



RULE-MAKING ORDER

PERMANENT RULE ONLY

CR-103P (December 2017)
(Implements RCW 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: September 01, 2023

TIME: 8:27 AM

WSR 23-18-059

Agency: Department of Ecology AO # 22-07

Effective date of rule:

Permanent Rules

- ☒ 31 days after filing.
☐ Other (specify) _____ (If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

- ☐ Yes ☒ No If Yes, explain:

Purpose: Washington State Department of Ecology developed and codified WAC 173-50 Accreditation of Environmental Laboratories and created the Laboratory Accreditation Unit (LAU) to maximize efficacy of the state, federal, or other relevant regulations.

The adopted rule amendments will achieve the following goals:

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

Updates and clarifications to definitions.

Require laboratories to submit Standard Operating Procedures (SOPs).

Update and clarify quality control requirements

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

Add data management and record traceability requirements

Require additional proficiency testing (PT) sample per parameter per year for microbiology parameters.

Clarify procedural requirements for PT.

- Per public feedback, we are only going to require one acceptable PT for bioassay parameters. It is not feasible to require more than one acceptable PT from these laboratories in one year.

Clarify and update audit procedures and frequency

Clarify requirements for accreditation of drinking water laboratories

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

Clarify that laboratories must notify Ecology at least 30 days prior to a permanent laboratory move.

- This section also clarifies expectations for laboratories that have had a temporary or emergency move.

Update reasons for suspension of accreditation to include: violation of federal law.

2. **Amend the fee-structure to meet the following objectives:**

- Remove the maximum fee.
- Update fees to meet Ecology Laboratory Accreditation Unit implementation costs.
- Increase the minimum fee to \$500.
- Add a processing fee of \$300 for initial accreditation or reinstatement of accreditation after 12 months of not being accredited.
- To increase fees in fiscal year 2025 and 2026.

- Include a formula to increase fees in fiscal year 2027 and in future years based on the State's Fiscal Growth Factor.

Other changes were made for clarification, to update references, and to restructure.

Citation of rules affected by this order:

New: N/A
 Repealed: N/A
 Amended: Chapter 173-50
 Suspended: N/A

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

Other authority: N/A

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 23-09-067 on April 19, 2023 (date).

Describe any changes other than editing from proposed to adopted version: RCW 34.05.325(6)(a)(ii) requires Ecology to 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, stating the reasons for the differences.

There are some differences between the proposed rule filed on April 19, 2023 and the adopted rule filed on September 1, 2023. Ecology made these changes for all or some of the following reasons:

- In response to comments we received.
- To ensure clarity and consistency.
- To meet the intent of the authorizing statute.

The following content describes the changes and Ecology's reasons for making them.

Changes to 173-50-040 Definitions

Change:

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

- Under the ownership and technical management of a single entity in a single geographical location or in a self-contained mobile unit;
- Where scientific determinations are performed on samples taken from the environment, including drinking water samples; and
- Where data are 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.

Reason for the change:

During final internal review, this change was made since it is common for "data" to be plural.

Change:

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

Reason for the change:

During final internal review, this change was made because it is more grammatically correct than the previous wording

Change:

"Limit of quantitation" or "LOQ" - The smallest concentration that produces a quantitative result ~~Lowest amount of analyte that can be measured~~ with acceptable precision and accuracy, as required by data quality objectives.

Reason for the change:

Per public comment a reword of this definition was suggested. We did not use their suggestion but chose to use the definition written here.

Change:

"Matrix spike" or "MS" – ~~Matrix spikes are~~ An aliquots of environmental samples to which known concentrations of certain target analytes have been added before sample preparation, cleanup, and determinative procedures have been ~~implemented~~ performed.

Reason for the change:

During final internal review, this change was made to remove the use of the term within its own definition and more accurately describe the term by replacing "implemented" with "performed".

Change:

"Proficiency testing (PT)" - ~~Evaluation of the results from the a~~ Analysis of samples in the accredited matrix, 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.

Reason for the change:

During final internal review, we removed unnecessary words to more clearly define the term.

Changes to 173-50-050 Responsibilities of the department

Change:

Subsection 1 contained a typo that read, “As a minimum” when the phrase “At a minimum” is appropriate.

Reason for the change:

During final internal review, this typo was fixed.

Changes to 173-50-060 Responsibilities of environmental laboratories

Change:

The term “fiscal officer” was removed from subsection 1 subdivision a.

Reason for the change:

During final internal review, the term was removed since a fiscal officer is no longer involved in the fee process.

Change:

The phrase “, at a minimum,” was removed from subsection 1 subdivision c.

Reason for the change:

During final internal review, the phrase was removed because it was unnecessary.

Changes to 173-50-061 Required quality control practices

Change:

Inserted an item i to subdivision a of subsection 2 that reads, “Exceptions can be made if a significant error’s cause can be clearly identified, the error is documented, and the calibration point is excluded for all analytes contained in the calibration point.”

Reason for the change:

During the public comment period two of the commenters suggested that we allow for valid exceptions to the requirement of subsection 2 subdivision a.

Change:

The word “otherwise” was added to the second sentence of subsection 2 subdivision b.

Reason for the change:

Per public comment, addition of this word was recommended. This change ensures that if a published method has a requirement similar to this section, the published method supersedes the WAC.

Change:

The words, “of calibration” were inserted prior to the word “points” in the second sentence of subsection 2 subdivision b.

Reason for the change:

Per public comment, addition of these words was recommended. This helps ensure that someone reading the WAC understands what type of points are being referenced.

Change:

Replaced, “where” with, “, in which case” in the second sentence of subsection 2 subdivision b.

Reason for the change:

Per public comment, this re-write was recommended. This change makes more sense to the reader than using the word “which”.

Change:

The second sentence of subsection 3 was edited to, “This standard must be met between 50 and 150 percent of the true value.”

Reason for the change:

During final internal review, this re-word was made to clarify that the acceptance range is 50% of the true value both in a positive and negative direction.

Change:

In the list contained within subsection 3, another item, “Mass Spectrometry” was added to the list.

Reason for the change:

During final internal review, this addition was made to ensure that there was no confusing with the previous “Spectrometry” term in the list. Within the context of the regulated community, this specification is necessary.

Change:

Subsection 4 was edited to read, “Matrix spikes are required as specified by the method. Observed matrix spikes that do not meet their acceptance criteria must be documented ~~issued~~ ~~must be addressed~~ for regulated parameters under the federal Safe Drinking Water Act and Clean Water Act.”

Reason for the change:

During the public comment period, we received multiple comments regarding this section. After reading and considering those comments we agreed that the original wording was not appropriate and that matrix spike issues need to be “documented”, rather than “addressed”, since there are often instances where no action capable of being taken to address the issue.

Change:

A subdivision a was added to subsection 4 that reads, "The lab must take corrective action if specified by the method."

Reason for the change:

With replacing the term addressed with documented in subsection 4 per public feedback, it was necessary to specify that action must be taken when capable and specified by the published method.

Change:

The following change was made to the beginning of subsection 5, "Unless the method specifies otherwise, Llaboratory..."

Reason for the change:

During the public comment period, we received a couple comments regarding some valid exceptions that exist to the requirement as previously written. We made the above change to accommodate those exceptions.

Change:

The following changes were made to subsection 6, "~~WFor compliance monitoring samples, if a laboratory control sample is outside of it's non-quality control samples for chemistry parameters such as a laboratory control sample are above their acceptance criteria for a parameter(s), the data for that parameter(s) eshouldan~~ only be reported if the laboratory can demonstrate:"

Reason for the change:

During the public comment period, we received multiple comments regarding this section. After reading and considering those comments, we clarified to what types of samples this requirement applies.

Change:

In subsection 6 subdivision c the word "the" was changed to "any".

Reason for the change:

During final internal review, this change was made since it needs to have the flexibility to be referring to multiple items.

Changes to 173-50-069 Data and Record traceability**Change:**

Subsection 1 subdivision c. added, "and sample extracts".

Reason for the change:

Per public feedback, we received a comment that we should add this term. Many methods that the regulated community employ specify certain storage requirements for samples extracts as well as samples.

Change:

Subsection 1 subdivision d received the following edits, "Document that all temperature-based equipment such as a refrigerator, oven, or incubator is within control. When electronic record keeping equipment is used, these records must be appropriately monitored by lab personnel to verify that temperatures meet relevant method and regulatory requirements; ~~Document that all temperature-based equipment such as a refrigerator, oven, or incubator is both within control and checked manually as required by the relevant analytical method;~~".

Reason for the change:

During public feedback, several comments were received regarding this section. We edited this subdivision to be much clearer as to what requirements need to be taken when checking temperature records. Regardless if they are taken manually or electronically.

Change:

Subsection 1 subdivision e received the following change, "Keep a logbooks for".

Reason for the change:

We received a public comment believing that the original wording implied that "logbooks" could not be electronic. This change was made to remove that possible implication.

Change:

Subsection 2 was edited to read, "When records are handwritten, they must be in indelible ink and comply with the relevant method requirements and include the date and time(s) of reading, temperature(s), and technician's initials.~~When records are handwritten, they must be in indelible ink and comply with the relevant method requirements. Incubator temperatures must be handwritten and include the date and time(s) of reading, temperature(s), and technician's initials."~~

Reason for the change:

During public feedback we received many comments regarding this subsection and felt it needed to be re-worded to improve clarity, specifically removing the 'incubator temperatures' comment since it was more appropriate to add that requirement in the next section.

Change:

Subsection 3 was edited and re-formatted to read, "Un-monitored use of continuous data-loggers is not an acceptable substitute when methods and/or regulations require temperature checks. Use of electronic record keeping equipment is allowed when:

- (a) The equipment can demonstrate the accuracy and precision required by the applicable method and/or regulations;
- (b) it includes the date and time the record was captured, using a fully traceable and secure format, and;
- (c) it is not being used on an incubator used for analysis of samples for microbiology parameters. ~~When records are kept electronically, they must be recorded at the time of reading, using a fully traceable and secure format. Use of continuous data-loggers is not an acceptable substitute for method and/or regulatory required incubator temperature checks."~~

Reason for the change:

During public feedback we received many comments regarding this subsection and felt it needed to be re-worded to improve readability, ensure the regulated community that use of electronic record keeping is allowable with appropriate use, add the 'handwritten incubator temperature' requirement that was removed from the previous section.

Changes to 173-50-070 Proficiency testing (PT)**Change:**

Addition of a subdivision a to subsection 2 that reads, "For Bioassay parameters, only one acceptable PT sample is required per parameter per year."

Reason for the change:

We received a public comment that mentioned that two acceptable PTs for bioassay parameters per accreditation year was not practical. After review of the comment and PT availability of bioassay parameters, this was an appropriate addition.

Change:

Subsection 7 received the following edits, "When two or more approved PTs providers make available a PT sample exist for a parameter in an appropriate matrix, the laboratory must analyze and pass a PT to gain or maintain accreditation, unless an exception is approved by the department."

Reason for the change:

During public feedback we received a proposed edit to this subsection that we felt was an improvement to the original language.

Changes to 173-50-080 Audits**Change:**

Subsection 1 subdivision a was edited to read, "By conducting The audits the department determines ~~seeks to determine~~ if SOPs and other documentation of analytical methods..."

Reason for the change:

During final internal review, we made these changes in order to clarify that the process of the audit determines the subsections of this section. We also believed the critical role SOPs play in audits needed us to include them in the updated rule language.

Changes to 173-50-190 Fee structure**Change:**

The column titled "Per Parameter Add Fee to Existing Method" in Tables 2 and 3 were replaced with "Per Parameter Addition Fee".

Reason for the change:

During public comment, we received a couple comments that asked for clarification on when this column applies. In conjunction with an edit made in subsection 11, we believe this edit addresses that ambiguity.

Change:

Subsection 11 received the following edit, "If a laboratory requests to add or reinstate a parameter to an existing method on their scope of accreditation outside of their initial application or renewal process, the laboratory will be invoiced a fee based on the type and number of requested parameters according to the "Per Parameter Addition Fee" column, per of Table 1, Table 2, Table 3, or as updated by Equation 1."

Reason for the change:

During public comment, we received a couple comments that asked for clarification on when the newly titled, "Per Parameter Addition Fee" column applies. In conjunction with the edits made in Tables 2 and 3 we, believe we have addressed that ambiguity.

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

Name: Ryan Zboralski

Address: Department of Ecology

Environmental Assessment Program

Lacey, WA 98503

Phone: (360) 764-9364

Fax: N/A

TTY: For Washington Relay Service or TTY call 711 or 877-833-6341.

Email: ryan.zboralski@ecy.wa.gov

Web site: <https://apps.ecology.wa.gov/publications/UIPages/SummaryPages/2303026.html>

Other: N/A

**Note: If any category is left blank, it will be calculated as zero.
No descriptive text.**

**Count by whole WAC sections only, from the WAC number through the history note.
A section may be counted in more than one category.**

The number of sections adopted in order to comply with:

Federal statute:	New	_____	Amended	_____	Repealed	_____
Federal rules or standards:	New	_____	Amended	_____	Repealed	_____
Recently enacted state statutes:	New	_____	Amended	_____	Repealed	_____

The number of sections adopted at the request of a nongovernmental entity:

New	_____	Amended	_____	Repealed	_____
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The number of sections adopted on the agency's own initiative:

New	<u>2</u>	Amended	<u>16</u>	Repealed	_____
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	<u>2</u>	Amended	<u>16</u>	Repealed	_____
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The number of sections adopted using:

Negotiated rule making:	New	_____	Amended	_____	Repealed	_____
Pilot rule making:	New	_____	Amended	_____	Repealed	_____
Other alternative rule making:	New	_____	Amended	_____	Repealed	_____

Date Adopted: September 1, 2023

Name: Laura Watson

Title: Director

Signature:

