Common Laboratory Assessment Findings

A Presentation at the TNI Assessor Forum

by

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Introduction

- This is simply a list of Common Assessment Findings provided by …
  - State assessors (NELAP and non-NELAP)
  - Several accredited laboratories
  - AEX's assessment experiences
- They are in no particular order (except my bias)
- Information contained is from assessments predominantly in 2005 and 2006

Introduction

- It is not my job to defend the findings, just to share the information.
- Findings have been paraphrased and combined for the purposes of this presentation.
- NELAC Standard citations have been removed.
- This is only a sampling of material.

It is an opportunity for all stakeholders to clarify, interpret and communicate to foster consistency.

Why Is This Information Important?

An Opportunity for Continuous Improvement

- Laboratory Perspective: Preventive Action
  - Areas to focus continuous improvement efforts
- Assessors Perspective: Program Development
  - Evaluation of Assessor procedures and areas of focus
- TNI Perspective: Guidance and Training Development
  - Areas for consideration in planning upcoming training and document/tool development

Lessons learned from others' experience

Introduction

- NELAC is a complex and detailed set of requirements.
- However, there are some common themes.
- It's important to understand that laboratories have a wide breadth of experiences with the Standard, from several rounds of audits to no previous audit experience.
- Should not be viewed as laboratories performing poorly.

Some Common Themes…

- The findings seem to fall into major buckets:
  - Document Control and Record Keeping
  - Following Published Methods
  - Following SOPS
  - Sustained Implementation by Management
  - Training and Competency
  - Implementing a Data Integrity Program
  - Effective Corrective Action (Repeat Findings)
  - Support Equipment
  - Reporting
  - And… the usual suspects… temperatures, balances and standards.

No Surprises…Right?

Quality System/Management Findings

- The Quality Manual is not reviewed annually or kept up-to-date.
- The laboratory does not consistently follow the requirements detailed in the Quality Manual.
- Annual internal audits have not been performed for all areas of the operation (i.e., support functions – project management, QA, report generation, etc.).
- The laboratory does not manage, track, and monitor corrective actions to ensure elimination of the problem.

Quality System/Management Findings

- LOD and LOQ verification procedures have not been addressed in Quality System documentation or verification practices implemented.
- Annual management reviews have not been performed.
- The laboratory does not have a procedure for estimating uncertainty of measurement.
- The laboratory does not routinely ensure that corrective actions from internal and external audits are implemented in the agreed upon timeframe.
- Corrective actions are not maintained after initial implementation (repeat findings).

Management Issues – PT Samples

- PT samples are not prepared and analyzed in the same manner as routine unknown samples.
  - Duplicate analyses
  - Consecutive analyses and dilutions
  - New calibration curves and standards
  - Known PT samples analyzed at the same time
- PT failure investigations have not been documented.
- PT failures are not reported to the Accrediting Authorities.

SOP Related Findings

- The SOPs do not accurately reflect current laboratory practice or contain sufficient detail specific to the laboratory practice.
- SOPs lack adequate information to perform the test method or lack sufficient detail for a similarly trained individual to duplicate the task.
- SOPs do not follow the current version of the published methods.
- SOPs are not reviewed on an annual basis.

SOP Related Findings

- SOPs do not contain or reference all of the steps in the preparation of samples and standards.
- Method modifications and deviations from the standard method are not clearly documented in the SOPs.
- Changes to the method are not clearly described. Findings include undocumented volume adjustments to standard and reagent preparations.
- The SOPs do not consistently establish requirements by the use of imperative language such as “shall” or “must” rather than conditional language such as “should” or “may”.

Training Related Findings

- Laboratory managers, QA managers, supervisors and analysts are not well versed in the 2003 NELAC Standard.
  - A significant number have not thoroughly read the Standard.
  - No formal or informal training is conducted by the laboratory.
- Training files are not current or are incomplete.
- The assessor was unable to determine which test analysis an analyst was trained and proficient to perform from the training records provided.

Training Related Findings

- The read and understand process is ineffective – some analysts signed off on documents (SOPs, Quality Manual), but the analysts are not well versed with the current versions of these documents.
- Some analysts have not read the published methods or been trained on the provisions and requirements of the current methods.

Basic Laboratory Training

- **Analysts are not sufficiently trained in proper basic lab practices and procedures. Examples include:**
  - Quantitative transfer of samples (bottle rinse, graduated cylinder rinse, K-D apparatus rinse)
  - pH measurement without contaminating the sample (strips dipped directly into the sample)
  - Mixing soil samples correctly prior to obtaining an aliquot
  - Handling the certified weights (weights placed directly on top of a dirty balances; weights being handled by analysts with an ungloved hand.)

Basic Laboratory Training

- **Analysts are not sufficiently trained in proper basic lab practices and procedures. Examples include:**
  - Accurately measuring sample volumes (handling mechanical micropipettes, glass volumetric pipettes, volumetric glassware)
  - Taking and recording temperature readings (applying temperature correction factors)
  - Adjusting reporting limits for reduced sample aliquots (volumes, reagents and dilutions)

Basic Laboratory Training

- **Analysts are not sufficiently trained in proper basic lab practices and procedures. Examples include:**
  - Sufficient understanding of the purpose, options, use and requirements for proper testing calibration
  - Removing interior calibration levels from initial calibration curves without proper technical reason
  - Proper use of calibration options, such as Quadratic
  - Sensitivity/noise and use of low calibration standards in chromatographic analysis

Data Integrity Policy Findings

- The data integrity program has not been implemented (with training and documentation).
- Annual signature evidence for each employee demonstrating that the employee has read, acknowledges and understands their personal and legal responsibilities…was not available.
- Annual training courses in ethical and legal responsibilities…are not provided for all staff.
- The Quality Manual does not define in detail the data integrity procedures including training, monitoring or documentation.
- Documentation of in-depth data integrity monitoring is not consistently followed.

Not Following Method Requirements

- Test analyses are not being controlled against method requirements (calibration, QC, reagents, procedural steps).
- Method-specific QC requirements are not included in the laboratory SOP and in analyst practice.
- The laboratory fails to add surrogates to all standards, samples, and QC for analyses in which surrogates are available.
- The laboratory does not demonstrate that it meets all requirements contained in a mandated test method or by regulation, even if the requirement is more stringent than the corresponding NELAC Standard.

Not Following Method Requirements

- Combined methods SOPs are in use but do not always follow the method specific criteria fully. Method specific acceptance criteria are not evaluated.
- SW846 methods are cited for NPDES samples (6010B vs. 200.7).
- Method 600 series analyses are being run as if Method 8000 series analyses.
- Reagent volumes are reduced, potentially changing the chemistry of the test sample preparation.

Not Following Method Requirements - Microbiology

- Sterility Checks - Laboratories are not checking sterility with a non-selective broth. They are usually using reagent water.
- Test Performance Verification - Micro test verifications are often skipped by laboratories, or they are trying to use alternate procedures for organism verification.
- Inhibitory Residue Test - Laboratories that wash and re-use glassware are not familiar with the requirement that this test be performed on an annual basis or when detergent type changes.

Computer System Findings

- Excel spreadsheet templates are not locked down or validated for accuracy.
- The password process is informal. The laboratory does not assign a unique password to each employee to track employee creation of, and alterations to, computer records located on the instrument data systems.
- There is no documented procedure for validation of in-house software including LIMS, network, or spreadsheets.

Document Control Related Findings

- The laboratory does not establish and maintain procedures to control all documents that form part of its quality system. Examples include:
  - Uncontrolled work instructions
  - Outdated versions of SOPs or Quality Manuals
  - Multiple versions of documented procedures or Quality Manuals in the laboratory
- The laboratory does not have a master list or equivalent document control procedure which identifies the current version status and distribution of documents.

Records Related Findings

- Incomplete records (COCs, analysis logs, benchsheets, checklists, etc.).
- Improper error correction techniques used.
- Not all logbooks and bench sheets are issued by QA and are controlled (have a unique ID).
- Failure to properly document "time" (i.e., time of analysis, wait time between [multiple methods]).
- Failure to document temperature when determining pH and dissolved oxygen. [Standard Methods]
- Log book reviews are not performed on a specified schedule as detailed in the Quality Manual.
- Expired standards were observed in the storage cabinet, not separated from standards currently in use.
- Standards are not properly labeled or traceable.

Support Equipment Findings

- Support equipment that isn't in working condition is not labeled as to its status. (Red Tag)
- Mechanical volumetric pipette and dispenser calibrations are not verified quarterly.
- Balances are not checked over specific range of use for an analysis.
- Instrument and equipment maintenance is not consistently recorded in the maintenance log book.

Sample Handling Related Findings

- Lack of unique number or identifier for individual sample containers.
- Samples, standards, reagents, and/or solvents incorrectly stored together.
- Cooler temperatures not taken in a manner representative of the shipping container.

Reporting Related Findings

- Data qualifiers not reported when QC fails.
- Page numbers and total pages not on reports.
- Reporting below the lowest standard (LOQ) without qualification.
- Reporting of non-NELAC accredited test results without flagging as such.

Summary

- Consistency is not an easy task to accomplish.
- The best approach is to share information and learn from each other.
- Let's take the opportunity for continuous improvement towards consistency.
- Now… it's your turn.