

## The 2016 TNI Laboratory Accreditation Standard

November 15, 2017

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. The standard has not been adopted into TNI's National Environmental Laboratory Accreditation Program (NELAP) at this time, but is being provided now so laboratories and Accreditation Bodies can begin plans for implementation. 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.

This standard consists of seven modules:

- Module 1: Proficiency Testing, Revision 2.0 (2/3/2017)
- Module 2: Quality Systems General Requirements, Revision 2.1 (2/22/2016)
- Module 3: Quality Systems for Asbestos Testing, Revision 2.0 (2/15/2015)
- Module 4: Quality Systems for Chemical Testing, Revision 2.2 (11/1/2017)
- Module 5: Quality Systems for Microbiological Testing, Revision 2.0 (3/15/2016)
- Module 6: Quality Systems for Radiochemical Testing, Revision 2.0 (9/28/2015)
- Module 7: Quality Systems for Toxicity Testing, Revision 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.

### 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.

### Rationale for Changes

1. Experimental Fields of Proficiency Testing have been incorporated as Accreditation Fields of Proficiency Testing or removed from the PT Program.
2. The 2009 TNI standard required that laboratories evaluate and report PT results to the lowest calibration standard or Limit of Quantitation (LOQ). The standard allowed laboratories to report a less than (<) value for an analyte that was present and be scored "Acceptable" as long as the value reported with the less than (<) sign was within the acceptance range. This evaluation of less than (<) values was a major stumbling block for many of the accrediting bodies (ABs). At the TNI conference in Seattle in 2015, the committee received many comments to move back to the PTRL reporting set of requirements.

3. The 2009 version of the standard required tracking PT results via analysis date for each analyte. This was an onerous requirement for the ABs as well as the laboratories. The 2009 standard also set a minimum timeframe between PT studies at 15 days. The timeframe was shortened to allow laboratories to regain or obtain new scope(s) of accreditation more quickly.

### **Summary of Editorial Changes for Module 1: Proficiency Testing**

Revision 2.0 of this standard was approved by the PT Committee on December 6, 2016. Early in 2017, the PT Committee made some minor editorial changes to the standard creating revision 2.1. These changes included:

1. Remove the Definition of Accreditation Body

This term is already defined in Volume 2, Modules 1 and 3, and uses the ISO 17011 language.

2. Clarify the role of the AB when a laboratory runs one method per technology.

The revised standard clearly indicates a lab would lose accreditation for all methods if it chose the technology route in Section 4.3.4.

3. Successful Analysis

Sections 5.1.1 and 5.2.1 discuss acceptable scores. Volume 2 defines success as more than getting a passing score. A Note was added to section 5.2.3 to further explain what successful means.

### **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.

### **Rationale for Changes**

The 2009 Standard had moved some language from ISO 17025 into the Technical Modules 3-7, but in an inconsistent manner and some language from 17025 was omitted. The 2016 standard faithfully contains all of 17025 in Module 2. The revised definition for Limit of Detection is consistent with the definition of Method Detection Limit in 40 CFR Part 136. Several “Notes” contained requirements and so the word “Note” was removed. The ISO 17025 language stating that Notes are guidance only was added back in to

Section 1.2. Section 5.5.13.1 was clarified to allow laboratories to use a single-point calibration check for support equipment. Other changes to definitions were made for clarity.

### **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.

### **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.

### **Rationale for Changes**

- The revised section on method validation and selections has clear language on how to add a new analyte to an existing method.
- The new procedures for detection and quantitation limits corrects problems with the existing EPA procedure in 40 CFR Part 136, most importantly allowing for the use of blank results where appropriate, and allows one set of spikes to serve to determine both a limit of detection and a limit of quantitation.
- The new section on calibration points was added based on comments from stakeholders.

### **Summary of Editorial Changes for Module 4: Quality Systems for Chemical Testing**

Revision 2.0 of this standard was approved by the Chemistry Committee on January 15, 2017. Early in 2017, the Chemistry Committee made some minor editorial changes to the standard creating revision 2.1. These changes included:

#### **1. Change MDL to DL**

The definition of MDL in Module 2 as written does not exactly equal the EPA definition of an MDL, and the procedure described in Module 4, while more generic, is still different. This could create confusion among laboratories on which procedure to use, if both procedures use the same term. By changing the term to Detection Limit (DL) in the TNI standard, it is clear that when a lab uses the term MDL they are using the Part 136 procedure.

#### **2. Method vs Instrument calibrations**

The sentence right before section 1.7.1.1 could create confusion and since this is not enforceable, the sentence was deleted. This concept could be discussed in the guidance.

#### **Summary of Additional Technical Changes for Module 4: Quality Systems for Chemical Testing**

Based on feedback from the NELAP Accreditation Council in early 2017, Sections 1.5.2.1.1, 1.5.2.1.3, 1.5.2.2, 1.5.2.2.1, 1.5.2.2.2 were modified. A Voting Draft Standard was published on September 1, 2017. After reviewing the comments received, the Chemistry Committee approved revision 2.2 of this module on November 1, 2017. The changes included:

- Removing sample preservation as a condition of the DL/LOQ studies,
- Clearly indicating that at least 7 low level spikes and 7 blanks are required for the DL,
- Removing the requirement that the LOQ be at least three times greater than the DL,
- Adding a quantitative recovery criteria for the LOQ spikes, and
- Revising the corrective action criteria for the LOQ verification test.

#### **Summary of Substantive Changes for Module 5: Quality Systems for Microbiological Testing**

This module was substantially revised to add clarity, reinforce the concept of minimum requirements and default to the use of the data. Section 1.5 on Method Validation was revised to allow the use of a statistically better method and allow for improvement. The Quality Control section (1.7) was reorganized to separate the activities done before analysis from those done during analysis. There are many other minor changes.

#### **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.

## 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.