



# Ensuring Reliable Data: An Overview

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## WHY WE TEST

- ❑ To protect public health
- ❑ To protect environmental health
- ❑ To demonstrate compliance with regulatory programs
- ❑ To meet customer needs

In short, the data produced by a laboratory is used to make decisions, sometimes tough ones, like boil notices or beach closings. The data produced must be accurate and trustworthy as it may very well affect YOU.





# 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 laboratory 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
  - <https://nelac-institute.org/docs/meetings/miami2009/NELAP%20Survey.pdf>
- ❑ White Paper: Benefits of Laboratory Accreditation
  - <https://nelac-institute.org/docs/comm/advocacy/White%20Papers/Benefits%20Of%20Laboratory%20Accreditation.pdf>
- ❑ Assuring Data Quality at USGS Laboratories (NAS)
  - <https://www.nap.edu/catalog/25524/assuring-data-quality-at-us-geological-survey-laboratories>
- ❑ Implementation and Practical Benefits of ISO/IEC 17025 in a Testing Laboratory
  - University of Mauritius Research Journal (Vol 17. 2011)
- ❑ Does PT Data Support the Value of Laboratory Accreditation?
  - <https://nemc.us/docs/2019/presentations/pdf/Monday-Operational%20and%20Advocacy%20Issues%20Impacting%20the%20Environmental%20Laboratory%20Industry-3.2-Wood.pdf>





# 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.**

Details on these previous efforts were presented at NEMC in 2020:

<https://apps.nelac-institute.org/nemc/2020/docs/presentations/pdf/8-17-20-Best%20Management%20Practices%20for%20Environmental%20Laboratories-22.01-Parr.pdf>





# 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.”  
Details on these new efforts were presented at NEMC in 2020:  
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# 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

- ❑ 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](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.



# The Purpose of This Session

- ❑ Provide additional insight into the elements of “Data You can Trust”
  - Sufficient Documentation to Reconstruct the Results
  - Ensure Results Are Reported Correctly
  - Traceability of Samples, Reference Materials, Reference Standards, and Reagents
  - Competency of Analysts
  - Meeting Daubert Standards for Data Admissibility





# THANK YOU!

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