

## 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 5<sup>th</sup> 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 to 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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