**Having a Strong Quality Management System Prevents Faulty Results**

July 6, 2023

## INTRODUCTION

The NELAC Institute (TNI) is a 501(c)3 non-profit organization that was created to administer the National Environmental Laboratory Accreditation Program (NELAP). Through fourteen state Accreditation Bodies (ABs), NELAP accredits over 1400 laboratories. As a voluntary consensus standards development organization accredited by the American National Standards Institute (ANSI), TNI creates and adopts standards in support of its programs. These include and expand upon ISO/IEC standards for accreditation of testing laboratories (NELAP and non-governmental ABs recognized by TNI – ISO/IEC 17025), field sampling and measurement organizations (FSMOs – ISO/IEC 17025), governmental and non-governmental ABs (all programs – ISO/IEC 17011), and proficiency testing providers (PT providers -- ISO/IEC 17043). This white paper focuses on testing laboratories, but the principles apply for the National Environmental Field Activities Program (NEFAP, accrediting FSMOs) and the PT Program (PT providers and ABs).

**Quality System, Management System, or Quality Management System**

The 1990 version of ISO/IEC 17025 used the term Quality System to describe the process by which a laboratory manages its operations to "assure the quality of the test results it generates." By the time the second edition was published in 2005, this term was changed to Management System, although the phrase quality management system also appeared in this version. The NELAC Institute started using Quality System in 1994, and on September 11, 2020 adopted the term Quality Management System.

In 2019, as part of a strategic planning effort, the TNI Board of Directors charged the TNI advocacy committee to "Develop a long-range plan for promoting the use of the TNI accreditation program to data users to show the value/benefits and demonstrate the improvement in performance and data quality." Phase 1 of this effort shows how the TNI standard improved both laboratory data quality and performance. This effort, initiated in late 2022, was done to show "real-life" examples of data quality problems and why they occurred.

## TNI'S PRIMARY ACTIVITIES

Our focus is on ensuring reliable data (*i.e.*, data of known and documented quality generated according to accepted professional practices of the industry) that form the basis for a variety of decisions:

- ✓ compliance to a regulated limit of contaminants in air, water, and soil,
- ✓ remediation to pre-determined contamination levels for site remediation,
- ✓ assessing risk to human health or environment,
- ✓ exposure levels used in health surveillance, and
- ✓ water and wastewater engineering and technology implementation.

What is "reliable" data? In any analysis, the result is only an estimate of the true concentration, and quality control (QC) results (e.g., reagent blanks, matrix spikes) can be misleading for a variety of factors. Quality assurance (QA) goes beyond QC and a quality management system (QMS), such as required by TNI's accreditation program, goes still further. A QMS incorporates documentation, training of analysts, frequency of QC and QA checks of equipment and reagents, plus oversight of all procedures performed and review of the results.

The guiding principles of the entire TNI Laboratory Standard are that a QMS will be:

- ✓ Flexible – allow freedom to use experience and expertise in performing work to allow for new and novel approaches by specifying the *What* and avoiding where possible the *How To*.
- ✓ Auditable – include sufficient detail so that the assessors can evaluate laboratories consistently.
- ✓ Practical and Essential – contain only necessary policies and procedures that should not place an unreasonable burden upon laboratories.
- ✓ Widely Applicable – be applicable to laboratories of all sizes and complexity.
- ✓ Appropriate – ensure that data generated in compliance with the Standard will be of known quality and that the quality is adequate for the intended use. (Not all data must be of the highest quality;' as sometimes a "screening result" is adequate, for instance.)

**TNI'S QUALITY MANAGEMENT SYSTEM**

Laboratories may say they generate "high quality" data, "definitive" data, data of "known and documented quality", "legally defensible" data, or "valid" data, without defining what these terms mean. A simple statement of intent is not evidence of performance. A QMS provides the actual evidence to back up the claim(s).

TNI's Quality Management System (Module 2 of the Laboratory Standard) has been developed over a 25-year period by a consensus body, TNI's Quality Management Systems committee, and is periodically updated as potential improvements are identified. In conformance with TNI's ANSI accreditation, this committee has a balanced representation from all affected stakeholders: Accreditation Bodies, laboratories, and "others". The "other" category includes data users, retirees, federal employees and other interests. The Standard itself is based on ISO/IEC 17025 (2005) with specificity added for environmental testing. In 2023, significant revisions are presently underway, including updating to ISO/IEC 17025 (2017).

In addition to the Quality Management Systems module of TNI's Laboratory Standard, there are presently five technical modules providing additional detail for specific types of testing, each developed and maintained by a balanced committee of experts in the specific field – chemistry, microbiology, asbestos, radiochemistry, and aquatic toxicity. There is also a module devoted to Proficiency Testing.

The TNI Laboratory Standard's Quality Management System module is organized the same way as the ISO/IEC 17025 (2005) document. It includes:

- ❑ Introductory Material
  - ✓ Introduction, scope, references, etc.
  - ✓ Mandated test methods
  - ✓ Environmental Health and Safety not included

- ❑ Management Requirements (Section 4)
  - ✓ Organization
  - ✓ Quality System
  - ✓ Document Control
  - ✓ Review of Work
  - ✓ Subcontracting
  - ✓ Purchasing
  - ✓ Complaints
  - ✓ Control of Nonconforming Work
  - ✓ Corrective Action
  - ✓ Preventive Action
  - ✓ Records Control
  - ✓ Internal Audits
  - ✓ Management Review
- ❑ Technical Requirements (Section 5)
  - ✓ General
  - ✓ Personnel
  - ✓ Facilities
  - ✓ Test Methods and Method Validation
  - ✓ Equipment
  - ✓ Traceability
  - ✓ Sampling
  - ✓ Handling of Samples
  - ✓ Assuring the Quality of Results
  - ✓ Reporting the Results

To illustrate the specificity of TNI's Laboratory Standard compared to the "basic" ISO/IEC 17025 (designed to be applicable to all types of calibration and testing laboratories, not just environmental), one should realize that the TNI QMS section (module 2) has 150 pages of management and technical requirement, compared to 35 pages of management and technical requirement in ISO/IEC 17025 (2005), which are included verbatim. In addition to specific requirements for environmental laboratories, the TNI Standard includes data integrity, method selection, method validation, demonstration of capability (DOC), instrument calibration, quality control, data acceptance/rejection, sample handling and instrument calibration.

As an example, the ISO/IEC 17025 language on calibration states:

> Before being placed into service, equipment shall be calibrated to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use.

A competent laboratory and a competent assessor could use this language to appropriate calibrate instruments. But an incompetent laboratory could assert the instrument came calibrated from the factory and no further calibration is needed while an incompetent assessor could issue a finding because the laboratory did not run a 10-point calibration standard with 10% RSD because the assessor thinks this is needed for data quality. The additional specificity in the TNI standard is designed to ensure both the laboratory and assessor clearly understand the requirements.

To illustrate the additional specificity, the instrument calibration section in Module 4 of the TNI standard contains seven pages of specific details relative to both initial and continuing calibration verification such as:

- removal of calibration standards – low/high or interior,
- linear range,

- minimum number of standards,
- replacement of calibration standards, and
- measure of relative error.

**WHY BOTHER?**

"We know we generate good data! We follow the method and do the QC. Why must we do all this 'management' stuff that does not relate to quality?" This is a type of a question that often arises. And some of the requirements in both the TNI standard and published test methods may or may not have a direct impact on data quality but do indicate system vulnerabilities that could lead to data quality problems.

For example, during assessments, laboratories frequently receive findings on expired standards, improper sample temperature, equipment not matched to sample, absence of trip blanks for volatiles, internal audits that did not cover all aspects of testing, interference check sample not analyzed, SOPs that do not reflect actual practice, deionized water bottle not labeled, and corrections that were not dated or initialed in the laboratory notebook. While these vulnerabilities indicate a problem with the quality management system, the data may or may not have been accurate; it is certainly is less reliable.

This white paper defines faulty data as

- inaccurate or incorrect results,
- insufficient documentation,
- non-conformance to mandated method, and
- failure to meet customer requirements.

The Appendix to this document provides several "real life" incidents that could have been avoided if a quality management system had been in place and followed. While many of these failures relate to sampling or analysis for environmental contaminants these types of failures are widespread affecting many kinds of laboratory testing, including clinical, food, forensics, and geochemical. They affect not just commercial laboratories but also those that work in state and federal agencies, including state criminal and public health laboratories, the US Geological Survey, the US EPA, and the Federal Bureau of Investigation.

This white paper does not address improper or questionable practices such as:

- Inappropriate manual integrations,
- Selective removal of calibration points,
- Spiking LCS/Surrogates into extract, not sample, or
- Adjusting time clocks.

These improper or questionable practices are usually performed in order to meet QC criteria and thus may or may not have affect the reported sample result. However, these issues all relate to not having a robust data integrity system, and as discussed above decrease the reliability of the reported results.

The reasons for data quality problems are endless, but there are some areas readily identifiable and easy to remedy. The biggest causes of data quality problems are inadequate training, inadequate

management, and insufficient resources, but they all result from a single root cause, the lack of a strong quality management system.

**SO HOW DOES TNI'S ACCREDITATION STANDARD ENSURE RELIABLE DATA**

Implementing a QMS provides confidence in the data.

- The reported result is good estimate of the true concentration.
- The reported result is of known and documented quality.
- The laboratory complied with mandated method requirements.
- The laboratory implemented a strong quality management system to ensure confidence in the result.
- The laboratory met customer requirements.

Implementing a QMS improves laboratory performance.

- The result can be reconstructed with sufficient documentation for sample results, calibration, QC results, and SOP in use to fully reconstruct the processes leading to the result.
- Reference materials, reference standards, and reagents are all traceable.
- Training records, PT results, and DOC results all demonstrate competency of analyst.
- Samples are handled correctly with the ability to trace the sample from receipt to reported result.
- Quality control results document data quality.
- Results are reported correctly by meeting requirements relating to quantitation limits and data flagging.

Implementing a QMS ensure the laboratory met Daubert standards for data admissibility (e.g., "legal defensibility").[1]

- The technique has been tested,
- There is a known rate of error, and
- There are professional standards controlling the technique's operation.

**SUMMARY**

Laboratory accreditation makes a difference. Accreditation is not just about a quantitative improvement in data quality and a quality management system that is committed to the maintenance of quality. Accreditation is the evidence that there are systems in place to aid in generating reliable data for use in making high confidence decisions.

The QMS requirements in the TNI standard have a direct impact on both data quality and laboratory performance. Following those requirements, as demonstrated by a laboratory's accreditation, will consistently avoid major failures that would result in unsafe drinking water, unnecessary remediation, illegal waste disposal, or other bad decisions based on faulty data. From the laboratory's perspective,

[1] *Daubert: The Most Influential Supreme Court Ruling You've Never Heard Of*. 2006 https://thepumphandle.wordpress.com/2006/12/07/daubert-the-most-influential-supreme-court-decision-youve-never-heard-of

following and correctly implementing a robust QMS can avoid loss of accreditation, decreased revenue, reanalysis, or data rejection.

**RECOMMENDATION**

Many laboratories in the US are accredited to the TNI standard, but the majority are not. Only a few field sampling and measurement organizations have demonstrated competency. As shown in the case studies which follow, the lack of a strong QMS can affect "simple" tests like BOD and coliform and can drastically affect sampling.

TNI believes **ALL** environmental laboratories and field sampling and measurement organizations in the US should be accredited to the applicable TNI standard.

Note: While the body of this White Paper is primarily concerned with laboratories, the case studies which follow show comparable data quality issues with field sampling and field measurements. Having a robust Quality Management System is equally important for field activities.

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TNI is active in working with many stakeholders, including state and federal agencies as well as trade associations representing different types of organizations. More information about this effort is available from TNI.

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## Appendix

### Examples of Faulty Results that could have been prevented by having a strong QMS

Below are many "Case Studies" of faulty results due to a failure of the Quality Management System. After each Case Study, a citation to the 2016 TNI Standard, *Management and Technical Requirements for Laboratories Performing Environmental Analysis* along with the relevant language is provided.

Note that while many of these cases studies relate to environmental sampling and analysis, many other examples are provided that show this issue affects all types of sampling and testing including clinical, food, forensics, and geochemical laboratories and all types of organizations including state and federal agencies that conduct sampling and/or testing.

**Case Study 1: The PE Sample**

- ❑ An engineering firm asked the laboratory to analyze a sample for 8 specific volatile organics using the low-level option of SW-846 Method 8260 (25mL purge). The engineering firm sent a double-blind Performance Evaluation (PE) sample to the laboratory. The laboratory analyzed the sample using the normal method option for all volatile organics in the method (5 mL purge). The laboratory reported everything as not detected. (This was the correct result under that option.) The engineering firm called the laboratory and said it was a PE sample. Could they look harder? The laboratory supervisor went into the computer system and was able to find 4 compounds below their normal reporting limits. The engineering firm called back and told the laboratory which 8 compounds were actually present. The laboratory supervisor "found" the other 4 compounds.
- ❑ Who committed fraud?
  - ❑ The engineering firm?
  - ❑ The customer service person?
  - ❑ The sample log-in person?
  - ❑ The supervisor?
- ❑ Who was charged with fraud?
  - ❑ The analyst

The analyst was on maternity leave when the data manipulations occurred and was found not guilty.

**QMS Failures:**

4.2.8 – Data Integrity. *The laboratory shall establish and maintain a documented data integrity system.*

4.4 – Review of Requests, Tenders, and Contracts. *The policies and procedures for reviews leading to a contract for testing and/or calibration shall ensure that the requirements, including the methods to be used, are adequately defined, documented and understood.*

4.13.2 – Technical Records. *All alterations to records shall be signed or initialed by the person making the correction.*

**References**


1. *8 Acquitted in Lab Fraud Case* 2001. https://www.brodenmickelsen.com/news/8-acquitted-lab-fraud-case/
2. Parr, Jerry; personal observation.

**Case Study 2: Newborn Screening for Propionic Acidemia**

- ❑ A state health laboratory obtained a result of 19.99830. Results greater than 20 indicate abnormal results and medical attention required. The results were reported as **Normal**, so no action was taken. Mel, now 10, has severe brain damage.

**QMS Failures**

5.4.6 – Uncertainty. *The laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty.*

5.10.3 – Test Reports. *Information on uncertainty is needed in test reports when it is relevant to the validity or application of the test result or when the uncertainty affects compliance to a specification limit.*

**Reference**

1. *The price of being wrong, December 9, 2016*. Milwaukee Sentinel Journal. https://projects.jsonline.com/news/2016/12/11/the-price-of-being-wrong.html

**Case Study 3: Brain Eating Amoeba (*Naegleria fowleri)***

- ❑ The Louisiana Department of Health and Hospitals (DHH) confirmed the presence of *Naegleria fowleri* in two treated public drinking water systems in September-October 2013. A child staying in St. Bernard Parish died from infection with *Naegleria fowleri*, and the ameba was found in the plumbing system of the home and in the treated drinking water system. The ameba was also found in the treated drinking water system in DeSoto Parish. In 2011, both parishes had a death associated with use of a neti pot (a sinus cavity rinsing device). The ameba is easily killed with chlorine, so St. Johns Parish directed two individuals to collect samples at the far ends of the distribution system and check for residual chlorine.

- ❑ Utility worker Branch did not stop at 30 of the 48 water inspections he claimed to have done and a co-worker Roussel did not stop for three of the six inspections. Investigators with the Louisiana State Police reviewed data from GPS systems on the parish vehicles assigned to Branch and Roussel and discovered that they were often nowhere near the testing sites when they should have been. These utility workers were indicted for failing to test the water supply and then lying about it.

**QMS Failures**

4.2.8 – Data Integrity. *The laboratory shall establish and maintain a documented data integrity system.*

5.7.3 – Sample Recording. *The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.*

**Reference**

1. *After brain-eating amoeba contamination of water, St. John Parish to get new utilities director*. 2015 https://www.nola.com/news/politics/after-brain-eating-amoeba-contamination-of-water-st-john-parish-to-get-new-utilities-director/article_fc9fbade-85e8-589b-8557-f1ce201ed267.html

**Case Study 4: Coliform Outbreak in Walkerton, Canada**

- ❑ The Walkerton *E. coli* outbreak was the result of a contamination of the drinking water supply of Walkerton, Ontario, Canada. The water supply was contaminated as a result of improper water treatment following heavy rainfall in late April and early May 2000, which had drawn bacteria from the manure of nearby cattle into the shallow aquifer of a nearby well. Walkerton Public Utilities Commission (PUC) manager Stan Koebel did not report lab results and did not inform the public that the well had been operating without a chlorinator.
- ❑ Koebel had been working for the PUC since the 1970s, when he was a teenager and his father worked at the PUC. He had no formal training in public utility operation or in water management, but by 2000, had been promoted to management positions on the basis of experience. Koebel carried certification as class 3 water distribution system operator, obtained through a legacy program run by the Ministry of the Environment (MOE) and based on work experience. Though Ontario law required that water systems operators receive 40 hours of continuing education per year, Koebel interpreted this to include activities only marginally related to water systems, such as CPR certification, and as a result he did not use continuing education time to gain or maintain expertise in water safety.
- ❑ Koebel did not want to interfere with Victoria Day and did not think coliform was that bad. The contamination caused gastroenteritis and sickened more than 2,000 people and resulted in six deaths.
    - Koebel sentenced to one year in jail.
    - $5 million in legal fees.
    - $1 billion class action lawsuit.
    - Ontario minister blamed for not regulating water quality.

**QMS Failures**

4.2.1 – Management. *The laboratory shall establish, implement and maintain a management system appropriate to the scope of its activities.*

5.10.1 – Reporting Results. *The results of each test carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively.*

**Reference**

*Walkerton E. coli outbreak*
https://en.wikipedia.org/wiki/Walkerton_E._coli_outbreak#:~:text=The%20Walkerton%20E.%20coli%20outbreak%20was%20the%20result,Canada%2C%20with%20E.%20coli%20and%20Campylobacter%20jejuni%20bacteria.

**Case Study 5: High Coliform Results**

- ❑ A large municipality had a MAJOR leak in a raw wastewater pipe under a river that resulted in fish kills across state lines.
- ❑ The laboratory was not prepared for handling samples that had high results outside of their normal range.
- ❑ An investigation revealed that the results had not been calculated correctly based on dilution factors.

**QMS Failures**

4.4.1 – Adequate Resources. *The policies and procedures for testing shall ensure that the laboratory has the capability and resources to meet the requirements*.

**Reference**

1. State agency, personal observation

**Case Study 6: Another Coliform Example**

- ❑ A total coliform result was obtained by the laboratory. Instead of following state protocol to report the positive result, the laboratory vacated the result as "laboratory error" and informed the client to submit another sample.

**QMS Failures**

5.10.13 – Reporting Results. *The results of each test, or series of tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test methods.*

**Reference**

2. State agency, personal observation

**Case Study 7: Train Car Derailment**

- ❑ A train carrying many cars filled with lime spilled and lime spread over the ground. EPA Region 9 laboratory analyzed samples and found the pH to be 12.5 and thus the spill was classified as hazardous waste. Lime is calcium hydroxide which is used to make pH 12 buffer and at 25° C has a pH of 12.454, or less than 12.5. The EPA laboratory did not correct for temperature or do an expanded readout as required by the method. This episode led to a revision of SW-846 Method 9045D in 2004.

**QMS Failure**

5.4.1 – Method Deviation. *Deviation from test methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.*

**Reference**

1. Public Docket to SW-846 rule-making

**Case Study 8: Pesticide Remediation**

- ❑ A major remediation project at a pesticide manufacturing facility generated hundreds of test results for organophosphate pesticides. During a pre-trial deposition, a review of the thousands of pages of raw data, the records to link the initial instrument calibration to the continuing calibrations could not be found. All of the data were ruled inadmissible by the court.

**QMS Failure**

4.13.3 – Historical Reconstruction .*All information necessary for the historical reconstruction of data shall be maintained by the laboratory.*

**Reference**

1. Parr, Jerry; personal observation

**Case Study 9: Pesticide Misidentification**

- ❑ An analyst incorrectly identified dieldrin in soil samples because the analyst did not know how to establish retention time windows correctly. The engineering firm performed unnecessary remediation.

**QMS Failures**

4.1.5 – Management. *The laboratory shall provide adequate supervision of testing staff, including trainees, by persons familiar with methods and procedures, purpose of each test, and with the assessment of the test or results.*

4.2.8.4 – Experienced personnel. *The laboratory shall have procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and are receiving any needed training.*

.5.2.1 – Management of personnel. *Laboratory management shall ensure the competence of all who operate specific equipment, perform tests, evaluate results, and sign test reports.*

1.6 (Module 4) – Demonstration of Capability. *An individual must successfully perform an initial Demonstration of Capability prior to using any method.*

**Reference**

1. Laboratory assessor, personal observation

**Case Study 10: Incorrect Spreadsheet**

- ❑ An unprotected cell in a spreadsheet got changed resulting in dry weight correction to be off by a factor of 2. 18 months of incorrect data was reported which affected decisions made by a large federal entity.

**QMS Failure**

4.3.3 – Document Control. *Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.*

**Reference**

1. Laboratory assessor, personal observation

**Case Study 11: Review of Data**

- ❑ Verbal results reported no volatile organics detected in several train cars of waste. Waste was then discarded in a municipal landfill not licensed for hazardous wastes. One week later, the final report showed volatile organics exceeded action level. Verbal results were associated with different samples.

**QMS Failure**

5.10.2 – Test Reports. *Each test report shall include an unambiguous identification of the item(s) tested.*

**Reference**

1. Laboratory assessor, personal observation

**Case Study 12: "Mixed Waste"**

- ❑ A laboratory salesperson assumed "mixed waste" to be a mixture of organic and inorganic substances and the request for proposal did not have a technical review by laboratory staff. Mixed waste actually refers to a mixture of radioactive and non-radioactive materials. Luckily, an assessor reviewed the capabilities of the laboratory before samples were shipped and discovered the laboratory did not have the ability to handle radioactive samples.

**QMS Failures**

4.1.5 – Technical Management. *The laboratory shall have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations.*

4.4 – Review of Requests. *The policies and procedures for reviews leading to a contract for testing shall ensure the laboratory has the capability and resources to meet the requirements.*

**Reference**

1. Laboratory assessor, personal observation

**Case Study 13: Incorrect Reagent**

- ❑ Some methods require use of reagents of specified purity (e.g., EPA 1664 requires 85% purity for hexane). The laboratory violated requirement in 40 CFR 136 to follow the method exactly as written. The result was likely accurate, but not acceptable.

**QMS Failure**

5.9.3– Mandated Methods. *The laboratory shall ensure that the essential standards outlined in Technical Modules or mandated methods or regulations (whichever are more stringent) are incorporated into their method manuals. When it is not apparent which is more stringent, the mandated method or regulations is to be followed.*

**Reference**

1. State accreditation body, personal observation

**Case Study 14: Benzidine? Really?**

- ❑ Laboratory reported benzidine (4,4'-diaminobiphenyl) in 100's of samples from petroleum contaminated sites. Identification based on retention time and mass spectrum of benzidine standard purchased from a vendor. Upon investigation, standard was actually dibenzothiophene, a compound with the same melting point.

**QMS Failures**5.6.3.2 – Reference Materials. *Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials.*

1.7.1.1 (Module 4) – Second Source Verification. *Standards used for calibration shall be traceable to a national standard, when commercially available. All initial calibrations shall be verified with a standard obtained from a second manufacturer or a separate lot prepared independently by the same manufacturer.*

**Reference**

1. *Benzidine? Really?*, Roy-Keith Smith, 1998. Waste Testing and Quality Assurance Symposium. https://nemc.us/docs/other/WTQA-1998-FINAL.pdf

**Case Study 15: The Sludge Pond Sample**

- A "sludge" sample sent in for soils analysis using EPA's Contract Laboratory Program procedures. The EPA procedure for soils requires a 30-gram sample that is then dried with sodium sulfate. The sample was aqueous with only 2 % solids, indicating a representation 30-gram sample could be problematic. The EPA procedure requires a gel permeation cleanup which requires results to be multiplied by 2. This correction factor was not applied. The EPA procedure requires results corrected to dry weight which would involve a 50X multiplier. The matrix spike was performed on another unrelated sample in the batch. Result passed data validation but made no logical sense.

**QMS Failures**

4.4.1 – Review of Requests, Tenders, and Contracts. *The policies and procedures for testing shall ensure that the requirements, including the methods to be used, are adequately defined, documented and understood and the appropriate test method is selected and is capable of meeting the customers' requirements.*

5.4 – Methods and Method Validation. *The laboratory shall use appropriate methods and procedures for all tests. The laboratory shall inform the customer when the method proposed by the customer is considered to be inappropriate.*

5.4.7 – Control of Data. *The laboratory shall ensure that computer software er is documented in sufficient detail and is suitably validated as being adequate for use.*

**Reference**

Parr, Jerry; personal observation

**Case Study 16: 6 and 7-Day BOD**

- ❑ The analyst did not want to come in on weekends and take readings for samples set up on Tuesday and Wednesday. Oxygen levels measured on Monday resulting in 6 or 7-Day BOD.

**QMS Failure**

5.4.1 – Deviation of Test Methods. *Deviation from test methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer*

**Reference**

State Accreditation Body finding

**Case Study 17: Another BOD Example**

- ❑ A laboratory analyzes three blanks when running samples for BOD. The laboratory reports the results, without qualifying, as long as one blank passes (<0.20 mg/L).

**QMS Failure**

1.7.3.1 (Module 4) – Negative Control. Each method blank shall be critically evaluated as to the nature of the interference and the effect on the analysis of each sample within the batch.

**Reference**

Laboratory assessor, personal observation

**Case Study 18: Arsenic at Elementary School**

- ❑ Laboratory reported high levels of arsenic in soil at an elementary school. The laboratory had modified the method without validating or receiving authorizations. The school was shut down. Another laboratory analyzed samples and showed results well below action levels. The first laboratory had not applied required Zeeman background correction due to high aluminum in soil.

**QMS Failures**

5.4.4 – Method Validation. *When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test.*

1.5.1 (Module 4) – Method Validation. *Prior to acceptance and institution of any method for which data will be reported, all methods shall be validated.*

**Reference**

Laboratory assessor, personal observation

**Case Study 19: Lead in Tuna**

- ❑ In the 1980's FDA issued an advisory suggesting pregnant or breast-feeding women should avoid eating tuna due to high levels of lead. The lead was coming from the can due to the solder. Tuna does contain lead, but not at the levels reported.
- ❑ Now, the FDA recommends pregnant and breast-feeding women now should moderate their intake of king mackerel, swordfish, and other species. Albacore and yellow fin tuna are now considered "good" choices and canned light tuna is a "best" choice.

**QMS Failures**

5.9.3 – Negative Controls. *All laboratories shall have detailed written protocols in place to monitor negative such as blanks.*

1.5.2 (Module 4) – Limit of Detection (DL). *The DL determination shall include data from low level spikes and routine method blanks prepared and analyzed over multiple days; at least one low level spike and routine method blank must be analyzed on each applicable instrument; a minimum of seven (7) replicates is required for both low level spikes and routine method blanks.*

**Reference**

Burrows, Richard, National Environmental Monitoring Conference, 2015

Settle, D.M. and Patterson. C.C., Lead in albacore: guide to lead pollution in Americans
Science, March 14, 1980.

https://www.epa.gov/system/files/images/2021-09/fish-chart.jpg

**Case Study 20: USEPA Region 5 Central Regional Laboratory**

- ❑ Data were provided to the regional program offices for decision making and enforcement actions that were of "unknown quality and indefensible."
    - Lack of an approved Quality Management Plan
    - Little or no oversight of day-to-day operations
    - Low priority to QC and customer needs in favor of analyzing samples
    - SOPs out of date or non-existent
    - Staff not evaluating the quality of data
    - Plus 18 more areas of concern

**QMS Failures**

4.0 Management

5.0 Technical

The extent of these findings demonstrates a complete lack of a QMS.

**Reference**

US EPA Office of Inspector General, Review of Region 5 Laboratory Operations, Audit Report Number 2000-P-3, https://www.epa.gov/sites/default/files/2015-12/documents/reg5crlaudit.pdf

**Case Study 21: US Geological Survey Energy Geochemistry Laboratory**

- ❑ QC procedures inadequate to detect quality issues. Analysts had violated method required activities without detection. "Chronic pattern of mis-conduct." Impacted 24 research projects with $108 million of funding, including:
    - trace metals analysis of water in the greater Everglades ecosystem;
    - assessment of uranium in the environment in and around Grand Canyon National Park for possible groundwater restoration; and
    - analysis of metals released into waters associated with natural gas production activities in Alaska.

**QMS Failures**

4.2.8.1 – Data Integrity Monitoring. *The laboratory shall establish and maintain a documented data integrity system including data integrity training, signed data integrity documentation for all laboratory employees, and periodic in-depth data monitoring.*

4.14 – Internal Audits. *The laboratory shall conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system. The internal audit shall address all elements of the management system, including the testing activities.*

**References**


1. *Assuring Data Quality at U.S. Geological Survey Laboratories*. Washington, DC: The National Academies Press. https://doi.org/10.17226/25524. 2019
2. *Inspection of Scientific Integrity Incident at USGS Energy Geochemistry Laboratory,* Report No. 2016-EAU-010, Office of Inspector General, Department of the Interior, June 13, 2016

**Case Study 22: FBI Forensic Laboratory**

- ❑ Flawed results on hair analysis. 2600 convictions, including 45 on death row, in the 1980's and 1990's. FBI examiners *"exceeded the limits of science"* when linking hair to crime-scene evidence. The FBI knew as early as 1970 that these methods were not appropriate.

**QMS Failure**

5.4.2 – Selection of Methods. *The laboratory shall use test methods which meet the needs of the customer and which are appropriate for the tests it undertakes.*

**Reference**


1. *FBI forensic lab misconduct could affect 2,600 convictions, 45 death row cases*. 2014 https://www.rt.com/usa/176744-fbi-forensic-lab-review/

**Case Study 23: Aleutian Islands Project**

- ❑ Phase 1 investigation into possible contamination from World War 2. Because of holding times, a decision was made to extract samples in start-up a lab in Anchorage and then ship extracts to continental US lab. All QC checks (LCS, MS, Surrogates) were 5-10% recovery (data of known and documented quality!)

**QMS Failure**

1.6 (Module 4) – Demonstration of Capability. *An individual who performs any activity involved with preparation and/or analysis of samples must have constant, close supervision (as defined in the laboratory's training procedure) until a satisfactory initial DOC is complete.*

**Reference**

Parr, Jerry; personal observation

**Case Study 24: Removal of Interior Standard Level to Pass Calibration Criteria**

- ❑ A laboratory analyzed 6 calibration points at 0.02, 0.1, 0.2, 0.4, 1.0, and 2.0 ng/uL and obtained an $r^2$ of 0.983, which failed a 0.99 requirement. The laboratory removed the 1.0 level standard and obtained an $r^2$ of 0.998.

**QMS Failure**

1.7.1.1 (Module 4) – Initial Calibration. *The laboratory may remove individual analyte calibration levels from the lowest and/or highest levels of the curve. Multiple levels may be removed, but removal of interior levels is not permitted.*

**Reference**

Arizona Department of Health Services, Instrument Calibration Training
https://www.azdhs.gov/documents/preparedness/state-laboratory/lab-licensure-certification/technical-resources/calibration-training/01-calibration-models-introduction.pdf

**Case Study 25: Selective Instrument Calibration**

- ❑ The laboratory removed the level 2 calibration data for 6 of 21 compounds and the level 3 point for one other compound to meet percent Relative Standard Deviation criteria.

**QMS Failure**

1.7.1.1 (Module 4) – Initial Calibration. *A laboratory that chooses to remove a calibration standard from the interior of the calibration shall remove that particular standard calibration level for all analytes. Removal of calibration points from the interior of the curve is not to be used to compensate for lack of maintenance or repair to the instrument.*

**Reference**

Arizona Department of Health Services, Instrument Calibration Training
https://www.azdhs.gov/documents/preparedness/state-laboratory/lab-licensure-certification/technical-resources/calibration-training/01-calibration-models-introduction.pdf

**Case Study 26: Use of $r^2$ Without Checking Error**

- ❑ The laboratory analyzed a 10-point calibration and obtained a $r^2$ of 0.996. The laboratory did not calculate relative error, which at the low point was 1335%. This error meant that a 0.5 ng/mL true value would be measured as 7.2 ng/mL

**QMS Failure**

1.7.1.1 (Module 4) – Measure of Relative Error. *The laboratory shall use and document a measure of relative error in the calibration.*

**Reference**


1. *Evaluating the Goodness of Instrument Calibration for Chromatography Procedures,* Burrows, R. and Parr, J., LC/GC North America, October 2020.
2. *Letter from the Environmental Monitoring Coalition to the USEPA, October 25, 2021.* *https://www.dropbox.com/s/rzrex1awfqiuuvt/EMC_letter_r2_EPA_211025.pdf?dl=0*

**Case Study 27: Wrong Method**

- ❑ Client asked laboratory to test for PBDEs, but did not specify the analytes, the method, or any data quality objectives. The laboratory used an internally developed method that did not meet client's needs.
    - Wrong analytes,
    - LOQ too high, and
    - Bias too high.

**QMS Failure**

**5.4.4 –** Non-Standard Methods. *When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test.*

**Reference**

State Agency; personal observation

**Case Study 28: > 85,000 Bad Data Points from the Massachusetts State Crime Laboratory**

- ❑ 27,000 faulty DUI results due to breath analyzer not being calibrated.
- ❑ 21,587 drug cases overturned because Annie Dookhan lied. Dookhan did not test samples but wrote down what the police suspected as the result. Productivity was 5 x greater than other laboratory staff. If police did not write something down, Dookhan would spike sample with cocaine and test.
- ❑ 35,000 drug cases overturned because Sonja Farak was a drug addict. Pipetted liquid Meth from refrigerator to "give her strength." Tasted, injected, or snorted other samples including LSD, cocaine, etc. Farak sentenced to 18 Months in jail. Netflix documentary "How to Fix a Drug Scandal." (4 1-hour episodes)

**QMS Failures**

4.1.5 – Laboratory Management. *The laboratory shall provide adequate supervision of testing staff, including trainees, by persons familiar with methods and procedures*.

4.2.8 – Data Integrity. The laboratory shall establish and maintain a documented data integrity system.

4.13.2 – Technical Records. *The records for each test shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test to be repeated under conditions as close as possible to the original.*

5.2.1 – Personnel. *The laboratory management shall ensure the competence of all who operate specific equipment, perform tests, evaluate results, and sign test reports.*

5.5.8 – Calibration. *Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labelled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.*

5.10.1 Reporting the Results. *The results of each test carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test methods,*

**References**


1. https://www.msn.com/en-us/news/crime/massachusetts-misconduct-faulty-breathalyzer-equipment-puts-27000-oui-convictions-at-risk/ar-AA1aoFnd
2. https://www.salemnews.com/news/sjc-rules-27-000-dui-cases-can-be-reconsidered-due-to-breathalyzer-misconduct/article_255fd9e8-e46c-11ed-9667-772c77005688.html
3. https://www.sciencehistory.org/distillations/why-did-annie-dookhan-lie
4. https://meaww.com/sonja-farak-drug-lab-chemist-negligence-saw-the-dismissal-of-35-000-criminal-cases-meth-cocaine-424575
5. https://www.netflix.com/title/80233339

**Case Study 29: Poor Sample Collection in Wetlands Leads to No Reportable Data**

- ❑ Collected water in marsh with depth of less than 5cm water (Requirement is no less than 10 cm). Sample not representative. All data were rejected.
- ❑ Field data measured by dipping metal pan into water and laying multiparameter instrument sideways in pan. Data not representative. All data were rejected.
- ❑ Collection of marsh samples by raking bottle through plants to obtain "water column" sample. Water was filled with detritus and periphyton. Water was then passed through a plastic screen mesh into another bottle which was submitted for "total" nutrients. Sample not representative. All data were rejected.

**QMS Failures**

5.4.1 – Methods. *The laboratory shall use appropriate methods and procedures for all tests within its scope. These include sampling…*

5.7 – Collection of Samples. *The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing. The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken. The sampling process shall address the factors to be controlled to ensure the validity of the test results.*

**Reference**

John Moorman, South Florida Water Management District; Personal observation

**Case Study 30: Data Integrity for Sampling (multiple events)**

- ❑ Coos Bay, OR Water Treatment Plant
  - 10 samples to be collected at various locations.
  - Sampler collected all 10 samples at one location.
  - Sampler sent to prison and Coos Bay had to immediately implement frequent sampling and testing.
- ❑ Oakland, CA sampling mess for cannabis
  - Sampler did not follow subsample requirements.
  - All test results rejected.
  - Laboratory closed.
- ❑ California laboratory issues for cannabis
  - Changed results to meet customer requests.
  - Sampled high THC portion of the plant.
  - Charged more for higher THC results.
- ❑ Cannabis results for pesticides and yeast and mold
  - Collected samples from plants that were not subject to pesticide application.
  - Sampled only those leaves that showed no visible mold.

**QMS Failures**

4.1.5 – Organization. *The laboratory shall have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity;*

5.2.7 - Data Integrity. Data integrity training shall be provided as a formal part of new employee orientation and shall also be provided on an annual basis for all current employees. Employees are required to understand that any infractions of the laboratory data integrity procedures shall result in a detailed investigation that could lead to very serious consequences including immediate termination, debarment or civil/criminal prosecution.

5.7 – Collection of Samples. *The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing. The sampling process shall address the factors to be controlled to ensure the validity of the test results.*

**Reference**

Gary Ward, GK Ward and Associates; June 7, 2023, TNI Field Sampling and Measurement Conclave

**Case Study 31: Blunders in Sampling and Analysis (multiple events)**

- ❑ The Lowes Hose
  - Residential wells showed significant levels of PAH.
  - Samples were to be collected directly from spigot.
  - Spigot low to the ground so a garden hose was connected to the spigot and used to collect the samples.
- ❑ Mercury Boots
  - Sampler walked into a mercury metering station where elemental mercury was on the floor.
  - Sampler then used his boots to identify where soil samples to be tested for mercury were to be taken.
- ❑ Dissolved Metals Everywhere
  - Nine metals consistently found in filtered samples and blanks, but not in unfiltered samples.
  - Filter and tubing not flushed with sample before sample collection although this was required in the SOP.
- ❑ Sure Looks Clean to Me
  - Monitoring well purge water discharged to parking lot which then entered nearby creek.
  - Work Plan specified purge water was to be containerized but since it looked "pretty clean," it was not.
  - Purge water had a pH of 9.3 resulting in a large fish kill.
- ❑ False Ethylene Glycol Detections
  - Ethylene glycol detected in all residential wells and laboratory blanks were clean.
  - Field samples preserved with HCl while blanks were not preserved.
  - HCl was the source of the contamination.
- ❑ Poor PE Sample Preparation and Laboratory Error
  - Performance Evaluation sample prepared by spiking PAH into the neck of the sample bottle where they stuck.
  - Very low recoveries measured.
  - Laboratory had not rinsed bottle with solvent as required by the method.
- ❑ DI Water Clean, but Metals found in Blanks
  - Six metals consistently found in groundwater and field blanks at Alaska's north slope.
  - The laboratory had changed to amber glass sample container not certified for metals.

**QMS Failures**

4.2.2 –Management. *The laboratory's management system policies related to quality shall ensure all personnel concerned with testing activities familiarize themselves with the quality documentation and implement the policies and procedures in their work*.

5.4.1 – Methods. *Deviation from methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.*

5.7 – Sampling. *The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling for subsequent testing. The sampling process shall address the factors to be controlled to ensure the validity of the results.*

1.7.3.1 – Blanks. While the goal is to have no detectable contaminants, each blank shall be critically evaluated as to the nature of the interference and the effect on the analysis of each sample within the batch. The source of contamination shall be investigated and measures taken to minimize or eliminate the problem and affected samples reprocessed or data shall be appropriately qualified.

**Reference**

David Blye, Environmental Standards; June 6, 2023, TNI Field Sampling and Measurement Conclave

**Case Study 32: Blunders in Sampling for Volatile Organics**

- A customer, located in the south, had monitoring wells related to a long term project and was collecting routine samples in July for volatile analysis. The results were not as expected and were erratic when compared to historical. In addition, new contaminants were showing up. They resampled the site and saw even more bizarre results.
- They contacted the laboratory to have them look into the analytical run and find the issue. The laboratory could find no problem with the QC or instrument performance. The laboratory contacted the customer's field sampling team and asked them to describe the sampling process.
- "We collect the water from each well place them in order with the vials on the tailgate of the truck (which stayed running to keep the cab cool). After filling all of the vials, we place the caps on each, and put them in the cooler with ice."

**QMS Failures**

5.4.1 – Methods. *The laboratory shall use appropriate methods and procedures for all tests within its scope. These include sampling…*

5.7 – Collection of Samples. *The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing. The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken. The sampling process shall address the factors to be controlled to ensure the validity of the test results.*

**Reference**

Commercial laboratory, personal observation.

**Case Study 33: Total Phosphorous**

- A manufacturing customer with a process water discharge permit had experienced historical issues with total phosphorous and was being fined on a regular basis. After many fines the regulatory actions were getting stronger, and the business was given a deadline to correct the issue.
- Phosphorous was not detected in the next set of samples received by the laboratory but the samples were so clear compared to previous samples that it raised a question regarding the other water quality tests which were found to be out of line also. Additional tests showed that chlorine was present, so the laboratory questioned the origin.
- After further investigation by the customer, they found that their employee had collected the samples from an outside drinking water spigot to avoid having to correct the actual problem.

**QMS Failures**

5.4.1 – Methods. *The laboratory shall use appropriate methods and procedures for all tests within its scope. These include sampling…*

5.7 – Collection of Samples. *The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing. The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken. The sampling process shall address the factors to be controlled to ensure the validity of the test results.*

**Reference**

Commercial laboratory, personal observation.