

TNI'S NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION STANDARD COMPARED TO ISO/IEC 17025

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A **standard** is an established norm or requirement published as a formal document that establishes uniform technical criteria, methods, processes and practices.

An important factor in establishing the quality of environmental data and ensuring that the data are adequate for the intended purpose is a consistent, stringent, comprehensive and yet practical accreditation program.

Background

EPA, with the states as its implementation partners, maintains requirements for the certification of drinking water laboratories. Many states have independently established accreditation programs covering the analysis of waste waters, solid and hazardous wastes, and air. In the 1980's, the commercial laboratory community began to advocate a national accreditation program that would consolidate the multiple state programs containing divergent accreditation requirements. A national program would provide the foundation for ensuring the capability and competence of laboratories to foster the generation of data of known and documented quality.

On February 16, 1995, state and federal officials established the National Environmental Laboratory Accreditation Conference (NELAC) as a standard setting organization. However, NELAC in its original structure did not meet the definition of a voluntary consensus standards body. In 2006, The NELAC Institute (TNI) was formed to continue the efforts of NELAC, but as a voluntary consensus standards body. TNI is a 501(c)3 non-profit organization whose mission 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. Members of the organization include individuals from laboratories, data users, federal and state agencies and anyone interested in promoting environmental data of known and documented quality.

TNI's Laboratory Accreditation Standards

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) developed a consensus standard, ISO/IEC 17025 (2005), that describes the requirements laboratories have to meet if they wish to demonstrate that they "operate a management system, are technically competent, and are able to generate technically valid results." ISO/IEC 17025 indicates that accreditation bodies should use this standard as the basis for their accreditation.

Note: ISO/IEC 17025 was revised in 2017. TNI has initiated efforts to incorporate the new 17025 into its standard, but that effort is likely to take several years.

The NELAC Institute (TNI) has developed four consensus standards for the operation of a National Environmental Laboratory Accreditation Program (NELAP). These standards are:

Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis

Volume 2: General Requirements for Accreditation Bodies Accrediting Environmental Laboratories

Volume 3: General Requirements for Environmental Proficiency Test Providers

Volume 4: General Requirements for an Accreditor of Environmental Proficiency Test Providers

Volume 1 of the TNI standard uses ISO/IEC 17025 as its basis. This document was primarily prepared to compare the differences between TNI's standard and ISO/IEC 17025, but also provide some information about the other standards.

There are four major differences between 17025 and TNI's NELAP standards. These are:

- TNI has added requirements for accreditation bodies, Proficiency Test (PT) providers, and PT provider accreditors. These requirements are found in Volumes 2, 3, and 4.
- TNI has added a module to Volume 1 describing laboratory requirements for proficiency testing.
- TNI has added much more detail and specificity to the 17025 requirements that focus on environmental testing. These details are essential to ensure that multiple accreditation bodies can assess laboratories consistently.
- TNI has added some additional requirements, such as a data integrity component, that are missing from 17025.

Volumes 2, 3 and 4

While 17025 describes the general requirements for the competence of testing laboratories, the document itself cannot be used as an accreditation program. An accreditation program has many components and in NELAP, TNI has defined the program as one where the competence of all participants—laboratories, accreditation bodies, PT providers, and PT provider accreditors—is assured.

A Comparison of TNI's Standard (Volume 1) to ISO/IEC 17025

TNI's laboratory accreditation standard (Volume 1) uses ISO/IEC 17025 as its basis. However, as discussed in more detail below, there are some major differences between ISO/IEC 17025 and TNI's standard. ISO/IEC 17025, *General Requirements for the Competence of Testing and Calibration Laboratories*, was developed for laboratories to use "in developing their management system for quality, administrative and technical operations." All of the language from ISO/IEC 17025 is contained in Module 2 of TNI's standard, *Quality Systems General Requirements*. TNI's standard contains 6 additional Modules, one focused on Proficiency Testing, while the other five provide detailed technical requirements for Asbestos, Chemical, Microbiological, Radiochemical, and Toxicity testing.

Module 1: Proficiency Testing

Proficiency testing is an essential component of an accreditation program as it is the only true objective measure of laboratory data quality. 17025 does mention proficiency testing, most notably in Section 5.9.1 where the standard indicates participation in proficiency testing programs is one way laboratories can "monitor the validity of tests." However, 17025 does not specify the frequency of such testing, not provide any further details on the analytes, concentration ranges, and acceptance limits. Module 1 of Volume 1, Proficiency Testing, sets forth explicit requirements for laboratories to analyze PT samples. The module describes the requirements for:

- Initial and Continued Accreditation,
- Sample Handling, Analysis and Reporting,
- Corrective Action, and
- Reinstatement after Suspension or Revocation.

This module is supported by Volumes 3 and 4 that provide requirements for PT providers and PT provider accreditors and Module 2 of Volume 2, which provides the requirements for accreditation bodies in

managing PT data. The standards are supported by TNI's PT Executive Committee which helps with the implementation of this program by establishing Fields of Proficiency Testing (the matrices, analytes, concentration ranges and acceptance limits for required PT sample participation) and by assessing and recognizing organizations as PT provider accreditors.

Module 2: Quality Systems

Section 3.0 Terms and Definitions

Section 3 of 17025 is the terms and definitions section. This section references ISO/IEC standards 9001 and 17000, and a document called *International vocabulary of basic and general terms in metrology* but provide no other definitions. These references contain very generic definitions for terms such as "accreditation" and "precision", but do not contain many terms in common use in laboratories. Section 3 of the TNI standard contains 59 definitions specific to environmental analyses, including terms such as Acceptance Criteria, Analytical Uncertainty, Assessment, Batch, Blank, Laboratory Control Sample, Limit of Detection, Matrix, Quality Control Sample, Quality System Matrix, and Standard Operating Procedures.

Section 4.0 Management Requirements

The requirements for laboratories in 17025 are found in two chapters. Chapter 4 describes the management requirements and Chapter 5 describes the technical requirements. The TNI standard has two comparable sections, but with much more detail. The subsections below summarize the differences in those sections where the TNI standard has supplemented the 17025 language with additional requirements.

4.1 Organization

This section describes the requirements for the basic organization and management of the laboratory. The TNI standard contains all of the 17025 requirements, but has added 2 new subsections that provide the specific requirements for the laboratory quality manager and technical manager.

4.2 Management

This section discusses the importance of quality and requires the laboratory to have a quality manual. The TNI standard has added a requirement for the laboratory to also implement a data integrity plan, has added what elements should be contained in or referenced in the quality manual, and has an added section on Standard Operating Procedures (SOPs) that requires the laboratory to have an SOP for each test method and describes 23 specific items (such as matrix, quality control, and pollution prevention) that must be included in test method SOPs.

4.11 Corrective Action

Corrective action is required for nonconforming work. The TNI standard has added requirements that relate to identifying the individuals involved in this process and for a root cause analysis be formed on any systematic errors.

4.13 Control of Records

17025 contains a number of requirements relating to records, and in particular, technical records such as raw data. The TNI standard has significantly expanded this section by adding many more details about the types of technical records that are to be controlled, emphasizing that everything needed to reconstruct the sample result is to be maintained.

4.14 Internal Audits

17025 requires internal audits to be performed to verify compliance with the standard. TNI has added language to require these audits to be performed on an annual basis and that clients be informed in a timely manner if any finding affects the validity of reported results.

4.15 Management Reviews

17025 requires a management review that focuses on the effectiveness of the management system. TNI has added language to require this review be performed on an annual basis.

4.16 Data Integrity Investigations

This section does not exist in 17025 and was added by TNI to require such investigations to be confidential and documented. These requirements were added to prevent inappropriate laboratory practices.

Section 5.0 Technical Requirements

Section 4 of 17025 is comparable to the general management system requirements in ISO/IEC 9001. However, the ISO/IEC community recognizes that ISO/IEC 9001 was not sufficient for organizations that perform testing. The introduction to 17025 states:

Conformity of the quality management system within which the laboratory operates to the requirements of ISO 9001 does not of itself demonstrate the competence of the laboratory to produce technically valid data and results.

Section 5 of 17025 contains all the technical requirements that are missing from ISO/IEC 9001.

5.2 Personnel

17025 requires all laboratory personnel to be technically competent. TNI has added two subsections to this section, one describing the specific qualifications and experience for the laboratory technical manager, and one requiring all laboratory personnel to take a new employee orientation and annual refreshing training in data integrity.

5.4 Environmental Methods and Method Validation

17025 provides general discussion on the importance of using test methods that are appropriate for their intended purpose and have been validated. TNI has expanded on these requirements with many more explicit details that are provided in Modules 3 through 7 and are defined for each type of analysis performed (asbestos, chemical, microbiological, radiochemical and toxicity). 17025 does not explicitly address test methods required by regulation. The TNI standard in many places states that requirements in mandated test methods or regulations supersede the technical requirements in the TNI standard.

5.5 Calibration

This section contains the most significant differences between 17025 and the TNI standard. The concepts of instrument calibration embodied in virtually every environmental test method are simply not covered in 17025. Section 5.5.2 requires equipment to be calibrated and checked before use, but no details are provided. TNI has added extensive requirements to two major areas, instrument calibration and support equipment. The instrument calibration requirements are not found in this module, but rather in Modules 3 through 7 and are specific for the types of testing to be performed (chemical, microbiological, radiochemical, etc.). The support equipment requirements added by TNI in section 5.5.13 relate to ovens, balances, incubators, etc. The TNI standards require these instruments to be calibrated and checked on each day of use.

5.6 Measurement Traceability

This section primarily addresses the use of reference standards and reference materials. TNI has added a section to focus on the traceability of prepared reagents and standards and a requirement to not use such materials after an expiration date.

5.7 Sampling

TNI has added a requirement that the date and time of sample collection be recorded.

5.8 Handling Samples and Test Items

The TNI standard has many more details in added sections focusing on documentation of sample identification, a sample acceptance policy, sample receipt protocols, chain-of-custody, and sample storage and disposal. These details provide specificity on issues such as verifying appropriate sample preservation and meeting holding times.

5.9 Quality Assurance

17025 has a basic requirement that laboratories have quality control procedures for monitoring the validity of tests and provides options such as using quality control samples, replicate analyses or re-testing. The TNI standard has added a significant new section, Essential Quality Control Procedures, which specifies 8 essential elements and then indicates that the specific details are found in Modules 3-7.

5.10 Reporting the Results

The TNI standard has added two subsections. One of these relates to the specialized reporting that occurs in in-house laboratories. The other subsection presents several specific requirements relating to reporting results.

Modules 3 through 7

Modules 3 through 7 contain detailed technical requirements for different types of laboratories, organized as follows:

- Module 3: Asbestos
- Module 4: Chemical
- Module 5: Microbiological
- Module 6: Radiochemical
- Module 7: Toxicity

Each Module has the same organization and content with the following sections:

- Introduction
- Scope
- Terms and Definitions
- Method Selection
- Method Validation
- Demonstration of Capability
- Technical Requirements

Some of the more important requirements in these modules are:

- Laboratories must validate all methods and the validation study must evaluate the limit of detection, limit of quantitation and precision,
- All analysts must demonstrate their proficiency in every test method,
- Analytical instruments used to measure environmental contaminants must be calibrated to specific criteria,

- Specific quality control samples (e.g., blanks, laboratory control samples, duplicates) must be analyzed at some prescribed frequency and corrective actions performed if results are not within acceptance limits.

None of these specific requirements are found in ISO/IEC 17025.

Summary

TNI has expanded upon ISO/IEC 17025 by adding specific details that relate to environmental analyses. An experienced assessor in the environmental field would likely believe these additional requirements are appropriate, but could use ISO/IEC 17025 without the added TNI language and identify applicable deficiencies in a laboratory's management system. However, such findings could be considered to be the opinion of the assessor and subject to challenge by the laboratory. Furthermore, two different assessors could easily have different opinions on such items as how frequent an internal audit should be performed or what quality control samples should be analyzed and at what frequency. The TNI standard provides sufficient detail to ensure the program can be implemented fairly and consistently across the nation.

This approach is very common nationally and internationally. For example, the American Association for Laboratory Accreditation, a non-governmental accreditation body, offers specific accreditation programs for "Animal Food Testing, Automotive EMC, Food Testing, Energy Star" and 10 others. Each of these programs has supplemental requirements in addition to 17025. Another non-governmental accreditation body, ANSI-ASQ National Accreditation Board (ANAB), has a 71-page document that sets forth the additional requirements for their ISO/IEC 17025 accreditation program. It includes requirements for the on-site assessment and proficiency testing not contained in ISO/IEC 17025 as well as supplemental technical requirements specific to different types of laboratories. The Canadian Association for Laboratory Accreditation (CALA) has published 16 documents that supplement ISO/IEC 17025 and cover topics such as proficiency testing, measurement uncertainty, reference methods and use of computers. The International Laboratory Accreditation Cooperation (ILAC), the organization that administers all accreditation programs world-wide, has published guidelines to be used for accreditation of forensic laboratories. That document states:

This document is intended to provide guidance for laboratories involved in forensic analysis and examination by providing application of ISO/IEC 17025.

ISO/IEC 17025 is a strong foundation upon which to build an accreditation program. However, any organization that wants to build such a program must supplement this document with additional requirements. TNI has expanded ISO/IEC 17025 into the environmental arena using a consensus process that consider the opinions of state and federal agencies, commercial and public-sector laboratories and other interests.