The 2016 TNI Laboratory Accreditation Standard

August 4, 2016

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 2.0. 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 is Volume 1 of the Environmental Laboratory sector standards. Volumes 2, 3, and 4, that relate to other aspects of NELAP, are nearing conclusion and should be released within the next few months.

This standard consists of seven modules:

- Module 1: Proficiency Testing, Revision 2.0
- Module 2: Quality Systems General Requirements, Revision 2.1
- Module 3: Quality Systems for Asbestos Testing, Revision 2.0
- Module 4: Quality Systems for Chemical Testing, Revision 2.0
- Module 5: Quality Systems for Microbiological Testing, Revision 2.0
- Module 6: Quality Systems for Radiochemical Testing, Revision 2.0
- Module 7: Quality Systems for Toxicity Testing, Revision 1.0

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

- Deleted section 1.3.3 that referred to an appendix that does not exist.
- In section 3.0, deleted definitions for analysis date, experimental fields of proficiency testing, and TNI PT Board. Added definitions for proficiency testing reporting limit (PTRL) and revised the definitions for PT study opening and closing dates. Several other minor clarifications.
- Section 4.0, Accreditation Requirements, is a new section containing three subsections discussing such items as analysis of PT samples and reporting results. The new subsection 4.3 on reporting describes the PTRL concept. A new section, 4.2.5, provides options for when a PT sample concentration is below the calibration range of the laboratory.
- The old Section 4, renamed and renumbered to 5.0, PT Study Frequency Requirements for Accreditation, has been clarified and includes new sections on PT testing for Whole Effluent Toxicity. The language in this section requiring PT samples to be analyzed "at least 5 months apart and no longer than 7" has been revised to state "no more than 7 months apart." A section on experimental PTs was deleted.
- The language in the old Section 5 was incorporated into the new Section 4.
- Language in the old section 6 on corrective action relating to make-up PT samples was deleted, but nothing in the new section prevents this practice as part of corrective action.
- Language was added to section 6 for corrective actions for whole effluent toxicity laboratories.

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.

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.

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 (ELAP), 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 any forthcoming conference calls, you should 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.