The 2016 TNI Laboratory Accreditation Standard and TNI Resources for Implementation

October 5, 2018

This document was prepared to provide laboratories on Changes to the TNI Standard some information to help with implementing the new standard.

TNI's Consensus Standards Development Program has released a new consensus standard for the accreditation of environmental laboratories, *Management and Technical Requirements for Laboratories performing Environmental Analyses*, Revision 2.1. Although the standard has been adopted into TNI's National Environmental Laboratory Accreditation Program (NELAP), the NELAP Accreditation Council has not established an implementation date. Each state Accreditation Body (AB) will be setting their own date based on their rule making process. Note this document only discusses Volume 1 of the Environmental Laboratory sector standards. Volumes 2, 3, and 4, that relate to other aspects of NELAP, were also revised.

1.0 Summary of Changes to Volume 1

This standard consists of seven modules:

Module	Title	Revision	Date
1	Proficiency Testing	2.1	2/3/2017
2	Quality Systems General Requirements	2.1	2/22/2016
3	Quality Systems for Asbestos Testing	2.1	2/15/2015
4	Quality Systems for Chemical Testing	2.2	11/1/2017
5	Quality Systems for Microbiological Testing	2.0	3/15/2016
6	Quality Systems for Radiochemical Testing	2.0	9/28/2015
7	Quality Systems for Toxicity Testing	1.0	3/12/2009

Module 7 was not revised but is included in the standard for completeness. Changes to the other six modules are summarized below.

1.1 Summary of Substantive Changes for Module 1: Proficiency Testing

- Removed all references and requirements related to Experimental Fields of Proficiency Testing.
- The proficiency testing (PT) reporting requirement has been reverted back to Proficiency Testing Reporting Limit (PTRL) reporting. Laboratories are required to evaluate and report results to the PTRL and the use of the less than (<) sign when the analyte is present in the PT sample will be evaluated as "Not Acceptable".
- The tracking of PT frequency is now based on the closing date and the required time between the closing date of one PT study and the opening date of a subsequent PT study is now 7 days.
- New sections have been added for Radiochemistry, Whole Effluent Toxicity (WET), and Cryptosporidium/Giardia analysis based on input from these committees.

1.2 Summary of Substantive Changes for Module 2: Quality Systems General Requirements

- Added ISO language to Section 1.2 indicating that Notes are guidance and not requirements.
- Added the following new definitions: Analyte, Data Integrity, In-depth Data Monitoring, Lot, Physical Parameter, and Reference Method.
- Revised the definitions for Demonstration of Capability, Limit of Detection, and Selectivity.
- Section 4.1.7 was clarified to indicate the quality manager and the technical manager can be the same person.
- Removed the Note in 4.1.7.1, and added the text in the Note to the beginning of the section.
- Added in Sections 5.4.4 and 5.5.5 from ISO 17025.
- Added in missing subsections from Section 5.4.6 of ISO 17025.
- Clarified that Sections 5.5.1 and 5.5.2 apply to environmental laboratories.
- Added in missing sections 5.6.1 and 5.6.2 from ISO 17025.
- Removed the Note from 5.8.7.3(b) thus making the note a requirement.
- Added in missing subsections from Section 5.10.4 of ISO 17025.
- Revised Section 5.5.13.1 to clarify the daily check for support equipment.

1.3 Summary of Substantive Changes for Module 3: Quality Systems for Asbestos Testing

- Sections 1.4 and 1.5 on Method Selection and Validation were revised to be consistent with other modules.
- Section 1.6, Demonstration of Capability, was revised for clarity and to allow for more options. The revised section reinforces that this demonstration applies to each individual that performs the test.

1.4 Summary of Substantive Changes for Module 4: Quality Systems for Chemical Testing

- Sections 1.4 and 1.5 on Method Selection and Validation were revised to be consistent with other modules.
- Section 1.5.2 on detection and quantitation limits was significantly revised to be consistent with the EPA MDL procedure in 40 CFR Part 136 and to reflect best professional practice.
- Section 1.6, Demonstration of Capability, was revised for clarity and to allow for more options. The revised section reinforces that this demonstration applies to each individual that performs the test.
- Sections 1.7.1 and 1.7.2 on instrument calibration have been extensively revised, describing various calibration options, discussing how to drop calibration points, and introducing a new quality control measure for evaluating calibration curves.

1.6 Summary of Substantive Changes for Module 6: Quality Systems for Radiochemical Testing

Module 6 was substantially revised by the Radiochemistry Expert Committee. While the substance of the 2009 standard was overall retained, the text underwent substantial reorganization and reformulation to add clarity and better address less well-developed concepts. The revised standard now better reflects current practices in environmental radiochemistry laboratories.

Changes in the revised Module 6 include the following:

- Definitions for key terms were added to Section 1.3.
- Requirements for method validation in Section 1.5 were refined to better address laboratory-developed/modified methods and to evaluate uncertainty and method performance at background (zero) activity.
- Section 1.6 requirements for Demonstrations of Capability include analysis of blanks, once again to address method performance at background activity.
- Technical requirements in Section 1.7 were reorganized to logically parallel set-up, calibration, calibration verifications, and quality control of instrumentation.
- Section 1.7.1 provides requirements for mathematical calibration methods, and for several approaches to background determination, both of which are in common use but neither of which are currently permitted.
- The most substantial change to method quality controls in Section 1.7.2, the Radiation Measurements Batch, was introduced to eliminate substantial confusion, and inconsistent implementation of batch quality controls for non-destructive analyses such as gamma spectrometry.
- Section 1.7.3 contains requirements for evaluating chemical yield which were not included in previous revisions. It also addresses reporting requirements for uncertainty.

Note: This Module was not addressed in the 2016 standard webinars that are planned for the fall of 2018 as a recording of an earlier webinar is available - https://nelac-institute.org/content/load_eds.php?id=90

2.0 Implementation Resources Available from TNI

To support this the implementation of the 2016 standard, TNI has developed, or is currently developing, a number of tools and other resources to help both the laboratories and the organizations that accredit laboratories.

2.1 Training Courses

TNI held four webinars in 2018 on Modules 1 (Proficiency Testing), 2 (Quality Systems), 4 (Chemistry) and 5 (Microbiology) in the fall of 2018. Recording of these webinars are available at: https://nelac-institute.org/content/eds-home.php. A course on Module 6 (Radiochemistry) was conducted in 2017 and a recording of this course is also available.

2.2 Revised Small Laboratory Handbook

This document is intended to help explain the requirements of the 2016 Standard and to provide environmental laboratories, especially small laboratories, with clear, simple guidance on how to develop the policies and procedures that will allow them to become accredited to the TNI Standard. This handbook is NOT a substitute for reading and understanding the TNI Standard. The revised handbook includes much more “How to” information. The revised handbook also contains a discussion of the accreditation process and several appendices with useful information, including common findings, SOP templates, and answers to standard interpretation requests. https://nelac-institute.org/content/NELAP/howto.php

2.3 2016 Quality Manual Template

The 2016 TNI Quality Manual Template is a tool designed for laboratories to help prepare a Quality Manual in compliance with the 2016 TNI Standard. The prefabricated sections of the Quality Manual follow the ISO/IEC 17025 outline but are completely fluid so that you can put sections, examples, links or references anywhere. The Template includes helpful notes, examples and text that can be edited to match each laboratory's particular circumstances. It can be used by a laboratory to create a Quality Manual from scratch or ideas and sections can be used to update a current Quality Manual. The primary change in this revised template was combining the multiple files into one file to make the template easier to edit and replacing the reference to the 2009 standard to the 2016 standard. Since both the 2009 and 2016 standards have the same organization and very comparable content, anyone who purchased the 2009 version, or has an existing Quality Manual, does not need to obtain the 2016 version. https://nelac-institute.org/content/NELAP/howto.php

2.4 Checklist

TNI has published a Checklist to allow laboratories to do an internal gap analysis for the TNI 2016 Standard. This checklist may be downloaded online if you own a copy of the TNI Standard. This analysis will laboratories to see where they might need to add policies, procedures, or other documentation. https://nelac-institute.org/content/NELAP/qscheck2016-access.php

2.5 New Guidance Documents

TNI is in the process of finalizing three guidance documents on these specific topics.

- Proficiency Testing Reporting Limit (PTRL)
- Detection and Quantitation
- Instrument Calibration

These documents are at the Final Draft stage and should be published by November 2018.

2.6 Standard Interpretation Requests (SIRs)

TNI has established an avenue for resolution of questions submitted electronically on interpretation of the Standards. Answers to the requests are currently organized by standard: 2003, 2009, or 2016. Some are now obsolete. Some of 2003 and 2009 SIRs are applicable to 2016. Expert Committees now reviewing status of all SIRs to map to 2016 where applicable. This effort is expected to be complete by January 2019 http://www.nelac-institute.org/content/NELAP/interpret.php

2.7 Comparison and Advocacy Documents

TNI has published an article that compares in detail the changes from the 2003 NELAC standard to the 2009 TNI standard, and 2009 to 2016. https://nelac-institute.org/docs/standards/2018/AR-TNIstandards-2003-2009-2016-7-7-18.pdf

2.8 Early Adoption

Many of the changes in the 2016 standard could be implemented now. For example, the new LOD/LOQ requirements in Module 4 could be implemented now as these requirements are more specific that what is in the 2009 standard. However, some of the new requirements may have to wait until the standard is effective in your state. For example, the PTRL reporting in Module 1 will have to wait until each AB adopts the standard into their rule. Another example is the single point calibration for support equipment (e.g., ovens, water baths) in Module 2. TNI held a special session on this topic in August 2018, and the notes from that session should be posted on the TNI website later this year. However, TNI recommends you talk to your AB about any of the changes you would like to implement now.

Appendix: TNI's Standard Development and Adoption Process

Accreditation standards are developed by Expert Committees using a consensus process that includes the elements of openness, balance, due process, and consensus as established by Circular A-119 published by the US Office of Management and Budget.

Circular A-119 defines a voluntary consensus standards body as one having the following attributes:

> *(i)openness; (ii) balance of interest; (iii) due process; (iv) an appeals process; and (v) consensus, which is general agreement, but not necessarily unanimity, and includes a process for attempting to resolve objections by interested parties, as long as all comments have been fairly considered, each objector is advised of the disposition of his or her objection(s) and the reason(s) why, and the consensus body members are given an opportunity to change their votes after reviewing the comments.*

Standards are developed by the TNI Consensus Standards Development Program (CSDP), in conformance with TNI's Procedures Governing Standards Development. The American National Standards Institute (ANSI) has approved the TNI process for standards development indicating that TNI meets the ANSI requirements. This means the TNI standards are developed through an open consensus process in which all members and the public may provide input and have their position considered, preventing dominance by any one group of stakeholders by assuring a balance of interests among the committee members who develop the standards. The Expert Committees each develop a **Working Draft Standard** that is presented to the membership and the public. As a result of input received during and following an open meeting, the Expert Committees modify their Working Draft Standard to produce the **Voting Draft Standard**. All TNI members may then vote electronically, providing comments in support of their positive or negative votes. The Expert Committees must allow for public debate on every comment. The Expert Committees hold meetings to rule each comment persuasive or non-persuasive. Persuasive comments require the Expert Committees to revise the standard in response to the comment.

Committees must resolve every persuasive comment, which may require modification of the standard. Some comments may suggest major changes to the standard (e.g., reduce proficiency test frequency to once per year instead of twice per year), and they may be placed on hold until the next standards revision cycle to allow consideration and debate by the membership and the public.

When persuasive comments are resolved and the standard modules are approved by a majority vote of the Committee Members, the standard then becomes final as the **TNI Standard**.

For the next revision of the standards, which may be expected within 4-5 years, a revised *Procedures Governing Standards Development* will be in use (this may be found on the TNI website as SOP 2-100, Version 2.0). This will improve, and in many cases shorten, the standards development process by providing substantial stakeholder outreach up front, and inviting input that will allow the expert committees to avoid the Working Draft Standard stage and to move straight into a Voting Draft Standard. This new procedure will take extra steps to assure stakeholder concerns are satisfied before finalizing the standard.

After a standard has been adopted by an expert committee, it undergoes an editorial review for consistency and then is published on the TNI website along with the Response-to-Comments document explaining the resolution of all written comments that accompanied the vote on the standard.

After resolution of appeals, the standard may be used by any organization. However, for use within TNI's National Environmental Laboratory Accreditation Program (NELAP), the TNI Laboratory Accreditation System Committee (LASC) reviews the adopted TNI Standard and develops supplementary documents (guidance, SOPs, etc.), when needed. The LASC then forwards the standards to the TNI NELAP for this program to adopt the standard for use by all Accreditation Bodies (ABs). TNI expects NELAP ABs will require a lead time of about two years to amend regulations and implement the standard. Because modifying regulations is restrictive and time-consuming, some NELAP ABs may possibly continue to accredit laboratories the 2009 version of the standards until their regulations are finalized.

The NELAC Institute (TNI) Procedures for Expert Committee Operations describe how any TNI member may participate, as an Associate Committee Member, in conference calls of any Expert Committee. The dates/times of scheduled calls are listed on each Expert Committee's web page as well as on the Event Calendar.

In order to participate in TNI committee meetings, any member may register with the chair of the Expert Committee(s) of interest. You will then receive an invitation to each conference call, together with an abbreviated agenda and any documentation pertinent to the meeting. If you wish to attend, you must so notify the chair at least 24-hours in advance of the meeting. You will then be provided with the call-in number and a telephone line will be made available for you.