



Adventures at the Frankenstein Factory

OR

Having a Strong Quality Management System
Prevents Faulty Results

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New TNI Strategic Initiative

- ❑ Develop a long-range plan for promoting the use of the TNI accreditation program to data users.
 - Show the value/benefits.
 - Demonstrate the improvement in performance and data quality.
- ❑ Phase One: *White Paper, Laboratory Accreditation Makes a Difference*, completed in 2020.
 - https://nelac-institute.org/docs/comm/advocacy/White%20Papers/WP-Value_101420.pdf
- ❑ Phase Two: Case Studies of Faulty Data





Many Decisions Are Based on Having Reliable Data

- Demonstrate compliance to a regulated limit.
- Continue or cease remediation.
- Assess risk to human health or environment.
- Health surveillance.
- Water and wastewater engineering and technology implementation.



What Is “Reliable” Data?

- ❑ What characterizes reliable data?
- ❑ How do we know that it is reliable?
- ❑ The result is only an estimate of the true concentration.
- ❑ Quality Control results can be misleading for a variety of factors.



Laboratory Data Quality

- ❑ Laboratories say they generate
 - High quality data,
 - Definitive data,
 - Data of known and documented quality,
 - Legally defensible data, or
 - Valid data.
- ❑ What do any of these terms mean? How do laboratories ensure and document reliability?
- ❑ Are there any documents that can help ensure reliable data?





TNI's Quality Management System - Module 2 of the Laboratory Standard

- ❑ Developed over a 25-year period by a consensus body, the TNI Quality Management Systems committee.
- ❑ Committee has a balanced representation from all affected stakeholders: Accreditation Bodies, laboratories, data users, and other interests.
- ❑ Based on ISO/IEC 17025 (2005) with specificity added for environmental testing.
- ❑ Significant revisions in development, including update to 17025 (2017).
- ❑ Technical Modules 2-7 provide additional detail for specific types of
The TNI NEFAP Standard has comparable requirements for Field Sampling and Measurement Organizations (FSMO)





But 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?”



Quality System Vulnerabilities

- Expired standards
- Sample temperature
- Equipment not matched to sample
- No trip blanks for volatiles
- Internal audits do not cover all aspects of testing
- Interference check sample not analyzed
- SOP does not reflect actual practice
- DI water bottle not labeled
- Corrections not dated or initialed

These types of **Vulnerabilities** indicate a problem with the quality system which may or may not affect the quality of the data but do diminish the confidence.



Definition of Faulty Data

- Incorrect sample
- Inaccurate or incorrect result
- Insufficient documentation
- Non-conformance to mandated method
- Not meeting customer requirements

Does not include **Inappropriate Practices** that may or may not have a direct impact on data quality, e.g.:

- Inappropriate manual integrations,
- Spiking LCS/Surrogates into extract, not sample, or
- Adjusting time clocks.

However, these all relate to not having a robust data integrity system.



Examples of Faulty Data

- ❑ 37 Case Studies with many more not presented.
- ❑ Citation to TNI standard provided.
- ❑ No particular order, but some were much worse than others.



Newborn Screening for Propionic Acidemia

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

QMS Failures

5.4.6 – Uncertainty

5.10.3 – Test Reports



Brain Eating Amoeba

Naegleria fowleri

- ❑ 2 deaths in St. John's Parish due to lack of chlorine in the distribution system attributed to lung exposure to amoeba (neti pot)
- ❑ Water utility decided to collect samples at the far ends of the system and check for residual chlorine.
- ❑ Two utility workers indicted for failing to test the water supply and then lying about it (after).
- ❑ Branch did not stop at 30 of the 48 water inspections he claimed to have done and Roussel did not stop for three of the six inspections.

QMS Failures

4.2.8 – Data Integrity

5.7.3 – Sample Recording



Coliform Outbreak in Walkerton, Canada

- ❑ Seven dead, 2,300 ill
- ❑ PUC manager Stan Koebel did not report lab results and did not inform public that well had been operating without a chlorinator
 - Did not want to interfere with Victoria Day
 - Did not think coliform was that bad
- ❑ 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

5.10.1 – Reporting Results





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



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 Failure

5.10.13 – Reporting Results



Train Car Derailment

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

QMS Failure

5.4.1 – Method Deviation



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



Pesticide Misidentification

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

QMS Failures

4.1.5 – Management

4.2.8.4 – Experienced personnel

5.2.1 – Management of personnel

1.6 (Module 4) – Demonstration of Capability



Incorrect Spreadsheet

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

QMS Failure

4.3.3 – Document Control



Data Review

- ❑ 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, final report showed volatile organics exceeded action level.
- ❑ Verbal results were associated with different samples.

QMS Failure

5.10.2 – Test Reports



Mixed Waste

- ❑ Salesperson assumed “mixed waste” to be a mixture of organic and inorganic substances and RFP 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 checked out the laboratory before samples were shipped and discovered the laboratory did not have the capability to handle radioactive samples.

QMS Failures

4.1.5 – Technical Management

4.4 – Review of Requests



Incorrect Reagent

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

QMS Failure

5.9.3– Mandated Methods



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

1.7.1.1 (Module 4) – Second Source Verification



The Sludge Pond Sample

- ❑ Sent in for CLP soils analysis.
- ❑ Sample had 2 % solids.
 - Representative 30 g sample?
- ❑ GPC correction factor not applied – 2X multiplier.
- ❑ Results corrected to dry weight – 50X multiplier.
- ❑ MS 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

5.4 – Methods and Method Validation

5.4.7 – Control of Data



6 and 7-Day BOD

- ❑ 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



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



Arsenic at Elementary School

- ❑ Laboratory reported high levels of arsenic in soil at elementary school.
- ❑ Laboratory had modified method without validating or receiving authorizations.
- ❑ School was shut down.
- ❑ Another laboratory analyzed samples and showed 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
1.5.1 (Module 4) – Method Validation



Lead in Tuna (Science, 1980)

- ❑ 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.
- ❑ Pregnant and breast-feeding women now should moderate their intake of king mackerel, swordfish, ...
- ❑ Albacore and yellow fin tuna are now considered "good" choices and canned light tuna is now a "best" choice.

QMS Failures

5.9.3 – Negative Controls

1.5.2 (Module 4) – Limit of Detection





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
- ❑ “The outcome of these actions resulted in making erroneous cleanup and enforcement decisions and spending additional resources to re-sample and re-analyze environmental samples to obtain reliable data.” Moreover, because these chemists had been with EPA for many years, the number of projects that were affected was very large.

QMS Failures
4.0 Management
5.0 Technical





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
- 4.14 – Internal Audits





FBI Forensic Laboratory

- ❑ 2600 convictions, including 45 on death row, in the 1980's and 1990's.
- ❑ Flawed results on hair analysis.
- ❑ 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.

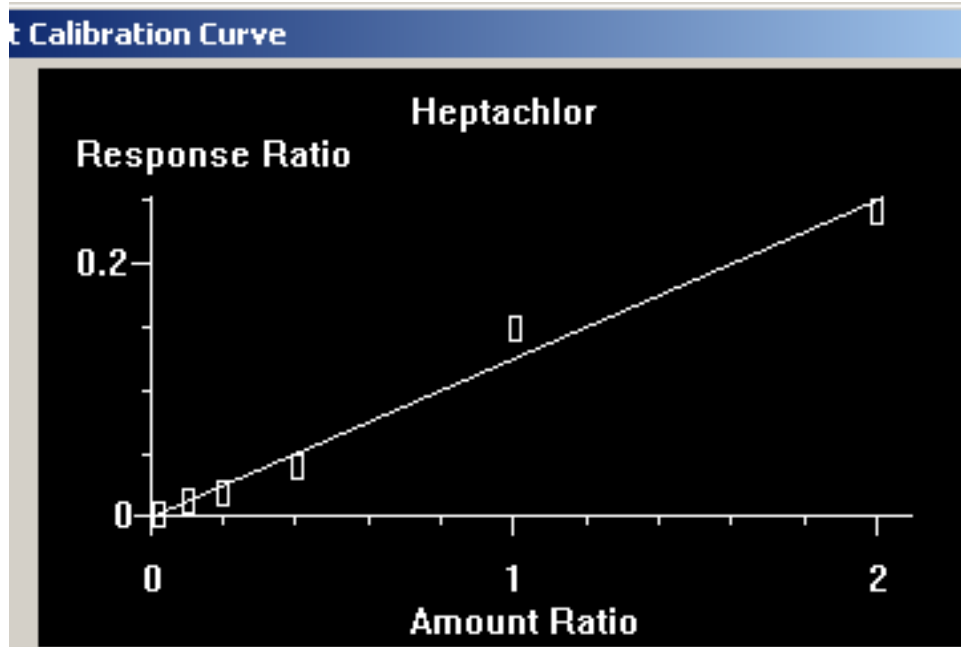
QMS Failure

5.4.2 – Selection of Methods



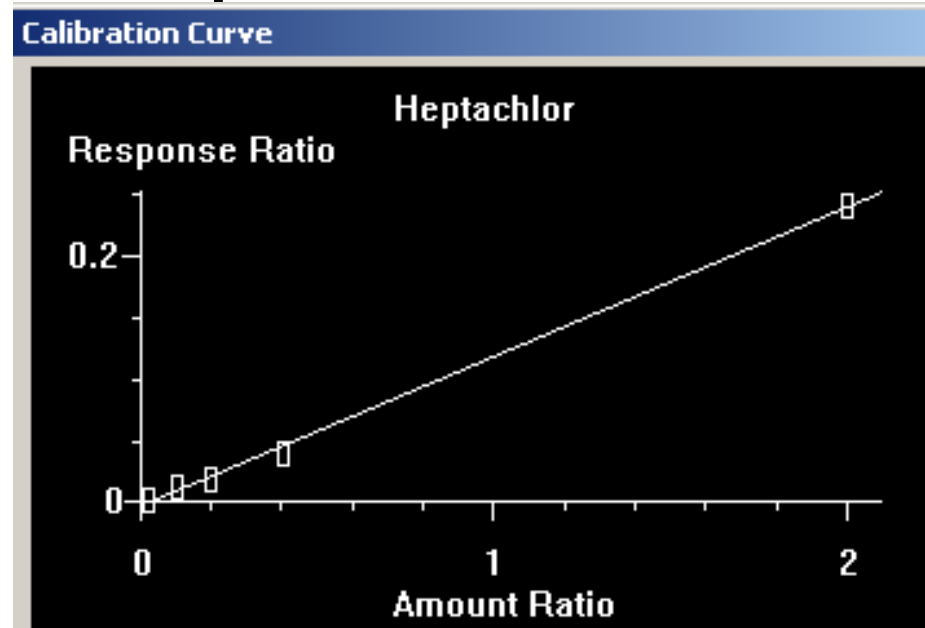
Removal of Interior Level to Pass Calibration Criteria

With 1.0 level standard



$R^2 = 0.983$

Drop 1.0 level standard



$R^2 = 0.998$

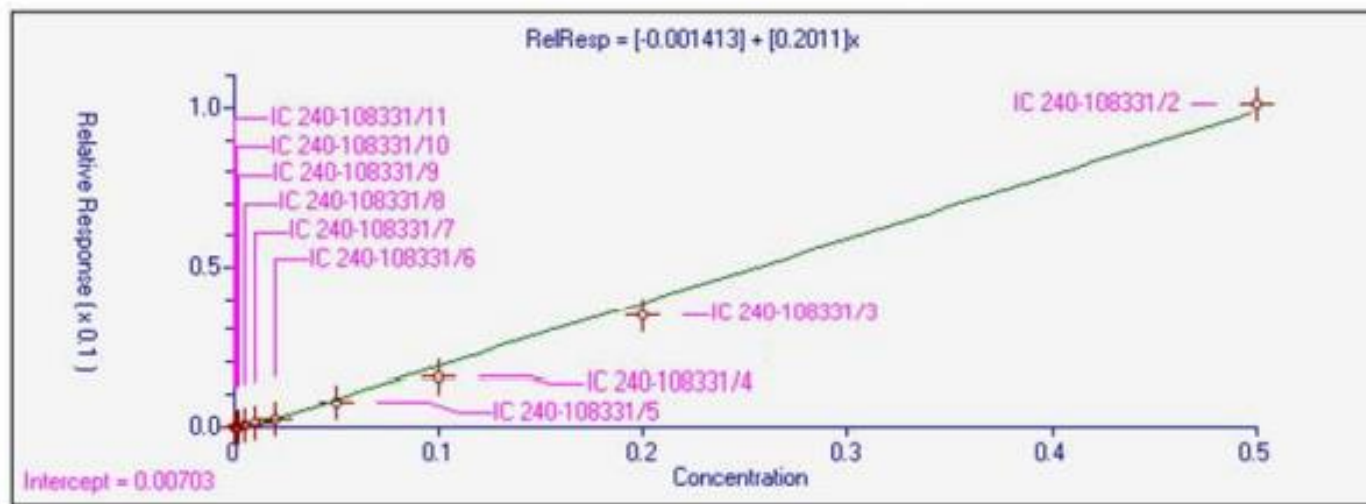
QMS Failure

1.7.1.1 (Module 4) – Initial Calibration



Use of R^2 Without Checking Error

2,4,5 Trichlorophenol, 0.5-500 ng/mL



Linear Unweighted

Coefficient of determination: **0.996**

Low point error **1335%**, bottom 4 points all > 85% error (RSE **535%**)

❑ **0.5 ng/mL true value reported as 7.2 ng/mL**

QMS Failure

1.7.1.1 (Module 4) – Measure of Relative Error





> 80,000 Bad Crime Laboratory Results in Massachusetts

- ❑ **27,000 DUI cases in jeopardy (4/25/23)**
 - Breath analyzer not calibrated.
- ❑ **Why did Annie Dookhan Lie?**
 - 21,587 cases overturned.
 - Dookhan did not test samples but wrote down what the police suspected as the result.
 - Productivity 5 x greater than other laboratory staff.
 - If police did not write something down, Dookhan would spike sample with cocaine and test.
 - Sentenced to prison for 3 years.

QMS Failures

4.1.5 – Laboratory Management

4.2.8 – Data Integrity

4.13.2 – Technical Records

5.2.1 – Personnel

5.5.8 - Calibration

5.10 - Reporting Results



> 80,000 Bad Crime Laboratory Results in Massachusetts

❑ Eight Years Later Fallout from Drug Lab Scandal Continues

- 35,000 drug cases overturned.
- Sonja Farak pipetted Meth daily from reference standard to “give her strength.”
- Also took cocaine and LSD from samples while working on the samples.
- “Total absence of any supervision or QC”
- 18 Months in jail.
- AG committed “Fraud on the Court.”
- Netflix documentary “How to Fix a Drug Scandal.” (4 1-hour episodes)

QMS Failures

- 4.1.5 – Laboratory Management
- 4.2.8 – Data Integrity
- 4.13.2 – Technical Records
- 4.14 Internal Audits
- 5.2.1 – Personnel
- 5.6.3.2 Reference Materials
- 5.10 - Reporting Results



7 More from David Blye and Rock Vitale

- The Lowes hose
- Mercury boots
- Dissolved metals everywhere
- Sure looks clean to me
- False Ethylene Glycol detection
- Poor PE sample preparation and laboratory error
- DI water clean but metals found in blanks.

QMS Failures

4.2.2 – Management

5.4.1 - Methods

5.7 – Collection of Samples

1.7.3.1 (M4) - Blanks



4 More from Gary Ward

- ❑ Coos Bay, OR Water Treatment Plant
- ❑ Oakland, CA sampling mess for cannabis
- ❑ California sampling issues for cannabis
- ❑ Cannabis results for pesticides and mold

QMS Failures

4.1.5 – Organization

5.2.7 – Data Integrity

5.7 – Collection of Samples



Conclusions

- ❑ Data quality problems identified for all types of laboratories and samplers
 - Commercial
 - Municipal (potable and non-potable water)
 - State
 - Federal
- ❑ Data quality problems identified for all types of testing
 - Clinical
 - Environmental
 - Food
 - Forensic
 - Geochemical





Reasons for Data Quality Problems

- Causes
 - Inadequate training
 - Inadequate management
 - Insufficient resources
 - Many, many more
- **Root Cause**
 - Lack of a Strong Quality Management System



Summary

- ❑ The QMS requirements in the TNI standard have a direct impact on data quality.
- ❑ Failures to correctly implement a robust QMS can result in loss of accreditation, decreased revenue, reanalysis, or data rejection.
- ❑ Failures can result in unnecessary remediation, illegal disposal, or other bad decisions based on faulty data.





New White Paper

□ Having a Strong Quality Management System Prevents Faulty Results

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 high confidence decisions.

<https://nelac-institute.org/docs/comm/advocacy/White%20Papers/WP-Reliable.pdf>



Recommendations

- ❑ TNI believes **ALL** environmental laboratories and FSMOs in the US should be accredited to the applicable TNI standard.
- ❑ NELAP - 1400 Accredited Laboratories, including:
 - Most commercial Laboratories,
 - All drinking water laboratories in NELAP states,
 - All laboratories in California (TNI-2), and
 - A few laboratories from regulated industry and research groups.
- ❑ What about all the others? How many are there?
- ❑ How much faulty data is generated each year?
- ❑ Lack of a strong QMS can affect frequently analyzed parameters like BOD and coliform.





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