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Issues from a Panel of Network Laboratories

(How do we advance assessment consistency?)


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Laboratory Network Panel

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Topic 1

Inconsistency in Audits

Charlie Carter

Depth, Breadth, and Rigor

- Largest variable both within and between States
- On site portion
  - 0.5 person days to 12 person days
- Highly literal review of each method versus review of systems
- Variation in attention to detail and completeness
- Different state programs and different personalities

Solutions

- Fundamentally change human nature
  - Too invasive
- One auditor for the entire country
  - Impractical
- Improved feedback system
  - Centralized to allow meaningful comparisons and protect confidentiality

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Focus on Strengths

Those awkward moments

Potential Solution

- We tend to audit to our strengths
  - Human nature
- DOE approach
  - Cross site variation in audit staff
  - Develop both consistency and depth
  - Potential administrative barriers

Attention to Specific Areas

- Data handling and reduction
  - 0% to 70% of on site audit effort

What is a Demonstration of Capability?

- Are they required for TCLP/SPLP?
- Are ongoing LCS results sufficient?
- Is an MDL study sufficient?

Audit report consistency

- Variable level of detail in audit reports.
- “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, and how do we respond?
- Solution – cite appropriate standard and reference, but provide sufficient detail to describe the specific issue.

Does consistent = good?

- Is there value in variation?
- US Air
  - Consistently late
- Avis in Philadelphia
  - Consistently rude
- Jack in the Box
  - Consistently inedible

Summary

- Common standard with different implementation schemes and different auditors
- Feedback database to track audit and auditor depth, breadth, and rigor
- Program to frequently share staff between accrediting authorities

Topic 2

Method Inconsistency

Dave Speis

Method Inconsistencies: Discussion Premises

- Accutest is a Four Facility Network
- Each Facility Carries Primary Accreditation in an Active NELAC State
- The Accrediting Authorities Have Sizeable Staffing (Rotating Intra-Lab Assessment Teams)
- Opportunities for Inter- and Intra-Laboratory Inconsistencies Exist

Method Inconsistencies

- Prep Method Review & Accreditation
  - Audit Process & Certificate Management
- Continuing Calibration Verification Requirement
  - Internal vs. External Std. Methods & Frequency
- MDL Study Qualification
  - Spike Accuracy Specifications, Corrective Action & Applicability

Method Inconsistencies

- Personal Interpretations
  - Existing Requirements, Non-Existent Requirements
- ICP Calibration Variation
  - Points Used, Data Qualification
- SOP Style
  - Listing Target Analytes, Dwelling on Style, Repetitive Edits

Topic 3

Interpretations of QC and NELAC Standard

Gary Ward

Quality Control Samples

- **"Environmental sample" definition - QC sample status**
- **QC requirement for metals – SRM, glass beads, Teflon chips, etc.**
- **QC acceptance windows – ie. SRM's, lab established, method**
- **Method blanks for "all" tests – ie., paint filter test, ignitability**

Quality Control Samples – Blank Contamination

- **Negative control procedures for reporting and reprocessing samples when blank contamination is present**
- **Failure of primary to recognize compliant systems**
- **Laboratories may define blank contamination as at the Method Detection Limits**

Quality Control Samples

- **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**

- **Since reporting limit is always greater than or equal to the MDL, considering blank contamination exceeds NELAC requirements**

Uncertainty

- **Uncertainty statements**
- **Uncertainty calculations**
- **Uncertainty requirements**

•NELAC requirement: reports shall include where applicable, a statement on the estimated uncertainty measurement; information on uncertainty is needed when a client's instruction so requires.

Preventative Actions

- What actions are required
- Varying documentation requirements
- SOP for preventative actions required or not
- NELAC requirement: If preventative action is required, action plans shall be developed, implemented and monitored to reduce likelihood of reoccurrence. Procedures for preventative action shall include initiation of such actions and application of controls to ensure they are effective

MS/MSD Failures

- **MS/MSD prepared every 20 samples or analyzed every 20 samples**
- **Matrix spike analyzed or prepared every 10 samples – does it meet the MS/MSD requirement for every 20 samples**
- **One state says the MSD does not qualify as a matrix spike**
- **Inconsistencies on how to handle MS/MSD failures in final report when they are performed on another client's sample**

Management Reviews

- **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.**

- **Not a NELAC requirement**

- **NELAC requirement: laboratory's executive management shall periodically and at least annually conduct a review of the laboratory's quality system and environmental testing activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements**

Manual Integrations

- **Inconsistent documentation requirements**
- **Inconsistent interpretations of “correct” manual integrations**
- **Inconsistent interpretations of required training and SOPs (ie., not enough examples, disagreement with examples, etc.)**

Next Steps

Thank You

Have a great day!