TNI Update

- Part 1: Adventures at the Frankenstein Factory
- Part 2: TNI's New Credentials Effort
- Part 3: Standards Development

Jerry Parr

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Adventures at the Frankenstein Factory

OR

How a Strong Quality Management System
Prevents Faulty Results

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 (and presented at OELA in2022).
  - 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

- 15 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

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

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

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

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

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

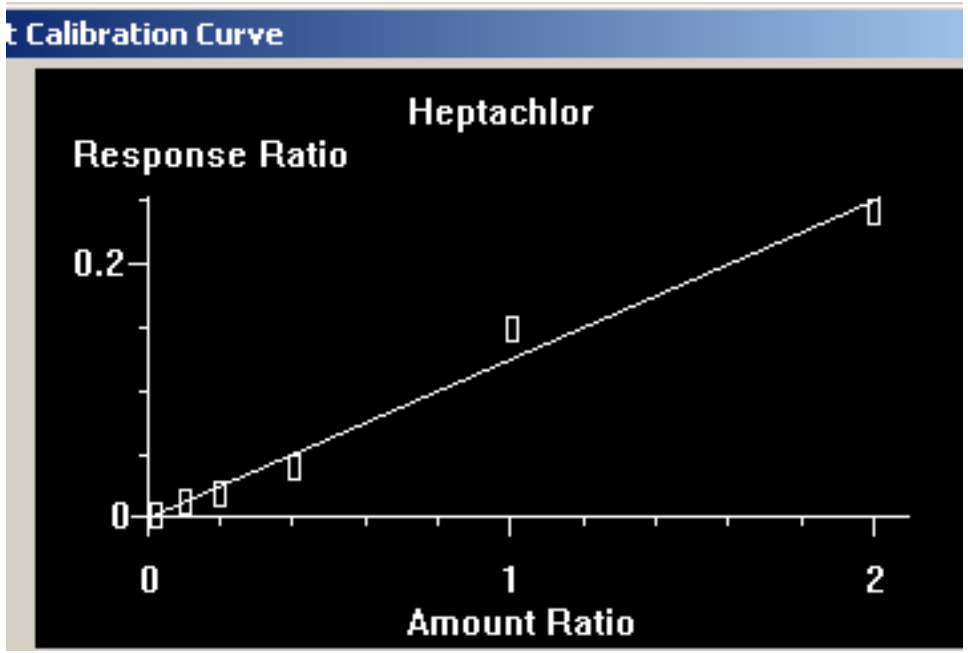
FBI Forensic Laboratory

- 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

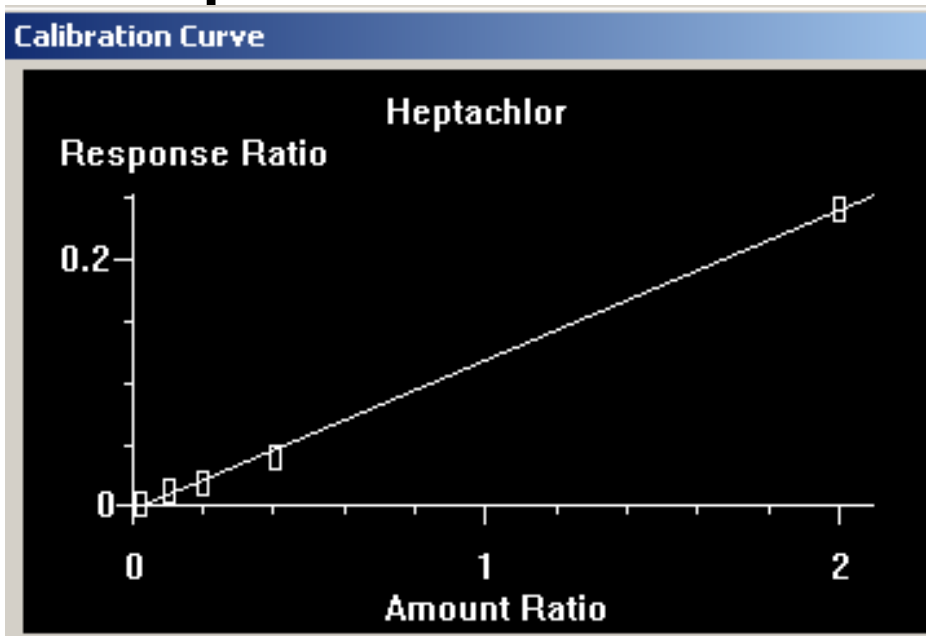
Removal of Interior Level to Pass Calibration Criteria

With 1.0 level standard



R^2 =0.983

Drop 1.0 level standard

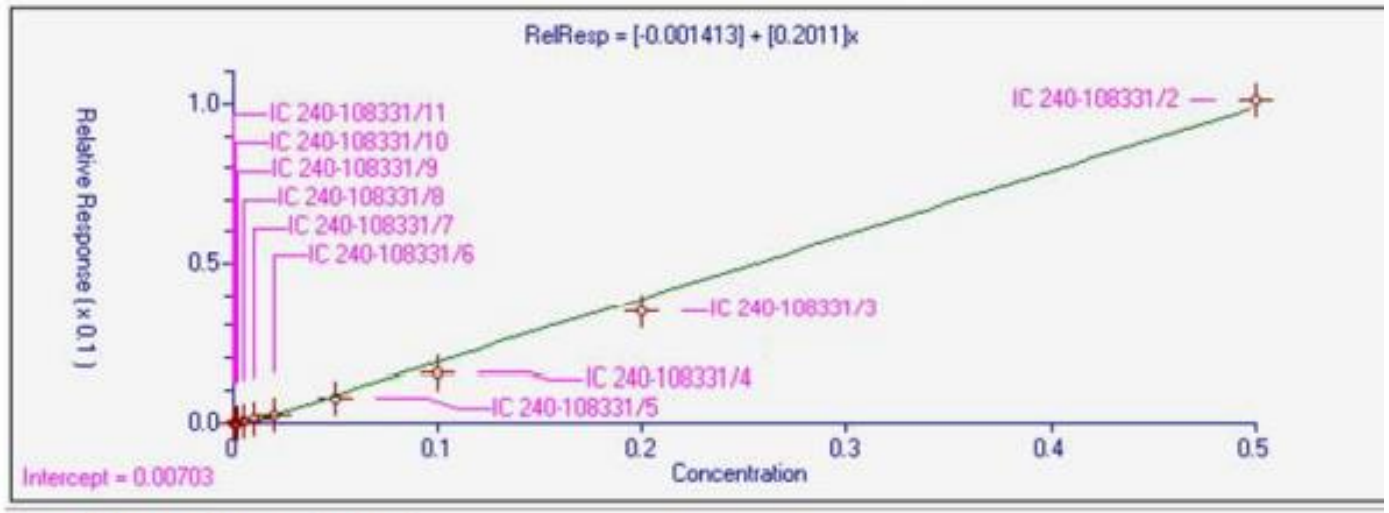


R^2 = 0.998

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%)

QMS Failure
1.7.1.1 (Module 4) – Measure of Relative Error

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

> 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

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

Conclusions

- Data quality problems identified for all types of laboratories
  - 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, or to some equivalent standard which contains a strong QMS foundation.
- 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.

Acknowledgements

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TNI's Credentialing Initiative

Background

- TNI 2020 Strategic Plan established a new goal:
  - Explore the feasibility of developing systems to document individual competency.
- This goal had the following objective:
  - Explore and make recommendations regarding systems to document competencies for Quality Managers, Technical Managers, Laboratory Assessors, Samplers and others as appropriate.
    - Note: Such documentation may involve credentialing.

Competence: ability to apply **knowledge** and **skills** to achieve the intended results.

Knowledge, Skills, and Abilities (KSAs)

Knowledge – "know what"

- Knowledge focuses on the understanding of concepts. It is theoretical and not practical. An individual may have textbook knowledge of a topic but have no experience. For example, someone might have read hundreds of articles on health and nutrition, many of them in scientific journals, but that doesn't make that person qualified to dispense advice on nutrition.

Skills – "know how"

- Skills are the capabilities developed through training or hands-on experience that lead to practical application of theoretical knowledge.

Abilities – "know why"

- Often confused with skills, yet there is a subtle but important difference. Abilities are the innate talents a person brings to a task. Many people can learn to negotiate competently by acquiring knowledge about it and practicing the skills it requires. A few are brilliant negotiators because they have the innate ability to persuade.

Achieving KSAs

- Knowledge
  - Read and comprehend the standard.
  - Take a Training Course.
  - Take a Training Course and earn a Badg
- Skill
  - Learn from experience.

TNI has no plans to require laboratories, ABs, or individuals to take training courses, become certified, or earn digital badges. This program will be voluntary to allow individuals to demonstrate their competency. Any employer may require this of certain staff, but that is beyond the scope of TNI's role.

Credentialing Overview

- Experience and Education Option (The “Full Credential”)
  - Minimum education and experience requirements
  - Comprehensive exam based on KSAs grouped into topics
  - Training Courses available, but not required
- Digital Badge Option
  - Training courses required, but some flexibility allowed
  - Pass exam for each badge based on KSAs for that badge
- Continuing Professional Development Hours for both options
- Certificate for a “Certified Professional” valid for 3 years

TNI Certified Laborattory Quality Management Systems Professional

- Individuals who want to become a certified Quality Management System Professional would need use the education and experience option **OR** the digital badge option.
- TNI would provide a notice of recertification 6 months before expiration to allow the individual to collect the information required to recertify.
- Individual would be listed in the TNI database of Certified Professionals.

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The Education and Experience Option

Education and Experience

- High School – Five years working in a laboratory, including at least one year in a position in quality.*
- Associate's, in related field** -- Four years working in a laboratory, including at least one year in a position in quality.*
- Bachelor's, in related field** -- Three years working in a laboratory, including at least one year in a position in quality.*
- Master's or higher degree in related field** -- Two years working in a laboratory, including at least one year in a position in quality.*

* Some capacity in the area of quality control, quality assurance, or quality management

** Related fields are chemistry, environmental sciences, biological sciences, physical sciences, chemical engineering, or equivalent scientific discipline

The Exam

- Applicants meeting the education and experience requirements may apply to take the exam for this “full credential”
- Proctored exam is open book, 150 hard but not “tricky” questions from a master database of all questions from all digital badge exams, 2.5 hours long. Passing score is 70 or higher
- Credential valid for three years
- Six months’ notice given when recertification is required
- Require a score of 70 or greater to pass
- Areas of improvement identified for those that fail.

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The Digital Badge Option

Digital Badging

- Digital Badge - an indicator of accomplishment or skill that can be displayed, accessed, and verified online.
- Examples
  - Data Integrity Specialist
  - Customer Service Specialist
- Would require passing test specific to the KSAs for that badge.
- Such person would be called a “Specialist.”

Example KSA – PT Specialist

§ 2.2.1 KSAs from the TNI Standard

Understands

- the requirement to participate in PT studies for each Field of Proficiency Testing (FoPT) adopted by TNI for which the laboratory seeks to obtain or maintain accreditation.
- how to schedule PT studies and how to use an accredited PT Provider accredited to Volume 3 of the TNI Environmental Laboratory Sector Standard.
- the requirements for analyzing PT samples.

And many more

2.2.2 KSAs from Volume 2

Understands the suspension, revocation, and reinstatement procedure employed by the AB for failures on PT samples.

Specialists for QMS Professional

1. Basic Quality Managment
2. Proficiency Testing (PT)
3. Data Integrity
4. Records and Document Control
5. Customer Service
6. Measurement Traceability
7. Internal Audit
8. Corrective Action
9. Method Validation
10. Sample Handling
11. Quality Control
12. Data Review and Reporting

Required Training Courses

- An individual would have to earn 4 hours of training for each badge, but there would be some flexibility in selecting courses.
- Example – Data Integrity Specialist requires 4 hours.
- Any of these classes could be used:
  - Ethics Training for the Environmental Professional – 2 hours
  - Establishing a Data Integrity Plan – 2 hours
  - Small Laboratory Implementation: Management of Ethics – 2 hours
  - Small Laboratory Implementation: Personnel – 2 hours
  - Analyst Competency Beyond the Demonstration of Capability – 4 hours

The Certificate

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IS HONORED TO CONFER UPON

Jane Justice

the designation of

Certified Quality Management Systems Professional

This designation is earned by demonstrating relevant knowledge, skills, and attributes through a comprehensive application and evaluation process designed to ensure high standards for the industry.

Awarded this day: January 11, 2023

Valid through: January 10, 2026

Alfredo Sotomayor

Alfredo Sotomayor, TNI Chair

Jerry Parr

Jerry Parr, TNI Executive Director

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Recertification for the Certified Professional

Recertification

- Applies to either approach.
- Remain employed in the field.
- Accumulate 24 Professional Development Hours (PDH) over 3 years.
- Pay the triennial fee.

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PDH Options

Activity	PDH earned	Maximum Hours
Training Course (Attendee)	0.1/hour for each hour of course	No limit
Training Course (Instructor)	1/hour for each hour of course	No limit
Continued Employment	0.1/month	3.6
College Course	1/credit hour	No limit
Meetings/Conferences	1/day	15
Committee Officer	2/year	10
Committee Member	0.5/year	5
Presentation at Conference	1/presentation	6
Membership in Professional Society	0.5/year/society	6
Proctor exam	3 hours per exam	No limit

Potential Benefits to the Individual

- Increased recognition by peers and respect of colleagues in the profession.
- Improved opportunities for employability and advancement.
- Greater confidence in their professional competence.
- Increased professional trust from employers or the public.
- Increased autonomy in the workplace.
- Better compensation and career longevity.

Potential Benefits to Employers

- Qualified individuals for employment or advancement.
- Recertification requirements for continued or enhanced competence.
- Reduced risk of errors, accidents and/or legal liability.
- Reduced employee turnover and increased job satisfaction.
- Justification for potential compensation differential.

TNI Standard Update

Revisions to Volume 1

Module 1: Proficiency Testing
Module 2: Quality Systems General Requirements
Module 3: Quality Systems for Asbestos Testing
Module 4: Quality Systems for Chemical Testing
Module 5: Quality Systems for Microbiological Testing
Module 6: Quality Systems for Radiochemical Testing
Module 7: Quality Systems for Whole Effluent Toxicity Testing

All are undergoing revision with drafts to be published late 2023 or early 2024

Proficiency Testing

- Early stage of modification
- All Volumes/Modules (V1M1, V2M2, V3, V4) will be revised
- Volumes 3 and 4 require the most ‘urgent’ revision due to ANSI requirements
- Workgroups formed to begin the process
- Changes to Module 1 are all editorial to improve clarity

Module 2 – Quality Systems

- ISO 17025:2005 → ISO 17025:2017
- Technical Manager → Technical Specialist
- Procedures, Policies, Documents
- Definitions: Annual, Quarterly, Customer, Procedure, Corrective Action

Module 4 - Chemistry

- Entire Module open for revision
- Focus (initially at least) on these items:
  - Detection/Quantitation Limits
  - Calibration Points
  - Relative Error
  - Demonstration of Capability

Module 5 - Microbiology

- Public Comment on the revised Module closed in November ‘21
- Additional comments were received after that date that the committee accepted for review
- All comments have been judged persuasive or non-persuasive

Hot Button Issues

- Incubator equilibrium requirements / uniformity of temperature requirements
- Requirements that are already in a method (such as in *Standard Methods*) being repeated in the Module

TNI Future Meetings

- Forum on Environmental Accreditation – January 22-25, 2024; Columbus, OH
  - Major focus will be the new draft standards
- Environmental Measurement Symposium – August 5-9, 2024; Orange County, CA

THANK YOU!

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