How TNI's Quality Management System Improves Data Quality and Laboratory Performance

"Data You Can Trust"

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Steve Arms

Chair, TNI Advocacy Committee

OELA October 18, 2022

TIMELINE

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SDWA Certification Program

CLP De-facto National Program

ACCREDITING AUTHORITY nelap

ISO Guide 25

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Adopt New Standard

1978 1980's 1995 1999 2001 2003 2006 2009 2016

State Programs expand into other media

nelac

ACCREDITED IN ACCORDANCE WITH nelac

2003 NELAC Standard 17025: 1997

Explore Module/Volume 17025:2005

TNI's Quality Management System

- Developed over a 25-year period by a consensus body, the TNI (NELAC) Quality Systems committee.
- Committee has a balanced representation from all affected stakeholders: Accreditation Bodies, laboratories, data users, and other interests.
- Based on ISO/IEC 17025 with specificity added for environmental testing.
- Continuous improvement; 2023 standard in development.
- Anyone can participate in the process.

OUR 30 YEAR OLD GUIDING PRINCIPLES

- TNI's accreditation program includes a requirement for a laboratory to implement a Quality Management System, designed to "assure the quality of the test results it generates."
- Accreditation is a demonstration of competency
- A competent lab will generate data of "known and documented quality."

CRITICISMS

- Most of the TNI QMS requirements have little to do with data quality.
- We know we do good work. We follow the method and do all the QC.
- Why do we have to do all these management things that do not improve the result?

For 25 years, TNI and others have attempted to establish that a QMS does improve data quality.

In 2020, we finally succeeded.

EFFORTS PRIOR TO 2018

- Benefits of Laboratory Accreditation
- White Paper: Benefits of Laboratory Accreditation
- Assuring Data Quality at USGS Laboratories (NAS Report)
- Implementation and Practical Benefits of ISO/IEC 17025 in a Testing Laboratory
- Does PT Data Support the Value of Laboratory Accreditation?

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NELAP SURVEY

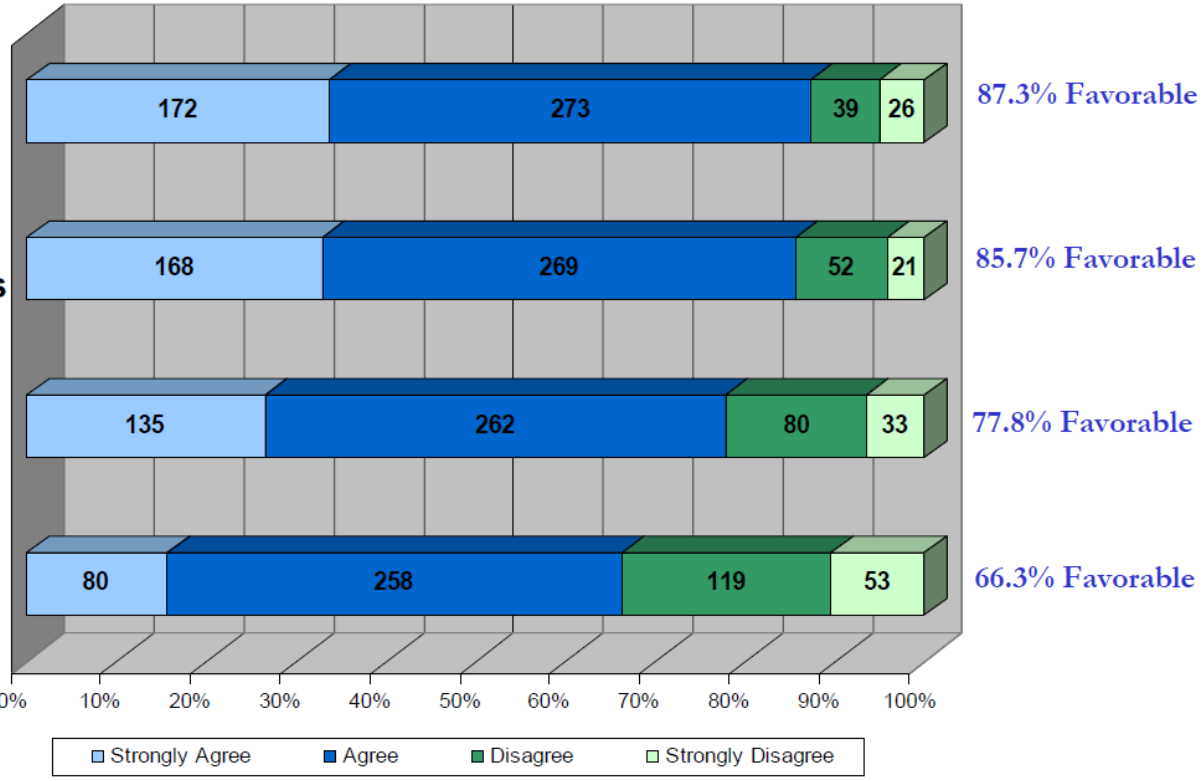
Conducted Nov. 7th to Dec. 20th, 2008

Judy Morgan
Environmental Science Corporation

https://nelac-institute.org/docs/meetings/miami2009/NELAP%20Survey.pdf

IMPROVED DATA QUALITY

>85% of Labs Believe that NELAP Improves Defensibility & Quality



But of course you believe that; self-serving survey!

2015 TNI WHITE PAPER (EXCERPTS)

- For data users, accreditation provides assurance that the laboratory has been evaluated and has met accepted standards established by experts in the environmental laboratory profession. Using a technically competent organization minimizes the risk of producing unreliable data and minimizes the need for expensive re-testing. Regulators will have more confidence in data produced by an accredited organization.
- If an organization is accredited to TNI's standards, it means that the organization has demonstrated their competence to produce data that are accurate, traceable and reproducible.
- Accreditation provides an objective way of showing that an organization has the demonstrated capability to provide the services they conduct.

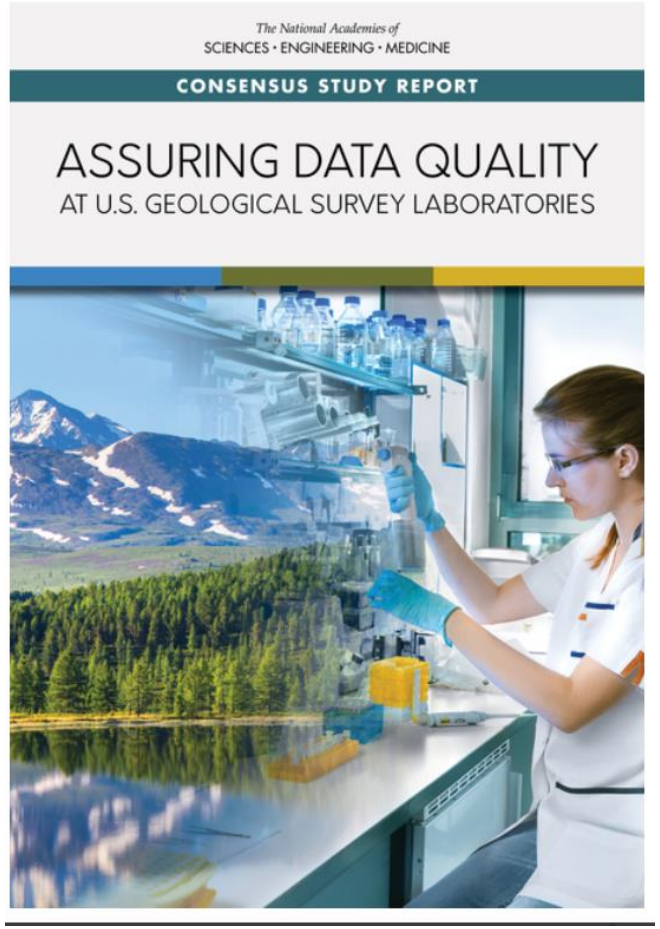
But of course you believe that; self-serving no data!

https://nelac-institute.org/docs/comm/advocacy/White%20Papers/Benefits%20Of%20Laboratory%20Accreditation.pdf

NAS REPORT

Conclusion

The committee commends the USGS for pursuing recognized best practices to produce data of known and documented quality. A well-resourced implementation of a flexible approach that incorporates institution-defined best practices for research activities and QMS for production activities would meet the quality goals of the USGS and the diverse needs of its laboratories, foster staff buy-in, and cultivate an enduring quality culture across the agency.



https://www.nap.edu/catalog/25524/assuring-data-quality-at-us-geological-survey-laboratories

NAS FINDINGS

Advantages and disadvantages of a Quality Management System approach.

- A QMS is a recognized and accepted method for assuring confidence in laboratory results.
- The use of a QMS should improve quality, reliability, work transparency, and consistency across the institution.
- An internally defined quality standard can be customized to address the specific needs of an organization.
- An effective QMS promotes opportunities for self-assessment and improvement of work habits through independent auditing and process review.
- Scientists may be reluctant to adopt a system that they perceive as adding work or restricting their autonomy, flexibility, and creativity.

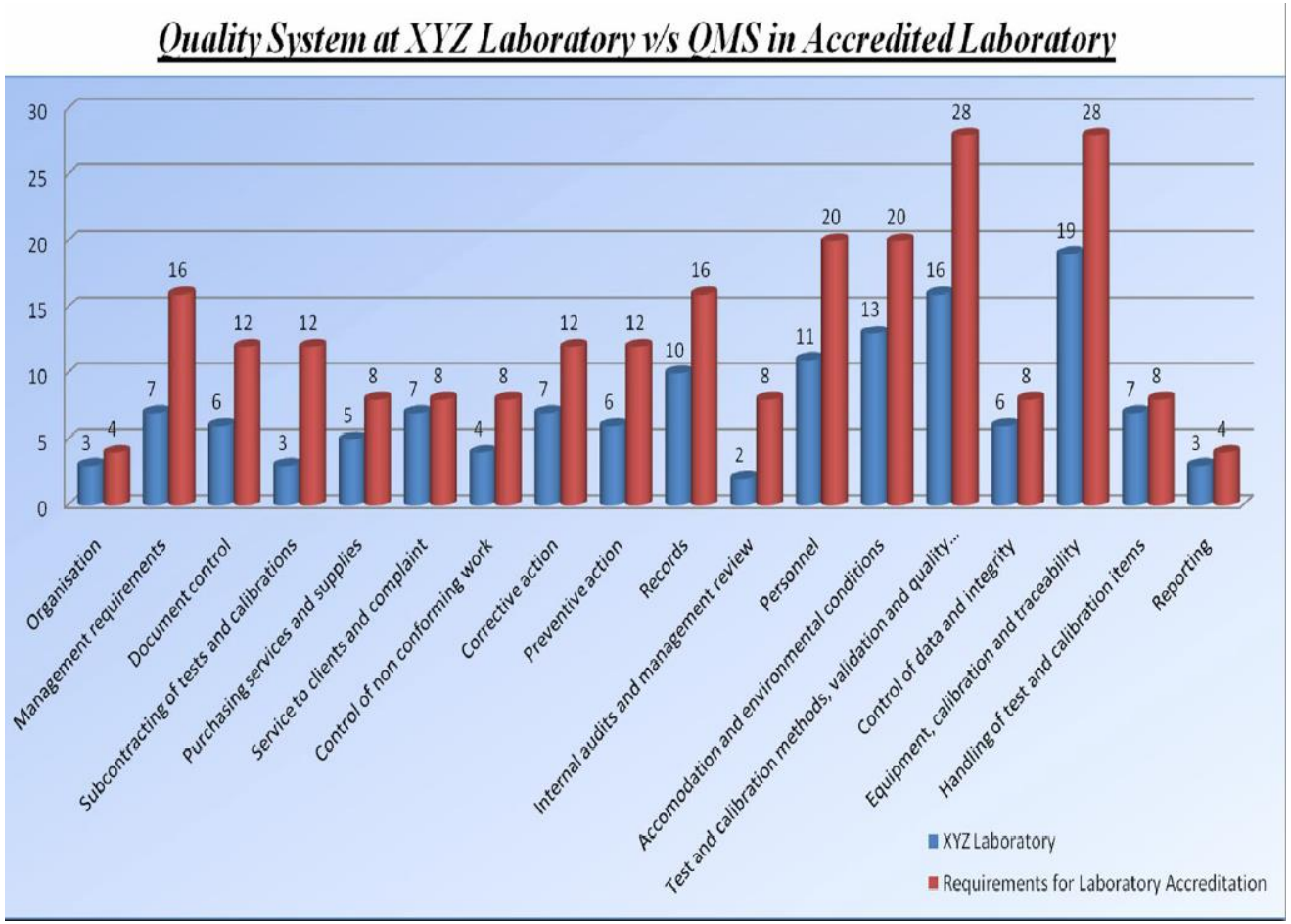
ADDITIONAL NAS FINDINGS

Advantages of an externally defined QMS

- Compliance with an external standard allows a laboratory to c
  that meet regulatory requirements to support high-risk applic
  demonstrate a high level of accountability through accreditat
  and external assessors.
- Most formal consensus-based standards are written with the unde hat there are many ways to comply with a given requirement. Therefor , the laboratory can customize how it will meet the requirements.
- Accreditation provides external recognition that the measurement was made under conditions that optimize the likelihood that the measurement is verifiable.
- A laboratory may have both accredited and nonaccredited test methods. If so, the QMS put in place to support the accredited tests is likely to enhance the management of the nonaccredited tests as well.

Totally made up and subjective!

Implementation and Practical Benefits of ISO/IEC 17025:2005 in a Testing Laboratory



UNIVERSITY OF MAURITIUS RESEARCH JOURNAL – Volume 17 – 2011
University of Mauritius, Réduit, Mauritius

Totally made up and subjective!

https://www.ajol.info/index.php/umrj/article/view/70730

Do accredited laboratories perform better in proficiency testing than non-accredited laboratories?

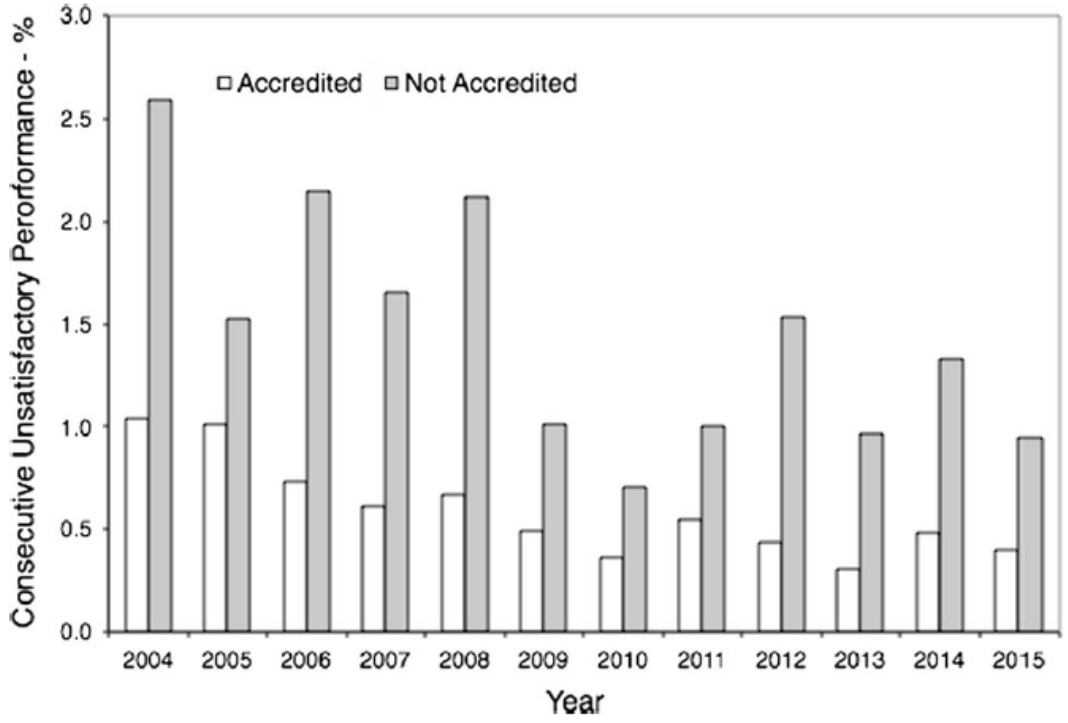


Fig. 4 Percentage of consecutive Unsatisfactory performance by analyte/matrix combination

Does 98% passing vs 99% justify the costs?

https://link.springer.com/article/10.1007/s00769-017-1262-z

Does PT Data Support the Value of Laboratory Accreditation?

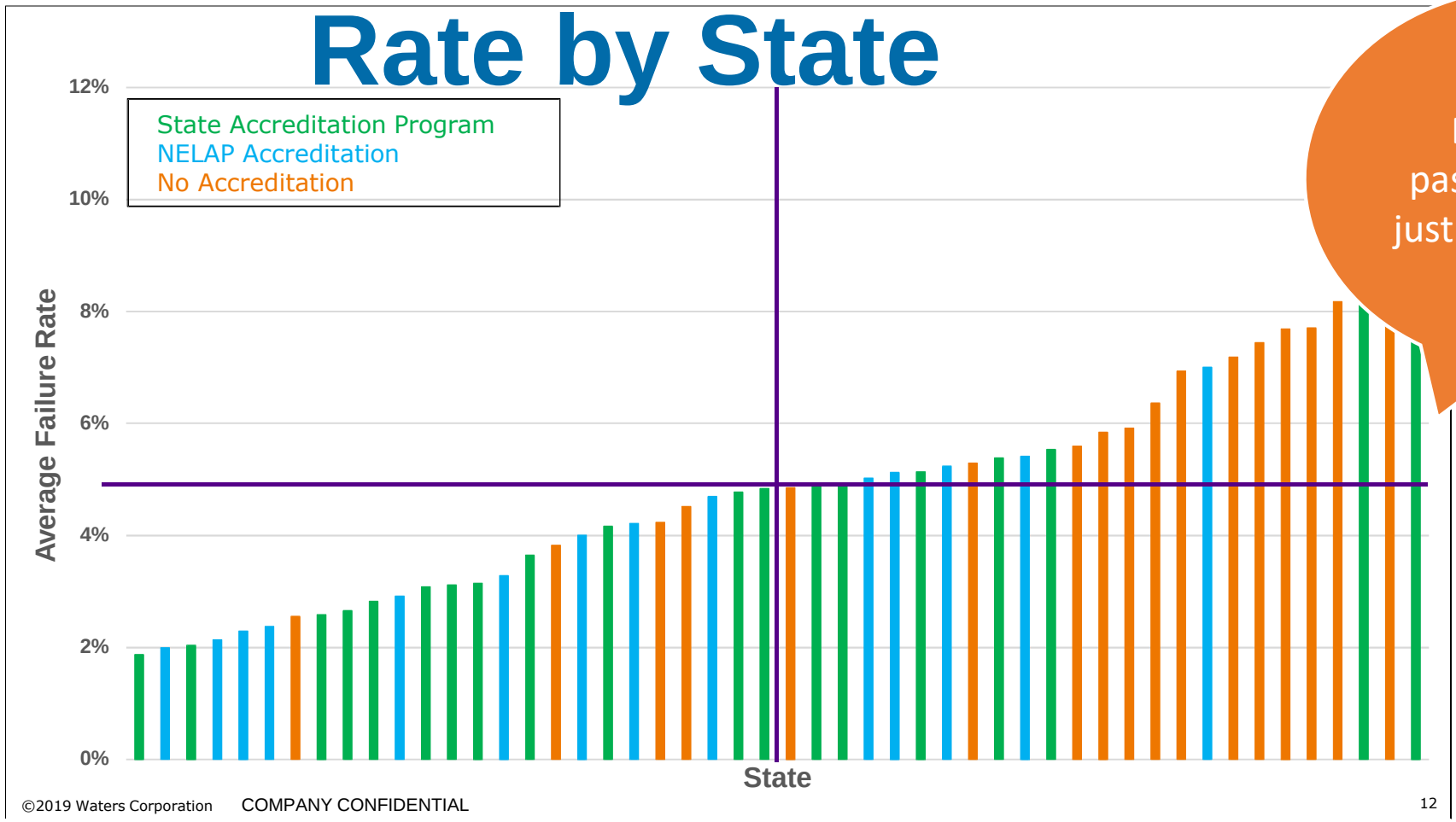
NEMC 2019 – Jacksonville, Florida
August 5, 2019

Curtis J. Wood

ERA, A Waters Company

https://nemc.us/docs/2019/presentations/pdf/Monday-Operational%20and%20Advocacy%20Issues%20Impacting%20the%20Environmental%20Laboratory%20Industry-3.2-Wood.pdf

Average WP Failure Rate by State



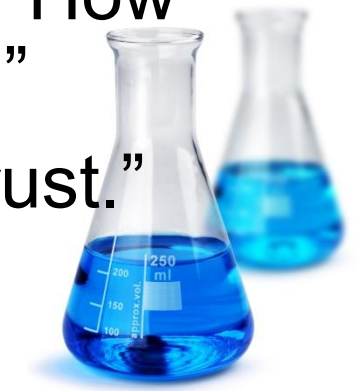
Does 98% passing vs 92% justify the costs?

COMMENTS ON PREVIOUS EFFORTS

- Laboratory survey self-serving.
- TNI White Paper subjective.
- Presentations on PT performance inconclusive.
- Other articles/reports subjective.
- **There are no definitive data to support the claims.**

NEW EFFORTS 2018-2020

- California efforts to use the TNI Standard
- Preliminary discussion in New Orleans in August, 2018 on Value of Accreditation
- Special session in Jacksonville, FL on August 5, 2019 on "Investigating the Value of Accreditation."
- Special session in Newport Beach, CA on February 5, 2020 on "Case Studies of Non-Conformances."
- Special session in Newport Beach on February 5, 2020 on "How Accreditation to the TNI Standard Improved My Laboratory."
- Development of a new Guiding Principle – "Data you can trust."



CALIFORNIA EFFORTS

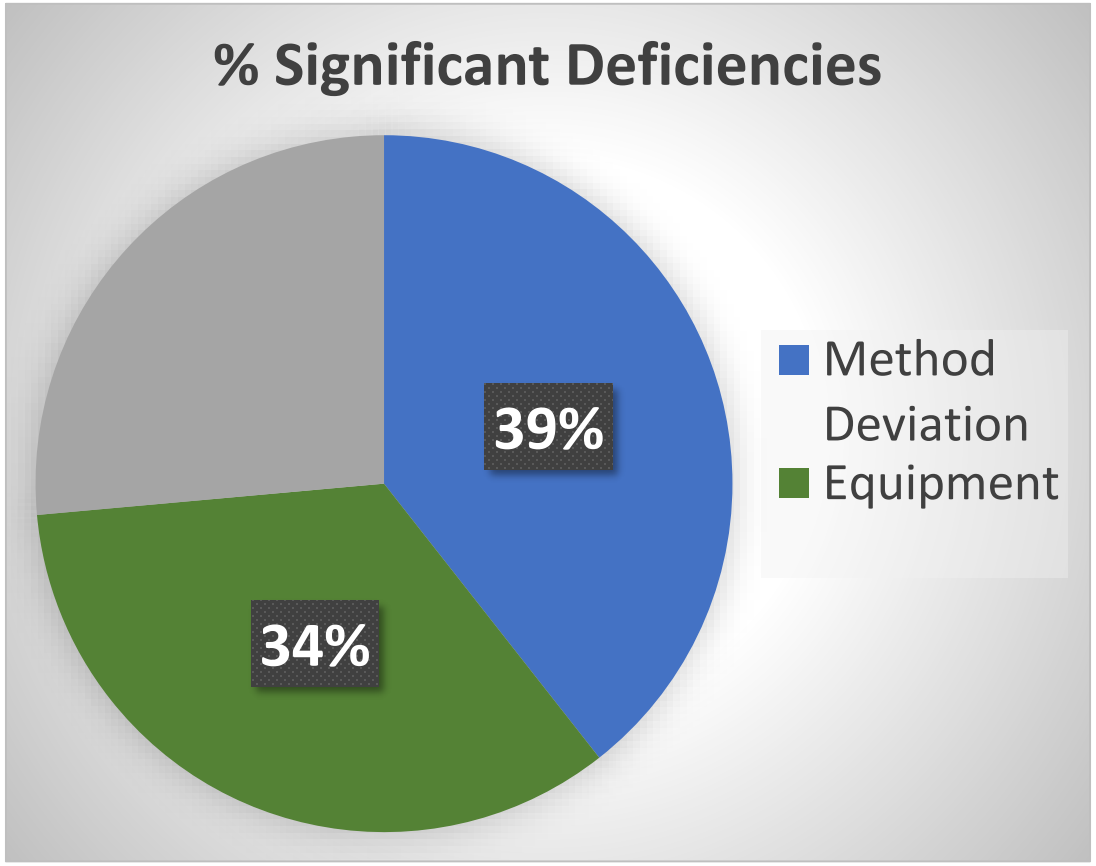
- California had decided to use the TNI standard as the basis for their reinvented program.
- Many California municipal laboratories strongly disagreed.
- State regulatory partners had little confidence in the results they were seeing.
- Independent assessment of California laboratories validated legitimate concerns over competency.

STATUS OF CALIFORNIA TRAINING AND AUDIT SUPPORT

Mitzi Miller, 509-531-0255 mitzi.miller@nv5.com

NV5

SEVERITY OF DEFICIENCIES



- The labs with a large number of deficiencies have deficiencies that are significant in nature
  - 39.4% are related to method deviations (labs do not implement QC per the method requirements)
  - 34.2% are related to improper use of laboratory equipment (labs do not calibrate or verify calibration)
  - The rest are quality assurance related
- Multiple significant deficiencies indicate a laboratory is not meeting minimum competency levels

EXAMPLES OF DEFICIENCIES

- Significant
  - No lab director, no one in charge, no notice to ELAP
  - Using LIMS with many incorrect calibration and QC limits, questionable data
  - Incorrect calculations
  - No method blanks, no duplicates or QC
  - Using expired media/standards
- More serious
  - Analyzing cyanide and do not know how to calibrate
  - Floors of gravel while analyzing metals; micro rooms dirty with no disinfectant
  - Insufficient volume used for micro testing – potential false negatives
  - Published methods have options for tests; lab does not know what they do
  - Manipulate proficiency test results

VALUE OF ACCREDITATION: 2018

- Panel discussion in 2018 in New Orleans – What is the value of accreditation to the TNI standard?
  - How do we make the connection between accreditation and improved data quality?
  - What are some activities that we might undertake to do?
- Draft white paper: “Does Accreditation Based on the TNI Standard Improve Environmental Laboratory Performance?”

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JACKSONVILLE MEETING

VALUE OF ACCREDITATION

- Panel discussion– What is the value of accreditation?
  - How do we make the connection between accreditation and improved data quality?
  - What are some activities that we might undertake to do?
- Draft white paper: “Does Accreditation Based on the TNI Standard Improve Environmental Laboratory Performance?”

2019 TNI WHITE PAPER (EXCERPTS)

- TNI believes that accreditation provides an objective way of showing clients, the community and the government that an organization has the demonstrated capability to provide the services they conduct.
  - Available research has shown that accredited labs tend to perform better on proficiency testing.
  - State statistics show fewer than 10% repeat deficiencies and fewer serious findings in accredited labs.
  - State Accreditation Bodies and individual laboratories can provide anecdotal evidence that there is a connection between accreditation and improvements in data quality.
  - A comprehensive study of two laboratories showed multiple advantages achieved from implementing a quality management system:

INVESTIGATING THE VALUE OF ACCREDITATION

- Proposed Solutions
  - Collect and analyze laboratory and AB performance data that can be used to demonstrate the value of accreditation, e.g. timeliness, PT data, numbers and types of enforcement cases, numbers and types of deficiencies, number of repeat deficiencies
  - Repeat study of California laboratory performance in three years
  - TNI should promote opportunities for ABs and others to establish uniform quantitative indicators to compare performance of accredited labs vs. non-accredited labs

DISCUSSIONS OF 2019 WHITE PAPER

- Still subjective.
- PT data may not be a good indicator.
- What do we mean by “data quality”? Can we measure precision? Do we ever know the true value?
- Can we look at simple, secondary indicators like sample preservation, temperature measurement, etc.?
- Trust and credibility can be assessed as well as data defensibility.
- Identify a way to measure benefits.
- PA saw increased trust in labs; MN has anecdotal evidence showing improvement.
- **We could have labs do presentations in Newport. Labs can pick the metric of their choice to show improvement.**
- **We could do a session in Newport on how non-conformances impacted data quality.**

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WELCOME

https://nelac-institute.org/content/meetings-prev.php

IMPACT OF NON-CONFORMANCES TO THE QUALITY MANAGEMENT SYSTEM

- Data Quality problems
  - Inaccurate or incorrect result
  - Insufficient documentation
  - Non-conformance to mandated method
  - Diminished confidence in result
  - Not meeting customer requirements

EXAMPLE – INACCURATE RESULT

Case Study 441, Adequate Resources - 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.

- The laboratory was cited for not having the "*capability and resources to meet the requirements.*"
- **Negative Impact** – Many results were rejected; data user lost confidence in laboratory.
- **Benefits of Correcting** – Usable data with fewer reanalysis; regained confidence of data user.

EXAMPLE – INSUFFICIENT DOCUMENTATION

Case Study 413, Control of Records- 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 was ruled inadmissible by the court.

- The laboratory was cited for not having records to "*enable the test to be repeated under conditions as close as possible to the original.*"
- **Negative Impact** – All results were rejected.
- **Benefits of Correcting** –Data can admissable.

EXAMPLE – METHOD NON-CONFORMANCE

Case Study 461; Purchasing Reagents - Some methods require use of reagents of specified purity (e.g., EPA 1664 requires 85% purity for hexane). Without a purchasing system/procedure to ensure the appropriate materials are procured, the wrong quality of reagent was purchased.

- The laboratory was cited for not having a *procedure for the selection and purchasing of services and supplies it uses that affect the quality of the tests.*
- **Negative Impact** – Data user lost confidence in laboratory; laboratory violated requirement in 40 CFR 136 to follow the method as written.
- **Benefits of Correcting** – Usable data.

EXAMPLE – DIMINISHED CONFIDENCE

Case Study 415, Undue Pressure - The TNI standard presents the specific requirements for training personnel to avoid improper practices. The TNI standard requires management to make sure all personnel are aware of the obligation NOT to do an improper activities.

- The laboratory was cited for not having *a documented data integrity system.*
- **Negative Impact** –Data user lost confidence in laboratory.
- **Benefits of Correcting** – Laboratory gained confidence of data user.

EXAMPLE – NOT MEETING CUSTOMER REQUIREMENTS

Case Study 472; Service to Client For most municipal laboratories, the customer is likely the Plant Superintendent or Pretreatment Supervisor, i.e., someone who is not actually part of the laboratory organization. A large municipal drinking water laboratory thought “complaints” were “Mrs. Jones on Elm Street thinks her water tastes bad.” Consequently, they had no procedure for real SERVICE issues. As it turned out, those issues were handled through a variety of undefined back channels that may or may not have gotten the issue resolved.

- The laboratory was cited for not having a system to *improve customer service.*
- **Negative Impact** – The real customer was dissatisfied with the laboratory.
- **Benefits of Correcting** – Improved relationship between the laboratory and their primary customer.

IMPACT OF NON-CONFORMANCES TO THE QUALITY MANAGEMENT SYSTEM

- Laboratory performance problems
  - Untrained analysts
  - System problems

EXAMPLE – LACK OF TRAINING

Case Study 410; Continuous Improvement - The laboratory continually failed PT samples because of a lack of training and no action by management. The laboratory QC results did not indicate a problem.

- The laboratory was cited for not having a system for *corrective and preventive actions and management review.*
- **Negative Impact** – PT failures resulted in suspension of accreditation and the laboratory had to subcontract out work.
- **Benefits of Correcting** – Regaining accreditation and improved data quality.

EXAMPLE – NOT HAVING A QMS

Case Study 411; Corrective Action - Multiple labs in Texas were suspended for excessive findings (fundamental failure to implement the standard), including failing to take corrective actions and failing to implement fundamental quality management systems.

- The laboratory was cited for not having *a procedure for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.*
- **Negative Impact** – Laboratory was suspended completely and unable to do any work with consequent loss of revenue.
- **Benefits of Correcting** – Laboratory able to regain accreditation and analyze samples.

SUMMARY OF THIS SESSION

- The QMS requirements in the TNI standard have a direct impact on both data quality and laboratory performance.
- Failures to correctly implement a QMS can result in loss of accreditation, decreased revenue, reanalysis, or data rejection.

HOW ACCREDITATION IMPROVED MY LABORATORY

- Bruce Medhurst, Mammoth Community Water District
  - Mammoth Lakes, CA
- Mary Johnson, Rock River Water Reclamation District
  - Rockford, IL
- Stacie Crandall/Reggie Morgan, Hampton Roads Sanitation District
  - Virginia Beach, VA
- Nan Thomey, Environmental Chemistry Services
  - Houston, TX
- Tiffany Adams, Snyderville Basin Water Reclamation District
  - Park City, UT
- Mychel Johnson, Blue Ridge Analytical
  - Wytheville, VA

HOW ACCREDITATION IMPROVED MY LABORATORY

- Bruce Medhurst

TNI is an insurance policy that you hope you'll never use.

We owe it to our community to be prepared to identify, or rule out, our municipal water supply as a source of contaminants or contagion and to do so quickly.

- **Benefits**
  - Internal audits of identified areas for improvement.
  - Traceability of reagents, standards and other materials improved the validity of the data.
  - A new Document Control system ensure correct versions of method SOPs were being used.
  - Training ensured new analysts were competent.

HOW ACCREDITATION IMPROVED MY LABORATORY

- Mary Johnson
- **Are we a better lab? Are our analyses "better?"**

  In 2010, my answer was "No, but we are surely better documented."

  By 2015, my answer had changed to "Yes, we are a better lab!"
- **Benefits**
  - SOPs are aligned with methods.
  - More documentation helps us identify sources of error.
  - Routine audits ensure continuous quality improvement.
  - Training is easier.
  - Reduced "questioning" of District data by regulated industries.

HOW ACCREDITATION IMPROVED MY LABORATORY

- Stacie Crandall
- **Benefits**
  - Identification of training deficiencies and improvement in analyst performance
  - Identification and improvements in gaps in communication and documentation
  - Improved sample tracking protocols
  - Improved sample identification system
  - Better organized sample storage areas
  - Flagged data has resulted in better informed decisions for compliance and other issues of concern

HOW ACCREDITATION IMPROVED MY LABORATORY

- Nan Thomey

Provides an "industry standard" to reference.

Identifies requirements to fulfill due diligence.

Removes guesswork from identifying "What is good enough?"

- **Benefits**
  - Consistent approach to corrective actions.
  - Confidence in the competency of all analysts.
  - "I was finally able to sleep at night."

HOW ACCREDITATION IMPROVED MY LABORATORY

- Tiffany Adams
- Before Accreditation
  - Off-site QA manager
  - Limited scope
  - Extensive use of contract laboratories reduced timeliness of reports
- **Benefits**
  - Reduced use of contract labs improving timeliness and questions about the data.
  - Quality System made it easier to bring on new methods.
  - Expanded scope allowed laboratory to bring on QA manager.

HOW ACCREDITATION IMPROVED MY LABORATORY

- Mychel Johnson

The TNI Standard provides the laboratory with the necessary foundation for all methods, instrumentation, documentation, and personnel.

- **Benefits**
  - Assessments done by qualified personnel.
  - More reliable & consistent data produced; improved traceability.
  - More easily identify trends in QC results, determine the sources of errors, and provide more effective corrective actions.
  - Laboratories have more credibility and can better stand behind the data they report.
  - Effective PT requirements.

FINDINGS

- We need to rethink the definition of “data quality.”
- Quality is much more than getting the right answer and being able to reconstruct the result.
- Quality includes confidence in the data as well as better laboratory operations.
- Laboratories accredited to the TNI standard have documented significant improvements.
  - Efficiency, additional capability, quicker reports, …
- Laboratories accredited to the TNI standard have more confidence in their data.
  - Traceability, training, sample tracking, documentation, better decisions…

CONCLUSION

There is no doubt that implementing a QMS based on the TNI standard makes a difference in the quality of the data and in laboratory performance.

OUR NEW GUIDING PRINCIPLE

Data you can trust

- Implementing a QMS provides confidence in the data
  - The reported result is good estimate of the true concentration.
  - The reported result is of known and documented quality.
  - The laboratory complied with mandated method requirements.
  - The laboratory implemented a strong quality management system to ensure confidence in the result.
  - The laboratory met customer requirements.
- Implementing a QMS improves laboratory performance
  - Better trained analysts
  - Better systems

DATA YOU CAN TRUST

- Result can be reconstructed
  - Sufficient documentation for sample, calibration, QC results, and SOP in use to fully reconstruct the processes leading to the result.
- Traceable
  - Reference materials, reference standards, and reagents are all traceable.
- Competent analysts
  - Training records, PT results, DOC results all demonstrate competency of analyst.
- Sample handled correctly
  - Ability to trace sample from receipt to reported result
- Quality control results document data quality
- Reliable and transparent data through known laboratory activities

DATA YOU CAN TRUST

- Meets Daubert standards for data admissibility (e.g., “legal defensibility”):
  - technique has been tested,
  - there is a known rate of error, and
  - there are professional standards controlling the technique’s operation.
- Reported correctly
  - Met requirements relating to quantitation limits and data flagging.

New White Paper (2020)

- **Laboratory Accreditation Makes a Difference**
  - *Data You Can Rely On*
- Accreditation is not just about a quantitative improvement in data quality and a Quality Management System that is committed to the maintenance of quality but about generating data that can be relied on for use in decision making.

https://nelac-institute.org/docs/comm/advocacy/White%20Papers/WP-Value_101420.pdf

NEXT STEPS

- Revise V1M2 1.2 (Scope)
  - This document contains the essential elements required to establish a quality system that produces data of known and documented quality and demonstrates proficiency through the use of proficiency testing and employee training.
  - This document contains the essential elements required to establish a **quality management system** that can demonstrate the laboratory's **technical competence**, its commitment to producing **reliable and trustworthy data**, its system for ensuring **proper documentation** of data quality, and its processes for **constant improvement** in laboratory operations. As part of the standard, laboratories shall demonstrate proficiency through the use of proficiency testing and employee training.

Laboratory Accreditation Improves Water Quality Data

- Journal AWWA, March 2022
- City of Wichita Falls

Three employees manage the Cypress Environmental Laboratory. Pictured from left to right: Sam Reeder, Hunter Adams, and Randall Barker.

Key Findings

- Improved records storage
- Current SOPs that reflect actual practice
- List of approved vendors and records of supplies
- Improved logs for training, equipment, and chemicals
- Better instrument calibration

Quality is more than a program— it is a mission, and accreditation is one mechanism that supports it.

Implementation of the TNI QMS

- It will take some time and effort.
- TNI has many resources to help.

https://nelac-institute.org/content/load_eds.php?id=224

- You will be a better laboratory at the end of this journey.

THANK YOU!

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