Concise Explanatory Statement
Chapter 173-50 WAC Accreditation of Environmental Laboratories

Summary of Rulemaking and Response to Comments

Washington State Department of Ecology
Olympia, Washington

September 2023, Publication 23-03-024

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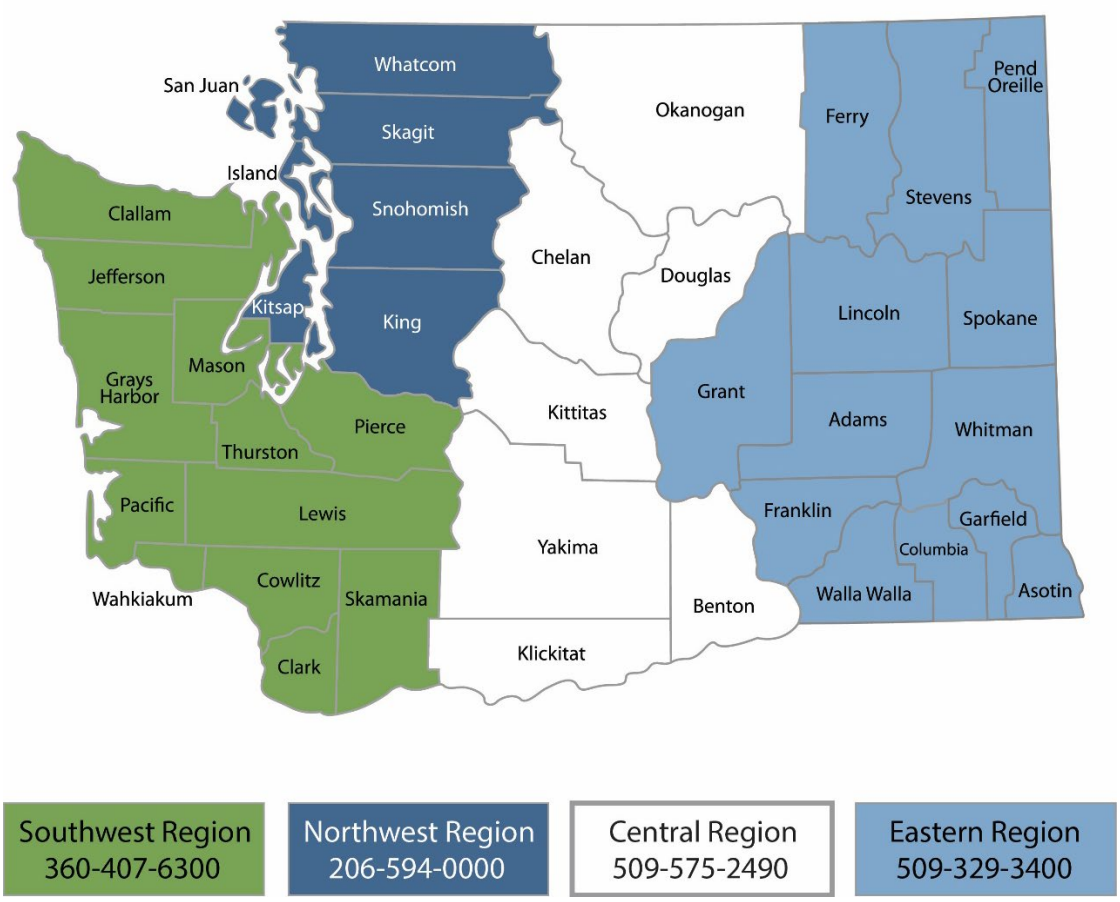

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Southwest	Clallam, Clark, Cowlitz, Grays Harbor, Jefferson, Mason, Lewis, Pacific, Pierce, Skamania, Thurston, Wahkiakum	PO Box 47775 Olympia, WA 98504	360-407-6300
Northwest	Island, King, Kitsap, San Juan, Skagit, Snohomish, Whatcom	PO Box 330316 Shoreline, WA 98133	206-594-0000
Central	Benton, Chelan, Douglas, Kittitas, Klickitat, Okanogan, Yakima	1250 W Alder St Union Gap, WA 98903	509-575-2490
Eastern	Adams, Asotin, Columbia, Ferry, Franklin, Garfield, Grant, Lincoln, Pend Oreille, Spokane, Stevens, Walla Walla, Whitman	4601 N Monroe Spokane, WA 99205	509-329-3400
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Concise Explanatory Statement

Chapter 173-50 WAC
Accreditation of Environmental Laboratories

Environmental Assessment Program
Washington State Department of Ecology
Olympia, WA

September 2023 | Publication 23-03-024

DEPARTMENT OF
ECOLOGY
State of Washington

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Introduction

The purpose of a Concise Explanatory Statement is to:

- Meet the Administrative Procedure Act (APA) requirements for agencies to prepare a Concise Explanatory Statement (RCW 34.05.325).
- Provide reasons for adopting the rule.
- Describe any differences between the proposed rule and the adopted rule.
- Provide Ecology's response to public comments.

This Concise Explanatory Statement provides information on The Washington State Department of Ecology's (Ecology) rule adoption for:

Title:	Accreditation of Environmental Laboratories
WAC Chapter(s):	173-50
Adopted date:	September 1, 2023
Effective date:	October 2, 2023

To see more information related to this rulemaking or other Ecology rulemakings please visit our website: https://ecology.wa.gov/About-us/How-we-operate/Laws-rules-rulemaking.

Reasons for Adopting the Rule

Ecology's Laboratory Accreditation Unit (LAU) provides accreditation services and support to environmental labs across the state. These labs provide data necessary to support decisions made by regulatory bodies tasked with protecting people and natural resources in Washington State. The data produced by these labs requires a high level of precision and accuracy, which in turn requires a rigorous accreditation process by Ecology's Laboratory Accreditation Unit. Additionally, new and emerging contaminants of concern, such as 6-PPD Quinone, have added to the complexity of the accreditation process and increased the technical assistance that laboratories need during the accreditation process. Administering the laboratory accreditation program is part of the important work that Ecology does to make sure that the data environmental labs produce is accurate and defensible.

The existing rule does not clarify which documents and other requirements LAU expects. Specifically, it is critical that laboratories have a Standard Operating Procedure for each method they are seeking accreditation. This document makes sure that the laboratories are adhering to the same procedures and quality control practices whenever they are performing that specific method and are being transparent in how they apply that method.

Many non-drinking water laboratories have gone several years since their last audit. Audits allow LAU to see the laboratory 'in action' and make sure their SOPs accurately reflect the work done in the lab. The rule revision makes it clear all labs are to return to a triennial audit schedule.

This rulemaking increases LAU's ability to enforce necessary changes when the unit determines a laboratory is not meeting state standards. Laboratories occasionally require a codified standard for them to make an accreditation change requested by the LAU to prevent harm to the communities or environment of Washington State. The new sections in the rule accomplish this.

With the current fee structure, LAU is unable to recover its operating costs. The workload has steadily increased and gained complexity since the last rulemaking in 2010. This is due to additional labs seeking accreditation as well as emerging pollutants that require a more rigorous accreditation process. Not only is our fee structure insufficient with the current staff, but more staff are also necessary to return all laboratories to a triennial audit schedule. The proposed fee structure funds LAU to meet current needs and the added workload of returning to a triennial audit schedule. The fee structure also includes growth over time using the state's Fiscal Growth Factor to minimize the need to return to rulemaking in the future to change the fee structure. The addition of the fiscal growth factor will also enable Ecology to implement fee increases on an annual basis.

The current fee structure does not cover accreditation work done outside of a laboratory's yearly accreditation cycle. The current fee structure also does not cover work performed in unsuccessful or prolonged accreditations. The new fee structure allows for the collection of fees to cover costs in these instances.

Differences Between the Proposed Rule and Adopted Rule

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~~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.

Reason for the change:

During the 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 rewording 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 aliquot~~s~~ 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 the final internal review, this change was made to remove the use of the term within its 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 the 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 the 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 the 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, the addition of this word was recommended. This change makes sure 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, the addition of these words was recommended. This helps make sure 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 rewrite 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~~meet~~ between 50 and 150 percent of the true value.”

Reason for the change:

During the 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 the final internal review, this addition was made to make sure there was no confusion 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 m~~Matrix spikes that do not meet their acceptance criteria must be document~~issues~~ed ~~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 is capable of being taken to address the issue.

Change:

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

Reason for the change:

By 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, ~~L~~laboratory…"

Reason for the change:

During the public comment period, we received a couple of 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, "~~W~~For compliance monitoring samples, if a laboratory control sample is outside of it's ~~hen 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) ~~e~~should~~an~~ 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 the 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 employs specify certain storage requirements for sample 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 of whether they are taken manually or electronically.

Change:

Subsection 1 subdivision e received the following change, “Keep a log~~books~~ 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, make sure the regulated community knows that the use of electronic record keeping is allowable with appropriate use, and 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 were not practical. After a 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 PT~~s~~ 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 the 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 was replaced with "Per Parameter Addition Fee."

Reason for the change:

During public comment, we received a couple of 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 of 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.

List of Commenters and Response to Comments

Ecology accepted comments from April 19, 2023, through June 7, 2023. Comments were accepted by mail, through our online public comment website, and verbally at two public hearings that were held via a Zoom webinar.

We received four submissions totaling 57 comments during the formal comment period. All comments were received via our online public comment website. Below is a table listing the commenter's name, affiliation, and associated comment number.

Commenter name	Affiliation	Comment Number
Ashley Romero	Individual	I-1-1
Arina Podnozova representing King County Environmental Lab	Agency	A-1-1
Arina Podnozova representing King County Environmental Lab	Agency	A-1-2
Arina Podnozova representing King County Environmental Lab	Agency	A-1-3
Arina Podnozova representing King County Environmental Lab	Agency	A-1-4
Arina Podnozova representing King County Environmental Lab	Agency	A-1-5
Arina Podnozova representing King County Environmental Lab	Agency	A-1-6
Arina Podnozova representing King County Environmental Lab	Agency	A-1-7
Arina Podnozova representing King County Environmental Lab	Agency	A-1-8

Commenter name	Affiliation	Comment Number
Arina Podnozova representing King County Environmental Lab	Agency	A-1-9
Arina Podnozova representing King County Environmental Lab	Agency	A-1-10
Arina Podnozova representing King County Environmental Lab	Agency	A-1-11
Arina Podnozova representing King County Environmental Lab	Agency	A-1-12
Arina Podnozova representing King County Environmental Lab	Agency	A-1-13
Arina Podnozova representing King County Environmental Lab	Agency	A-1-14
Arina Podnozova representing King County Environmental Lab	Agency	A-1-15
Arina Podnozova representing King County Environmental Lab	Agency	A-1-16
Arina Podnozova representing King County Environmental Lab	Agency	A-1-17
Arina Podnozova representing King County Environmental Lab	Agency	A-1-18
Arina Podnozova representing King County Environmental Lab	Agency	A-1-19

Commenter name	Affiliation	Comment Number
Arina Podnozova representing King County Environmental Lab	Agency	A-1-20
Arina Podnozova representing King County Environmental Lab	Agency	A-1-21
Arina Podnozova representing King County Environmental Lab	Agency	A-1-22
Arina Podnozova representing King County Environmental Lab	Agency	A-1-23
Arina Podnozova representing King County Environmental Lab	Agency	A-1-24
Arina Podnozova representing King County Environmental Lab	Agency	A-1-25
Arina Podnozova representing King County Environmental Lab	Agency	A-1-26
Arina Podnozova representing King County Environmental Lab	Agency	A-1-27
Arina Podnozova representing King County Environmental Lab	Agency	A-1-28
Arina Podnozova representing King County Environmental Lab	Agency	A-1-29
Arina Podnozova representing King County Environmental Lab	Agency	A-1-30

Commenter name	Affiliation	Comment Number
Arina Podnozova representing King County Environmental Lab	Agency	A-1-31
Arina Podnozova representing King County Environmental Lab	Agency	A-1-32
Arina Podnozova representing King County Environmental Lab	Agency	A-1-33
Arina Podnozova representing King County Environmental Lab	Agency	A-1-34
Arina Podnozova representing King County Environmental Lab	Agency	A-1-35
Arina Podnozova representing King County Environmental Lab	Agency	A-1-36
Arina Podnozova representing King County Environmental Lab	Agency	A-1-37
Alex Boyle representing Eurofins Seattle	Organization	O-1-1
Alex Boyle representing Eurofins Seattle	Organization	O-1-2
Alex Boyle representing Eurofins Seattle	Organization	O-1-3
Alex Boyle representing Eurofins Seattle	Organization	O-1-4
Alex Boyle representing Eurofins Seattle	Organization	O-1-5
Alex Boyle representing Eurofins Seattle	Organization	O-1-6

Commenter name	Affiliation	Comment Number
Stuart Magoon representing Tacoma Environmental Services Laboratory	Other	OTH-1-1
Stuart Magoon representing Tacoma Environmental Services Laboratory	Other	OTH-1-2
Stuart Magoon representing Tacoma Environmental Services Laboratory	Other	OTH-1-3
Stuart Magoon representing Tacoma Environmental Services Laboratory	Other	OTH-1-4
Stuart Magoon representing Tacoma Environmental Services Laboratory	Other	OTH-1-5
Stuart Magoon representing Tacoma Environmental Services Laboratory	Other	OTH-1-6
Stuart Magoon representing Tacoma Environmental Services Laboratory	Other	OTH-1-7
Stuart Magoon representing Tacoma Environmental Services Laboratory	Other	OTH-1-8
Stuart Magoon representing Tacoma Environmental Services Laboratory	Other	OTH-1-9
Stuart Magoon representing Tacoma Environmental Services Laboratory	Other	OTH-1-10
Stuart Magoon representing Tacoma Environmental Services Laboratory	Other	OTH-1-11

Commenter name	Affiliation	Comment Number
Stuart Magoon representing Tacoma Environmental Services Laboratory	Other	OTH-1-12
Stuart Magoon representing Tacoma Environmental Services Laboratory	Other	OTH-1-13

I-1: Ashley Romero

Comment I-1-1

In regards to section WAC 173-50-070, Proficiency Testing (PT), provision 2, the paragraph is amended to require applying accredited laboratories "to analyze a minimum of two PT samples per applicable parameters per year. After which 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 results in subsequent accreditation years. This applies as long as there are no intervening unsatisfactory PT sample results." This would require newly applying bioassay environmental laboratories to conduct two rounds of PT testing in the first accreditation year. PT studies for bioassay labs are extensive studies which involve many considerations that make it difficult for labs to run more than one study in a year. Multiple test solutions are needed for multiple species (i.e. vertebrate, invertebrate) for various test durations (i.e. acute, chronic). It is often difficult to schedule these multiple tests amongst an already full testing schedule for clients conducting compliance WET testing. In addition, a significant amount of time and effort is needed to prepare, conduct, and analyze the results of all testing to ensure all requirements of the PT tests are met. Furthermore, if an unsatisfactory PT result occurs, an opportunity to identify areas of improvement are afforded and only the unsatisfactory test is re-run to validate the implementation of the corrective actions. Therefore, the requirement to conduct two initial PT studies, especially if one PT study yields satisfactory results for all species, is excessive and unnecessary.

Response to I-1-1

Thank you for your comment. After consideration we agree that since there is only one scheduled group study available per year (DMR-QA WET) from our three approved providers, one satisfactory PT is reasonable. However, if a laboratory fails that study they must report another successful PT to establish or maintain accreditation. We will add clarity to the rule language to address this concern.

A-1: Arina Podnozova representing King County Environmental Laboratory

Comment A-1-1

There are a number of proposed additions to the WAC that we have fundamental concerns about, and they are identified in the comments below. In some cases we recommend placing them in Ecology's Accreditation Procedural Manual because:

a. the Procedural Manual may be updated more frequently than the WAC; therefore allowing it to stay current with new promulgated regulatory methods and guidelines.

b. there would be more time and space for LAU to provide the clarity needed for these types of additions.

In other cases, we are respectfully asking you to delete these proposed additions (i.e. corrective actions for matrix spikes) because these type of requirements and guidelines:

a. are already directly addressed by specific EPA methods, Standard Methods, and other official regulatory documents and programs

b. are unable to do an adequate job of addressing all types of environmental disciplines and analyses

c. are likely to conflict in the future with new EPA methods and technologies

d. disregard the appropriate place of data qualification, validation, interpretation, and end use of individual data sets

e. in some cases the proposed language already conflicts with EPA method requirements and guidelines

Conflicting language between and EPA methodology and the WAC can make things impossible for laboratories to satisfy all regulations and has the potential to put customers at risk in terms of data usage per their regulatory programs. Additionally, our concern is that placing information in the WAC that is already covered by regulatory guidance will lead to confusion of where to look and how to interpret methodology when EPA and Standard Methods already have this well covered.

Response to A-1-1

We plan to update the procedural manual in the coming months. The procedural manual is used to provide clarity and guidance on good laboratory practices, but cannot serve as an enforceable document. The added items into WAC were placed in order to add the authority to the items that cannot be provided from the procedural manual.

Comment A-1-2

WAC-173-50-040 Definitions - Calibration Curve – KCEL respectfully requests you delete this definition from the WAC. Why? The WAC is not adequate to cover all of the potential calibration curves used in environmental analyses. For instance, there are calibration curves for air analyses that are not based upon solutions (liquids) and therefore not covered by the proposed language. These types of definitions are already adequately defined in each EPA method. Thank you for addressing this comment. New language looks good.

Response to A-1-2

Thank you for your feedback.

Comment A-1-3

WAC-173-50-040 Definitions - Data traceability or traceability: We have two questions and a recommendation:

a. Does traceability include weights for checking balances, calibration certificates for balances done by an outside vendors, and thermometer calibration certificates?

b. Does the traceability requirement end with the Washington State Record Retention's requirements for raw data? Our LIMS contains final results forever, but our normal retention period for raw data including the information alluded to in this paragraph is 10 years for routine data.

c. KCEL believes that traceability is a laudable goal for LAU to address, but we suggest putting this type of definition in the Procedural Manual.

Why? So that it may be updated and kept fresh as more protocols are defined (i.e., shifting from a hardcopy world to the digital world).

Response to A-1-3

1. Traceability includes all records of measurement necessary to recreate the final result, and to verify the results meet quality control measures and other requirements.

2. The requirement to maintain data traceability does not affect data retention requirements.

3. Thank you for your recommendation, however we must codify the data traceability requirements in order to ensure all laboratories are following them.

Comment A-1-4

WAC-173-50-040 Definitions - Drinking water certification manual: KCEL suggests that you change this verbiage to "The most recent promulgated EPA edition of the Manual for the Certification of Laboratories Analyzing Drinking Water." Additionally, we suggest LAU not put links in the WAC. Why? It's possible that the 5th Edition may be updated someday. The WAC is rarely updated and links may be broken by future updates.

Response to A-1-4

We are required to use the language provided. The link was provided in the draft language as a reference, we are intending to remove the hyperlink in the final language.

Comment A-1-5

WAC-173-50-040 Definitions - Laboratory Control Sample: KCEL requests that you remove this and other already existing method defined definitions from the WAC. Why? EPA uses different terminology in different places for similar QC Types and a WAC definition would lead to unnecessary confusion. For instance EPA 200.7 uses the term Laboratory Fortified Blank (LFB) while the corresponding EPA SW-846 6020 b method uses the term Laboratory Control Sample (LCS). EPA and Standard Methods already have a nomenclature for their methods and there is no reason for LAU to define them in the WAC.

Response to A-1-5

It is necessary to define terms used within the WAC. It does not prohibit use of different terms that describes identical items or procedures.

Comment A-1-6

WAC-173-50-040 Definitions - Instrument or instrumentation: KCEL requests that you remove this from the WAC. Why? We see no benefit to add this short and method untethered definition to the WAC.

Response to A-1-6

It is necessary to define terms used within the WAC. It does not prohibit use of different terms that describe identical items or procedures.

Comment A-1-7

WAC-173-50-040 Definitions - Limit of Quantitation: KCEL requests that you remove this and other already existing EPA method defined definitions from the WAC. Why? EPA and other regulatory methods have language covering the concepts and criteria for the limit of quantitation. We see no benefit to add this short and method untethered definition to the WAC. It can only

serve to confuse laboratory staff already using EPA and Standard Methods' protocols and procedures.

Response to A-1-7

It is necessary to define terms used within the WAC. It does not prohibit use of different terms that describe identical items or procedures.

Comment A-1-8

WAC-173-50-040 Definitions - Limit of Quantitation: According to EPA 1633, rev. 3, the definition is: Limit of Quantitation (LOQ) – The smallest concentration that produces a quantitative result with known and recorded precision and bias. The LOQ shall be set at or above the concentration of the lowest initial calibration standard (the lowest calibration standard must fall within the linear range). Therefore we ask that if this is to be cited in the WAC, the language should match EPA's.

Response to A-1-8

Thank you for your suggestion, however we believe the definition we have used is a more accurate description.

Comment A-1-9

WAC-173-50-040 Definitions - Matrix Spike or MS: KCEL requests that you remove this and other already existing method defined definitions from the WAC. Why? EPA and other regulatory methods have language covering the concept of matrix spikes, their criteria, and interpretation. We see no benefit to add this short and method untethered definition to the WAC.

Response to A-1-9

It is necessary to define terms used within the WAC. It does not prohibit use of different terms that describe identical items or procedures.

Comment A-1-10

WAC-173-50-040 Definitions - Method Detection Limit or MDL: KCEL requests that you remove this and other already existing method defined definitions from the WAC. Why? EPA and other regulatory methods have language covering the concept and criteria for determining the MDL. Additionally, EPA has over time changed the procedures, calculations, and protocols for the determination of MDLs and that could occur again which would then make the WAC incorrect until updated. We see no benefit to adding this definition to the WAC.

Response to A-1-10

It is necessary to define terms used within the WAC. It does not prohibit use of different terms that describe identical items or procedures.

Comment A-1-11

WAC-173-50-040 Definitions - Procedural Manual: KCEL suggests that you change this verbiage to "The most recent edition of the WDOE Accreditation Procedural Manual . . . , which can be found on LAU's website." Why? The WAC will not need to be updated for Procedural Manual update name changes. Thank you for updating this language. It looks good.

Response to A-1-11

Thank you for your comment, we appreciate your engagement throughout the rulemaking process.

Comment A-1-12

WAC-173-50-060 Responsibilities of environmental laboratories, (2): KCEL highly endorses the generic language used in (2) For laboratories to be accredited... must follow requirements designed in the drinking water certification manual. Why? This language will not become stale with updates and name changes to the drinking water manual. We request you use this strategy in other places that we've pointed out.

Response to A-1-12

Thank you for your feedback. Unfortunately we are required to use the language used in the other sections.

Comment A-1-13

WAC-50-061: Required Quality Control Practices: (2, midpoints): KCEL requests that you remove this proposed change from the WAC. Why? EPA and Standard Methods already address how to construct a valid calibration curve. Different methods have different criteria and legitimate corrective actions. This is unnecessary to write into the WAC.

Response to A-1-13

It is necessary for us to include this requirement in order to address questionable laboratory practices when they are encountered. Some of the methods we accredit for are insufficient on this matter. However, we are looking to improve this language include some instances where midpoints can be removed with proper documentation.

Comment A-1-14

WAC-50-061: Required Quality Control Practices: (3, calibration point's value against the curve): KCEL requests that you remove this proposed change from the WAC. Why? EPA and Standard Methods already address the specific criteria for a calibration curve on a method by method basis. It would be incorrect to suggest that there is an appropriate generic criteria for all methods as you are suggesting. For instance the language indicates an LOQ criteria of 50- 150% is acceptable, when in fact the Trace Metals' criteria is 70-130%. We have seen changes in criteria over the years from both EPA and Standard Methods and expect to see more as technology changes. Therefore codifying this in the WAC is inappropriate. If EPA and Standard Methods do not specify criteria in this way for a method, there may also be a valid reason they chose not do so. By including this in the WAC, you are now forcing labs to look in multiple places for guidance when the method should be the source of truth.

Response to A-1-14

The rule language is specifically targeted at methods that do not specify any of those requirements. It is very important that laboratories are able to verify their limits of quantitation. This is a key aspect of verifying accuracy and defensibility of the data.

Comment A-1-15

WAC-50-061: Required Quality Control Practices: (4, LOQ annual verification): KCEL requests that you remove this proposed change from the WAC. Why? This language is incorrect. Every

time you produce a curve, the LOQ is validated for some of the analyses you listed. Additionally some methods require this to be done quarterly. The 50% requirement is not correct for all the methods listed. These criteria are also subject to change by EPA and Standard Methods as technology changes. There is no benefit to putting this into the WAC.

Response to A-1-15

The rule language is specifically targeted at methods that do not specify any of those requirements. It is very important that laboratories are able to verify their limits of quantitation. This is a key aspect of verifying accuracy and defensibility of the data.

Comment A-1-16

WAC-50-061: Required Quality Control Practices: (5, Matrix Spike and Addressing Issues): KCEL requests that you remove this proposed change from the WAC. Why? "Observed matrix issues must be addressed." gives the lab no guidance at all on what the word "addressed" means. There are a multitude of corrective actions that one can take based upon the project, the matrix, the spike amount, the failure, the other QC results, and the analysis in question. These range from using a qualifier to re-prepping and reanalyzing the sample. This language serves no useful purpose as written for inclusion into the WAC.

Response to A-1-16

We are deliberately undetailed on this item so that corrective actions can be tailored to the situation encountered. We are adding this to ensure laboratories are not ignoring this quality control requirement.

Comment A-1-17

WAC-50-061: Required Quality Control Practices: (6, LCS and MS analytes to be spiked): In general, KCEL agrees that this is a best practice. However, there are times that it is either impossible or unnecessary due to the already high levels of native analyte in the sample. For instance, minerals are rarely if ever spiked high enough in seawater to produce a valid recovery for a matrix spike. We suggest that WDOE relies upon the EPA and Standard Methods' language in terms of accreditation. We therefore request that you remove this proposed change from the WAC. Why? Because must is too strong for all scenarios and this should be covered by the EPA and other regulatory methods. Thank you for updating this language for the MS. It looks good.

Response to A-1-17

Thank you for your comment, we appreciate your engagement throughout the rulemaking process.

Comment A-1-18

WAC-50-061: Required Quality Control Practices: (7, MS corrective action and reporting requirements): KCEL requests that you remove this proposed change from the WAC. Why? Matrix Spikes are not meant to reject data sets, but provide useful information about the ability to recover an analyte in a given matrix and analysis. In fact, EPA clearly defines that percent recoveries in Trace Metals analyses may only be evaluated when the spike was at least 4x the native concentration, and yet the parameter may still be reported. Any attempt to dictate corrective actions in the WAC should be avoided. This is because there are other ways to accommodate imperfect data sets including data qualification and validation reports. Putting this

in the WAC also does not take into account the data's end use, regulatory program requirements, or whether it is for informational or research purposes. Legislating such corrective actions in the WAC should be avoided at all costs. Thank you for updating this language for the MS. It looks good.

Response to A-1-18

Thank you for your comment, we appreciate your engagement throughout the rulemaking process

Comment A-1-19

WAC-50-061: Required Quality Control Practices: (6 Quality Control Samples): Please define exactly all of the "quality control samples" you are referring to for this comment. Why? It is not clear what additional QC types you are referring since the language used is "such as a laboratory control sample…".

Response to A-1-19

Thank you for pointing this out. We will look to improve this language to make the applicable QC types more clear.

Comment A-1-20

WAC-50-061: Required Quality Control Practices: (6 Quality Control Samples): Please articulate whether or not the lab must satisfy (a) and (b) and (c) vs. (a) or (b) or (c) when a laboratory control sample fails high. Why? Also why is the language in here at all? Why only if it fails high? Why can a lab NOT report data when it could qualify the data? KCEL respectfully asks that you really think about this proposed update. As written it could make reporting of data for certain parameters more difficult that could currently be reported by EPA and Standard Method guidelines. It seems inappropriate.

Response to A-1-20

This language has been added to address the propensity of laboratories to submit qualified data for compliance monitoring samples. We will look to clarify this wording to me more inclusive of different analytical circumstances. Such as changing, "can only be reported" to, "should only be reported" or adding "for compliance monitoring samples" at the beginning of the requirement.

Comment A-1-21

WAC 173-55-069 Data and record traceability: WAC 173-55 is a typo. All sections should be 173-50. Thank you for updating this. It looks good.

Response to A-1-21

Thank you for pointing this typo out in our draft rules. This has been fixed.

Comment A-1-22

WAC 173-55-069 Data and record traceability – 1 (a): How long would a lab need to maintain traceability for a final result? KCEL recommends that this coincide with the Washington State Records Retention policies for raw data. Why? WDOE Accreditation requirements should not be in conflict with records retention requirements.

Response to A-1-22

Laboratories are expected to meet data retention requirements under the applicable regulations for the data generated.

Comment A-1-23

WAC 173-55-069 Data and record traceability 1 (b) & 1 (c): KCEL has a question and a recommendation. What is meant by this verbiage? Can you please provide more detail in terms of what you mean by "documenting proper storage of chemicals and samples"? KCEL recommends that LAU move this type of verbiage to the Procedural Manual. Why? Then this type of information can be updated more frequently and as needed. It can also be more detailed about what is meant by chemicals, etc.

Response to A-1-23

This language is to ensure laboratories are both properly storing and documenting the storage of their reagents, samples, chemicals, and media. We need to be able to adequately address circumstances where laboratories are not doing so.

Comment A-1-24

WAC 173-55-069 Data and record traceability 1 (d): "Document that all temperature based equipment…is within control and checked manually as required by the relevant method". KCEL recommends changing the language to: "data loggers must meet the precision and bias of the equipment/method temperature requirements." Why? This permanently codifies that temperatures be manually checked in the WAC. There are already certified methods to use technology to record temperatures and achieve more accurate and timely data than using humans to do it. The FDA for instance certified data loggers for the transportation of covid vaccines during the pandemic. Even if data loggers do not meet your standards in 2023, it is quite likely they will at some future date. This language would prohibit the use of data loggers when they are inappropriate, but allows their use when they meet proper requirements. KCEL also recommends putting this type of verbiage in the Procedural Manual. Why? Then this type of information can be updated more frequently and as needed.

Response to A-1-24

We are not preventing laboratories from using continuous monitoring equipment. However we are requiring that temperature checks are documented by a person (whether electronic or hand-written) at the method required interval. This ensures that out of control equipment is addressed as soon as possible, with active engagement of the corrective action process. We will re-word this item to add clarity to this requirement.

Comment A-1-25

WAC 173-55-069 Data and record traceability (2, incubators): "Incubator temperatures...". KCEL recommends deleting proposed verbiage from the WAC. Why? Even if data loggers do not meet your standards in 2023, it is quite likely they will at some future date. This could be changed to: "data loggers must meet the precision and bias of the equipment/method temperature requirements." KCEL also recommends putting this type of verbiage in the Procedural Manual. Why? Then this type of information can be updated more frequently and as needed. Please review this additional information on the current state of data loggers: https://www.sensoscientific.com/applications/covid-19-vaccine-temperature-monitoring/ Also

note that A2LA approved this type of equipment as it now has FDA approval for some applications.

Response to A-1-25

Thank you for your recommendation. We will look to incorporate your language.

Comment A-1-26

WAC 173-55-069 Data and record traceability: Can you clarify that the only prohibition WDOE would like to make on data loggers is for incubators? This is unclear.

Response to A-1-26

The requirement of hand-written records is only for incubators.

Comment A-1-27

WAC 173-55-069 Data and record traceability (3, electronic record population): KCEL is confused by this verbiage. What is meant by populated? Also KCEL requests that the prohibition of data-loggers be struck from this language. Why? This permanently codifies that data-loggers not be allowed by the WAC for temperature checks. There are already certified methods to use technology to record temperatures and achieve more accurate and timely data than using humans to do it. If WDOE is concerned about putting this type of check on "auto-pilot", LAU could require humans to monitor the data-logger system instead of prohibiting it. KCEL also recommends putting this type of verbiage in the Procedural Manual. Why? Then this type of information can be updated more frequently and as needed. It also would allow for laboratories to take advantage of improved technologies as EPA allows.

Response to A-1-27

We do not the language to prohibit the use of data-loggers and other continuous monitoring equipment for items other than incubators. We are looking to ensure our WAC states that they must be used properly. We want to avoid laboratories setting up continuous monitoring equipment and not properly monitoring the equipment and tracking readings on a timely basis.

Comment A-1-28

WAC 173-50-070 Proficiency testing (3): KCEL has a question: Under what specific circumstances might a laboratory be required to provide raw PT data? KCEL also recommends putting this type of verbiage in the Procedural Manual. Why? This does not need to be codified into the WAC.

Response to A-1-28

Having this requirement in WAC is necessary to ensure auditors have access to this data if and when necessary.

Comment A-1-29

WAC 173-50-070 Proficiency testing (6): - Note that DMRQA WET samples can require test conditions that differ from our standard analytical process and Laboratory guidance and whole effluent toxicity test review criteria, DOE publication #WQ-R-95-80. Thank you for revising. This is good.

Response to A-1-29

Thank you for your comment, we appreciate your engagement throughout the rulemaking process.

Comment A-1-30

WAC 173-50-070 Proficiency testing - (7): KCEL suggests edits added in red. When two or more approved PT providers are available for a parameter in the appropriate matrix, the laboratory must analyze and pass a PT to gain or maintain accreditation. Thank you for revising. This is good.

Response to A-1-30

Thank you for your comment, we appreciate your engagement throughout the rulemaking process.

Comment A-1-31

WAC 173-50-70 Proficiency testing (8, presence-absence): KCEL does not necessarily disagree with LAU's sentiment that lab's should be able to pass at 100%. However, this verbiage would now be in disagreement with EPA's Manual for Certification of Laboratories Analyzing Drinking Water 5th ed. as stated in Section 7.2. Therefore KCEL requests that you delete this proposed language. Why? It is a laboratory's nightmare to serve multiple conflicting jurisdictions. Laboratories should have only place to go to determine passing criteria, and clearly this falls to EPA to dictate the terms of passing proficiency tests.

Response to A-1-31

States with primacy are allowed to be more stringent than the manual specifies. We have decided to be more stringent in this case.

Comment A-1-32

WAC 173-50-80 On-site audit 4(b): KCEL requests clarification as to whether LAU is requesting data for every single method or just the ones it will focus in on for the audit. It is doubtful the LAU would have time to review all accredited methods for a large laboratory even with a 2 week window and it takes time on the part of laboratories to put these requests together. KCEL also seeks clarification as to what is in the data package? Is this raw data, associated calibration curves, etc. KCEL recommends putting this type of verbiage in the Procedural Manual. Why? Then this type of information can be updated more frequently and as needed. For instance, you may find that 2 weeks is not enough, and yet you'd be held to a now codified 2-week WAC standard.

Response to A-1-32

Document requests would only be applicable to parameters being audited. Regarding the 2-week window, this language is to ensure laboratories provide LAU enough time to review data and other documents prior to an audit. Documents can be submitted earlier than 2-weeks.

Comment A-1-33

WAC 173-50-80 On-site audit 4 (c): Please provide representative examples of what additional documentation may be. KCEL recommends putting this type of verbiage in the Procedural Manual. Why? Then this type of information can be updated more frequently and as needed.

Response to A-1-33

That information would be specific to the parameters and laboratory involved in the audit. Some examples will look to be added to the Procedural Manual.

Comment A-1-34

WAC 173-50-120 Accreditation categories - section 3: Did this section get deleted on purpose? No longer see it in the revised addition. : KCEL strongly requests that LAU consider accrediting labs for the SW-846 methods under the Non-Potable Water matrix. Why? Liquid matrices are explicitly allowed in EPA SW-846 methodology. The current practice of listing those methods only under Solids and Chemical Materials makes it very difficult to determine if a lab is actually accredited for testing water samples using SW-846 methods. If LAU decides not to take this step, it should revise WAC 173-50-070 (Proficiency testing) to clearly indicate that for the SW-846 methods to be applicable to non-potable water, the lab must analyze Non-Potable Water PT samples along with Solid PT samples. This would clarify what needs to be done to be able to use SW-846 methods for both types of matrices. Also, the LAU appears to be using the NELAC designations for accreditation, but the LAU maintains that the lab accreditation program is not part of NELAC. Why not sever the appearance of being part of NELAC? At a minimum, LAU should put in the Procedural Manual how to get accredited for non-potable water using SW-846 methods and to list those accreditations on the lab's WDOE accreditation listing both on-line and on paper.

Response to A-1-34

Section 120 was not removed, the official proposed language document does not include a section that is not receiving any changes. The Solid and Chemical Materials category does include certain aqueous matrices. For the Washington ELAP the Non-Potable Water matrix includes samples for NPDES compliance monitoring, which also includes ambient and wastewater samples. We will look to include more clarity on this topic in our procedural manual. If you have any questions regarding this topic please reach out to Rebecca Wood at the Laboratory Accreditation Unit.

Comment A-1-35

WAC 173-50-140 Denying accreditation: (2) "A laboratory may be denied accreditation for a specific parameter for unsatisfactory proficiency testing results." KCEL recommends changing the term parameter to analyte in order to be on par with the fee schedule and the fact that LAU may just deny one analyte within the WAC defined "Parameter". KCEL requests clarification of the term "unsatisfactory" and how it relates to denial of accreditation. It implies that labs could be denied accreditation for missing a single PT result. Also, please consider using the term "unacceptable PT sample result", which is consistent with PT vendor reports. Can you specifically describe how many PTs you can miss and how many you need to pass in a row to restore full accreditation? Thank you for changing from "unsatisfactory" to "unacceptable". KCEL respectfully requests that you change to this term throughout the entire document.

Response to A-1-35

The term parameter is necessary to allow for an analyte to be acceptable if a PT failure is specific to one method and/or matrix.

Comment A-1-36

WAC 173-50-190 Fee Structure, Table 1: Please clarify how the agency will assign fees for bioassay parameters that may require multiple test organisms under one analytical method. For example, the PSEP 1995 Bioassay protocols requires the use of 1 of 3 amphipods based on sample grain size and salinity; will accreditation and fee structure be based on the single PSEP method or based on each individual organism? The PSEP Echinoderm method also requires multiple organisms under one analytical method based on seasonality of the test organisms.

Response to A-1-36

Laboratories will only be charged for each accredited bioassay method; similar to Metals and Organics. When a laboratory wishes to add accreditation for a new organism to an existing method it will be assessed a one-time addition fee.

Comment A-1-37

WAC 173-50-190 Fee Structure, (4 and 6): KCEL wonders if there is an inconsistency between (4 and 6). Under (4), the word three is struck out and five has been added. But in (6), the word three has been added. We wonder if LAU meant five.

Response to A-1-37

These fees are different because they cover different costs.

O-1: Alex Boyle representing Eurofins Seattle

Comment O-1-1

WAC 173-50-061 (2)(a), pg. 4 Comment: Middle calibration points should be allowed for removal if there is documented and demonstrable error with the injection or standard preparation. E.g. incorrect concentration prepared, internal standard inadvertently omitted, or instrument autosampler malfunction. Suggested verbiage: “A laboratory must not remove any midpoints from a calibration curve with the exception of consecutive points at either end of the curve, unless a significant error occurred with the standard preparation or sample introduction, and the error is documented and calibration point is excluded for all analytes.”

Response to O-1-1

This is a reasonable suggestion. We will look to incorporate this change to the language.

Comment O-1-2

WAC 173-50-061 (3), pg. 4 Comment: Need clarification on the 50% of true value check on LOQ. “…laboratories must analyze a standard at their limit of quantitation at least annually. This standard must meet 50 percent of the true value.” This could be interpreted as 50% of true value or greater with no upper limit. Should it be +/- 50% of true value?

Response to O-1-2

The term, "true value" in this case is the calculated LOQ. It is important for laboratories to be able to accurately recover an analyte at their LOQ.

Comment O-1-3

WAC 173-50-069 (1)(d), pg. 6 Comment: Allow for either automated or manual checks, as long compliant with method or WA rules. Automated, continuous monitoring should be allowed if not

otherwise restricted by method or by WA, such as in WAC 173-50-069 (3) regarding incubators. Suggested verbiage: “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;”

Response to O-1-3

Our rule does not prevent laboratories from using continuous monitoring equipment. However, we are requiring that temperature checks are documented and done by a person per method/regulatory requirements. We do not want laboratories to have the ability to set up a continuous monitoring equipment and not regularly checking it. We need laboratories to be properly using the temperature recording equipment and addressing out of control equipment as soon as possible. We understand the current wording is confusing, and will look to add clarity in our final language to address this concern.

Comment O-1-4

WAC 173-50-190 Table 2&3, pg. 13 Comment: Difficult to understand what “Per Parameter Add Fee to Existing Method” column means. Suggest adding a section or footnote to explain the changes from Table 1 to Table 2, namely in regard to the aforementioned column.

Response to O-1-4

The fees you mentioned are only applied when a laboratory requests to add a parameter to an existing accredited method. We will look to add clarity to the fee table and associated rule language to make it more clear when that column applies.

Comment O-1-5

WAC 173-50-190 (11), pg. 14 Comment: Clarification requested. In the following statement, does “reinstate a parameter” include returning parameter from suspension or just revocation? “If a laboratory requests to add or reinstate a parameter to their scope of accreditation outside of their initial application or renewal process, the laboratory will be invoiced a fee based on the type and number of requested parameters, per Table 1, Table 2, Table 3, or as updated by Equation 1.” As such, if a parameter is suspended for 2 failing PTs, is a fee required to reinstate that parameter after a passing PT is achieved?

Response to O-1-5

A parameter that was Denied, is still invoiced at renewal and will not be invoiced again when a revision is done to return the parameter to Provisional, Interim, or Good Standing. The term, "re-instatement" typically only applies to parameters that were Withdrawn or Suspended.

Comment O-1-6

WAC 173-50-061 (5), pg. 5 Comment: Spiked control samples should account for exceptions for multi-component analytes, such as PCBs. Suggested verbiage: “Laboratory control samples must include all analytes of interest in the respective analysis, unless method exceptions are specified.”

Response to O-1-6

This is a reasonable suggestion. We will look to incorporate this change to the language.

OTH-1-1: Stuart Magoon representing Tacoma Environmental Services Laboratory

Comment OTH-1-1

WAC 173-50-040 Definitions., p.8 Tacoma ES_Lab suggests the following edits: "Drinking water certification manual" - The Environmental Protection Agency Manual for the Certification of Laboratories Analyzing Drinking Water, ~~5th Edition, January 2005~~ current approved edition.

Response to OTH-1-1

We are required to use the language as written.

Comment OTH-1-2

WAC 173-50-060 Responsibilities of environmental laboratories. Item (2), p.15 Tacoma ES_Lab suggests the following edits: (2) For laboratories to be accredited for drinking water parameters, the laboratory must follow requirements designated in the current approved drinking water certification manual.

Response to OTH-1-2

We are required to use the language as written.

Comment OTH-1-3

WAC-173-50-061: Required Quality Control Practices item (2), p.16 Comment: Midpoints should be allowed to be removed if there is a demonstrable error with the preparation/injection and the point is removed for ALL analytes in the calibration. Tacoma ES_Lab suggests this section read: A laboratory must not remove any midpoints from a calibration curve with the exception of consecutive points at either end of the curve OR there is a demonstrable error with the preparation/injection and the point is removed for ALL analytes in the calibration.

Response to OTH-1-3

This is a reasonable suggestion. We will look to incorporate similar language into our rules.

Comment OTH-1-4

WAC-173-50-061: Required Quality Control Practices item (3), p.16 Comment: This language is confusing and appears to be missing some words. Tacoma ES_Lab suggests this section read: Unless otherwise specified in the method, each calibration point must have its percent error meet the calibration verification acceptance limits from the method; with the exception of calibration points at or below the LOQ, it which case ~~where~~ the limit is 50-150%.

Response to OTH-1-4

This is a reasonable suggestion. We will look to incorporate this change to the language.

Comment OTH-1-5

WAC-173-50-061 Required Quality Control Practices item (4), p.16 Tacoma ES_Lab recommends removing this section because standard calibration acceptance criteria (including the standard at the limit of quantitation) is covered in the preceding section (3). Note: The word “standard” is not defined in the definitions section and we read this with the understanding that the term “standard” as used here is synonymous with “calibration point” used in item (3) in this

section, assuming a “calibration point” is one the “series of solutions of known analyte concentrations…” that make up a “Calibration Curve”.

Response to OTH-1-5

We are not referring to a calibration point in this instance. We'll add some clarity that the standard in this section must be separate from the calibration and only applies when the method does not specify and LOQ verification requirements.

Comment OTH-1-6

WAC-173-50-061: Required Quality Control Practices. Item (6), p.17 Consideration should be given to analyses with multi-component analytes for example, PCB aroclors, or toxaphene. Tacoma ES_Lab suggests the following edit: (6) For single component analytes, Laboratory control samples and matrix spikes must include all analytes of interest in the respective analysis, unless there are method specified exceptions.

Response to OTH-1-6

This is a reasonable suggestion. We will look to incorporate this change to the language.

Comment OTH-1-7

WAC-173-50-061: Required Quality Control Practices. Item (7), p.17-18 Tacoma ES_Lab requests that this section be removed. This section is confusing, contradicts other EPA method guidance, and is not consistent with some of our Ecology approved project specific requirements for demonstrating NPDES compliance. It too broadly stated and will unnecessarily sensor useful information.

Response to OTH-1-7

This language has been added to address the propensity of some laboratories to submit qualified data for compliance monitoring. We will look to clarify this wording to me more inclusive of different analytical circumstances. Such as adding, "For compliance monitoring samples" to the beginning of the section, or changing the words, "can only be reported" to, "should only be reported."

Comment OTH-1-8

WAC 173-55-069 Data and record traceability. (should be WAC 173-50-069) Item 1 (d), p. 20 Tacoma ES_Lab suggests the following change: (d) Document that all temperature-based equipment such as a refrigerator, oven, or incubator is both within control ~~and checked manually~~ as required by the relevant method; and Reason: The only way to properly “Document” that these items are operating within control is to check them and record the data. This can be accomplished with a digital logger or manually writing down the value at the date(s) times required to demonstrate “control”. Tacoma ES_Lab recommends removing “and checked manually” from this sentence because it is not necessary.

Response to OTH-1-8

Our rule does not prevent laboratories from using continuous monitoring equipment. However, we are requiring that temperature checks are documented and done by a person per method/regulatory requirements. We do not want laboratories to have the ability to set up a continuous monitoring equipment and not regularly check it. We need laboratories to be properly

using the temperature recording equipment and addressing out of control equipment as soon as possible.

Comment OTH-1-9

WAC 173-55-069 Data and record traceability. (should be WAC 173-50-069) Item 1 (c), p.20 Tacoma ES_Lab suggests the following change: (c) Document proper storage of samples and sample extracts as required by the specific method;

Response to OTH-1-9

This is a reasonable suggestion. We will look to incorporate this change to the language.

Comment OTH-1-10

WAC 173-55-069 Data and record traceability. (should be WAC 173-50-069) Item 1 (e), p.20 Tacoma ES_Lab suggests the following change: (e) Keep a logbooks for any and all instruments, including documentation of installation, setup, maintenance, and removal from service. Reason: By removing "books" from the word log this more clearly allows either a hand-written record in a logbook or an electronic record aka an electronic log. Note that item 2 in this section states "When records are hand-written,…" – the key word to us is that electronic records are acceptable since the first word in this sentence is "when" which implies there is a when not. This is reinforced in item (3) in this section that states "When records are kept electronically,…"

Response to OTH-1-10

This is a reasonable suggestion. We will look to incorporate this change to the language.

Comment OTH-1-11

WAC 173-55-069 Data and record traceability. Item (3), p20-21 Tacoma ES_Lab suggests the following edits: (3) ~~When records are kept electronically,~~ Electronically captured records ~~they~~ must include the date and time the record was captured. ~~be populated at the time of record,~~ using a fully traceable and secure format. Use of continuous data-loggers is not an acceptable substitute for where method-required temperature checks must be performed manually.

Response to OTH-1-11

This is a reasonable suggestion. We will look to incorporate this change to the language.

Comment OTH-1-12

WAC 173-50-070 Proficiency testing (PT). Item (7), p.22 Tacoma ES_Lab suggest the following edits: (7) When two or more approved PT providers ~~are~~make available a PT sample for a parameter in the appropriate matrix, the laboratory must analyze and pass a PT to gain or maintain accreditation.

Response to OTH-1-12

This is a reasonable suggestion. We will look to incorporate this suggestion to the language. We want to ensure our language covers both scheduled and rapid return PT studies.

Comment OTH-1-13

WAC 173-50-140 Denying accreditation. Item (2), p.36 Tacoma ES_Lab suggest the following edits: (2) A laboratory may be denied accreditation for a specific ~~parameter~~ analyte in a matrix for ~~unsatisfactory~~ unacceptable proficiency testing results.

Response to OTH-1-13

Thank you for your suggestion, but we need to ensure that the correct method is incorporated as part of passing the PT study.

Appendix A: PDFs received during Public Comment Period

King County Environmental Laboratory

6.7.2023

General Comments:

There are a number of proposed additions to the WAC that we have fundamental concerns about, and they are identified in the comments below.

In some cases we recommend placing them in Ecology's Accreditation Procedural Manual because:

a. the Procedural Manual may be updated more frequently than the WAC; therefore allowing it to stay current with new promulgated regulatory methods and guidelines.
b. there would be more time and space for LAU to provide the clarity needed for these types of additions.

In other cases, we are respectfully asking you to delete these proposed additions (i.e. corrective actions for matrix spikes) because these type of requirements and guidelines:

a. are already directly addressed by specific EPA methods, Standard Methods, and other official regulatory documents and programs
b. are unable to do an adequate job of addressing all types of environmental disciplines and analyses
c. are likely to conflict in the future with new EPA methods and technologies
d. disregard the appropriate place of data qualification, validation, interpretation, and end use of individual data sets
e. in some cases the proposed language already conflicts with EPA method requirements and guidelines

Conflicting language between and EPA methodology and the WAC can make things impossible for laboratories to satisfy all regulations and has the potential to put customers at risk in terms of data usage per their regulatory programs.

Additionally, our concern is that placing information in the WAC that is already covered by regulatory guidance will lead to confusion of where to look and how to interpret methodology when EPA and Standard Methods already have this well covered.

WAC-173-50-040 Definitions - Calibration Curve – KCEL respectfully requests you delete this definition from the WAC. **Why?** The WAC is not adequate to cover all of the potential calibration curves used in environmental analyses. For instance, there are calibration curves for air analyses that are not based upon solutions (liquids) and therefore not covered by the proposed language. These types of definitions are already adequately defined in each EPA method. Thank you for addressing this comment. New language looks good.

WAC-173-50-040 Definitions - Data traceability or traceability: We have two questions and a recommendation:

a. Does traceability include weights for checking balances, calibration certificates for balances done by an outside vendors, and thermometer calibration certificates?
b. Does the traceability requirement end with the Washington State Record Retention's requirements for raw data? Our LIMS contains final results forever, but our normal retention period for raw data including the information alluded to in this paragraph is 10 years for routine data.
c. KCEL believes that **traceability** is a laudable goal for LAU to address, but we suggest putting this type of definition in the Procedural Manual. **Why?** So that it may be updated and kept fresh as more protocols are defined (i.e., shifting from a hardcopy world to the digital world).

WAC-173-50-040 Definitions - Drinking water certification manual: KCEL suggests that you change this verbiage to "The most recent promulgated EPA edition of the Manual for the Certification of Laboratories Analyzing Drinking Water." Additionally, we suggest LAU not put links in the WAC. **Why?** It's possible that the 5th Edition may be updated someday. The WAC is rarely updated and links may be broken by future updates.

WAC-173-50-040 Definitions - Laboratory Control Sample: KCEL requests that you remove this and other already existing method defined definitions from the WAC. **Why?** EPA uses different terminology in different places for similar QC Types and a WAC definition would lead to unnecessary confusion. For instance EPA 200.7 uses the term Laboratory Fortified Blank (LFB) while the corresponding EPA SW-846 6020 b method uses the term Laboratory Control Sample (LCS). EPA and Standard Methods already have a nomenclature for their methods and there is no reason for LAU to define them in the WAC.

WAC-173-50-040 Definitions - Instrument or instrumentation: KCEL requests that you remove this from the WAC. **Why?** We see no benefit to add this short and method untethered definition to the WAC.

WAC-173-50-040 Definitions - Limit of Quantitation: KCEL requests that you remove this and other already existing EPA method defined definitions from the WAC. **Why?** EPA and other regulatory methods have language covering the concepts and criteria for the limit of quantitation. We see no benefit to add this short and method untethered definition to the WAC. It can only serve to confuse laboratory staff already using EPA and Standard Methods' protocols and procedures.

WAC-173-50-040 Definitions - Limit of Quantitation: According to EPA 1633, rev. 3, the definition is: Limit of Quantitation (LOQ) – The smallest concentration that produces a quantitative result with known and recorded precision and bias. The LOQ shall be set at or above the concentration of the lowest initial calibration standard (the lowest calibration standard must fall within the linear range). Therefore we ask that if this is to be cited in the WAC, the language should match EPA's.

WAC-173-50-040 Definitions - Matrix Spike or MS: KCEL requests that you remove this and other already existing method defined definitions from the WAC. **Why?** EPA and other regulatory methods have language covering the concept of matrix spikes, their criteria, and interpretation. We see no benefit to add this short and method untethered definition to the WAC.

WAC-173-50-040 Definitions - Method Detection Limit or MDL: KCEL requests that you remove this and other already existing method defined definitions from the WAC. **Why?** EPA and other regulatory methods have language covering the concept and criteria for determining the MDL. Additionally, EPA has over time changed the procedures, calculations, and protocols for the determination of MDLs and that could occur again which would then make the WAC incorrect until updated. We see no benefit to adding this definition to the WAC.

WAC-173-50-040 Definitions - Procedural Manual: KCEL suggests that you change this verbiage to "The most recent edition of the WDOE Accreditation Procedural Manual . . . , which can be found on LAU's website." **Why?** The WAC will not need to be updated for Procedural Manual update name changes. Thank you for updating this language. It looks good.

WAC-173-50-060 Responsibilities of environmental laboratories, (2): KCEL highly endorses the generic language used in (2) For laboratories to be accredited... must follow requirements

designed in the drinking water certification manual. **Why?** This language will not become stale with updates and name changes to the drinking water manual. We request you use this strategy in other places that we've pointed out.

WAC-50-061: Required Quality Control Practices: (2, midpoints): KCEL requests that you remove this proposed change from the WAC. **Why?** EPA and Standard Methods already address how to construct a valid calibration curve. Different methods have different criteria and legitimate corrective actions. This is unnecessary to write into the WAC.

WAC-50-061: Required Quality Control Practices: (3, calibration point's value against the curve): KCEL requests that you remove this proposed change from the WAC. **Why?** EPA and Standard Methods already address the specific criteria for a calibration curve on a method by method basis. It would be incorrect to suggest that there is an appropriate generic criteria for all methods as you are suggesting. For instance the language indicates an LOQ criteria of 50-150% is acceptable, when in fact the Trace Metals' criteria is 70-130%. We have seen changes in criteria over the years from both EPA and Standard Methods and expect to see more as technology changes. Therefore codifying this in the WAC is inappropriate. If EPA and Standard Methods do not specify criteria in this way for a method, there may also be a valid reason they chose not do so. By including this in the WAC, you are now forcing labs to look in multiple places for guidance when the method should be the source of truth.

WAC-50-061: Required Quality Control Practices: (4, LOQ annual verification): KCEL requests that you remove this proposed change from the WAC. **Why?** This language is incorrect. Every time you produce a curve, the LOQ is validated for some of the analyses you listed. Additionally some methods require this to be done quarterly. The 50% requirement is not correct for all the methods listed. These criteria are also subject to change by EPA and Standard Methods as technology changes. There is no benefit to putting this into the WAC.

WAC-50-061: Required Quality Control Practices: (5, Matrix Spike and Addressing Issues): KCEL requests that you remove this proposed change from the WAC. **Why?** "Observed matrix issues must be addressed." gives the lab no guidance at all on what the word "addressed" means. There are a multitude of corrective actions that one can take based upon the project, the matrix, the spike amount, the failure, the other QC results, and the analysis in question. These range from using a qualifier to re-prepping and reanalyzing the sample. This language serves no useful purpose as written for inclusion into the WAC.

WAC-50-061: Required Quality Control Practices: (6, LCS and MS analytes to be spiked): In general, KCEL agrees that this is a best practice. However, there are times that it is either impossible or unnecessary due to the already high levels of native analyte in the sample. For instance, minerals are rarely if ever spiked high enough in seawater to produce a valid recovery for a matrix spike. We suggest that WDOE relies upon the EPA and Standard Methods' language in terms of accreditation. We therefore request that you remove this proposed change from the WAC. **Why?** Because must is too strong for all scenarios and this should be covered by the EPA and other regulatory methods. Thank you for updating this language for the MS. It looks good.

WAC-50-061: Required Quality Control Practices: (7, MS corrective action and reporting requirements): KCEL requests that you remove this proposed change from the WAC. **Why?** Matrix Spikes are not meant to reject data sets, but provide useful information about the ability to recover an analyte in a given matrix and analysis. In fact, EPA clearly defines that percent recoveries in Trace Metals analyses may only be evaluated when the spike was at least 4x the native concentration, and yet the parameter may still be reported. Any attempt to dictate corrective actions in the WAC should be avoided. This is because there are other ways to accommodate imperfect data sets including data qualification and validation reports. Putting this in the WAC also does not take into account the data's end use, regulatory program requirements, or whether it is for informational or research purposes. Legislating such corrective actions in the WAC should be avoided at all costs. Thank you for updating this language for the MS. It looks good.

WAC-50-061: Required Quality Control Practices: (6 Quality Control Samples): Please define exactly all of the "quality control samples" you are referring to for this comment. **Why?** It is not clear what additional QC types you are referring since the language used is "such as a laboratory control sample…".

WAC-50-061: Required Quality Control Practices: (6 Quality Control Samples): Please articulate whether or not the lab must satisfy (a) and (b) and (c) vs. (a) or (b) or (c) when a laboratory control sample fails high. **Why?** Also why is the language in here at all? Why only if it fails high? Why can a lab NOT report data when it could qualify the data? KCEL respectfully asks that you really think about this proposed update. As written it could make reporting of data for certain parameters more difficult that could currently be reported by EPA and Standard Method guidelines. It seems inappropriate.

WAC 173-55-069 Data and record traceability: WAC 173-**55** is a typo. All sections should be 173-50. Thank you for updating this. It looks good.

WAC 173-55-069 Data and record traceability – 1 (a): How long would a lab need to maintain traceability for a final result? KCEL recommends that this coincide with the Washington State Records Retention policies for raw data. **Why?** WDOE Accreditation requirements should not be in conflict with records retention requirements.

WAC 173-55-069 Data and record traceability 1 (b) & 1 (c): KCEL has a question and a recommendation. What is meant by this verbiage? Can you please provide more detail in terms of what you mean by "documenting proper storage of chemicals and samples"? KCEL recommends that LAU move this type of verbiage to the Procedural Manual. **Why?** Then this type of information can be updated more frequently and as needed. It can also be more detailed about what is meant by chemicals, etc.

WAC 173-55-069 Data and record traceability 1 (d): "Document that all temperature based equipment…is within control and checked manually as required by the relevant method". KCEL recommends changing the language to: "data loggers must meet the precision and bias of the equipment/method temperature requirements." **Why?** This permanently codifies that temperatures be manually checked in the WAC. There are already certified methods to use technology to record temperatures and achieve more accurate and timely data than using humans to do it. The FDA for instance certified data loggers for the transportation of covid vaccines during the pandemic. Even if data loggers do not meet your standards in 2023, it is quite likely they will at some future date. This language would prohibit the use of data loggers when they are inappropriate, but allows their use when they meet proper requirements.

KCEL also recommends putting this type of verbiage in the Procedural Manual. **Why?** Then this type of information can be updated more frequently and as needed.

WAC 173-55-069 Data and record traceability (2, incubators): "Incubator temperatures...". KCEL recommends deleting proposed verbiage from the WAC. **Why?** Even if data loggers do not meet your standards in 2023, it is quite likely they will at some future date. This could be changed to: "data loggers must meet the precision and bias of the equipment/method temperature requirements."

KCEL also recommends putting this type of verbiage in the Procedural Manual. **Why?** Then this type of information can be updated more frequently and as needed. Please review this

additional information on the current state of data loggers:
https://www.sensoscientific.com/applications/covid-19-vaccine-temperature-monitoring/

Also note that A2LA approved this type of equipment as it now has FDA approval for some applications.

WAC 173-55-069 Data and record traceability: Can you clarify that the only prohibition WDOE would like to make on data loggers is for incubators? This is unclear.

WAC 173-55-069 Data and record traceability (3, electronic record population): KCEL is confused by this verbiage. What is meant by populated? Also KCEL requests that the prohibition of data-loggers be struck from this language. **Why?** This permanently codifies that data-loggers not be allowed by the WAC for temperature checks. There are already certified methods to use technology to record temperatures and achieve more accurate and timely data than using humans to do it. If WDOE is concerned about putting this type of check on "auto-pilot", LAU could require humans to monitor the data-logger system instead of prohibiting it.

KCEL also recommends putting this type of verbiage in the Procedural Manual. **Why?** Then this type of information can be updated more frequently and as needed. It also would allow for laboratories to take advantage of improved technologies as EPA allows.

WAC 173-50-070 Proficiency testing (3): KCEL has a question: Under what specific circumstances might a laboratory be required to provide raw PT data? KCEL also recommends putting this type of verbiage in the Procedural Manual. **Why?** This does not need to be codified into the WAC.

WAC 173-50-070 Proficiency testing (6): - Note that DMRQA WET samples can require test conditions that differ from our standard analytical process and *Laboratory guidance and whole effluent toxicity test review criteria,* DOE publication #WQ-R-95-80. Thank you for revising. This is good.

WAC 173-50-070 Proficiency testing - (7): KCEL suggests edits added in red. *When two or more approved PT providers are available for a parameter in the appropriate matrix, the laboratory must analyze and pass a PT to gain or maintain accreditation*. Thank you for revising. This is good.

WAC 173-50-70 Proficiency testing (8, presence-absence): KCEL does not necessarily disagree with LAU's sentiment that lab's should be able to pass at 100%. **However,** this verbiage would

now be in disagreement with EPA's Manual for Certification of Laboratories Analyzing Drinking Water 5th ed. as stated in Section 7.2. Therefore KCEL requests that you delete this proposed language. **Why?** It is a laboratory's nightmare to serve multiple conflicting jurisdictions. Laboratories should have only place to go to determine passing criteria, and clearly this falls to EPA to dictate the terms of passing proficiency tests.

WAC 173-50-80 On-site audit 4(b): KCEL requests clarification as to whether LAU is requesting data for every single method or just the ones it will focus in on for the audit. It is doubtful the LAU would have time to review all accredited methods for a large laboratory even with a 2 week window and it takes time on the part of laboratories to put these requests together.

KCEL also seeks clarification as to what is in the data package? Is this raw data, associated calibration curves, etc.

KCEL recommends putting this type of verbiage in the Procedural Manual. **Why?** Then this type of information can be updated more frequently and as needed. For instance, you may find that 2 weeks is not enough, and yet you'd be held to a now codified 2-week WAC standard.

WAC 173-50-80 On-site audit 4 (c): Please provide representative examples of what additional documentation may be. KCEL recommends putting this type of verbiage in the Procedural Manual. **Why?** Then this type of information can be updated more frequently and as needed.

WAC 173-50-120 Accreditation categories - section 3: Did this section get deleted on purpose? No longer see it in the revised addition. : KCEL strongly requests that LAU consider accrediting labs for the SW-846 methods under the Non-Potable Water matrix. **Why?** Liquid matrices are explicitly allowed in EPA SW-846 methodology. The current practice of listing those methods only under Solids and Chemical Materials makes it very difficult to determine if a lab is actually accredited for testing water samples using SW-846 methods.

If LAU decides not to take this step, it should revise WAC 173-50-070 (Proficiency testing) to clearly indicate that for the SW-846 methods to be applicable to non-potable water, the lab must analyze Non-Potable Water PT samples along with Solid PT samples. This would clarify what needs to be done to be able to use SW-846 methods for both types of matrices.

Also, the LAU appears to be using the NELAC designations for accreditation, but the LAU maintains that the lab accreditation program is not part of NELAC. Why not sever the appearance of being part of NELAC? At a minimum, LAU should put in the Procedural Manual how to get accredited for non-potable water using SW-846 methods and to list those accreditations on the lab's WDOE accreditation listing both on-line and on paper.

WAC 173-50-140 Denying accreditation: (2) "A laboratory may be denied accreditation for a specific parameter for *unsatisfactory* proficiency testing results." KCEL recommends changing the term parameter to analyte in order to be on par with the fee schedule and the fact that LAU may just deny one analyte within the WAC defined "Parameter".

KCEL requests clarification of the term "unsatisfactory" and how it relates to denial of accreditation. It implies that labs could be denied accreditation for missing a single PT result. Also, please consider using the term "unacceptable PT sample result", which is consistent with PT vendor reports. Can you specifically describe how many PTs you can miss and how many you need to pass in a row to restore full accreditation?

Thank you for changing from "unsatisfactory" to "unacceptable". KCEL respectfully requests that you change to this term throughout the entire document.

WAC 173-50-190 Fee Structure, Table 1: Please clarify how the agency will assign fees for bioassay parameters that may require multiple test organisms under one analytical method. For example, the PSEP 1995 Bioassay protocols requires the use of 1 of 3 amphipods based on sample grain size and salinity; will accreditation and fee structure be based on the single PSEP method or based on each individual organism? The PSEP Echinoderm method also requires multiple organisms under one analytical method based on seasonality of the test organisms.

WAC 173-50-190 Fee Structure, (4 and 6): KCEL wonders if there is an inconsistency between (4 and 6). Under (4), the word three is struck out and five has been added. But in (6), the word three has been added. We wonder if LAU meant five.

KCEL sincerely thanks WDOE LAU for the invitation to comment. Please don't hesitate to get in touch if you have questions about what we have written. You may contact:

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Tacoma Environmental Services Laboratory

The City of Tacoma Environmental Services Laboratory offers the following comments regarding Lab Accreditation Rulemaking in the proposed changes to WAC 173-50:

WAC 173-50-040 Definitions., p.8

Tacoma ES_Lab suggests the following edits:

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

WAC 173-50-060 Responsibilities of environmental laboratories. Item (2), p.15

Tacoma ES_Lab suggests the following edits:

(2) For laboratories to be accredited for drinking water parameters, the laboratory must follow requirements designated in the current approved drinking water certification manual.

WAC-173-50-061: Required Quality Control Practices item (2), p.16

Comment: Midpoints should be allowed to be removed if there is a demonstratable error with the preparation/injection and the point is removed for ALL analytes in the calibration.

Tacoma ES_Lab suggests this section read:

A laboratory must not remove any midpoints from a calibration curve with the exception of consecutive points at either end of the curve OR there is a demonstratable error with the preparation/injection and the point is removed for ALL analytes in the calibration.

WAC-173-50-061: Required Quality Control Practices item (3), p.16

Comment: This language is confusing and appears to be missing some words.

Tacoma ES_Lab suggests this section read:

Unless otherwise specified in the method, each calibration point must have its percent error meet the calibration verification acceptance limits from the method; with the exception *of* calibration points at or below the LOQ, it which case ~~where~~ the limit is 50-150%.

WAC-173-50-061 Required Quality Control Practices item (4), p.16

Tacoma ES_Lab recommends removing this section because standard calibration acceptance criteria (including the standard at the limit of quantitation) is covered in the preceding section (3).

Note: The word "standard" is not defined in the definitions section and we read this with the understanding that the term "standard" as used here is synonymous with "calibration point" used in item (3) in this section, assuming a "calibration point" is one the "series of solutions of known analyte concentrations…" that make up a "Calibration Curve".

WAC-173-50-061: Required Quality Control Practices. Item (6), p.17

Consideration should be given to analyses with multi-component analytes for example, PCB aroclors, or toxaphene.

Tacoma ES_Lab suggests the following edit:

(6) For single component analytes, Laboratory control samples and matrix spikes must include all analytes of interest in the respective analysis, unless there are method specified exceptions.

WAC-173-50-061: Required Quality Control Practices. Item (7), p.17-18

Tacoma ES_Lab requests that this section be removed.

This section is confusing, contradicts other EPA method guidance, and is not consistent with some of our Ecology approved project specific requirements for demonstrating NPDES compliance. It too broadly stated and will unnecessarily sensor useful information.

WAC 173-55-069 Data and record traceability. (should be WAC 173-50-069) Item 1 (d), p. 20

Tacoma ES_Lab suggests the following change:

(d) Document that all temperature-based equipment such as a refrigerator, oven, or incubator is both within control ~~and checked manually~~ as required by the relevant method; and

Reason: The only way to properly "Document" that these items are operating within control is to check them and record the data. This can be accomplished with a digital logger or manually writing down the value at the date(s) times required to demonstrate "control". Tacoma ES_Lab recommends removing "and checked manually" from this sentence because it is not necessary.

WAC 173-55-069 Data and record traceability. (should be WAC 173-50-069) Item 1 (c), p.20

Tacoma ES_Lab suggests the following change:

(c) Document proper storage of samples and sample extracts as required by the specific method;

WAC 173-55-069 Data and record traceability. (should be WAC 173-50-069) Item 1 (e), p.20

Tacoma ES_Lab suggests the following change:

(e) Keep a log~~books~~ for any and all instruments, including documentation of installation, setup, maintenance, and removal from service.

Reason: By removing "books" from the word log this more clearly allows either a hand-written record in a logbook or an electronic record aka an electronic log. *Note that item 2 in this section states "When records are hand-written,…" – the key word to us is that electronic records are acceptable since the first word in this sentence is "when" which implies there is a when not. This is reinforced in item (3) in this section that states "When records are kept electronically,…"*

WAC 173-55-069 Data and record traceability. Item (3), p20-21

Tacoma ES_Lab suggests the following edits:

(3) ~~When records are kept electronically~~, Electronically captured records ~~they~~ must include the date and time the record was captured~~. be populated at the time of record~~, using a fully traceable and secure format. Use of continuous data-loggers is not an acceptable substitute ~~for~~ where method-required temperature checks must be performed manually.

WAC 173-50-070 Proficiency testing (PT). Item (7), p.22

Tacoma ES_Lab suggest the following edits:

(7) When two or more approved PT providers ~~are~~make available a PT sample for a parameter in the appropriate matrix, the laboratory must analyze and pass a PT to gain or maintain accreditation.

WAC 173-50-140 Denying accreditation. Item (2), p.36

Tacoma ES_Lab suggest the following edits:

(2) A laboratory may be denied accreditation for a specific ~~parameter~~ analyte in a matrix for ~~unsatisfactory~~ unacceptable proficiency testing results.

WAC 173-50 Proposed Rulemaking Comments

Eurofins Seattle

June 2023

WAC 173-50-061 (2)(a), pg. 4

Comment: Middle calibration points should be allowed for removal if there is documented and demonstrable error with the injection or standard preparation. E.g. incorrect concentration prepared, internal standard inadvertently omitted, or instrument autosampler malfunction.

Suggested verbiage: "A laboratory must not remove any midpoints from a calibration curve with the exception of consecutive points at either end of the curve, unless a significant error occurred with the standard preparation or sample introduction, and the error is documented and calibration point is excluded for all analytes."

WAC 173-50-061 (3), pg. 4

Comment: Need clarification on the 50% of true value check on LOQ. "…laboratories must analyze a

standard at their limit of quantitation at least annually. This standard must meet 50 percent of the true value." This could be interpreted as 50% of true value or greater with no upper limit. Should it be +/- 50% of true value?

WAC 173-50-069 (1)(d), pg. 6

Comment: Allow for either automated or manual checks, as long compliant with method or WA rules. Automated, continuous monitoring should be allowed if not otherwise restricted by method or by WA, such as in WAC 173-50-069 (3) regarding incubators.

Suggested verbiage: "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;"

WAC 173-50-190 Table 2&3, pg. 13

Comment: Difficult to understand what "Per Parameter Add Fee to Existing Method" column means. Suggest adding a section or footnote to explain the changes from Table 1 to Table 2, namely in regard to the aforementioned column.

WAC 173-50-190 (11), pg. 14

Comment: Clarification requested. In the following statement, does “reinstate a parameter” include returning parameter from suspension or just revocation?

“If a laboratory requests to add or reinstate a parameter to their scope of accreditation outside of their initial application or renewal process, the laboratory will be invoiced a fee based on the type and number of requested parameters, per Table 1, Table 2, Table 3, or as updated by Equation 1.”

As such, if a parameter is suspended for 2 failing PTs, is a fee required to reinstate that parameter after a passing PT is achieved?

WAC 173-50-061 (5), pg. 5

Comment: Spiked control samples should account for exceptions for multi-component analytes, such as PCBs.

Suggested verbiage: “Laboratory control samples must include all analytes of interest in the respective analysis, unless method exceptions are specified.”

Thanks for your consideration!