An Overview of Environmental Testing Laboratories’ Quality System and Data Integrity Programs

Raymond Frederici
Vice President of Quality and EHS
Presentation Topics

• What is a laboratory quality system and its purpose?
• What are typical QA/QC performed and their purpose?
• What is data integrity?
• What are unethical laboratory practices, what are the causes and how can it be prevented?
• What does laboratory certification mean?
• What are your risks in selecting a laboratory?
Quality Standards

- and ISO 17025 International Quality Standards for all types of Laboratories
- TNI- NELAP: Based on ISO 17025, U.S. National standard for Environmental Laboratories
Quality System

by ANSI/ASQ/NELAC

A structured and documented management system of an organization for ensuring quality in its work processes, products and services.

- Policies
- Objectives
- Procedures

- Authority
- Responsibility
- Accountability
- Planning
- Implementation
- Assessment
Quality System -
Element Examples

- Quality policy and objectives
- Organization and management structure
- Inter-relationship between management and technical operations
- Contract review
- Client feedback and corrective action
- Audits and data review
- Ensuring personnel have adequate experience and training
- Data integrity and ethics
- Data security
Quality Assurance vs Quality Control

Why should you care about laboratory QC samples? How do they impact the data?

**Quality Assurance (QA)**

The system of checks and balances designed to ensure data quality.

Examples include Quality Assurance Project Plan (QAPP), Lab QA Manual, Field Sampling Plan

**Quality Control (QC)**

The individual field or laboratory measurements that are used to determine data acceptability.

Examples include Field QC (FB, TB), Lab/Batch QC (MB, LCS/LCSD, MS/MSD)
Lab QC samples are prepared in the laboratory and accompany samples through all stages of extraction and analysis. They identify bias that may be present in the associated sample results.

**Method Blanks (MB)** are deionized (DI) water samples used to measure background contamination potentially introduced in the laboratory. A detection in the MB could indicate that samples were contaminated in the laboratory.

**Laboratory Control Samples (LCS)** are DI water samples to which a known concentration of target analytes is added. The LCS allows the lab to determine the recovery of target analytes from a sample free of interferences.

**Matrix Spike and Matrix Spike Dup (MS/MSD)** samples are environmental (client) samples to which a known concentration of target analytes is added. The MS/MSD samples provide insights into possible matrix interference.
Blanks – Control For False Positives

Field Blanks, Equipment Blanks, and Trip Blanks

- Measures contamination from sampling and transportation

Method Blanks (lab)

- Processed with, and under same conditions as, samples through all steps of the analytical procedures
- Measures background laboratory contamination

Why Run Them?

- Demonstrates the absence of contamination
- Do we see analytes in the blanks even if they are not in the sample?
Dilutions are performed when the concentration of an analyte exceeds the upper limit of the calibration range of an instrument. Diluting a sample in the laboratory reduces the concentration of the sample, allowing it to be analyzed and quantified. Without dilutions, results can not be accurately reported.

After performing a dilution in the laboratory, a dilution factor (Dil Fac) is applied to the result and the MDL/RL to reflect the actual concentration of the analyte.
Duplicates

**Sample Duplicate:** The analyses of two laboratory selected subsamples of the same sample location or colocation to measure the method precision and sample homogeneity

**Field Duplicate:** The analyses of two field selected subsamples of the same sample to measure field precision and sample homogeneity
Field Duplicates?
Definition: Organic compounds that are similar in chemical composition & behavior as the chemicals of concern in the sample
  • These compounds are highly unlikely to naturally occur in environmental samples
  • Known amount is spiked in the sample prior to extraction or analysis

Purpose:
  • Checks Sample Prep – spills, over/under concentrated
  • Checks Analysis – Dilution error, injection error, instrument problems.
  • Assists in measuring matrix interferences
  • Verifies that the preparation/extraction process was acceptable
Calibration Verification

Initial Calibration Verification (ICV): This standard is used to validate the initial calibration prior to the analyses of any samples. This standard is prepared from a reference material that is independent of the calibration curve (i.e., second source).

Continuing Calibration Verification (CCV): A calibration standard ran prior to analytical sequence. This standard is used to check the continuing validity of the initial calibration.
Data Integrity

Core Value:

*Integrity* - We adhere to the highest moral and ethical principles in all that we do.
Data Integrity Leadership

“Data quality and legal defensibility are critical factors for our clients and for TestAmerica. Compliance with data integrity rules supersedes all other requirements and is the cornerstone of our reputation.”

− Rachel Brydon Jannetta, CEO
Examples of Data Integrity Failures

• The following slides list some inappropriate practices that have been discovered by EPA and investigators over the past few decades.

• These examples are not an entire list, but are used to illustrate the challenges in preventing and deterring unethical behavior.
Fabrication

- Making up data without performing the analysis (drylabing).
- Recording data or information that is not true.
- Create data for an analysis that was not performed.
- Create information for a sample that was not collected.
- Cut and paste data or information into reports or data that are not true.
Misrepresentation

- Misrepresenting QC Samples as digested or extracted when these have not undergone the same steps as prepared samples.
- Report post-digested QC as pre-digested.
- Add surrogates into samples after sample extraction unless specifically called for by the method or procedure.
- Use more or less surrogate to already extracted samples to enhance recovery.
Misrepresentation

• Using more or less than the prescribed amount of spike solution without adjusting the calculation.

• Prepare or analyze QC samples, PTs, or Standards under analytical conditions different from samples.

• Intentionally subcontract PT samples and represent data or results as your own.
Improper Date/Time-Setting

- Record date or time incorrectly or set clocks improperly (Time Travel).
- Alter recorded times that samples were collected, extracted or analyzed.
- Set instrument clocks to make it appear that samples were analyzed within holding time.
Improper Peak Integration

- Performing technically unsound or improper peak integrations in order to pass QC criteria.
- Inappropriately subtract an interfering peak for the purpose of passing calibration or QC.
- Intentionally integrate a compound and represent it as another compound for the purpose of passing calibration or QC.
Improper Calibration

- Deviating from technically sound calibration practices by manipulating instruments or software to make calibrations appear to pass acceptance criteria.
- Performing multiple calibration runs until finally passing without corrective action or maintenance in between.
- Deleting or disregarding analyte responses from the center of a calibration curve without solid technical justification.
Unwarranted Sample Dilution

- Diluting samples or blanks, without documentation, explanation and technical justification, in order to eliminate target analyte responses.
- Dilute samples or blanks to reduce the appearance of contamination.
Improper Alteration of Analytical Conditions

• Altering analytical conditions between samples, standards, QC samples without appropriate, documented and technical justification.

• Changing analytical or instrument conditions from those stated in the method or SOP without documentation and approval.

• Failing to run standards, samples and QC samples under the same conditions unless specifically called for in the methods.
Unwarranted Software Manipulation

- Disabling automated data trail or flagging systems.
- Removing operational codes to eliminate or hide manipulations or manual integration flags.
- Inappropriately adjusting baselines.
- Improperly changing calculations or algorithms for the purpose of passing calibration or QC.
Data Integrity and Unethical Practice Prevention
Organize for Ethics and Quality

- Employ independent and uninhibited quality assurance staff for observing, assessing and reporting on operational activities
- Make sure at least two employees are successfully trained in each procedure
- Clearly define stop work authority for all staff
- Provide alternative chain-of-command reporting routes for reporting unethical behavior
- Signed Ethics Agreement/commitment from all staff
Develop Policies and Procedures

✓ Have detailed up-to-date Standard Operating Procedures describing analytical methods

✓ Documenting analytical decisions in run logs, maintenance logs, case narratives, corrective action reports etc.

✓ Ethics Policy: with clearly defined do’s and don’ts

✓ Procedures for confidential reporting of data integrity issues: Hotline Corrective action procedures

✓ Data qualification and data recall procedures

✓ Record retention, archival and disposal practices

✓ Policy for appropriate manual integration
Proper Hand Corrections of Data

Hand corrections performed by:

- Drawing a single line through the incorrect information.
- Write the correct information next to the line out.
- Initial and date the correction.
- Document reason for corrections which are not obvious.
- Corrections to data already released to clients requires corrective action or data recall.
Peak Integration Examples

✓ All employees working on chromatographic data systems must be trained in “acceptable manual integration practices”

✓ The Training must include examples of appropriate and inappropriate integrations.
Create a Good Work Environment

- Create an atmosphere where problems are brought forward and addressed rather than hidden
- Prevent “Undue Pressure”, or pressure without relief or recourse.
  - Report Narrative
  - Stop work authority for all employees
  - Data integrity line available to all staff
  - Data recall notification process
  - Out-side of chain-of-command reporting process
Inspections and Assessments

✓ Secondary data verification reviews: supervision
✓ Data authenticity assessments of analyst work product and instrument raw data
✓ Electronic data monitoring
✓ Electronic audit trail monitoring for being turned on
✓ Monitor compliance with manual integration policies
Consequences of Unethical Behavior

- Possible downward spiral
- Damaged reputation
- Loss of business
- Less than desirable financial performance
- Potential loss of jobs
- Potential lab closures
- Potentially huge financial penalties,
- Impact on our clients, environment and Public Health.
- All bad things!

People that have falsified data have received both civil and criminal convictions. Some are convicted felons, and some are serving jail time.
Key Take Away Messages

• Data Integrity is vital for the Environmental Industry.

• All Labs must have Ethics Policies and data integrity programs.

• All labs must ensure reported concerns are fully investigated.

• Look for companies that train all employees in ethics and data integrity practices and require employees to sign Ethics Statements.
Lab Accreditation

▶ Accreditation (Certification)
  • Based on National and International Standards
  • Acceptable to your regulator/auditor (variation)

▶ Quality System Based
  • ISO 17025 “General requirements for the competence of testing and calibration laboratories”
  • NELAP “National Environmental Laboratory Accreditation Program”

▶ Qualifications and Experience

▶ Facilities
Laboratory Accreditation

• The current state of accreditation
• National Accreditation (NELAP)
• DoD and DOE NELAP
• Non-NELAP States
• Regionalization of Labs because of increasing Cost of accreditation
• Lab networks can provide national coverage
Accreditation Risk

• Accreditation audits occur every 2 or 3 years
• Audits are a snap-shot in time, lab conditions can change and sometimes rapidly
• Some States and Agencies are better than Others
• Accreditation's verify the minimal requirements of the Quality Standard are met, But it really doesn’t indicate how good a lab is.
Conclusion

- Have you been in your laboratory lately; beyond the sample receiving doors?
- Is your laboratory meeting your needs?
- You deserve to have your samples analyzed by trained and qualified professionals at modern facilities with quality and ethics that you can trust!
Questions?

Ray Frederici
Ray.Frederici@testamericainc.com
Phone: 708.534.5200
Thank you for attending

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