



Does Laboratory Accreditation Make a Difference?

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Steve Arms
Chair, TNI Advocacy Committee





OUR 30 YEAR OLD GUIDING PRINCIPLES

- ❑ Accreditation is a demonstration of competency
- ❑ The TNI Standard ensures data of “known and documented quality.”





BASIC PREMISE

- ❑ 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.”
- ❑ Proposition: Accreditation to the TNI Standard ensures laboratory competency.
- ❑ Outcome: A competent laboratory will generate quality data.

Quality System:	ISO 17025: 1990 and TNI
Management System:	ISO 17025: 2005 and 2017
Quality Management System:	TNI interim language





CRITICISMS

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





EFFORTS PRIOR TO 2019

- ❑ ESC Laboratory survey
- ❑ TNI White Paper (2015)
- ❑ NAS Report
- ❑ Mauritius article
- ❑ Presentations on PT Performance
- ❑ TNI White Paper (2019)





NELAP SURVEY

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

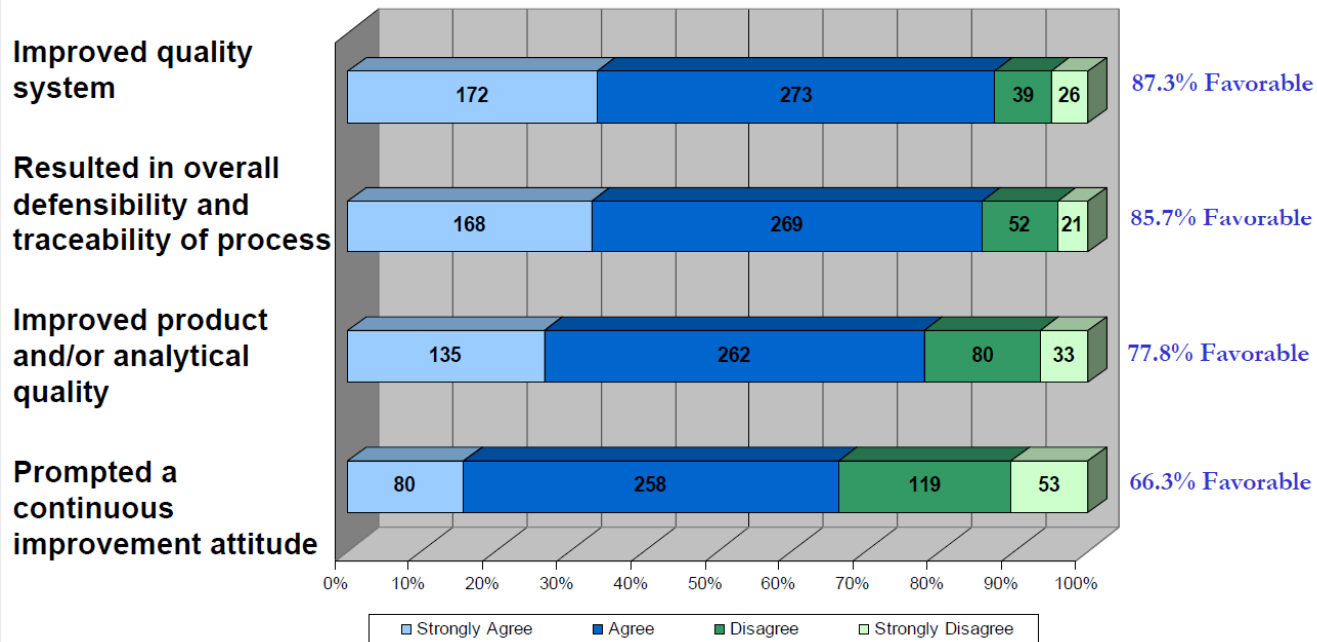
Judy Morgan
Environmental Science Corporation





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 serves a consumer protection purpose. It 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 - critical components in governmental decision-making.
- ❑ 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.

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





NAS REPORT

Conclusion

The committee commends the USGS for pursuing recognized best practices to produce data of known and documented quality. A well-resourced and gradual 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.





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

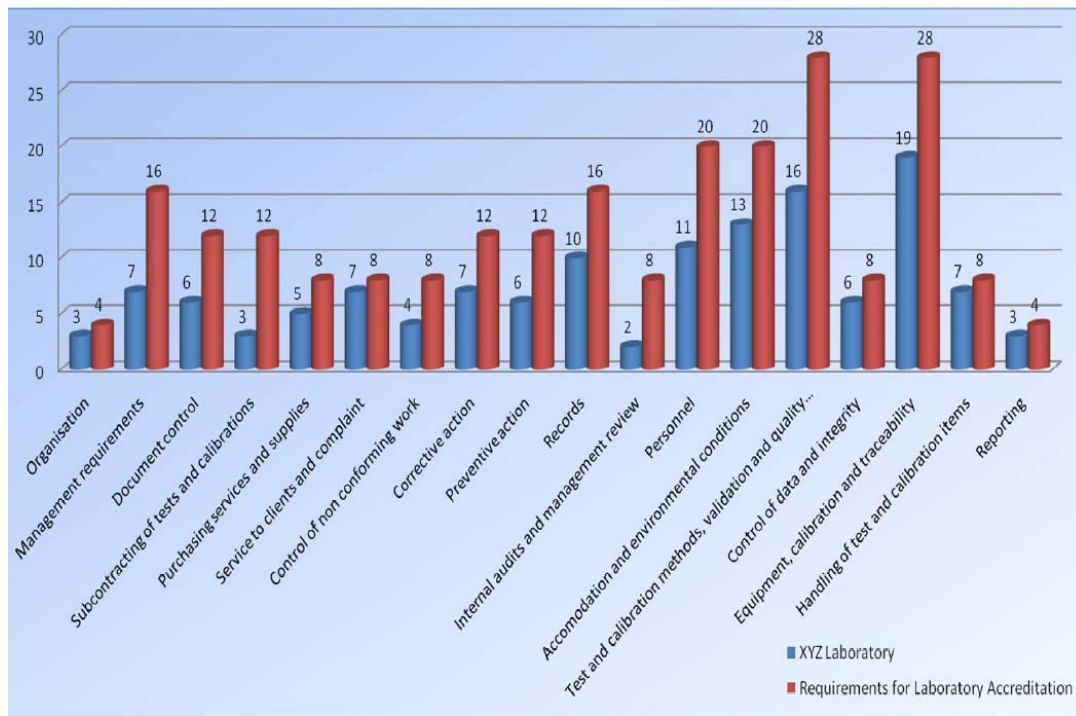
Advantages of an externally defined QMS

- Compliance with an external standard allows a laboratory to conduct analyses that meet regulatory requirements to support high-risk applications and to demonstrate a high level of accountability through accreditation by independent and external assessors.
- Most formal consensus-based standards are written with the understanding that there are many ways to comply with a given requirement. Therefore, 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.



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

Quality System at XYZ Laboratory v/s OMS in Accredited Laboratory



Totally made up and subjective!





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

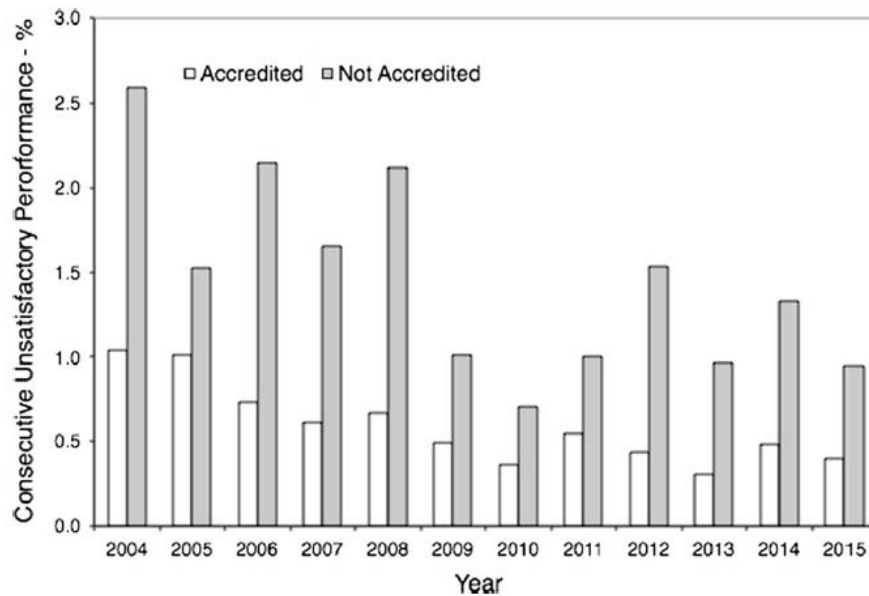


Fig. 4 Percentage of consecutive Unsatisfactory performance by analyte/matrix combination

Accred Qual Assur (2017) 22:111–117

DOI 10.1007/s00769-017-1262-z

Does 98% passing vs 99% justify the costs?



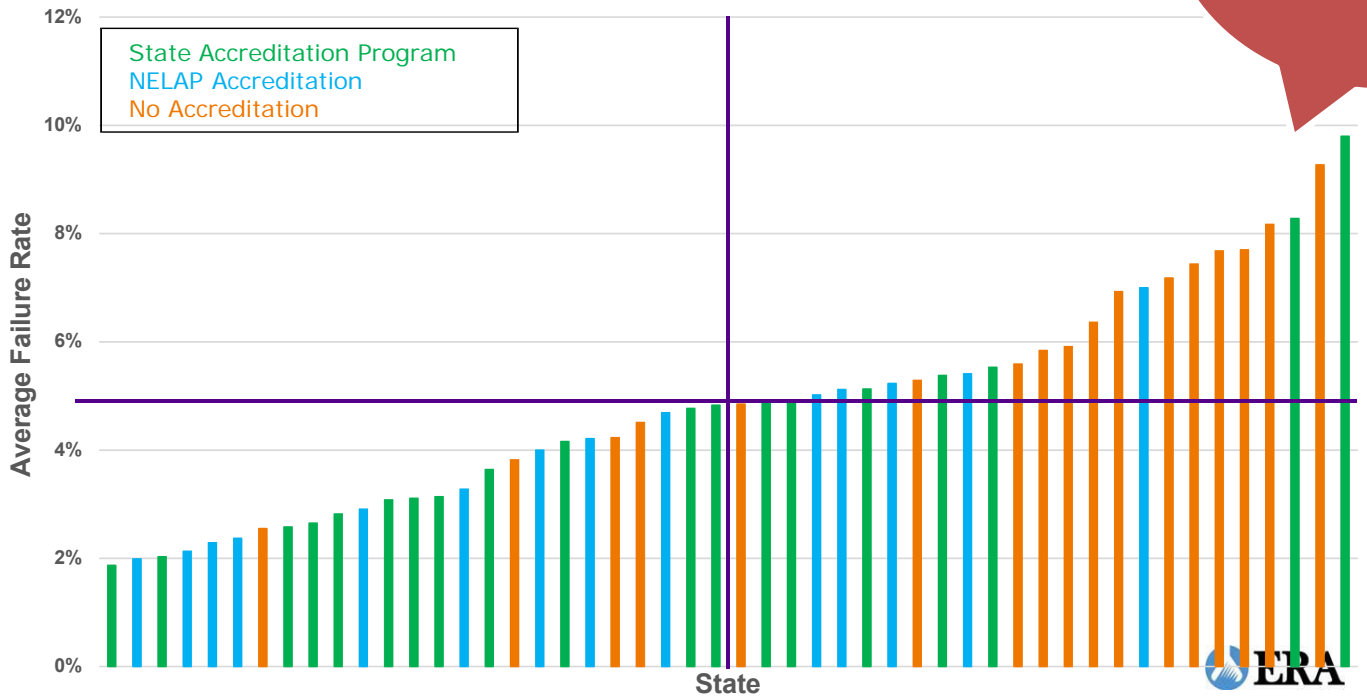
Does PT Data Support the Value of Laboratory Accreditation?

NEMC 2019 – Jacksonville, Florida
August 5, 2019

Curtis J. Wood
ERA, A Waters Company

CW1

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 is no 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.

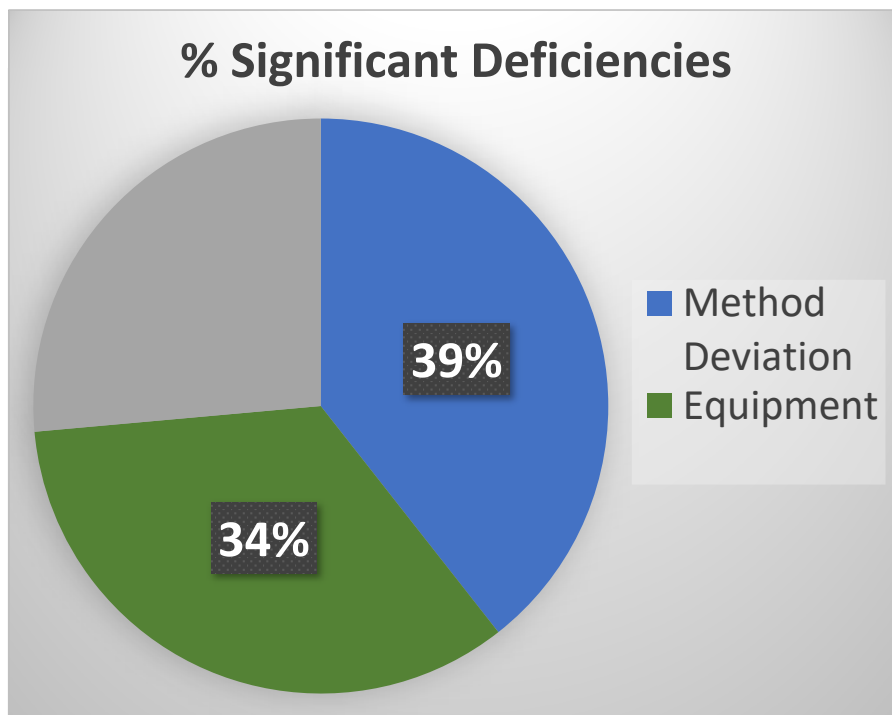




STATUS OF CALIFORNIA TRAINING AND AUDIT SUPPORT

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

N|V|5



- ❑ 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?”





JACKSONVILLE MEETING





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.**





WELCOME

Forum on Environmental Accreditation
NEWPORT BEACH, CALIFORNIA -- FEBRUARY 3-7, 2020

REGISTRATION
NOW OPEN!





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 happen in a raw wastewater pipe under a river that resulted in fish kills across state lines. As a result, that municipality was required to do additional testing. The in-house laboratory was not prepared for handling samples that had high results outside of their normal range. In particular, the E. coli results from the in-house laboratory were questioned; and a subsequent 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.*”





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.*”





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 and 98% purity for hexadecane and stearic acid). Without a purchasing system/procedure to ensure the appropriate materials are procured, the wrong can be 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.*





EXAMPLE – DIMINISHED CONFIDENCE

Case Study 415, Undue Pressure - The TNI standard indicates that the laboratory must be free of undue pressures, which relates to data integrity that is further addressed in V1M2, 4.2.8. TNI presents the specific requirements for training personnel to require management avoid improper practices. EPA has stressed the need in the DW program to review data for improper practices and the TNI standard requires management to make sure all personnel are aware of the obligation NOT to do an improper practice.

- The laboratory was cited for not having *a documented data integrity system*.





EXAMPLE – NOT MEETING CUSTOMER REQUIREMENTS

Case Study 472; Service to Client For most municipal laboratories, the customer is likely either Plant Superintendent, Pretreatment Supervisor, or something of that nature 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 system/procedure for real SERVICE issues. As it turned out, real service issues were handled through a variety of undefined back channels that may or may not have gotten the issue resolved (and certainly wasn’t tracked or had any management visibility).

- The laboratory was cited for not having a system to *improve customer service*.





EXAMPLE – NOT MEETING CUSTOMER REQUIREMENTS

Case Study 4121; Preventative Action - A municipal laboratory had been accredited for metals. The metals instrument needed to be repaired and the instrument manufacturer didn't support it anymore. The laboratory purchased a new instrument and scheduled an install date a couple of months before their assessment. However, the laboratory did not evaluate whether or not they had the proper setup for the instrument and upon arriving the manufacturer couldn't install the instrument due to improper wiring and a lack of proper ventilation. They had to schedule building maintenance and reschedule the installation - neither of which was accomplished prior to their assessment. The laboratory ended up losing their metals accreditation.

- ❑ The laboratory was cited for not having an *action plan to reduce the likelihood of the occurrence of nonconformities*.





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*.





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.*





SUMMARY OF THIS SESSION

- ❑ The QMS requirements in the TNI standard have a direct impact on both data quality and laboratory performance.





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





Mammoth Community Water District
Mammoth Lakes, CA

Our Road to TNI Compliance

Bruce Medhurst – Laboratory Analyst
bmedhurst@mcwd.dst.ca.us

Blair Hafner – Laboratory Director





How TNI Improved Our Lab

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.





How TNI Improved Our Lab

- Initiated an internal audit of all existing methods, protocols, policies, and bench sheets.
- Traceability
- Document Control
- Training





Accreditation and Laboratory Improvement
TNI 2020 Winter Meeting

Stacie Crandall
Chief, Laboratory Division
scrandall@hrsd.com
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Deviation from SOP

- Short term **Negative** Impact
 - Costly- resampling and/or reanalysis
 - Loss of compliance or customer data

- Long term **Positive** Impact
 - Identification of training deficiencies and improvement in analyst performance
 - Identification and improvements in gaps in communication and documentation

Sample not Analyzed within Holding Time

- Short term **NEGATIVE** impact
 - Violate permit requirements for monitoring requirements
 - Costly re-sampling
 - Customer requirements not met

- Long term **POSITIVE** impact
 - Identify and improve sample tracking protocols
 - Improve sample identification system
 - Better organize sample storage areas

Flagged data has resulted in better informed decisions for compliance and other issues of concern

- In-valid results excluded in calculations
- More complete information for customers

Not all flagged data is considered unusable

- Evaluated based on limits
- Informational purposes versus compliance monitoring
- Other data quality objectives

Continuous Improvement can result from

- Corrective and preventive action
 - Changing “negatives” to “positives”
 - Changing “weaknesses” to “strengths”
- Data validation and flagging
 - Improves communication on data quality
 - Facilitates better decision making based on data quality objectives

TNI for Small Labs
Why our plant fought to keep
our certification and expand
our scope of parameters

Tiffini Adams,
Laboratory Director
Snyderville Basin Water
Reclamation District
Feb 5, 2020



WE ARE PROUD THAT WITH
OUR CERTIFICATION:

- LEGALLY DEFENSIBLE
DATA
- MAXIMIZE THE BENEFITS
OF OUR CERTIFICATION
AND RESOURCES





NELAP ACCREDITATION

A MUNICIPAL LABORATORY'S EXPERIENCE

MARY JOHNSON, RRWRD

Thoughts on Accreditation

Did RRWRD achieve promoted NELAP benefits?

- Are laboratory operations smoother and more efficient?
- Have we improved public trust?
(easier to defend data in enforcement situations)
- Have we eliminated need for multiple certifications?
- Do we have more business from outside companies?

Are we a better lab?

- Are our analyses “better?”
 - more reliable?
 - more accurate?
 - more precise?
- 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!”

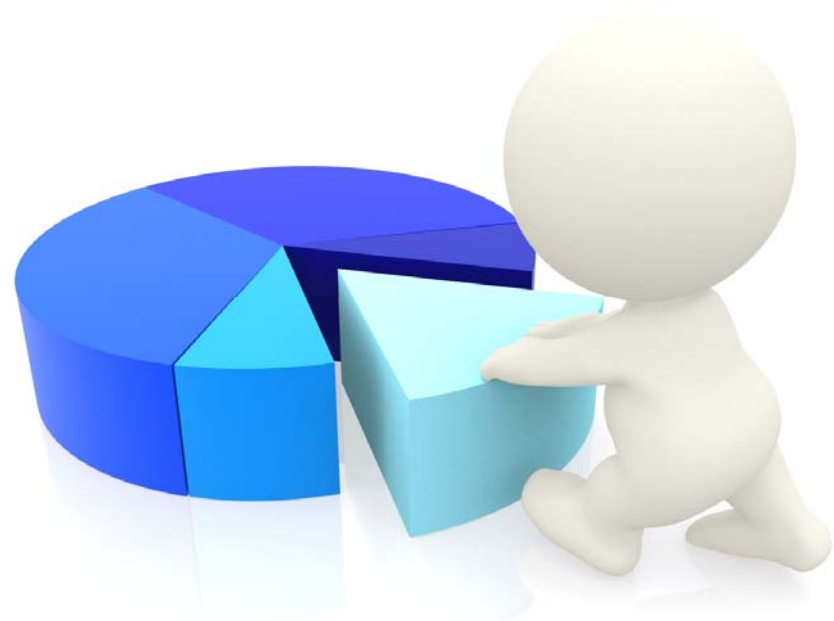
Why are we a better lab?



- SOPs are aligned with methods.
- More documentation helps us identify sources of error associated with analyses.
- Routine audits of SOPs and procedures ensure continuous quality improvement.
- Training is easier.

More benefits

- Reduced “questioning” of District data by regulated industries.
- Increased revenue stream.
There is no contract laboratory within easy driving distance of Rockford. We do analyses for other municipalities and some local industries.



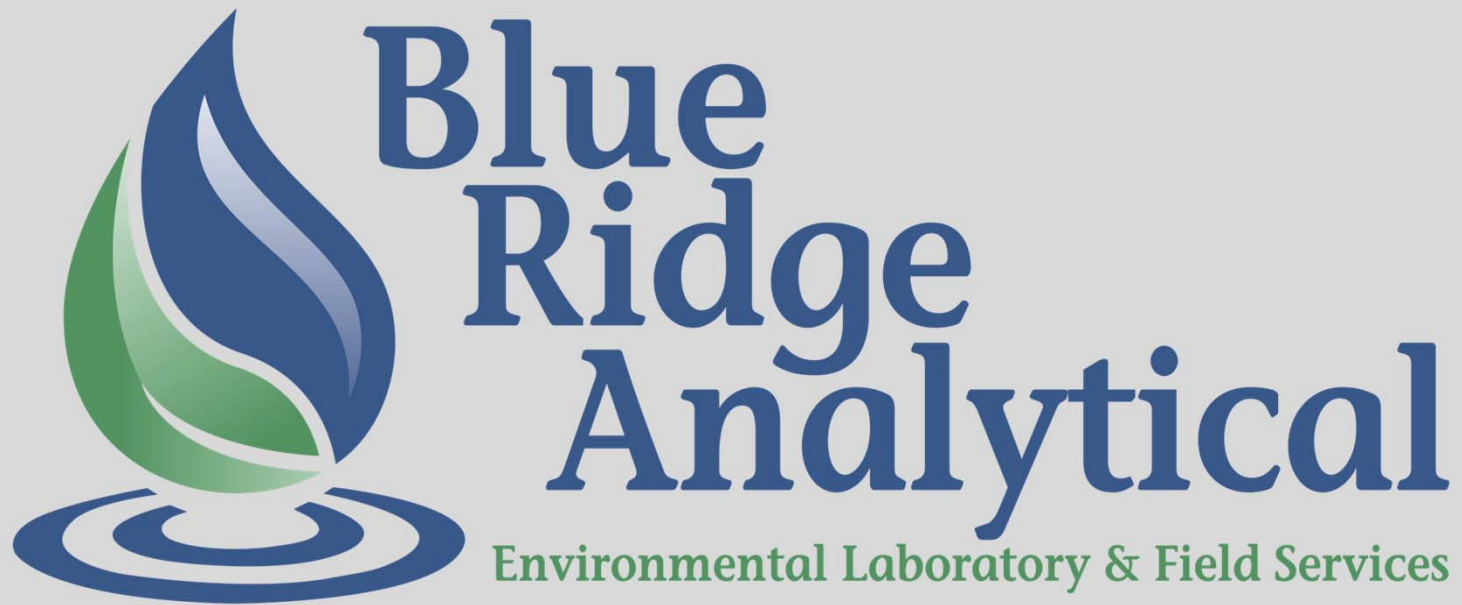
Importance of TNI Accreditation Professional

Nan Thomey

Environmental Chemistry, Inc.

TNI Accreditation Provides a Business Model

- ❑ Uniform Standards
 - ❑ Provides an “industry standard” to reference
 - ❑ Identifies requirements to fulfill due diligence
 - ❑ Removes guesswork from identifying “What is good enough?”
-



Mychel Johnson
Owner & Laboratory Director

www.blueridgeanalytical.com

THE MOST IMPORTANT BENEFIT

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

This foundation is key to the success of an environmental laboratory!



<http://petermargaritis.com>



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 accreditation to the TNI standard makes a difference in the quality of the data and in laboratory performance.





OUR NEW GUIDING PRINCIPLE

Data you can trust.

- ❑ Accreditation to the TNI Standard 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.
- ❑ Accreditation to the TNI Standard 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.





NEXT STEPS

- Continue to collect case studies of non-conformances.
- Continue to collect examples of laboratory improvement.
- Collect data on AB performance.
- Continue to refine the new Guiding Principle.
- 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...
 - This document contains the essential elements required to establish a quality management system that ensures laboratory competence and produces data that can be relied on...





THANK YOU: TNI ADVOCACY COMMITTEE

Lynn	Bradley	The NELAC Institute
Teresa	Coins	Arkansas Analytical, Inc.
Robin	Cook	City of Daytona Beach EML
Stacie	Crandall	Hampton Roads Sanitation District
Zonetta	English	Louisville Jefferson Co., MSD
Martina	McGarvey	Pennsylvania DEP
Sharon	Mertens	Milwaukee Metropolitan Sewerage District
Marlene	Moore	Advanced Systems, Inc.
Trinity	O'Neal	City of Austin Water Utility
Lara	Phelps	USEPA /CEMM
Janice	Willey	NAVSEA LQAO

Program Administrator: Carol Batterton





THANK YOU!

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