NOTES

Update
Standard Interpretation

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Agenda

- Introduction
- Policies and Interpretations Review
- Open Questions

Objectives

- 2003 NELAC Standard
  - Interpretations / Discussion
Policies Interpretations

- AA Committee in 2005
  - FAQs - March 2006
  - See Attachment

PT Reports

- No re-issued reports accepted unless to correct mistake made by Proficiency Testing Provider

Sample Receipt Protocols

- NELAC 5.5.8.3.1
- Temperature - per lab procedure
- Any practice acceptable
  - Must be scientifically sound
  - How do you know?
Method Edition

- Lab Accreditation Requests Include:
  - Method number
  - Revision or edition number
- Tracked by Accrediting Authority
  - Lab may have several versions of sample method number
- Lab Must Select Correct Method

PT Data Review

- Assessors Must Check:
  - Lab must log in samples like routine
  - Dilutions are made per PT instructions
  - Sample prep must be the same as routine sample
  - Handling low and high level values in SOP
  - Samples handled as routine
  - Multiple analysis of PTs must be same as routine
  - QC frequency and type same as routine
  - Calibration same as routine
  - SOP on reporting PT results if different from routine

PT Data Review

- Assessor must report to AA and AA must report to PT Board if any of the following is found:
  - PT provider recommends use of extra QC
  - PT provider recommends instructions on preservation and preparation for PT samples
- If any exceptions are allowed by AA these must be documented
PT Failure

- Write Deficiency if any of the items are found
- If systemic, repeated or serious
  - Then fail all PT analytes for field of testing
  - Lab may be suspended for that PT

Marginal Exceedance (D.1.1.2.1.e)

- No corrective action required
- Report must identify exceedance

Personnel Records

- Demonstration of Capability (5.5.2.6)
  - Must include all steps as SOP
  - Must be on Appendix C form
  - Reagent water covers both DW and Non-potable
- Demonstration of Continued Proficiency (5.5.2.6.c.3)
  - No special form required
  - Show how analyst remains proficient
    - Acceptance limits
    - Calculations
    - Source of raw data
Uncertainty (5.5.4.6)
- Laboratory must have procedure that is scientifically defensible
- Resources available
  - measurementuncertainty.org

Uncertainty Estimation
- Uncertainty Procedures
  - Testing (5.5.1.1, 5.5.1.2, 5.5.4.1, 5.5.4.4, 5.5.4.5.2, 5.5.10.3)
- References:
  - GUM
  - ISO/IEC Guide 5725
  - Eurochem/Citac document (Chemistry)
  - A2LA - Policy for Life Sciences
    - Chemistry
    - Microbiology

Uncertainty

\[ \overline{X} \pm U \] 95% confidence level, \( k = 2 \)

Where,
\( \overline{X} \) = the mean of \( n \) measurements
\( U \) = the uncertainty
\( k \) = the coverage factor for a confidence level of approximately 95%
Assessment Procedure

- Review Procedure
  - Are calculations documented?
  - What is the reference for this procedure?

- Review Data
  - Are all components included in the data?
  - Are calculations correct?
  - Does the data make sense?

Microbiology (D.3.1.a.4 and D.3.1.b.1)

- Media checks and container lots
  - Must be performed by lab
  - Do not contract out

Analytical Records (5.4.12.2.5.3)

- Run logs are not required
- Examples are presented in standard
- Helps the assessor, but not required
Biological Waste Disposal

- 20th edition SM 1090H
  - Requires autoclaving of biological waste
- May be in-house or contracted to waste disposal service
- Documentation of sterilization required prior to disposal

Policies and Procedures

- Policy
  - General description of what is to be done
- Procedure
  - Specific description of what is to be done
- Documented if required by standard, method or regulation
  - If practice is not uniformly followed assessor may write finding on need to document procedure

Reagent Traceability

- Must be documented as in the past
  - Standard change did not remove the requirement
  - 5.4.12.5.3.1, 5.5.6.4.c and 5.5.6.4.d
Negative Control (D.1.1.1)

- Batch control versus sample specific
  - Lab must take corrective action
  - Lab must document determination as applied to each sample


cBOD Acceptance Limits

- Standard Methods 5210B 20th edition
  - Develop in-house limits
    - At least 25 points (5210B 6.a)
    - Seed contribution 0.6 to 1.0 mg/L
    - RSD must be less than 7.5% or used as the default.
    - GGA must be > 150 mg/L
    - All QC must contain inhibitor


LOD and LOQ

- Office of Water data
  - MDL is LOD (not really - but...)
  - PQL is LOQ (not always - but....)
- These terms need clarification
- Does laboratory have records of evaluation of Lod or LOQ?
Open Questions

Do you have any questions about the NELAC standard?

Appendix C

Demonstration of Capability

- Analyst
- Method
  - Evaluation

Appendix D

On-going Demonstration

- Method performance
  - By Category
  - Defines Section 5.5.9.2
  - Essential quality control
**Audit Report Consistency**

- Variable level of detail in audit reports from assessors
- “The laboratory’s analytical data does not indicate that the quality control protocols in the test methods manual are being followed (e.g., EPA 375.4).”
  - What does this mean?
  - What corrective action must be taken?
  - What else should be stated?

**Management Review**

- Finding: The laboratory does not have in place in which the work of the quality manager is reviewed. The laboratory shall develop a plan for independent review of the work of its quality manager and submit that plan for review.
  - Is this a NELAC requirement?
  - Some labs say no - How do you defend?

**Internal Audit**

- What records do you observe for a internal audit?
- What must be audited?
- How often?
SOP Review or Update

- Is each SOP signed to indicate annual review?
  - If yes, why?
  - If no, why?
- Does every SOP have to be updated (new rev #) once per year?

Preventive Action

- NELAC requirement: If preventive action is required, action plans shall be developed, implemented and monitored to reduce likelihood of reoccurrence. Procedures for preventive action shall include initiation of such actions and application of controls to ensure they are effective
  - Is this the requirement?
  - What actions are required?
  - What are the documentation requirements?
  - Is an SOP for preventive actions required?

Corrective Action

- What records do you review?
  - What do you expect to see in the records?
- How do you evaluate the effectiveness of the corrective action program at the laboratory?
Quality Control Samples

- "Environmental sample" definition
- QC sample definition
- QC requirement for metals
  - What matrix for solid metals?
    - SRM, glass beads, Teflon chips, etc.
- QC acceptance windows
  - SRM's, lab established, method
- Method blanks required for "all" tests
  - paint filter test, ignitability, TCLP

Method Blank

- NELAC requirement:
  - data must be qualified if concentration of any analyte in the blank is above the reporting limit AND greater than 1/10 of the amount in the sample or
  - the blank contamination otherwise affects the sample results as per method requirements or project data quality objectives
- When is the blank contaminated?
- How and when is a blank qualified?
- When is corrective action taken?

Manual Integrations

- What are the documentation requirements for manual integrations?
- What are "correct" manual integrations?
- What is the required training and SOP content? (i.e., not enough examples in training or SOP, disagreement with examples given, etc.)
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NOTES

MS/MSD Failures

- Is the MS/MSD prepared every 20 samples or analyzed every 20 samples?
  - NELAC requirement?
- If the MS is analyzed or prepared every 10 samples – does it meet the MS/MSD requirement for every 20 samples?
  - Does the MSD qualify as a matrix spike?
- How is the MS/MSD failure handled in the final report when they are performed on another client’s sample?

Demonstration of Capability

- Is DOC required for TCLP/SPLP?
  - Is measurement uncertainty required for TCLP?
- Are ongoing LCS results sufficient?
  - What if not on-going LCS available?
- Is an MDL study sufficient to meet requirements of DOC?

Questions/ Answers

- Any questions?