Having a Strong Quality Management System Prevents Faulty Results

March 20, 2024

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

- ❑ 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 appropriately 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 can 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, traceability between equipment and samples, 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 vulnerability with the quality management system; the data may or may not have been accurate, but it is certainly less reliable.

This white paper defines faulty data as:

- inaccurate or incorrect results,
- insufficient documentation,
- non-conformance to a 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 to meet QC criteria and thus may or may not have affected 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 STANDARD ENSURE RELIABLE DATA?

Implementing a QMS provides confidence in the data.

- The reported result is a 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 such as measurement quality objectives including precision, accuracy (bias), representativeness, completeness, and comparability (PARCC).

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

Implementing a Quality Management System makes a difference by ensuring there are systems in place to facilitate the generation of 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 results in consistently avoiding 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, following and correctly implementing a robust

[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

QMS can ensure continued compliance with accreditation standards, prevent loss of revenue, minimize sample reanalysis, or data rejection.

A robust and integrated quality management system (QMS) is crucial for testing laboratories for several reasons:

1. **Compliance:** Accredited laboratories are required to meet robust QMS requirements developed by standard setting bodies such as CLIA (Clinical Laboratory Improvement Amendments), ISO (International Organization for Standardization) and TNI. A robust QMS that is being followed by the laboratory ensures that the laboratory operates in compliance with laboratory accreditation standards, which is essential for maintaining accreditation and credibility.
2. **Standardization**: The laboratory's QMS guides laboratory staff in the processes and procedures that are to be followed in order to ensure the reliability and comparability of test results, regardless of who is conducting the testing or when the analysis is conducted.
3. **Ensuring Accuracy and Reliability**: The QMS creates the framework for the laboratory to establish protocols and maintain procedures to ensure the accuracy and reliability of test results. This includes properly calibrating equipment, using validated testing methods, and implementing rigorous quality control measures. By adhering to a QMS standard, laboratories can provide reliable and reproducible results. This is essential for laboratory testing to ensure that informed decisions based on these results are sound and reliable.
4. **Traceability and Documentation**: The QMS specifies how the laboratory maintains comprehensive documentation of all processes and procedures. Following the QMS ensures traceability of test results and provides a clear audit trail, which is essential for accountability and demonstrating compliance with regulatory requirements.
5. **Customer Confidence:** A robust QMS ensures reliability of results, and therefore confidence among clients (whether a patient or wastewater treatment facility) and other stakeholders. By consistently following the practices and procedures described in the QMS, the laboratory demonstrates their commitment to quality and customer satisfaction. This can lead to repeat business and positive referrals, contributing to the long-term success of the laboratory.
6. **Risk Management:** A QMS helps identify and mitigate potential risks that could affect the quality and reliability of test results. By assessing risk during the various laboratory processes and including proactive measures to eliminate or minimize said risks, the QMS can minimize errors, deviations, and other factors that may compromise the integrity of the testing.
7. **Continuous Improvement:** A key principle of quality management is continuous improvement. Implementing a QMS provides a systematic approach to identifying areas for improvement and implementing corrective actions. By regularly reviewing and refining their processes, laboratories can enhance efficiency, effectiveness, and overall performance.
8. **Legal and Ethical Obligations:** Environmental testing often has legal implications related to environmental protection and public health. Other types of testing (e.g., clinical, forensic, food) have comparable legal and ethical implications. A robust QMS helps ensure that testing

practices adhere to legal and ethical standards, protecting both the laboratory and its clients from potential liabilities.

SUMMARY

Developing and following a robust quality management system is essential for laboratories as it helps to demonstrate a laboratory's competency, ensures compliance with standards, improves accuracy and precision, ensures reliability and integrity of testing services, builds customer confidence, manages risks, fosters continuous improvement, and fulfills legal and ethical obligations. For an environmental testing laboratory, having a QMS ultimately contributes to protection of public health and the environment. 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.

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 through attaining accreditation. As shown in the case studies which follow, the lack of a strong QMS can adversely affect even "simple" tests like BOD (biological oxygen demand) and coliform and can drastically affect sampling.

TNI believes **ALL** environmental laboratories and field sampling and measurement organizations in the US should implement a strong quality management system such as the QMS in the TNI standard.

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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Acknowledgements

TNI would like to thank these individuals for their personal stories.

- Steve Arms, Florida DOH (retired)
- David Blye, Environmental Standards
- Richard Burrows Eurofins (retired)
- Stephanie Drier, Minnesota ELAP
- Tony Francis, SAW Environmental
- Steve Gibson, TCEQ
- Silky Labie, ELCAT
- Diane Lawver, Quality Assurance Solutions
- Marlene Moore, Advanced Systems
- John Moorman, South Florida Water Management District
- Judy Morgan, Pace Analytical Services
- Michael Shepherd, Shepherd Technical Services
- Christine Sotelo, California ELAP
- Rock Vitale, Environmental Standards
- Gary Ward, GK Ward and Associates

Appendix

Examples of Faulty Results that may 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, examples of how this error could have been prevented are shown with the relevant section(s) from the 2016 TNI Standard, *Management and Technical Requirements for Laboratories Performing Environmental Analysis* (Volume 1). Except as otherwise stated, all language is from Module 2.

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 cannabis, clinical, food, forensics, and geochemical laboratories and all types of organizations including state and federal agencies that conduct sampling and/or testing.

Also, while some of the faulty data concerned only sampling, the examples included here all involve incidents where the laboratory had some responsibility for the sampling. As defined in ISO/IEC 17025: 2017, a laboratory is "a body that performs one or more of the following activities: testing; calibration; or sampling, associated with subsequent testing or calibration."

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 sample was incorrectly logged in as a normal 8260 (5 mL purge) for all compounds in the method. The sample was a double-blind Performance Evaluation (PE) sample. 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, using the log-in name and password of the analyst, improperly went into the computer system and was able to find 4 compounds below their normal reporting limits. The engineering firm called back and improperly told the laboratory which 8 compounds were actually present. The laboratory supervisor "found" the other 4 compounds by improperly integrating some noise at the correct retention time. EPA charged the analyst with fraud.
- ❑ Who committed fraud?
    - The engineering firm? By telling the laboratory what was in the sample
    - The customer service person? By not setting up the project as requested by the customer.
    - The sample log-in person? By not following instructions for the analysis.
    - The supervisor? By the improper integrations and falsely logging in is as the analyst.
- ❑ Who was charged with fraud?
    - The analyst

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

How the TNI Standard Could Have Prevented this from Occurring

Section 4.2.8 requires the laboratory to establish and maintain a documented data integrity system that includes data integrity training and data monitoring, including requirements for manual integrations. Section 4.4 requires the laboratory to ensure that the requirements, including the methods to be used, are adequately defined, documented, understood, and communicated to the individuals performing the analyses. Section 4.13.2 requires all alterations to records to 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.
   Note: The evidence above was admitted during the lengthy trial.

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.

How the TNI Standard Could Have Prevented this from Occurring

Section 5.4.6 requires the laboratory to attempt to identify all the components of uncertainty and make a reasonable estimation to ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Section 5.10.3 requires the laboratory to provide information on uncertainty 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

* While this was not an environmental laboratory, and thus the TNI Standard is not directly applicable, the basic principles apply; a robust QMS such as the TNI Standard could have prevented this error.

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 amoeba was found in the plumbing system of the home and in the treated drinking water system. The amoeba 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 amoeba 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.

How the TNI Standard Could Have Prevented this from Occurring

Section 4.2.8 requires the laboratory to establish and maintain a documented data integrity system, including examples of ethical behavior. Section 5.7.3 requires the laboratory to have procedures for recording relevant data and operations relating to sampling including, the identification of the sampler, environmental conditions (if relevant), and diagrams or other equivalent means to identify the sampling location as necessary.

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 a 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.

- Instead of checking for residual chlorine, Koebel would look at the bubble in the chlorinator and "guesstimate" the concentration. The laboratory reported high levels of coliform to Koebel, but not to the Ontario Ministry of the Environment as required by regulation. 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.

How the TNI Standard Could Have Prevented this from Occurring

Section 4.2.1 requires the laboratory to establish, implement and maintain a management system appropriate to the scope of its activities. Section 5.10.1 requires the results be reported accurately, clearly, unambiguously, and objectively.

Reference

1. *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.

More Coliform Issues

- ❑ **Case Study 5: Sample Dilutions**
    - 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.
- ❑ **Case Study 6: Rejected Result**
    - 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.

How the TNI Standard Could Have Prevented this from Occurring

Section 5.10.1 requires the results be reported accurately, clearly, unambiguously, and objectively, and in accordance with any specific instructions in the test methods. Section 4.4.1 requires the laboratory to have the capability and resources to meet the requirements. Section 5.2.1 requires all personnel to be competent.

Reference

1. 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 under the EPA hazardous waste regulations. Lime is calcium hydroxide which is used to make pH 12 buffer and at 25° C has a pH of 12.454, less than 12.5, which according to the legal system means it is not a hazardous waste. 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.

This incident resulted in a major civil trial where the court ruled that yes, 12.454 is less than 12.5 and thus it was not a hazardous waste spill. And, with temperature correction and expanded readout, pH can be measured to the third decimal point.

How the TNI Standard Could Have Prevented this from Occurring

Section 5.4.1 requires the laboratory to use test methods which meet the needs of the customer and which are appropriate for the tests it undertakes.

Reference

1. Public Docket to SW-846 rule-making
2. Measurement Uncertainty Calculations for pH Value Obtained by an Ion-Selective Electrode https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6022053/

Analyses for Pesticides

- ❑ **Case Study 8: Historical Reconstruction**
    - 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.
- ❑ **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.

How the TNI Standard Could Have Prevented this from Occurring

Section 5.4.1 requires the laboratory to retain all information necessary for the historical reconstruction of data. Section 4.1.5 requires laboratory management to provide adequate supervision of testing staff, including persons familiar with methods and procedures. Section 4.2.8.4 requires the laboratory to have procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and are receiving any needed training. Section 5.2.1 requires management to ensure the competence of all who operate specific equipment, perform tests, evaluate results, and sign test reports. Section 1.6 (Module 4) requires all individuals performing chemical analyses successfully perform an initial DOC prior to using any method.

References

1. Parr, Jerry; personal observation
2. Laboratory assessor, personal observation

Reporting Results

- ❑ **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. Eighteen months of incorrect data was reported which affected decisions made by a large federal entity.
- ❑ **Case Study 11: Review of Data**
    - Verbal results reported no volatile organics detected in several train cars of waste. The waste was then discarded in a municipal landfill not licensed for hazardous waste. One week later, the final report showed volatile organics exceeded action level. Verbal results were associated with different samples.

How the TNI Standard Could Have Prevented this from Occurring

Section 4.1.5 requires the laboratory to have procedures to describe how changes in documents maintained in computerized systems are made and controlled. Section 5.10.2 requires the laboratory to include an unambiguous identification of the item(s) tested in the test report.

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.

How the TNI Standard Could Have Prevented this from Occurring

Section 4.1.5 requires the laboratory to 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. Section 4.4 requires the laboratory ensure it 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. For example, EPA 1664 requires 85% purity for the hexane used to extract samples for the method defined parameter "Hexane Extractable Material (HEM)", a replacement for the older term "oil and grease." The method is based on evaporating the hexane to dryness and measuring the residue gravimetrically. The hexane used by the laboratory was not 85 % pure. It also contained pentanes. The laboratory violated the requirement in 40 CFR 136 to follow the method exactly as written. The result was likely accurate, since the pentanes would affect neither the partition coefficient nor the drying step, but the results were not acceptable.

How the TNI Standard Could Have Prevented this from Occurring

Section 5.9.3 requires the laboratory to ensure that the requirements in mandated methods or regulations are incorporated into their method manuals.

Reference

1. State accreditation body, personal observation

Case Study 14: Benzidine? Really?

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

How the TNI Standard Could Have Prevented this from Occurring

Section 5.6.3.2 requires the laboratory to reference materials traceable to certified reference materials. Section 1.7.1.1 (Module 4) requires standards used for calibration be traceable to a national standard, when commercially available. All initial calibrations must 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 was sent in for soils analysis using EPA's Contract Laboratory Program (CLP) 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 and furthermore that the CLP water method would be more appropriate for this sample.
- 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, based on the % solids results, involved a 50X multiplier.
- The matrix spike was performed on another unrelated sample in the batch, highlighting the fundamental problem with this type of QC check. The results only apply to the sample that was spiked, not the others in the batch. The QC results passed data validation criteria but made no logical sense.

How the TNI Standard Could Have Prevented this from Occurring

Section 4.4.1 requires the methods to be used be adequately defined, documented and understood and the appropriate test method is selected and is capable of meeting the customers' requirements. Section 5.4 requires the laboratory to use appropriate methods and procedures for all tests and inform the customer when the method proposed by the customer is considered to be inappropriate. Section 5.4.7 requires the laboratory to ensure that computer software is documented in sufficient detail and is suitably validated as being adequate for use.

Reference

1. Parr, Jerry; personal observation

Analyses for Biochemical Oxygen Demand

- ❑ **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.
- ❑ **Case Study 17: BOD Blank Results**
    - 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).

How the TNI Standard Could Have Prevented this from Occurring

Section 4.4.1 requires deviations from test methods occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer. Section 1.7.3.1 (Module 4) requires method blanks to be critically evaluated as to the nature of the interference and the effect on the analysis of each sample within the batch.

Reference

1. State Accreditation Body finding
2. 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.

How the TNI Standard Could Have Prevented this from Occurring

Section 1.5.1 (Module 4) requires all methods be validated.

Reference

1. 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.

How the TNI Standard Could Have Prevented this from Occurring

Section 5.9.3 requires all laboratories to have detailed written protocols in place to monitor negative such as blanks. Section 1.5.2 (Module 4) requires detection limit determinations include data from low level spikes and routine method blanks prepared and analyzed over multiple days. Section 1.7.2.1 requires method blanks to be processed along with and under the same conditions as the associated samples to include all steps of the analytical procedure and determine if a method blank is contaminated.

References

1. Burrows, Richard, National Environmental Monitoring Conference, 2015
2. Settle, D.M. and Patterson. C.C., Lead in albacore: guide to lead pollution in Americans
3. Science, March 14, 1980.
   https://www.epa.gov/system/files/images/2021-09/fish-chart.jpg

* While this was not an environmental laboratory, and thus the TNI Standard is not directly applicable, the basic principles apply; a robust QMS such as the TNI Standard could have prevented this error.

Case Study 20: USEPA Region 5 Central Regional Laboratory

- ❑ The report cited below involved hundreds of samples analyzed over many years.
- ❑ Data were provided to the EPA 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

How the TNI Standard Could Have Prevented this from Occurring

This case study represents a total lack of any quality management system.

Reference

1. 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.

How the TNI Standard Could Have Prevented this from Occurring

Section 4.2.8.1 requires the laboratory to 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. Section 4.14 requires the laboratory to conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system.

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

* While this was not an environmental laboratory, and thus the TNI Standard is not directly applicable, the basic principles apply; a robust QMS such as the TNI Standard could have prevented this error.

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.

How the TNI Standard Could Have Prevented this from Occurring

Section 5.4.2 requires the laboratory to use test methods which meet the needs of the customer and which are appropriate for the tests it undertakes.

References

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/
2. *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

* While this was not an environmental laboratory, and thus the TNI Standard is not directly applicable, the basic principles apply; a robust QMS such as the TNI Standard could have prevented this error.

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 a start-up a laboratory in Anchorage and then ship the extracts to a continental US laboratory. All QC checks (LCS, MS, Surrogates) were 5-10% recovery, which is below method specified acceptance limits. Though the data is of known and documented quality, it was not usable to make any type of meaningful decision.

How the TNI Standard Could Have Prevented this from Occurring

Section 1.6 (Module 4) requires an individual who performs any activity involved with preparation and/or analysis of samples have constant, close supervision until a satisfactory initial Demonstration of Capability is complete.

Reference

1. Parr, Jerry; personal observation

Instrument Calibration Issues

- ❑ **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/µL 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.
- ❑ **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.
- ❑ **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 1,335%. This error meant that a 0.5 ng/mL true value would be measured as 7.2 ng/mL.

How the TNI Standard Could Have Prevented this from Occurring

Section 1.7.1.1 (Module 4) allows a laboratory to remove individual analyte calibration levels from the lowest and/or highest levels of the curve, but removal of interior levels is not permitted. Section 1.7.1.1 (Module 4) allows a laboratory to remove a calibration standard from the interior of the calibration if all analytes are removed. Section 1.7.1.1 (Module 4) requires a laboratory to use and document a measure of relative error in the calibration.

References

1. 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
2. *Evaluating the Goodness of Instrument Calibration for Chromatography Procedures,* Burrows, R. and Parr, J., LC/GC North America, October 2020.
3. *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.

How the TNI Standard Could Have Prevented this from Occurring

Section 5.4.4 requires a laboratory to use methods subject to agreement with the customer and that includes a clear specification of the customer's requirements and the purpose of the test.

Reference

1. State Agency; personal observation

> 85,000 Bad Data Points from the Massachusetts State Crime Laboratory*

- ❑ **Case Study 28:** 27,000 faulty DUI results due to breath analyzer not being calibrated.
- ❑ **Case Study 29:** 21,587 drug cases overturned because Annie Dookhan lied. Dookhan did not test samples, but wrote down what the police suspected as the result. Her productivity was 5 x greater than other laboratory staff. If the police did not write something down, Dookhan would spike the sample with cocaine and test.
- ❑ **Case Study 30:** 35,000 drug cases overturned because Sonja Farak was a drug addict. Pipetted liquid Meth from the refrigerator to "give her strength." Tasted, injected, or snorted other samples including LSD, cocaine, etc. Sonja Farak was sentenced to 18 months in jail. A Netflix documentary "How to Fix a Drug Scandal" (4 1-hour episodes) describes this case in detail and shows the courage of defense attorneys.

How the TNI Standard Could Have Prevented this from Occurring

Section 4.1.5 requires laboratory management to provide adequate supervision of testing staff, including trainees, by persons familiar with methods and procedures. Section 4.2.8 requires the laboratory to establish and maintain a documented data integrity system. Section 4.13.2 requires the laboratory to retain records for each test that contain sufficient information to enable the test to be repeated under conditions as close as possible to the original. Section 5.2.1 requires laboratory management ensure the competence of all who operate specific equipment, perform tests, evaluate results, and sign test reports. Section 5.5.8 requires all equipment under the control of the laboratory 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. Section 5.10.1 requires the results of each test carried out by the laboratory 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

* While this was not an environmental laboratory, and thus the TNI Standard is not directly applicable, the basic principles apply; a robust QMS such as the TNI Standard could have prevented this error.

Poor Sample Collection in Wetlands Leads to No Reportable Data

- **Case Study 31:** Collected water in marsh with a depth of less than 5 cm water (Requirement is no less than 10 cm). Sample not representative. All data were rejected.

- **Case Study 32:** Field data measured by dipping metal pan into water and laying multiparameter instrument sideways in pan. Data not representative. All data were rejected.

- **Case Study 33:** 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.

How the TNI Standard Could Have Prevented this from Occurring

Section 5.4.1 requires the laboratory to use appropriate methods and procedures for all tests within its scope including sampling. Section 5.7 requires the laboratory to 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 are to be available at the location where sampling is undertaken. The sampling process must address the factors to be controlled to ensure the validity of the test results.

Reference

1. John Moorman, South Florida Water Management District; Personal observation

Data Integrity for Sampling (multiple events)

- **Case Study 34:** 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.

- **Case Study 35:** Oakland, CA, sampling mess for cannabis
  - Sampler did not follow subsample requirements.
  - All test results rejected.
  - Laboratory closed.

- **Case Study 36:** California laboratory issues for cannabis
  - Changed results to meet customer requests.
  - Sampled high THC portion of the plant.
  - Charged more for higher THC results.

- **Case Study 37:** 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.

How the TNI Standard Could Have Prevented this from Occurring

Section 4.1.5 requires the laboratory to have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity. Section 5.2.7 requires data integrity training 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 can result in a detailed investigation that could lead to very serious consequences including immediate termination, debarment or civil/criminal prosecution. Section 5.7 requires the laboratory to have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing. The sampling process must address the factors to be controlled to ensure the validity of the test results.

Reference

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

Blunders in Sampling and Analysis (multiple events)

- **Case Study 39:** The Lowes Hose
  - Residential wells showed significant levels of polynuclear aromatic hydrocarbons 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.

- **Case Study 40:** 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.

- **Case Study 41:** 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.

- **Case Study 42:** Sure Looks Clean to Me
  - Monitoring well purge water discharged to parking lot which then entered nearby creek. The Work Plan specified purge water was to be containerized but since it looked "pretty clean" the water was not containerized. The purge water had a pH of 9.3 resulting in a large fish kill.

- **Case Study 43:** 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.

- **Case Study 44:** 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.

- **Case Study 45:** 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.

How the TNI Standard Could Have Prevented this from Occurring

Section 4.2.2 requires laboratory management ensure all personnel concerned with testing activities familiarize themselves with the quality documentation and implement the policies and procedures in their work. Section 5.4.1 requires deviation from methods occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer. Section 5.7 requires the laboratory have a sampling plan and procedures for sampling when it carries out sampling for subsequent testing. The sampling process must address the factors to be controlled to ensure the

validity of the results. Section 1.7.3.1 requires blanks be critically evaluated as to the nature of the interference and the effect on the analysis of each sample.

Reference

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

Case Study 46: 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 where the ambient temperature was close to 100 degrees F. 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."

How the TNI Standard Could Have Prevented this from Occurring

Section 5.4.1 requires laboratory management laboratory shall use appropriate methods and procedures for all tests within its scope, including sampling. Section 5.7 requires the laboratory to have a sampling plan and procedures for sampling. The sampling process must address the factors to be controlled to ensure the validity of the test results.

Reference

1. Commercial laboratory, personal observation.

New Orleans Drinking Water Issues

- ❑ **Case Study 47: Sample Collection**
  - Samples were to be collected for residual chlorine at 1900 locations over 5 years. 24% of locations were skipped once and 34% of those were skipped twice. Some locations were never sampled. Eight different individuals were involved.

- ❑ **Case Study 48: DPD Reacts Quicker in New Orleans**
  - Hach requires the color to be read (for the DPD reaction for residual chlorine) between 3 and 5 minutes. Readings less than 3 minutes can result in a low bias; results read after 5 minutes can result in a high bias. "Even if just the minimum times to run the tap (two minutes), mix the DPD (20 seconds) and complete the DPD reaction (three minutes) were all that were required, there were still between 4.5% and 38% of stops that didn't span that amount of time." "The employee actually spent more time when going through the McDonald's drive-thru." "The deputy general superintendent of engineering said the standard method and Hach's instructions did not apply to New Orleans' particular water chemistry, and that waiting for the DPD reaction to run to completion was unnecessary."

- ❑ **Case Study 49: Coliform Testing Begun Before Samples Reached the Laboratory and Incubation Times Exceeded**
  - Time of initiation of incubation rounded to minutes divisible for 5 or 10. "On Jan. 25, data submitted to the state claimed 10 coliform samples began their testing in at 11 a.m. However, GPS records for the sampler that morning show he was still on the road at 11 a.m. Records show him parking in front of the lab 14 minutes after the samples he was carrying had supposedly been placed in the incubator to begin testing." In nearly a fifth of the batches, test durations exceeded the 24-hour maximum. The excessive incubation times, from a few minutes up to an hour, occurred regularly throughout the seven months studied.

How the TNI Standard Could Have Prevented this from Occurring

Section 5.4.1 requires laboratory management laboratory shall use appropriate methods and procedures for all tests within its scope, including sampling. Section 5.7 requires the laboratory to have a sampling plan and procedures for sampling. The sampling process must address the factors to be controlled to ensure the validity of the test results. Section 4.4.1 requires deviations from test methods occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer. Section 5.8.6 requires the laboratory to record the date and time of sample collection and Sectio 5.8.7 requires the laboratory to record the date and time of receipt by the laboratory. Section 5.10.11 requires the laboratory to record the date and time of sample preparation and analysis.

References

1. *Tapped Out: Investigation reveals S&WB employees skipped, falsified drinking water tests.* https://lailluminator.com/2023/11/07/tapped-out-investigation-reveals-swb-employees-skipped-falsified-drinking-water-tests/
2. *Tapped Out: New Orleans drinking water testing procedures don't follow gov't regulations.* https://lailluminator.com/2023/11/08/new-orleans-water/

Case Study 51: The Phantom of Heilbronn*

- ❑ Suspected unknown female serial killer in Austria, France and Germany 1993 – 2009.
- ❑ Connection was DNA evidence of an eastern European female.
- ❑ Female was identified as a factory worker who made cotton swabs for testing.
- ❑ While sterile, the swabs were not certified for DNA testing. ISO consequently published 13385 for consumables used for DNA testing.

How the TNI Standard Could Have Prevented this from Occurring

Section 5.6 requires the laboratory to establish and maintain metrological traceability of its measurement results. Section 5.9.3 requires the laboratory to have detailed written protocols in place to monitor negative controls.

Reference

1. https://en.wikipedia.org/wiki/Phantom_of_Heilbronn

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