NOTES

Update
Standard Interpretation

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August 2007

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Agenda

- Introduction
- Policies and Interpretations Review
- Open Questions

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Objectives

- 2003 NELAC Standard
  - Interpretations / Discussion

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NOTES

Policies Interpretations

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

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PT Reports

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

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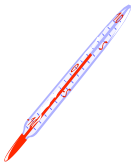
Sample Receipt Protocols

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



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NOTES

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

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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

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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

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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

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Marginal Exceedance (D.1.1.2.1.e)

- No corrective action required
- Report must identify exceedance

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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

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Uncertainty (5.5.4.6)

- Laboratory must have procedure that is scientifically defensible
- Resources available
  - measurementuncertainty.org

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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

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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%

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NOTES

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?

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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

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Analytical Records (5.4.12.2.5.3)

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

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NOTES

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

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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

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Reagent Traceability

- Must be documented as in the past
  - Standard change did not remove the requirement
  - 5.4.12.5.3.I, 5.5.6.4.c and 5.5.6.4.d

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NOTES

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

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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 $\geq$ 150 mg/L
  - All QC must contain inhibitor

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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?

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Open Questions

- *Do you have any questions about the NELAC standard?*

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Appendix C

- Demonstration of Capability
  - Analyst
  - Method
    - Evaluation

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Appendix D

- On-going Demonstration
  - Method performance
    - By Category
    - Defines Section 5.5.9.2
      - Essential quality control

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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?

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Management Review

- Finding: The laboratory does not have in a system 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?

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Internal Audit

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

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NOTES

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?

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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?

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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?

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NOTES

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

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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?

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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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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?

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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?

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Questions/ Answers

- Any questions ?

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