCW 34.05.325(6)(a)(iii)):

In the summary of the comments and testimony below, the paragraph numbers refer to the following persons:

1.1 Steve Twiss, Twiss Analytical, Poulsbo

1.2 Aaron Young, AmTest, Inc., Redmond

1.3 Kurt Johnson, Friedman and Bruya, Inc., Seattle

1.4 Charles White, Puyallup Water Pollution Control Plant

1.5 Laura Mrachek, Cascade Analytical, Wenatchee

1.6 Chris Mueller, Water Management Laboratories, Tacoma

1.7 Larry Henderson, Edge Analytical, Burlington

The full text of their comments or testimony is presented in Appendix A, Sections A1.1 through A1.7. Ecology's response to comments is italicized below.

Effects of Fee Increase

1.1 In addition to your fee increase, other state agencies are increasing fees and taxes. If we can't sell additional services to meet those increases, we will be force(d) to cut staff and/or raise our prices significantly. The impact of these increases is that water systems will pay more for analytical services and labs will hire fewer people, resulting in fewer dollars being returned to the local economy.

1.2 The price increase is going to make it harder for some of the laboratories to continue to be profitable.

1.3 We are in agreement with the increase of accreditation fees.

1.5 This fee increase puts us in an increasingly noncompetitive position vs noncommercial laboratories with the 50 percent increase in accreditation fees and 20 percent increase in our B&0 tax effective May 1. A loss of 5 to 7 percent of commercial laboratory capacity in the state could affect the ability of the regulated community to meet their compliance monitoring requirements in a timely manner.

Ecology's Response:
We have maintained our current schedule of accreditation fees for nearly eight years despite rising costs. Accredited labs have financially benefited from this, but Ecology had to increasingly rely on state general fund subsidies to support the accreditation program. In addition, we eliminated one of seven positions in the accreditation program last year. The 2009 legislature authorized Ecology to raise accreditation fees to cover program costs so that the state general fund was no longer subsidizing the accreditation program.

All Laboratories Should Pay the Same Fees for Accreditation

1.1 All laboratories should be treated the same when it comes to fee increases. There should be no favoritism shown to out of state labs with third party accreditation since they create no jobs in Washington.

1.1 All laboratories should be accredited even, the state laboratories, especially if they are performing routine work that could be done in the private sector.

1.3 Out-of-state laboratories are not paying their fair share of the cost of the accreditation program. For out-of-state laboratories to be charged only for selected costs associated with the program appears to be unfair.

1.5 Out of state laboratories should be charged the full fee because they do not pay B&0 tax in this state.

1.6 All state, county and cities should be made to pay accreditation fees. Manchester lab does not and is in direct competition with commercial laboratories. Out-of-state labs should pay 100 percent of the fees the rest of us do. Last year my lab paid almost $63,000 in taxes to the state. Out of state labs pay zero. We also employ 24 people here in the state.

1.7 The 75 percent fee to third-party laboratories is rather onerous on us. We pay B&0, property, and use taxes. We have lost significant business to out of state laboratories that do not pay those taxes. Our costs are much heavier in this state and it's not fair. I don't know how the attorney general ever came up with the idea that it's not fair to charge those labs full price, but it is unfair to the laboratory community in this state. Government labs should pay the same fees as commercial laboratories pay, particularly the Manchester lab. It is not fair. It's an undue burden on the commercial laboratories that pay for the bulk of the accreditation program.

Ecology's Response:
Out-of-state labs pay the same accreditation fees as in-state labs. Many out-of-state labs and some in-state labs are accredited by third parties, and our proposed fee structure includes a 25% price discount for these labs because we do not have to conduct on-site audits for them. Those audits are instead performed by a third-party accrediting authority to whom the labs are paying a separate accreditation fee -- one that is sometimes significantly higher than the fee Ecology charges. Also, while we do not conduct on-site audits of third-party labs, there is significant effort involved in monitoring the audits by the other accrediting authorities, and those costs are included in our proposed fee structure.

While not specifically addressed in the accreditation rule, Ecology's longstanding practice has been to waive accreditation fees for labs operated by the two state lab accreditation authorities (i.e., the departments of Ecology and Health). In the past we have also waived accreditation fees for the two principal labs designated by the state Department of Health: Water Management and Edge Analytical. Ecology will include language in the final accreditation rule to provide for fee waivers in limited circumstances.

<u>Offset the Fee Increase by Reducing the PT Requirements</u>

1.2 AmTest is required to perform two Water Supply, two Water Pollution and two Soil performance evaluation studies per year as well as the microbiological PT studies. Last year, AmTest's cost of the PT studies was $14,700. AmTest pays currently about $9,000 per year for our accreditation. With your proposal for increase that will go to about $13,770 per year. So, just for our lab to be accredited with WA DOE will cost a total of about $29,000 per accreditation year. I am proposing that WA DOE may want to take a look at the PT requirements and find a way that would lower the number of annual PT samples required by the accredited labs.

1.6 I'd like to see Ecology drop their requirements of two PT studies per year on chemistry to one. Last year, PT samples cost us $9,500 and will probably cost over $10,000 this year.

Ecology's Response:
We do currently accept WS (drinking water) PT results for both drinking water and non-potable water accreditation for the same parameter. This was done to keep costs down and we propose to continue that policy, though it does complicate the processing of the PT results.

With the proposed reduction in auditing oversight of non-drinking water accreditation, Ecology is reticent to further reduce that oversight by reducing the PT requirement as well. However,

considering the relatively high costs to the labs, Ecology will modify PT requirements in the proposed rule to allow labs with consistently good PT results to participate in just one chemistry PT study per year. This will partially offset the increase in accreditation fees for many laboratories.

Fees Should Be Based on Lab Revenues

1.1 Fee increases should be based on a laboratory's revenues not on the number of parameters for which they are accredited. Our lab is considered "big" because of the number of accreditations we hold while our revenues put us in the small category. It would be a disproportional burden to increase our fees by the estimated 53% that you indicated would be our increase under this proposal.

Ecology's Response:
This approach is contrary to the fee-for-service basis for accreditation. It would result in many county and municipal labs paying no fees because they generate no revenue, and would shift the burden of the cost of the accreditation program to commercial labs.

Onsite Audits Should Be Required for All Labs

1.3 On-site visits by WA DOE, or their representatives, should be a requirement for all laboratories regardless of third party accreditation and the costs must be borne by the laboratories.

Ecology's Response:
On-site audits are required for all labs, and those audits are conducted by either Ecology or third-party accrediting authorities.

Analysts Should Also Be Accredited

1.4 The lab isn't the one performing the testing. What about having the lab technician/specialist also be accredited? We're the ones actually doing the work. Maybe this can be an endorsement to our Wastewater License or a complete separate accreditation by the state just for the lab person.

Ecology's Response:
Ecology evaluates the credentials of lab staff as part of our application review and on-site audit, so laboratory personnel are included in the overall accreditation process.

There Should Be an Advisory Committee

1.5 There should be an advisory committee on the rule making process so that commercial laboratories can have a more active role in this process in the next go-around.

Ecology's Response:
We used an advisory committee in the previous rule-making due to the complexity of transferring the drinking water certification program from DOH to Ecology. Since this rule-making involves primarily our fee structure and affects all of the labs in our program, we held workshops to solicit input from the lab community rather than forming an advisory group. We will consider using an advisory group in future rule-making, depending on the complexity of proposed rule revisions.

Labs Should Pay the Actual Cost of Audits

1.5 I'd prefer to see all labs charged for the actual cost of the audits. For example it would cost the Department of Ecology more to audit me than it would another laboratory that's closer to their office.

1.7 I would like to include the actual cost of conducting audits in the fee structure, including travel time and expenses. That would help to recover some of the costs when auditors come to our laboratory.

Ecology's Response:
One state does charge all labs for the full cost of on-site audits. However, this would add significantly to the complexity of the fee structure and billing process. The effort involved in conducting the audit is proportional to the number and type of parameters for which the lab is accredited, which in turn is proportional to the accreditation fee the lab pays. We make every effort to group our audits of labs to make the travel as efficient as possible.

Manchester Lab Should Be Closed

1.5 It's time to shut down the Manchester laboratory. They compete with the commercial laboratories and don't pay taxes to the state. There is excess capacity in commercial laboratories.

1.6 Manchester laboratory should be closed. It is in direct competition with the private sector. They pay nothing in taxes. Ecology could probably save billions right there.

1.7 I would like to see Manchester lab remove itself from operation. There's plenty of capacity in this state to handle all of the work that they do. This would be an enormous savings. I would ask Ecology to look at the cost savings that has occurred since the DOH laboratory ceased operations in drinking water and use that as a guide to see potential savings.

Ecology's Response:
Ecology has evaluated this option in the past, and concluded that as a regulatory agency, it needs to maintain in-house analytical capability. Most of the work done by Manchester Lab is from samples submitted by Ecology staff, who benefit from ease of access, custom analyses, consistency over time, and impartiality. Manchester's prices for analytical services are comparable to commercial labs – higher than some but lower than others. Manchester Lab cannot accept work from non-governmental bodies, and does not compete for work in the private sector.

Accreditation Should Not Be Conditioned on Reporting to DOH

1.5 Initially commercial laboratories were reporting results to DOH in a courtesy fashion, not required by state law. We heard that if we didn't do that we would lose our accreditation. I would like to have it somewhere in the text that inadvertent nonreporting of results to DOH will not cause a denial or a provisional accreditation.

Ecology's Response:
We believe this comment refers to the DOH rule revision related to drinking water data reporting. This comment is not related to the lab accreditation rule.

Ecology Should Have Been Raising Fees by the Allowed Amount Each Year

1.6 DOE had the authority over the years to increase fees at a set rate. I think they only did it maybe twice since 1988. I think their management at fault with the problems that the certification people are dealing with today.

Ecology's Response:
We have tried to avoid successive fee increases for a couple of reasons. First, the absence of fee increases for the past eight years has been financially advantageous to labs during that time, especially when compared to the fee structures of other states. Second, increasing fees requires rulemaking which is a time and resource intensive process. Therefore, we believed the better course was to increase fees less frequently, although we are sensitive to the fact that fewer fee increases means that fee increases, when they do occur, tend to be higher than they would if we were increasing on a more regular basis.

The issue of fee increases became more difficult with the passage of Initiative 960 in 2007. The initiative requires legislative approval for all proposed fee increases by any agency. The legislature granted this authority to Ecology in 2009 so that fees would fully cover the costs of running the lab accreditation program. After we received this authorization, we immediately started working on rules to accomplish this objective.

Principal Labs Should Not Pay Fees

1.6 WML and Edge Analytical agreed to be EPA certified, to assist the state in any problems that have occurred, and have acted as a training lab for DOE auditors. This is the reason that Edge and Water Management didn't pay any fees. We have kept up our end on this agreement. EPA gives the state money to fund drinking water. Part of that funding was to go to lab certification. I think that should be where the money should come from.

Ecology's Response:
In the past Ecology has fully waived accreditation fees for the two principal labs designated by the state Department of Health: Water Management and Edge Analytical. Our current Memoranda of Agreement with these two labs allow us to charge for direct accreditation for those parameters not covered by EPA's drinking water certification. In the interests of fee equity among all accredited labs, we are planning to charge the principal labs for their direct

accreditation in the future. Ecology will include language in the final accreditation rule to waive principal lab fees for parameters directly accredited by EPA.

Costs of the Accreditation Program

1.5 I'd like to see more detail on program costs, like the number of people, hours put in, that kind of thing.

1.6 I'd like to see is a breakdown on the $1.8 million cost of the program - overhead costs, wage costs, benefit costs, travel costs and everything.

Ecology's Response:
Two-year costs for Ecology's lab accreditation program are as follows (July 2009 - June 2011):

Position	*FTE*	*Salaries & Benefits*	*Specialty*
Chemist 4	*1.0*	*$196,740*	*Supervisor, General Chemistry*
Chemist 4	*1.0*	*196,740*	*Metals*
Chemist 4	*1.0*	*196,740*	*Organics*
Microbiologist 4	*1.0*	*196,740*	*Microbiology*
Environmental Specialist 5	*0.8*	*141,049*	*Toxicology*
Environmental Specialist 2	*1.0*	*120,230*	*Office support*
Sub-totals	*5.8*	*1,048,239*	
*Indirect costs**		*385,752*	
Supplies, travel, etc.		*65,922*	
Biennial totals		*$1,499,913*	

** 36.8% of salaries & benefits*

IV. Summary of Public Involvement Opportunities

a) Please provide a summary of public involvement opportunities for this rule adoption:

Workshop dates and locations:

- November 17, 2009 in Lacey
- November 18, 2009 in Everett
- November 19, 2009 in Moses Lake

Hearing dates and locations:

- April 27, 2010 in Lacey (3 persons attended, none testified)
- April 29, 2010 in Moses Lake (10 persons attended, 3 testified)

Mass mailings:
We sent two e-mails to about 450 interested parties, including our contact persons at all labs that we accredit. The first e-mail, in September 2009, announced the rule-making and workshops. The second e-mail, in March 2010, announced the public hearings. We sent letters to another 20 accredited labs for which we did not have e-mail addresses.

These mailings included links to our web site which provided a September 2009 focus sheet, a March 2010 news release, and our March 2010 proposed revisions to the rule. These documents and the e-mail messages are included in the appendices of this document.

Appendix A - Comments and Testimony

A1.1 Comment from Steve Twiss

Here are my comments about the proposed fee increases for laboratory accreditation.

1. For every dollar increase in expenses we have here at Twiss Analytical Laboratories, Inc. we need to sell an additional two dollars in services or products in order to break even. That is very difficult to do in a down market such as we are experiencing at present. In addition to you fee increase other parts of the state government are trying to increase their revenues by increasing fees and taxes. If we can't sell additional services to meet those increases we will be force to cut staff and/or raise our prices significantly. We have already cut one chemist from our staff due to the down market. Many of the small group A water systems we service don't need another increase in the price of analytical services (we raised our prices 5% in January).
2. Increased fees will prolong the time until we are able to begin hiring again.
3. All laboratories within the state and without should be treated in the same manner when it comes to fee increases. There should be no favoritism shown to out of state labs who hold third party accreditation as they create no jobs within the state of Washington whereas in state labs do provide Washington jobs.
4. Fee increases should be based on a laboratory's revenues not on the number of parameters they request accreditation for. Our lab is considered "big" because of the number of accreditations we hold while our revenues put us in the small category. It would be a disproportional burden to increase our fees by the estimated 53% that you indicated would be our increase under this proposal.
5. All laboratories should be accredited even the state laboratories especially if they are performing routine work that could be done in the private sector.

I realize that in this time of diminishing budgets everyone needs additional sources of revenue and things are generally going to cost more. The main impact of the sum of these types of increases is that water systems will pay much more for the services they receive from us and we will hire fewer people resulting in fewer dollars being returned to the local economy.

I only ask that increases that are made to accreditation fees are done in an evenhanded manner with reasonable increases and that priority is given to laboratories whose principal offices are within the state of Washington.

Best regards,

Steve Twiss, President
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A1.2 Comment from Aaron Young

I attended the hearing for the Lab Accreditation Rule Revision on 04/24/2010 in Lacey at the community center and had a couple of concerns that you requested I write in an official email.

I understand the need for WA DOE to increase the prices for accrediting laboratories, to cover the cost of the accreditation program. I am concerned that the price increase is going to make it harder for some of the laboratories to continue to be profitable and I am wondering if there are other places we can look to cut cost for the labs. For example, AmTest is a full service laboratory that is required by WA DOE to perform two Water Supply, two Water Pollution and two Soil performance evaluation studies per year as well as all of the microbiological PT studies. In AmTest's accreditation year 2005-2006 the cost of the PT studies was $13,915.46, in 2006-2007 it was $11,906.15, in 2007-2008 it was $10,944.15, in 2008-2009 it was $14,698.90 and thus far this year our total is $12,466.45 and we still have a couple studies left to do. The prices increased in 2008 and you can see the cost went up quite a bit. AmTest pays WA DOE currently about $9,000 per year for our accreditation and with your proposal for increase of 53% that will go to about $13,770 per year. So, just for our lab to be accredited with WA DOE it will cost us a total of about $29,000 per accreditation year. I am proposing that WA DOE may want to take a look at the PT requirements and find a way that would lower the number of annual PT samples required by the accredited labs.

One suggestion might be, if we pass the first PT study of each accreditation year, then a second one is not necessary for that analyte. If we fail the first study, we then have to do the make-up sample within 30 days and also participate in a second study six months later.

Another suggestion might be that if we pass the same analyte three studies in a row, then we can go to once per year until that analyte fails again, then we have to pass three in a row again.

I understand that this is a very difficult subject, but if WA DOE could at least consider some alternatives to the current requirements, I would be very appreciative.

Thanks for your time.

Have a great day!

Aaron Young
Lab Manager
AmTest, INC.
425-885-1664

A1.3 Comment from Kurt Johnson

Stew,

Thanks for the clarification. In addition, the following are comments that we are submitting for review/comment regarding the proposed WAC-173-50 amendments that you notified us about.

1. We are in agreement with the increase of accreditation fees. We believe that on-site visits by WA DOE, or their representatives, should be a requirement for all laboratories regardless of third party accreditation. Clearly, these costs must be born by the laboratories.

2. We are concerned that the out-of-state laboratories are not paying their fair share of the cost of the accreditation program. As with our higher education system, out-of-state parties have avoided the costs associated with the implementation of this program over its life time. For out-of-state laboratories to be charged only for selected costs associated with the program appears to be unfair.

Respectfully,

Kurt Johnson
Director, Chemist
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A1.4 Comment from Charles White

Mr. Lombard,

Is the upcoming workshop in April just for updating the fee structure to which Accredited Labs will have to pay the D.O.E., or is it also for updating/amending what is accredited by the D.O.E.? I realize the importance of working in an accredited lab but the lab isn't the one performing the testing. What about having the lab technician/specialist also be accredited? Were the ones actually doing the work. Has this ever been brought up? Maybe this can be an endorsement to our Wastewater License or a complete separate accreditation by the state just for the lab person. I'm not sure if it would be better to attend the meeting or just inform you of my concerns and questions.

Sincerely,

Charles G. White
Lab Specialist, T.P.O. II

City of Puyallup, Water Pollution Control Plant
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e-mail: charlesw@ci.puyallup.wa.us

A1.5 Testimony of Laura Mrachek

My name is Laura Mrachek with Cascade Analytical, 3019 GS Center Road, Wenatchee, Washington 98801. I have a commercial, agricultural and environmental laboratory. We have been in business for well over 30 years. I have about a half dozen comments.

The first being I would like to insist on an advisory committee on the accreditation program rule making process so that commercial laboratories can be more an intrinsic part of this process in the next go-around.

It is critical that laboratories that provide comprehensive services be allowed to participate in this process; otherwise, there are considerations that cannot be made under the current workshop formal hearing process. It's just a very cumbersome way to deal with some of the details.

Second point, I'd like to see out of state laboratories charged the full fee because they do not pay B&0 tax in this state. And to note in the recent legislation effective May 1, which is next week, laboratories which are service industries will be paying an
increase of 20 percent on our B&O tax revenues to the State of Washington.

Number 3, the -- I'd prefer actually to see the actual cost of the audits as opposed to this -- let's see, I'd like to see a cost comparison as opposed to looking at just backfilling a certain amount to support the program, looking at what the actual fees are, the fee structures, number of people, hours put in, that kind of thing. I'm sure that that's in some of the background documents that the Department of Ecology has.

For example, from Olympia or from Manchester, it would cost the Department of Ecology more to audit me than it would another laboratory that's closer to them in proximity, at least there's some logic to how that would occur.

Number 4, I think it's time to shut down the Manchester laboratory. They are a laboratory that competes with the commercial laboratories and so basically they are tax-favored competitors. They don't have to pay Department of Revenue taxes to the state. I don't know if they pay accreditation fees, etc. There's some tax favoring going on there. There is excess capacity in commercial laboratories.

Number 5, this particular fee increase puts us under an increasing -- increasingly noncompetitive position as noncommercial laboratories and its owners with 50 percent increase in the level of fees, not including the 20 percent increase in our B & 0, and to acknowledge that a loss of 5 to 7 percent of laboratory capacity in the state is acceptable could be a real issue in compliance work that the state is ultimately responsible for making sure occurs in a timely manner.

Number 6, the meetings that were held kind of early on also had a component about reporting results for the Department of Health. I want to make sure that initially the way it was set up, commercial laboratories were reporting results to the Department of Health in a courtesy fashion, it was not required by state law. And we had heard at one point in time that if we didn't do that we would lose our accreditation.

So I would like to have it somewhere in the text, wherever this may apply. I don't know if it's in this particular ruling, but inadvertent nonreporting to the Department of Health results will not cause a denial or a provisional accreditation rating.

Thank you.

A1.6 Testimony of H. Chris Mueller

Chris Mueller, Water Management Laboratories, Tacoma, Washington, 1515 80th Street East, 98404.

I'd like to talk about the lab fees. Number 1, all state, county and cities should be made to pay fees. Manchester lab does not and is in direct competition with all laboratories, commercial laboratories.

Out of state labs, 75 percent, no. If they want to do business here, they pay 100 percent of the fees like the rest of us do.

Last year, my company paid in B & 0, property taxes, and most of you people don't know what personal property taxes is, but that's if we buy a piece of furniture, we pay taxes on that every year until you throw it away. We paid almost 63,000 dollars in taxes to the state. Out of state labs pay zero. The only time they will pay any B & 0 tax is if they get caught by the Department of Revenue doing business here. Rarely do they.

We also employ 24 people here in the state. So giving out-of-state labs a discount, no way. They have to pay what we pay.

Item 2 is I'd like to see the Department of Ecology drop their requirements of two PT studies per year on chemistry to one. The reason, in 2003, our costs for PT studies was 3,263 dollars. Last year, they are now 9,500 a year. So far this year, just on micro on drinking and waste water, the fee was almost 3,000 dollars. Then you have two studies on chemistry, which will probably put this bill up over 10,000 this year.

Another item is DOE had the authority over the years to increase fees at a set rate. I think during that period of time since 1988, they only did it maybe twice. So I think that their management should be looked at as part of the fault with the problems that the certification people are dealing with today. That's an internal problem that they have.

Again, on Manchester laboratory, it should be closed. It is in direct competition with the private sector. They pay nothing in taxes. I will tell you the Department of Ecology could probably save billions right there.

One of the other things is that WML and Edge Analytical are the two largest state reference labs. We agreed to do this to have the program saved on drinking water. To do that, we agreed to be EPA certified, go through the certification every three years, which we have both been doing.

We agreed to assist the state in any problems that have occurred. We have done that. We also have acted as a training lab for DOE auditors. And this is the reason that Edge and Water Management didn't pay any fees.

We have kept up our end on this agreement. The state's not going to back out on it. DOE is going to have to come up for the funding for our two labs because we do not feel we should have to pay. We kept our end of the bargain, they have a problem with theirs.

This includes Denise Clifford with the state Department of Health drinking water program because the EPA gives the state money to fund drinking water. Part of that funding was to go to lab certification issues. They have not put a dime into the program since ecology took over, so they have just pocketed the money and blew it on other items. I think that should be where the money should come from.

And what else? And one of the other things I'd like to see is a complete breakdown on the cost of the 1.8 million dollars, I want to know what the overhead costs are, wage costs, benefit costs, travel costs and everything. They have to have that, so I would like to see that.

Thank you.

A1.7 Testimony of Larry Henderson

My name is Larry Henderson with Edge Analytical, and that is at 1620 South Walnut Street in Burlington.

I'd like to talk about the 75 percent fee to out of state laboratories, or more specifically to third-party laboratories. It's based on the amount of taxes that we pay, both in B & 0, property, use tax. It's rather onerous on us.

We have lost significant business to out of state laboratories that do not pay those type of things. The bids were very close, but we don't -- our costs are much heavier in this state. And it's not fair.

And I don't know how the state's attorney general office ever came up with the idea that it's not fair to pay those fees full price, but it is unfair to the laboratory community in this state.

I would like to also have some of these costs reevaluated based on doing audits on an actual cost basis. If somebody is in Spokane, sorry if you are in Spokane, but if you are in Spokane, there should be actual costs associated with that and not thrown into a pool of general accreditation costs. There's additional travel time, per diem, values that go on there.

It's the same values that we have to pay when we go to third-party accreditations. That would help to recover some of the costs when auditors come to our laboratory, they stay there for a few days. It's only reasonable to expect that there are some specific and direct costs associated with those costs.

I would also like to see government labs pay the same fees that laboratories, that commercial laboratories have to pay, particularly the Manchester lab. I don't know, there might be others, maybe the Department of Ag lab, I don't know. But it is not fair. It's an undue competition between the commercial laboratories that pay the burden of the accreditation program to have them ride on our shoulders.

I'd just like to reflect agreement with the other two individuals that have spoken. I would like to see the Department of Ecology's Manchester lab remove itself from operation. There's no reason, there's plenty of capacity in this state, plenty of technology in this state, to handle all of the work that they do. This would be an enormous savings.

I would ask the department to look at the cost savings that has occurred since the Department of Health laboratory in Seattle has ceased operations in drinking water and use that as a guide to see potential savings to a program.

We all recognize that the state is in a great shortfall for funds. I suggest that a better way to help shortfalls is to quit spending so much money instead of trying to extract it out of businesses.

Thank you.

Appendix B - Public Information

Focus on Laboratory Accreditation

DEPARTMENT OF ECOLOGY
State of Washington

Environmental Assessment Program **September 2009**

Environmental Laboratory Accreditation rule revision

(WAC 173-50)

The problem

The current fee structure for lab accreditation does not provide sufficient revenue to cover the cost of the Department of Ecology's (Ecology) Environmental Laboratory Accreditation Program. As a result, the state general fund has been subsidizing the program.

Through its 2009 operating budget, the Legislature directed Ecology to raise fees to cover the full cost of the program.

The solution

To begin easing the funding shortfall, Ecology has eliminated one of seven positions in the accreditation program. It must now increase lab accreditation fees by about 45 percent to fully fund the remaining program. Ecology strives to maintain a revenue-neutral program. Lab accreditation fee increases will help the state break even.

With the loss of one position, Ecology will also need to change some business practices in the rule that will reduce its oversight of accredited laboratories. Ecology will explore various business alternatives through this rule-making process, and also adjust fees to reflect the level of effort required to accredit different types of labs.

You are invited to learn more

Ecology will invite all interested parties to participate in workshops during November 2009 to discuss proposed changes to WAC 173-50. We will hold public hearings on those proposed changes during April 2010.

You can visit our web site to get more information about this rule making:

www.ecy.wa.gov/programs/eap/labs/lab-accreditation.html

Why it matters

Ecology runs an accreditation program for about 460 environmental laboratories, including labs that analyze drinking water.

Accreditation of environmental laboratories ensures that labs are capable of providing accurate and defensible analytical data to Ecology, the state Department of Health, and other data users. This helps protect public health and the environment.

Washington State drinking water permits and environmental permits require the use of accredited labs.

Contact
Stew Lombard
360-895-6148
Stew.Lombard@ecy.wa.gov

B-2 Workshop Announcement (e-mail)

From: Schreiber, Connie (ECY)
Sent: Friday, September 25, 2009 10:49 AM
To: Schreiber, Connie (ECY)
Subject: Washington State Dept of Ecology - WAC 173-50 Rule Corrected URL

The address for Ecology's current rule making site was incorrect in the email I sent on September 22. Please see below for the correct address. I apologize for any inconvenience this may have caused.

The Washington State Department of Ecology is beginning a public process to revise its rule concerning the Environmental Lab Accreditation Program (Chapter 173-50 of the Washington Administrative Code). Ecology's current fee structure has not kept up with the costs of funding the accreditation program, and the 2009 Legislature directed us to raise fees to fully pay for the program. Ecology has already taken one step to reduce program costs by eliminating one of the seven positions in the program. We are also changing some of our business practices to reduce operating costs.

The enclosed Focus Sheet has more information about this rule revision. We will have workshops in November 2009 to discuss the proposed rule changes, and we will hold public hearings during April 2010. The process is expected to take about a year to complete.

Additional information on the rule revision is on Ecology's current rule making site
http://www.ecy.wa.gov/laws-rules/wac17350/0909.html

Please let other people in your organization who may be interested know about the rule revision.
You can contact Stew Lombard, Lab Accreditation Unit Supervisor, if you have questions or comments.
Email: Stew.Lombard@ecy.wa.gov Phone: (360) 895-6148.

Connie Schreiber
Environmental Specialist
Washington State Department of Ecology
Environmental Laboratory Accreditation Program
PO Box 488
Manchester, WA 98353
Telephone (360) 895-6145
Fax (360) 895-6180

Accreditation Program internet address:
http://www.ecy.wa.gov/programs/eap/labs/lab-accreditation.html

B-3 Public Hearing Announcement (e-mail)

From: Schreiber, Connie (ECY)
Sent: Thursday, March 25, 2010 2:21 PM
To: Lombard, Stew (ECY)
Subject: Washington State Department of Ecology Laboratory Accreditation Program - Rule Revision Notification

The Washington Department of Ecology is amending a rule to address a funding deficit for its State Environmental Laboratory Accreditation Program. The 2009 legislature authorized Ecology to increase fees in the 2009-2011 biennium as necessary to meet the actual costs of conducting business. The rule changes include increasing the fees for accreditation and changing some Ecology business practices to reduce operating costs.

Public Hearings and Opportunity to Comment

Ecology will hold two public hearings to collect comments about the proposed rule.
Date: April 27, 2010
Time: 1:00 p.m.
Location: Lacey Community Center
6729 Pacific Avenue, Lacey, WA

Date: April 29, 2010
Time: 10:00 a.m.
Location: Moses Lake Fire Department
701 E. Third Ave, Moses Lake, WA

Written Comments Accepted

You can also send written comments to:

Stew Lombard
Lab Accreditation Comments
Department of Ecology
P.O. Box 488
Manchester, WA 98353-0488
stew.lombard@ecy.wa.gov

Comment Deadline

Written comments must be postmarked or e-mailed no later than 5 p.m., May 7, 2010.

Rule-making Documents

Documents related to the rule making, including Ecology's draft rule language, can be viewed on Ecology's current rule making page.

Current Version of the Rule

The link for the current rule is Chapter 173-50 WAC, Accreditation of Environmental Laboratories.

B-3 Public Hearing Announcement (e-mail)

Contacts:

Stew Lombard
Lab Accreditation Unit Supervisor
(360) 895-6148
stew.lombard@ecy.wa.gov

Connie Schreiber
Environmental Specialist
(360) 895-6145
connie.schreiber@ecy.wa.gov

FOR IMMEDIATE RELEASE – March 26, 2010
10-053

State seeks public input on fee changes for accredited environmental labs

OLYMPIA – The Washington Department of Ecology (Ecology) invites public comments on proposed changes to the fee structure of the State Environmental Laboratory Accreditation Program.

The state Legislature has authorized Ecology to increase fees to adequately cover the program's costs of conducting business. The changes include increasing the fees for accreditation. Also, Ecology proposes to change some of its business practices to reduce operating costs.

Ecology administers the accreditation program for about 460 environmental laboratories, including labs that analyze drinking water. Accreditation ensures that labs are capable of providing accurate and defensible analytical data to Ecology, the state Department of Health, and other local, state and tribal agencies. This helps protect public health and the environment. In addition, state drinking water and environmental permits require the use of accredited labs.

The last time Ecology changed fees for lab accreditation was in 2002.

The proposed changes are posted on Ecology's website at: www.ecy.wa.gov/laws-rules/wac17350/0909.html.

Ecology will hold two public hearings to collect testimony about the proposed change. The first hearing will be at 1 p.m. Tuesday, April 27, in Lacey at the Lacey Community Center, 6729 Pacific Avenue. The second will be at 10 a.m. Thursday, April 29, in Moses Lake at the Moses Lake Fire Department, 701 E. Third Ave.

The public can provide oral comments by testifying at the public hearing or they can submit written, hard-copy or email comments to Stew Lombard. Email them to stew.lombard@ecy.wa.gov or mail them to Lab Accreditation Comments, Department of Ecology, P.O. Box 488, Manchester, WA 98353-0488. Ecology must receive written, postmarked or e-mailed comments no later than 5 p.m., May 7.

After the public comment period closes, Ecology will compile all the comments received regarding the draft rule and develop a final rule change. Ecology expects to adopt the final change in August 2010.

If you have questions, contact Stew Lombard at 360-895-6148.

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B4 News Release

Media Contact: Sandy Howard, 360-407-6408 (desk); 360-791-3177 (cell), sandy.howard@ecy.wa.gov

Ecology Lab Accreditation Program Web site:
www.ecy.wa.gov/programs/eap/labs/lab-accreditation.html

Ecology's Web site: http://www.ecy.wa.gov

Broadcast version
The state Department of Ecology invites input about changes to the fee structure of the State Environmental Laboratory Accreditation Program.

The program protects public health and the environment by ensuring that labs are capable of providing accurate and defensible analytical data. State drinking water and environmental permits require the use of accredited labs.

The Legislature authorized Ecology to increase fees to support the full cost of the program.

Ecology will hold public hearings on the changes in Lacey on April 27 and in Moses Lake on April 29.

Get more information by searching "lab accreditation" at Ecology's website at www.ecy.wa.gov.

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Appendix C - WAC 173-50 Revisions

AMENDATORY SECTION (Amending Order 01-12, filed 10/1/02, effective 11/1/02)

WAC 173-50-020 Scope. (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. ((~~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).~~))

(2) Accreditation in itself does not authorize use of a specific method for any specific program or project. If such authorization is not granted in documentation governing a program or project within which samples are being analyzed, authorization should be obtained from the laboratory's data user.

(3) Accreditation does not guarantee validity of analytical data submitted by the accredited laboratory but rather assures that the laboratory has demonstrated its capability to reliably generate and report the analytical data (WAC 173-50-040, definition of "accreditation").

AMENDATORY SECTION (Amending Order 01-12, filed 10/1/02, effective 11/1/02)

WAC 173-50-030 Objectives. Objectives of the ((~~accreditation program~~)) WA ELAP are to:

- Assure accredited laboratories have a demonstrated capability to accurately and defensibly analyze environmental samples;
- Assist environmental laboratories in improving their quality assurance/quality control procedures; and
- Foster cooperation between the state departments of ecology and health, local agencies, other users of environmental data, and operators of environmental laboratories.

AMENDATORY SECTION (Amending Order 01-12, filed 10/1/02, effective 11/1/02)

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

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

- The term "accredit" as used in this chapter is intended to have the same meaning as the term "certify" as used in RCW 43.21A.230.
- Any laboratory accredited under this chapter shall be deemed to have been certified under RCW 43.21A.230.
- The department does not, by accrediting any laboratory pursuant to these rules, vouch for or warrant the accuracy of any particular work done or report issued by that laboratory.

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

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

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

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

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

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

"Drinking water certification manual" - the Environmental Protection Agency *Manual for the Certification of Laboratories Analyzing Drinking Water*, ((~~4th~~)) 5th Edition, ((~~March 1997~~)) January 2005.

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

"Environmental laboratory" or **"laboratory"** - a facility:

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

"Lab accreditation unit" - the lab accreditation unit of the

((~~environmental assessment program of the~~)) department of ecology.

((~~**"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.~~))

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

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

((~~NELAP accreditations may include other matrices as designated in the NELAC standards.~~

~~**"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 NELAC.~~)) **"On-site audit"** - an on-site inspection and evaluation of laboratory facilities, equipment, records and staff.

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

"Parameter" - ((~~a single determination or sampling procedure, or group of related determinations or sampling procedures using a specific written method~~)) 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.

"Principal laboratory" - a laboratory designated by the Washington department of health to support the drinking water certification program.

"Procedural manual" - the *Department of Ecology's Procedural Manual for the Environmental Laboratory Accreditation Program* dated ((~~November 2002~~)) September 2010.

"Proficiency testing (PT)" - evaluation of the results from the analysis of samples, the true values of which are known to the supplier of the samples but unknown to the laboratory conducting the analyses. PT samples are provided by a source external to the environmental laboratory.

((~~**"Quality control"** - activities designed to assure analytical data produced by an environmental laboratory meet data quality objectives for accuracy and defensibility. Those activities may include routine application of statistically based procedures to~~

~~evaluate and control the accuracy of analytical results.~~))

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

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

((~~**"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.~~)) **"Quality control (QC)"** - the routine application of statistically based procedures to evaluate and control the accuracy of analytical results.

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

((~~**"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.~~))

"((~~Secondary NELAP~~)) Third-party accreditation" - recognition by the ecology accrediting authority of ((~~a NELAP~~)) accreditation ((~~that was~~)) granted by another ((~~NELAP~~)) accrediting authority.

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

AMENDATORY SECTION (Amending Order 01-12, filed 10/1/02, effective 11/1/02)

WAC 173-50-050 Responsibilities of the department. (1) The department maintains a procedural manual describing specifics of the accreditation process. As a minimum, the procedural manual describes the procedures for:

- Submitting an application and fee;
- Preparing a quality assurance manual;
- Performing proficiency testing;
- Conducting on-site ((~~assessments~~)) audits;
- Accrediting out-of-state laboratories;
- ((~~Issuing~~)) Granting, denying, suspending, and revoking accreditation; and
- Notifying laboratories and authorized government officials of accreditation actions.

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

(2) Department personnel assigned to assess the capability of

drinking water laboratories participating in the ((~~environmental laboratory accreditation program~~)) WA ELAP must meet the experience, education, and training requirements established in the ((~~Environmental Protection Agency~~)) drinking water certification manual.

((~~(3) When granting NELAP accreditations, the ecology accrediting authority is responsible for those actions designated in applicable chapters of the NELAC standards. If a NELAC standard is more stringent than the corresponding standard in this chapter, the NELAC standard applies for laboratories seeking NELAP accreditation.~~))

AMENDATORY SECTION (Amending Order 01-12, filed 10/1/02, effective 11/1/02)

WAC 173-50-060 Responsibilities of environmental laboratories. When applying for initial accreditation (see WAC 173-50-130 for maintaining an existing accreditation), managers of environmental laboratories must:

- Submit an application (WAC 173-50-063) and required fees (WAC 173-50-190) to the department fiscal officer;
- Submit a copy of the laboratory's quality assurance manual (WAC 173-50-067);
- Submit an initial set of ((~~acceptable~~)) satisfactory PT sample ((~~analysis~~)) results (WAC 173-50-070); and
- Undergo an on-site ((~~assessment~~)) audit (WAC 173-50-080).

AMENDATORY SECTION (Amending Order 01-12, filed 10/1/02, effective 11/1/02)

WAC 173-50-063 Application. (1) Through the application, laboratory managers:

- Request accreditation for specific parameters;
- Calculate fees due to the department; and
- Provide evidence that sufficient personnel and equipment are available to successfully perform analytical methods as specified in the application.

(2) Through review of the application submitted by the applicant laboratory, the lab accreditation unit determines if:

- Requested parameters are eligible for accreditation;
- The fee calculated by the applicant laboratory is correct; and
- Personnel and equipment are adequate to support successful performance of requested parameters.

(3) Following the review, the lab accreditation unit advises the applicant laboratory of any required changes.

AMENDATORY SECTION (Amending Order 01-12, filed 10/1/02, effective 11/1/02)

WAC 173-50-067 Quality assurance manual. (1) The lab accreditation unit reviews and approves the laboratory's QA manual prior to the initial on-site ((~~assessment~~)) audit. The QA manual submitted concurrently with the application must be in detail and scope commensurate with the size and mission of the laboratory. Guidelines for contents of the QA manual are in the procedural manual.

(2) The QA manual must address QA and QC requirements of applicable regulatory programs. For drinking water laboratories, such requirements are found in the drinking water certification manual.

((~~(3) For laboratories applying for primary NELAP accreditation, QA requirements, including the conduct of specific QC tests, are those designated in the NELAC standards. If a NELAC standard is more stringent than the corresponding standard in this chapter, the NELAC standard applies for laboratories seeking NELAP accreditation.~~))

AMENDATORY SECTION (Amending Order 01-12, filed 10/1/02, effective 11/1/02)

WAC 173-50-070 ((~~Performance audit.~~)) Proficiency testing (PT). (1) The lab accreditation unit advises applying laboratories of specific requirements for participation in proficiency ((~~tests. Such tests are completed~~)) testing (PT) studies 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~~)) these requirements. The lab accreditation unit determines the sufficiency of such ((~~audits~~)) proficiency tests.

(2) ((~~Drinking water~~)) 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. For chemistry parameters, after an accredited laboratory submits two satisfactory PT sample results and no unsatisfactory results in an accreditation year, the laboratory is required to submit only one satisfactory PT sample result in subsequent

accreditation years. This applies as long as there are no intervening unsatisfactory PT sample results.

(3) The lab accreditation unit may require the laboratory to submit raw data along with the report of analysis of PT samples.

(4) The lab accreditation unit may waive proficiency tests for certain parameters if PT samples are not readily available or for other valid reasons.

(5) Applying laboratories are responsible for obtaining PT samples from vendors ((~~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.

((~~(6) For laboratories applying for NELAP accreditation, proficiency testing 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 for laboratories seeking NELAP accreditation.~~))

AMENDATORY SECTION (Amending Order 01-12, filed 10/1/02, effective 11/1/02)

WAC 173-50-080 On-site ((~~assessment~~)) audit. The laboratory must undergo ((~~a system~~)) an on-site audit by the department to assess critical elements and areas of recommended practices. The laboratory must assist/accommodate department of ecology personnel during on-site ((~~assessments~~)) audits as required.

(1) **Critical elements for accreditation.** Elements of an environmental laboratory's operations which are critical to the consistent generation of accurate and defensible data are critical elements for accreditation. Critical elements are subject ((~~of~~)) to intense scrutiny throughout the accreditation process. The ecology accrediting authority may deny, revoke, or suspend accreditation for deficiencies in critical elements. Functional areas including critical elements are:

(a) **Analytical methods.** The on-site ((~~assessment~~)) audit seeks to determine if documentation of ((~~mandatory or recognized~~)) analytical methods:

- Are present at the laboratory;
- Readily available to analysts; and
- Being implemented. If the laboratory is using a locally-developed method, the on-site ((~~assessment~~)) audit may include an evaluation of the adequacy of that method.

(b) **Equipment and supplies.** The on-site ((~~assessment~~)) audit seeks to determine if sufficient equipment and supplies as required by analytical methods are:

- Available;
- Being adequately maintained; and
- In a condition to allow successful performance of applicable

analytical procedures.

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

(c) **QA and QC records.** The on-site ((~~assessment~~)) audit includes a review of QA and QC records for programs/projects within which the laboratory is generating analytical data for submission to the data user.

(d) **Sample management.** The on-site ((~~assessment~~)) audit includes a review of applicable procedures for receipt, preservation, transportation, and storage of samples. The laboratory is responsible only for those elements of sample management over which it has direct control. To gain and maintain accreditation, laboratories must demonstrate that sample management requirements of applicable regulatory programs are being met.

(e) **Data management.** The on-site ((~~assessment~~)) audit includes a review of activities necessary to assure accurate management of laboratory data including:

- Raw data;
- Calculations; and
- Transcription, computer data entry, reports of analytical results.

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

(2) **Recommended practices.** Recommended practices are those elements of laboratory operations which might affect efficiency, safety, and other administrative functions, but do not normally affect quality of analytical data. Normally these practices would not be the basis for denial or revocation of accreditation status. Functional areas within which recommended practices may be noted are:

(a) **Personnel.** The department seeks to determine if managerial, supervisory, and technical personnel have adequate training and experience to allow satisfactory completion of analytical procedures and compilation of reliable, accurate data. Minimum recommended education and experience criteria for laboratory personnel are specified in the ((~~program~~)) procedural manual.

(b) **Facilities.** The department seeks to determine if laboratory facilities allow efficient generation of reliable, accurate data in a safe environment.

(c) **Safety.** The department may refer serious safety deficiencies to appropriate state or federal agencies.

(3) ((~~**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.~~

~~(4)~~)) **Drinking water laboratory requirements.** For laboratories applying for accreditation of drinking water parameters, on-site ((~~assessment~~)) audit requirements are those

designated in the drinking water certification manual. If such a standard is more stringent than the corresponding standard in this chapter, the drinking water certification manual applies.

AMENDATORY SECTION (Amending Order 01-12, filed 10/1/02, effective 11/1/02)

WAC 173-50-090 Evaluation and issuance of certificate. (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 may:

- List((~~s~~)) findings;
- ((~~Assesses~~)) Assess the importance of each finding; and
- Make((~~s~~)) recommendations concerning actions necessary to assure resolution of problems.

(2) After completing the accreditation review, the ecology accrediting authority decides whether accreditation should be granted.

(a) If accreditation is warranted, the department issues a certificate and accompanying scope of accreditation. The certificate remains the property of the department and must be surrendered to the department upon revocation or voluntary termination of accreditation status.

(b) If accreditation is not warranted, the department issues a report specifying areas of deficiency and steps necessary to upgrade the laboratory to accredited status. In such cases, the laboratory must provide documentation that the specified deficiencies have been corrected. Based on such documentation the ecology accrediting authority decides whether to grant or deny accreditation.

AMENDATORY SECTION (Amending Order 01-12, filed 10/1/02, effective 11/1/02)

WAC 173-50-100 Interim accreditation. ((~~(1)~~)) If ((~~for valid reasons resulting from a deficiency in~~)) the department ((~~and not~~)) is unable to complete the accreditation process through no fault of the laboratory, the ecology accrediting authority may grant interim accreditation ((~~may be granted~~)). To be considered for interim accreditation, the laboratory must:

- Submit an application and applicable fees;
- Successfully complete applicable proficiency tests; and
- Submit a QA manual that meets the requirements of WAC 173-

050-067.

The lab accreditation unit may also require the laboratory to submit an analytical data package as evidence of analytical capability.

((~~(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.~~))

AMENDATORY SECTION (Amending Order 01-12, filed 10/1/02, effective 11/1/02)

WAC 173-50-110 Provisional accreditation. (1) The ecology accrediting authority may grant provisional accreditation to laboratories which can consistently produce valid analytical data but have deficiencies requiring corrective action. When the laboratory has corrected such deficiencies, it must provide evidence of correction to the lab accreditation unit, or request a follow-up on-site ((~~assessment~~)) audit, as appropriate. If the lab accreditation unit determines the deficiencies have been corrected, the ecology accrediting authority awards full accreditation as in WAC 173-50-090.

(2) The ecology accrediting authority may renew a provisional accreditation for a subsequent accreditation period if laboratory management has demonstrated that all reasonable measures to correct deficiencies have been exhausted.

(3) For drinking water laboratories, specific conditions warranting provisional accreditation and specific actions required of the laboratory when provisional accreditation is granted are found in the drinking water certification manual.

((~~(4) Provisional accreditation does not apply to NELAP accreditations.~~))

AMENDATORY SECTION (Amending Order 01-12, filed 10/1/02, effective 11/1/02)

WAC 173-50-120 Accreditation categories. (1) Environmental laboratories are accredited within one or more of the matrix groups defined in WAC 173-50-040. ((~~Additionally~~)) Within each matrix group, accreditation is granted within the following broad categories:

- General 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)~~)) (Category II methods use mass spectrometer detectors);
- ((~~Radioactivity;~~))
- Microbiology;
- Radiochemistry;
- Bioassay((~~/Toxicity~~));
- Immunoassay; and
- Physical.

Within these categories, laboratories are specifically accredited for well-defined parameters, such as, but not limited to, those suggested in the procedural manual, using specific((~~, recognized~~)) analytical methods or sampling techniques chosen by the applying laboratory.

(2) The scope of accreditation accompanying the accreditation certificate indicates the parameters for which the laboratory is accredited, and any applicable qualifications, such as interim or provisional accreditation.

(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 (GC/ECD) or inductively coupled plasma/mass spectrometry (ICP/MS), associated with each parameter.~~))

AMENDATORY SECTION (Amending Order 01-12, filed 10/1/02, effective 11/1/02)

WAC 173-50-130 Requirements for maintaining accreditation status. (1) Accreditation is granted for a one-year period (the accreditation year) and expires one year after the effective date of accreditation. ((~~Except for NELAP accreditation which is limited to one year, exceptions to the one year accreditation may be made for documented cause. In such cases, accreditation may be granted for a period up to two years.~~))

(2) Renewal requires the laboratory to submit:

- An application and appropriate fees;
- An update of the laboratory's ((~~quality assurance~~)) QA manual if applicable; ((~~and~~))
- Evidence of accreditation by a third party when appropriate; and

- Successful completion of proficiency testing requirements.

(3) For laboratories accredited for drinking water parameters, on-site ((~~assessments~~)) audits are required at periods not to exceed three years from the previous on-site ((~~assessment~~)) audit. ((~~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.

AMENDATORY SECTION (Amending Order 01-12, filed 10/1/02, effective 11/1/02)

WAC 173-50-140 Denying accreditation. (1) The ecology accrediting authority may deny accreditation if the applicant laboratory:

- Fails to comply with standards for critical elements of the on-site ((~~assessment~~)) audit;
- Misrepresents itself to the department;
- Fails to disclose pertinent information in the application;
- Falsifies reports of analysis including ((~~PT~~)) proficiency testing results;
- Engages in unethical or fraudulent practices concerning generation of analytical data;
- Is deficient in its ability to provide accurate and defensible analytical data; or
- Fails to render applicable fees.

(2) A laboratory may be denied accreditation for a specific parameter for unsatisfactory ((~~analysis of that parameter in~~)) proficiency ((~~tests~~)) testing results.

(3) Laboratories denied accreditation may appeal under the provisions of WAC 173-50-200. If an appeal does not result in action favorable to the laboratory, and following correction of deficiencies, laboratories denied accreditation may reapply for accreditation to include payment of appropriate fees as determined in WAC 173-50-190.

((~~(4) Reasons for denial of NELAP accreditation are as specified in the NELAC standards.~~))

AMENDATORY SECTION (Amending Order 01-12, filed 10/1/02, effective 11/1/02)

WAC 173-50-150 Revoking or suspending accreditation. (1) Revocation of accreditation is the withdrawal of a previously granted accreditation. Revocation may involve the entire laboratory or one or more individual parameters.

(2) Suspension of accreditation is for a specified period ((~~not to exceed six months~~)) during which the affected laboratory corrects deficiencies that led to the suspension. Suspension may involve the entire laboratory, or one or more individual parameters.

((~~(2)~~)) (3) The ecology accrediting authority may suspend or revoke accreditation if the accredited laboratory:

- Fails to comply with standards for critical elements of an on-site ((~~assessment~~)) audit;
- Violates a state rule relative to the analytical procedures for which it is accredited;
- Misrepresents itself to the department;
- Falsifies reports of analysis including ((~~PT~~)) proficiency testing results;
- Engages in unethical or fraudulent practices concerning generation of analytical data;
- Is deficient in its ability to provide accurate and defensible analytical data; ((~~or~~))
- Refuses to permit entry for enforcement purposes (WAC 173-50-210);
- Fails to render applicable fees;
- Fails to maintain third-party accreditation; or
- Reports two consecutive unsatisfactory PT sample results.

((~~(3)~~)) (4) A laboratory having had its accreditation suspended or revoked may appeal under the provisions of WAC 173-50-200. If an appeal does not result in action favorable to the laboratory, and following correction of deficiencies, a laboratory having had its accreditation revoked may reapply for accreditation to include payment of appropriate fees as determined in WAC 173-50-190.

((~~(4) Reasons for revocation or suspension of NELAP accreditation are as specified in the NELAC standards.~~))

AMENDATORY SECTION (Amending Order 01-12, filed 10/1/02, effective 11/1/02)

WAC 173-50-170 Third-party accreditation. (1) The department may recognize accreditation (or certification, registration, licensure, approval) of a laboratory by a third party when the accreditation process is determined to be equivalent to that described in this chapter.

(2) Laboratories applying for recognition of a third party's accreditation submit:

- An application and associated fee (WAC 173-50-190(7));
- A copy of the third party's certificate;
- A copy of the third party's scope of accreditation;
- A copy of the third party's most recent on-site ((~~assessment~~)) audit report;
- A copy of the laboratory's corrective action report relative to the on-site ((~~assessment~~)) audit, if applicable; and
- ((~~A complete set of the most~~)) Recent ((~~PT~~)), satisfactory proficiency test results for the applicable parameters.

(3) In consideration of a request to recognize a third party's accreditation as the basis for accreditation by the ecology accrediting authority, the lab accreditation unit reviews the application and supporting documentation to assure compliance with minimum accreditation requirements as stated in this chapter. If the review is favorable, a certificate and scope of accreditation are granted as in WAC 173-50-090.

(4) Laboratories granted third-party accreditation must notify the laboratory accreditation unit immediately of changes in the status of their third-party accreditation.

(5) Washington laboratories accredited or applying for accreditation in recognition of a third party's accreditation must notify the lab accreditation unit of on-site ((~~assessments~~)) audits scheduled by the third party and allow a department observer to attend such on-site ((~~assessments~~)) audits.

((~~(5) Primary NELAP accreditation cannot be granted in recognition of the accreditation by a third party.~~))

AMENDATORY SECTION (Amending Order 01-12, filed 10/1/02, effective 11/1/02)

WAC 173-50-190 Fee structure. (1) Fees in this chapter are in U.S. dollars and are established to cover costs of administering the ((~~accreditation program~~)) WA ELAP. 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 ((~~for each matrix~~)) where applicable, are identified in Table 1.

(2) Examples of parameters or methods for each category are published in the procedural manual. Accreditation may be requested for parameters in addition to those listed in the procedural manual.

(3) When a fee is assessed ((~~only once~~)) for a ((~~given~~)) specific drinking water parameter ((~~even though that specific~~)) or method, the laboratory may be accredited for the same parameter ((~~may be accredited under more than one matrix~~)) or method in nonpotable water without paying an additional fee.

TABLE 1 - FEE SCHEDULE

~~((MATRIX~~	~~CATEGORY~~	~~FEE/ PARAMETER~~	~~MAX FEE PER CATEGORY~~
~~Nonpotable Water~~	~~Chemistry I (General)~~	~~$65~~	~~$1150~~
	~~Chemistry II (Trace Metals)~~	~~$65~~	~~$975~~
	~~Organics I (GC/HPLC)~~	~~$115~~	~~$975~~
	~~Organics II (GC/MS)~~	~~$345~~	~~$1035~~
	~~Radioactivity~~	~~$145~~	~~$1380~~
	~~Microbiology~~	~~$175~~	~~$520~~
	~~Bioassay/Toxicity~~	~~$230~~	~~$1435~~
	~~Immunoassay~~	~~$65~~	~~$390~~
	~~Physical~~	~~$65~~	~~$260~~
~~Drinking Water~~	~~Chemistry I (General)~~	~~$60~~	~~$305~~
	~~Chemistry II~~	~~$60~~	~~$720~~
	~~Organics I (GC/HPLC)~~	~~$155~~	~~$615~~
	~~Organics II (GC/MS)~~	~~$155~~	~~$155~~
	~~Microbiology~~	~~$155~~	~~$460~~
~~Solid and Chemical Materials~~	~~Chemistry I (General)~~	~~$65~~	~~$1150~~
	~~Chemistry II (Trace Metals)~~	~~$65~~	~~$975~~
	~~Organics I (GC/HPLC)~~	~~$115~~	~~$975~~
	~~Organics II (GC/MS)~~	~~$345~~	~~$1035~~
	~~Radioactivity~~	~~$145~~	~~$1380~~
	~~Microbiology~~	~~$175~~	~~$520~~
	~~Immunoassay~~	~~$65~~	~~$390~~
	~~Physical~~	~~$65~~	~~$260~~
~~Air and Emissions~~	~~Chemistry I (General)~~	~~$65~~	~~$1150~~
	~~Chemistry II (Trace Metals)~~	~~$65~~	~~$975~~
	~~Organics I (GC/HPLC)~~	~~$115~~	~~$975~~
	~~Organics II (GC/MS)~~	~~$345~~	~~$1035~~))

CATEGORY	FEE PER PARAMETER	FEE PER METHOD	MAX FEE PER CATEGORY
General Chemistry	$80	--	$1,600
Trace Metals	--	$400	--
Organics I	--	$200	--
Organics II	--	$500	--
Microbiology	$200	--	--

CATEGORY	FEE PER PARAMETER	FEE PER METHOD	MAX FEE PER CATEGORY
Radiochemistry	$250	--	--
Bioassay	$300	--	$3,000
Immunoassay	$80	--	--
Physical	$80	--	--

(4) The minimum fee for accreditation, either direct or through recognition of a third-party accreditation, is three hundred dollars.

(5) In addition to paying the fee indicated in Table 1, out-of-state laboratories must pay for the actual cost of travel associated with on-site ((~~assessments~~)) audits. The department invoices the laboratory for such costs after completion of the on-site ((~~assessment~~)) audit.

((~~(5)~~)) (6) The laboratory must pay applicable fees before:

- Its quality assurance manual is reviewed by the department;
- The on-site ((~~assessment~~)) audit is conducted if applicable; and
- Interim, provisional, or full accreditation is granted.

((~~(6)~~)) (7) 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.~~

~~(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.~~

~~(8) The fee for recognition of accreditation 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.~~

~~(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.~~

~~(10)~~)) is three-fourths (75%) of the fee indicated in Table 1.

(8) If a laboratory withdraws from the accreditation process after the application has been processed, but before accreditation is granted, the fee is ((~~nonrefundable~~)) refundable, less an amount up to ((~~an amount of two~~)) three hundred ((~~thirty~~)) dollars as reimbursement for costs of processing the application. If a laboratory withdraws from the accreditation process after the on-site ((~~assessment~~)) audit has been completed, the department may retain the entire fee including reimbursement of travel costs if applicable.

((~~(11) Dollar amounts listed in Table 1 and subsections (6), (7), (8), (9), and (10) of this section may be adjusted every year based on inflation as indicated by the *Implicit Price Deflator for State and Local Government Services* as published by the economic and revenue forecast council.~~)) (9) Dollar amounts listed in Table 1 and subsections ((~~(6), (7),~~)) (4) and (8)((~~, (9), and (10)~~)) of this section may be decreased at any time the department determines

they are higher than needed to meet accreditation program requirements. The department notifies affected parties of any fee adjustment at least thirty days prior to the effective date of the adjusted fee.

(10) Accreditation fees are waived for laboratories operated by the Washington state departments of ecology and health. Accreditation fees are also waived for drinking water parameters certified by EPA Region 10 at designated principal laboratories.

AMENDATORY SECTION (Amending Order 01-12, filed 10/1/02, effective 11/1/02)

WAC 173-50-210 Enforcement. (1) For the purpose of conducting on-site ((~~assessments or otherwise enforcing~~)) audits or inspections to ensure compliance with this chapter, the department may, during regular business hours, enter ((~~any~~)) business premises in which analytical data pertaining to accreditation under the provisions of this chapter are generated or stored.

(2) Refusal to permit entry for such purposes ((~~shall~~)) may result in denial((~~,~~)) or revocation((~~, or suspension~~)) of accreditation ((~~or registration status~~)).

AMENDATORY SECTION (Amending Order 01-12, filed 10/1/02, effective 11/1/02)

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

REPEALER

The following sections of the Washington Administrative Code are repealed:

WAC 173-50-160 Reciprocity.

WAC 173-50-180 Exemptions.