Will Accrediting Authorities allow PT Providers to reissue a result report if the lab identifies a reporting problem?

Sponsor: Bill Hall

Resolution: Accrediting Authorities will not accept re-issued reports from PT Providers unless the re-issued report was to correct a mistake made by the PTP.

NELAC 2003 - 5.5.8.3.1 Sample Receipt Protocols

What is required for the documentation of sample temperature? Can labs use a temperature blank, sample surface temperature, spot check a sample, or must they measure temperature in every container?

Sponsor: Scott Siders

Resolution: Laboratories must describe their policy for determining temperature of the samples and as long as it is scientifically sound and being followed, the procedure would be accepted.

Method Edition

Is it required that the method edition be tracked by the lab and the accrediting authority?

Sponsor: Steve Arms

Resolution: The specific edition of the method that a laboratory requests for accreditation and employs must be included with the reference number. The laboratories may need to be accredited for several method editions. Accreditation for separate editions will be tracked by the accrediting authorities. Laboratories are reminded that it is their responsibility to use the correct edition of the method as determined by the client.

NELAP Accrediting Authorities' (AA) Policy and Implementation of Section 2.5 of the NELAC 2003 Standard, Policy Revision 4

Performance Testing (PT) Samples must be Analyzed as Routine Samples.

Sponsor: Mike Miller

Section 2.5 of the NELAC standard states the following:

"**The samples shall be analyzed and the results returned to the PT Provider no later than 45 calendar days from the opening of the study (i.e. first day that samples are shipped or available to laboratories). The laboratory's management and all analysts**

shall ensure that all PT samples are handled (i.e., managed, analyzed, and reported) in the same manner as real environmental samples utilizing the same staff, methods as used for routine analysis of that analyte, procedures, equipment, facilities, and frequency of analysis.

> **When analyzing a PT sample, a laboratory shall employ the same calibration, laboratory quality control and acceptance criteria, sequence of analytical steps, number of replicates and other procedures as used when analyzing routine samples".**

NELAP Accrediting Authorities (AA) shall assess the laboratory's compliance with the requirements of this section of the standards during data review and on-site assessments. The laboratories shall be penalized for violations in accordance with the NELAC standards and the AA's due process rules.

The AAs at a minimum will check for the following:

1. PT samples are entered into the laboratory sample receipt log as samples and are tracked through the laboratory as routine environmental samples. The laboratory records used to track PT samples (e.g., chain-of-custody) can be initiated by laboratory personnel such as the Quality Assurance Officer.
2. PT samples received as ampules are diluted according to the PT provider's instructions. The diluted PT sample becomes the routine environmental sample. The sample is added to a routine sample batch.
3. Sample Preparation for PT samples (e.g., digestion or extraction) is the same as for routine environmental samples.
4. Instructions shall be included in the laboratory's standard operating procedure (SOP) for how low level samples will be analyzed, including concentration of the sample or adjustment of the normality of a titrant. Theses instruction shall be followed when the concentration of a PT sample falls below the range of their routine analytical method. Instructions shall be included in the laboratory's SOP for how high level samples will be analyzed, including preparation of multiple dilutions of the sample. These instructions shall be followed when the concentration of a PT sample falls above the range of their routine analytical method.
5. PT samples that consist of a set of individual samples (e.g., microbiology PTs) shall be analyzed according to the laboratory's routine procedures.
6. PT samples shall not be analyzed multiple times unless routine environmental samples are analyzed multiple times. Results from multiple

analyses must be calculated in the same manner as routine environmental samples.

7. The type, composition, concentration, and frequency of quality control samples analyzed with the PT samples shall be the same as with routine environmental samples.
8. Initial and continuing calibrations shall be at the same frequency as with routine environmental samples.
9. The PT Provider requirements for reporting PT results to the PT Provider are different than the requirements for reporting routine sample results. The laboratory shall have directions in its SOP on how to meet the requirements of the PT Provider for reporting PT results.
10. The AA must make a documented determination when exceptions to any of these requirements are applicable on the basis of the laboratory's routine environmental sample composition and SOPs.

Any AA that finds a PT Provider directing or suggesting that laboratories use additional QC, offering QC samples that are specifically designed for a given PT, or providing instructions beyond sample preservation and preparation of Pt samples from ampules, shall report the actions to the NELAC PT Board with documentation.

NELAC 2003 2.5 PT Samples

What action should the lab expect from the AA if it fails to treat PT samples in the same manner as environmental samples?

Sponsor: Ken Jackson

A deficiency will be noted whenever a laboratory treats PT samples differently than environmental samples, as outlined in the policy. If the deficiency is repeated, systemic, or serious, the AA will fail that PT study for all affected PT Fields of Testing. This could result in the laboratory being suspended for that PT FOT.

NELAC 2003 D.1.1.2.1.e – Marginal Exceedances

Must a laboratory qualify analytes meeting the criteria for marginal exceedance?

Sponsor: Steve Arms

Resolution: The standard allows the laboratory to have results for a small portion of analytes in the LCS, number is dependent on total number of target analytes, that fall between 3 and 4 standard deviations for which no corrective

action is required. While the laboratory is not required to perform corrective action it is expected that these analytes will be appropriately qualified in the final report

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.**NELAC 2003 5.5.2.6.c.3 – Personnel Records**

What records are required for documentation of Demonstration of Capability and Demonstration of Continued Proficieny?

Sponsor: Steve Arms, SRC

Resolution: Documentation for the initial Demonstration of Capability must be recorded on the form as provided in Chapter 5, Appendix C. A specific form documenting Continued Proficiency is not required. What is needed in the file, as a minimum, is the information to trace how the laboratory determined that the analyst met the standard for continuing proficiency. This must include the acceptance limits used, calculations and identification of the source of raw data.

NELAC 2003 5.5.2.6 – Demonstration of Capability

Are Demonstrations of Capability or Demonstrations of Continuing Proficiency for Drinking Water and Non-potable Water interchangeable?

Sponsor: Steve Arms

Resolution: Although Demonstrations of Capability are normally performed on laboratory pure water for both Drinking Water and Non-potable Water, the standard requires that they be taken through the exact steps as samples. Laboratories are required to document the method or SOP followed. In cases where the SOP covers both Drinking Water and Non-potable Water, a single demonstration can be used so long as the results meet the required acceptance limits for each program.

NELAC 2003 5.5.4.6 - Estimation of Uncertainty of Measurement

The interpretation of the standard is that though the laboratory is not expected to calculate uncertainty for every result, they are required to have a procedure in place and they expected to identify the sources of uncertainty for things over which they have control. Members of the SRC felt that this issue is not clear enough in the standard and guidance is needed for the laboratories in the form of a clearer interpretation.

Sponsor: Steve Arms, SRC

Resolution: At this point, Accrediting Authorities will not be prescriptive but will be looking for the laboratory to have a procedure for determining uncertainty that is scientifically defensible. Links to resources that provide procedures for the determination of uncertainty will be posted on the web.

NELAC 2003 D.3.1.a.4 and D.3.1.b.1 – Sterility Checks and Blanks

Can Microbiological QC testing of media and container lots be sent out to a contract lab?

Sponsor: Steve Arms

Resolution: It was agreed that the intent of the standard was that the laboratory must perform all the QC tests for methods in their scope of accreditation.

NELAC 5.4.12.2.5.3 – Analytical Records

Are laboratories required to have run logs for every analysis?

Sponsor: Dan Hickman

Resolution: "5.4.12.2.5.3 The essential information to be associated with analysis, such as strip charts, tabular printouts, computer data files, analytical notebooks, and run logs shall include:"…

The standard includes run logs as an example of the records that an assessor might look at. The standard does not require any specific type of formal run log, however, as long as the samples and QC in the batch can be easily identified, grouped and linked to the raw data. It was clear that the assessors believe that run logs make the assessment go much easier and quicker and recommended that these be kept by the laboratory.

20th Edition Standard Methods 1090H

Method requires that all biological waste be autoclaved. Is the laboratory required to do that in-house or can they send it out for sterilization?

Sponsor: Steve Arms

Resolution: Laboratories may sterilize the waste in-house or use a waste disposal service to sterilize their waste. They must maintain documentation to show that the biological waste has been sterilized prior to disposal.

Policies and Procedures

Are policies and procedures different and must they always be documented?

Sponsor: Steve Arms

Resolution: Policies describe generally what is being done where procedures describe the specifics of how it is being done. Policies and procedures need only to be documented if the standard, method, or regulation requires specific documented policies or procedures. AAs may require labs to document other

policies and procedures if it is clear that non-documented ones are not being uniformly followed.

NELAC 2003 5.4.12.5.3.i, 5.5.6.4.c, 5.5.6.4.d – Reagent Traceability

Since it was the intention of the NELAC Chapter 5 committee to remove the requirements for reagent traceability, can NELAP make an editorial change to the standards to remove that requirement?

Sponsor: Lara Autry

Resolution: The standard language that was voted on and approved included the requirements for reagent traceability. This is not an editorial change and would require a new standard. There was no support to move forward with that request. AAs will continue to require reagent traceability.

NELAC D.1.1.1 – Negative Control

What action must the laboratory take when some samples in a batch are affected by a contaminated blank?

Sponsor: Dave Mendenhall

Resolution: The section of the Chapter was written for method or "batch" QC. As such it meant that any failure of a QC component made the batch invalid and required reprocessing [or at least qualification] of all samples in the batch.

Earlier standards emphasized that “each method blank must be critically evaluated as to the nature of the interference and the effect on the analysis of each sample within the batch.” The 2003 standard was revised by adding D.1.1.1.d.3 to clearly allow the lab to make a determination on individual samples within each batch.

The blank is considered contaminated when the concentration is both above the laboratories reporting limit **and** 1/10 or more of the value of the lowest concentration measured in any sample in the batch. –**OR** - The blank contamination measured at any level is described in the method used or in the data quality objectives with which the laboratory is working, as affecting the samples.

When the blank is considered contaminated as defined in D.1.1.1.d.1 or 2), each sample in the batch must be evaluated for the best course of action which may be reprocessing, reporting with a qualifier, or any other action determined by the laboratory. As an example, samples in a batch with a contaminated blank, with a measured value more than ten times the blank measurement may or may not be qualified or reprocessed. The required action is determined by the laboratory’s Quality System. The, decisions about each sample, and ultimate action must be

documented. The investigation into the contamination must lead to measures to eliminate or minimize the cause of the contamination.

Standard Methods 5210B - cBOD Acceptance Limits

Is the laboratory required to meet the control limits given in Standard Methods for GGA (198 +/- 30.5 mg/L) when performing the Carbonaceous BOD test

Sponsor: Steve Arms

Resolution: If a laboratory is conducting the analysis for CBOD following method 5210B found in the 20th Edition of Standard Methods, then the analyst may over-seed the Glucose-Glutamic Acid (GGA) standard as allowed by the method, but the results must be within the range 198 +/- 30.5 mg/l to be considered acceptable. The laboratory may either meet the above criterion as the acceptance range for GGA recovery, or has the option of developing its own acceptance criteria for GGA recovery under the conditions described below:

1) The dissolved oxygen uptake from the seed contribution should be between 0.6 - 1.0 mg/l.
2) In establishing in-house GGA control acceptance limits, the laboratory must use accepted statistical treatments of in-house data for no less than 25 GGA checks over a period of weeks or months (Standard Methods 5210B 6.a.).
3) The control limits established by the laboratory must be set at three standard deviations from the derived mean. The relative standard deviation (RSD) must not exceed 7.5%. If the laboratory's calculated acceptance range exceeds 7.5% RSD, the laboratory must default to 7.5% RSD as its control limit range.

Any single GGA value determined by the laboratory cannot be less than 150 mg/l.

Clarification Comments

The 18th, 19th and 20th Editions of Standard Methods all allow for the laboratory to establish their own limits for BOD and CBOD, but only the 20th Edition addresses the quality control criteria for GGA in CBOD in Section 6 of method 5210B.

The laboratory must treat both the GGA standard and all related samples (including QC samples such as seed blanks and PT samples) in the same way. Evaluation of the various components under CBOD is a check on the inhibitor capacity and its effectiveness. The following terms are defined to help clarify the various components and requirements of the cBOD analysis.

- CBOD Seed Blank – bottle containing the same amount of seed that is added to the buffered dilution water for each sample plus the nitrification inhibitor.
- CBOD Seed Controls – bottle containing larger amounts of seed added to the buffer dilution water plus the nitrification inhibitor, which gives at least 2.0 mg/l depletion.
- CBOD Seed Contribution – the calculated amount of depletion from the CBOD Seed Control that has been rationed back to the amount of seed added to each sample.

LOD/LOQ and MDL

Are labs still required to determine MDLs since they are no longer mentioned in NELAC Chapter 5? It appears that the LOD and the LOQ have replaced the MDL and the PQL.

Sponsor: Lara Autry

Response: MDLs must be performed whenever required by program or by regulatory method. For EPA Office of Water the current procedure is found in 40 CFR Part 136 Appendix B.

Definitions for LOD and LOQ are not clear and need more work.

Dropping calibration points

Work Cell

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