Laboratory Accreditation Makes a Difference

Data You Can Rely On

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INTRODUCTION

The NELAC Institute (TNI) and other proponents of environmental laboratory accreditation have always promoted accreditation as a demonstration of competency. TNI believes that accreditation to the TNI Standard and its Quality Management System (QMS) requirements ensures data of "known and documented quality." The basic premise is that accreditation to the TNI Standard ensures laboratory competency, and thus gives the data user and regulators confidence that the laboratory generated data are reliable.

Quality System, Management System, or Quality Management System

The 1990 version of ISO/IEC 17025 used the term Quality System to describe the process by which a laboratory manages its operations to "assure the quality of the test results it generates." By the time the second edition was published in 2005, this term was changed to Management System, although the phrase quality management system also appeared in this version. The NELAC Institute started using Quality System in 1994, and on September 11, 2020 adopted the term Quality Management System.

Accreditation bodies that are considering becoming recognized under TNI's standard as well as laboratories considering accreditation often ask TNI for data to justify becoming an Accreditation Body (AB) or an accredited laboratory. TNI can provide considerable evidence supporting the benefits of environmental laboratory accreditation. After focusing on the connection between accreditation and data quality, we have come to believe that 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..

BACKGROUND

Accreditation to the TNI standard provides an independent, third party evaluation of a laboratory's QMS and of its technical competence, resulting in a formal recognition by a recognized authority, called an Accreditation Body (AB). TNI's National Environmental Laboratory Accreditation Program (NELAP) accredit over 2000 laboratories in 47 states and four foreign countries. Several Non-Governmental Accreditation Bodies (NGABs) also accredit laboratories to the TNI Standard. Accreditation to the TNI standard is unique among laboratory accreditation programs because:

- it is based on internationally recognized standards (ISO 17025 and ISO 17011) that have been expanded to focus on unique aspects of environmental testing,

- it is performed with respect to a specific scope of accreditation through assessments conducted by qualified assessors, and
- it involves review of results of periodic proficiency testing (PT) performed by the laboratory.

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 such a laboratory minimizes the risk of producing unreliable data and minimizes the need for expensive re-testing. Data users and regulators generally have more confidence in data produced by an accredited organization. TNI believes that accreditation provides an objective way to demonstrate to clients, the community, and the government that a laboratory has the capability to provide the services they conduct.

For over 25 years TNI (and its predecessor organizations) has promoted laboratory accreditation as a way to positively document laboratory competence. However, some are still skeptical of the value of laboratory accreditation and have alleged that many of the requirements in the TNI standards have little to do with data quality. We disagree with this argument, and over the past few years TNI initiated a series of activities to explore the impact accreditation has on laboratory performance and data quality.

This white paper focuses on **laboratory measurements**. TNI recognizes **sampling** can be just as important, if not more so, in the overall measurement error. While this document does not address sampling, the concepts of implementing a QMS apply equally to sampling and TNI encourages organizations that perform sampling to become accredited to the TNI Standard for Field Sampling and Measurement Organizations.

DISCUSSION

Previous Efforts

Various studies and papers prior to 2019 have noted the connection between data quality and accreditation by a TNI recognized accreditation body. These include:

- A survey of accredited laboratories in 2008[1] showed that 85% of the laboratories reported improvement in data quality as well as in defensibility and in traceability of process.
- A National Academy of Science[2] report reviewing the U.S. Geological Survey Laboratories noted these 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 use both accredited and nonaccredited test methods. If so, the QMS put in place to support its accredited tests is likely to enhance the management of the nonaccredited tests as well.

- A comprehensive study[3] of two laboratories showed multiple advantages achieved from implementing a QMS:
    - better traceability,
    - involvement of personnel in decision making processes,
    - acknowledgement of testing competence,
    - benchmark for performance,
    - marketing advantage,
    - international recognition,
    - risk minimization,
    - customer confidence, and
    - cost reduction.
- Available research has shown that accredited labs tend to perform better on proficiency testing.[4,5]
- State statistics show fewer than 10% repeat deficiencies and fewer serious findings in accredited laboratories.[6]
- TNI Mentor Sessions[7] have shown how an effective QMS can quickly correct problems.

To further explore the connection between accreditation and data quality, TNI sponsored a panel discussion at its New Orleans meeting in August 2018 to solicit input. This discussion resulted in a draft white paper which proposed that we 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. A "pre-accreditation vs. post-accreditation" comparison study of California laboratory performance in three years was also proposed. In addition, TNI could promote opportunities for current accreditation bodies and others to establish uniform quantitative indicators to compare performance of accredited laboratories vs. non-accredited laboratories. However, the discussion at this meeting showed most attendees did not feel these options were viable and suggested a different approach, which was to collect case studies to document laboratory improvement.

Recent Initiatives

Thus, to continue to explore ways to provide more substantive data supporting laboratory accreditation, TNI began a series of activities in 2019 aimed at gathering quantitative information from laboratories who had experienced improvements as a result of becoming an accredited laboratory as well as examples of failures resulting from lack of adherence to QMS principles.

Following further discussion of these recommendations at the Jacksonville meeting in August 2019, TNI decided that the best way to obtain data was to invite laboratories to attend the Newport meeting in February 2020 and share individual stories on the impact of TNI accreditation on their laboratory experience.

Invited speakers at the Newport meeting gave actual examples of the impact of non-conformances to Module 2, Section 4 and 5 of the TNI standard on Data Quality. These impacts included:

- Data quality problems
- Inaccurate or incorrect result
- Insufficient documentation
- Non-conformance to mandated method

- Diminished confidence in result
- Not meeting customer requirements
- Lack of training
- Not having a QMS

A second panel of speakers related their experiences obtaining TNI accreditation and the impacts they saw on their own laboratory. While some acknowledged that there were short term negative impacts on their laboratory resources while going thru through initial accreditation process, they felt the long-term benefits outweighed the initial costs. Comments from speakers included:

"Continuous Improvement can result from corrective and preventive action"

"Data validation and flagging which improves communication on data quality and facilitates better decision making based on data quality objectives."

"Legally defensible data is produced."

"SOPs are aligned with methods."

"More documentation helps identify sources of error associated with analyses."

"Routine audits of SOPs and procedures ensure continuous quality improvement."

"Training is easier."

"'Questioning'" of data by regulated industries is reduced."

"TNI accreditation provides a business model with uniform standards, industry reference point, requirements to fulfill due diligence, and removing guesswork from identifying 'What is good enough?'"

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

"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."

Independent of the two efforts above, TNI had already collected information on how accredited laboratories that identified non-conforming activities were quickly able to resolve these non-conformances.[7] The session focused on data integrity issues such as data errors affecting multiple clients, an ethics violation that impacted data, and a computer issue resulting in data losses. It explored the frequency of these kinds of problems and the steps taken to remedy them. The session documented that laboratories that had implemented a TNI QMS were able to address such issues effectively.

CONCLUSION

There is no doubt that accreditation to the TNI standard makes a difference in the quality of the data and in laboratory performance.

However, the experiences of the laboratories that participated in this effort led TNI to believe that we need to redefine what we mean by "data quality". Providing quality data 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. The laboratory QMS in and of itself does not generate better quality data, but if followed, ensures that the data will be of documented quality and that the laboratory management is committed to fostering a culture of quality. Laboratories accredited to the TNI standard have documented significant improvements which include efficiency, additional capability, and quicker reports. Traceability, training, sample tracking, and documentation all contribute to better decisions and contribute to laboratories with TNI accreditation having more confidence in their data.

Our New Guiding Principle - Data You Can Rely On

The value of accreditation to the TNI Standard is that it provides confidence in the data, to the laboratory's client and to regulators, which means:

- The reported result is a good measure of the true concentration.
- The reported result is of known and documented quality.
- The laboratory complied with mandated method requirements.
- The laboratory has a strong Quality Management System that helps ensure confidence in the result.
- The laboratory met customer requirements.
- Accreditation to the TNI Standard improves laboratory performance.

Relying on the data means:

- The processes leading to the result can be reconstructed because there is sufficient documentation for the sample, calibration, QC results, and SOP s used,
- The reference materials, reference standards, and reagents are all traceable,
- Competency of analysts is demonstrated by training records, PT results, and Demonstration of Capability results,
- Samples are handled correctly and can be traced from receipt to reported result,
- Quality control results document data quality,
- The data meet Daubert standards for data admissibility (e.g., "legal defensibility") because the technique has been tested, there is a known rate of error, and there are standards controlling the technique's operation,[8] and
- The result is reported correctly and has met requirements relating to quantitation limits and data flagging.
- The requested methodology was followed in generating the data.

Next Steps

TNI will continue to pursue opportunities to document the value of accreditation to the TNI standard by:

- Continuing to collect case studies of non-conformances,
- Continuing to collect examples of laboratory improvement,
- Collecting data on AB on how the AB helped laboratories to identify and correct problems, and
- Refining the new guiding principle.

In addition to the points above, TNI has proposed revising EL-V1M2-2016-Rev2.1: Quality Systems General Requirements, Section 1.2 (Scope) to reflect the new guiding principle. The proposed change is noted below.

Current language	"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"
Proposed new language	"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.

This new guiding principle will also require TNI to change its Mission in the current Bylaws, which states:

> the purpose of TNI is to foster the generation of environmental data of known and documented quality through an open, inclusive, and transparent process that is responsive to the needs of the community.

REFERENCES:

[1] Morgan, Judith. *The Benefits of Laboratory Accreditation*, TNI Forum on Laboratory Accreditation, January 12, 2009, Miami, FL.

[2] National Academies of Sciences, Engineering, and Medicine. 2019. *Assuring Data Quality at U.S. Geological Survey Laboratories*. Washington, DC: The National Academies Press. https://doi.org/10.17226/25524.

[3] Khodabocus, F. and Balgobin, K. (2011) *Implementation and Practical Benefits of ISO/IEC 17025:2005 in a Testing Laboratory*, UNIVERSITY OF MAURITIUS RESEARCH JOURNAL, Vol. 17, pp. 27-80.

[4] Middlebrook, Ken. (2017) *Do accredited laboratories perform better in proficiency testing than non-accredited laboratories?* Accred Qual Assur Vol.22, pp.111-117.

[5] Wood, Curtis J. (2019) *Does PT Data Support the Value of Laboratory Accreditation?* Paper presented at NEMC 2019, Jacksonville, FL.

[6] Minnesota Dept. of Health (2018) Minnesota Environmental Laboratory Accreditation Program, *Key Performance Indicators*.

[7] TNI Mentor Session (2018) *Responding to Data Integrity Problems*, Presented at NEMC 2018, New Orleans, LA.

[8] Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 US 579 (1993).

TNI is active in working with many stakeholders, including state and federal agencies as well as trade associations representing different types of laboratories. If you want to learn more about this effort, please contact TNI.

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