NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION STANDARDS

July 7, 2018

Jerry L. Parr
The NELAC Institute (TNI)
jerry.parr@nelac-institute.org

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

DISCLAIMER This document highlights changes to the various standards used in the National Environmental Laboratory Accreditation Program (NELAP). The goal of this document is to capture all changes, but if errors are noted, please let us know. Laboratories and Accreditation Bodies should not rely on this document, but rather the standard itself.

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. Such a program, the National Environmental Laboratory Accreditation Program (NELAP), is designed to ensure the competency of all environmental testing laboratories and related sampling and measurement organizations in the United States. The goal of NELAP is to foster cooperation among the accreditation activities of different states and to unify the state requirements into a single standard. Each of the recognized accreditation bodies must implement the standards, and must accept the accreditation of laboratories accredited by other NELAP accreditation bodies. However, recognizing the sovereignty of state governments, NELAP does not require every state to implement accreditation standard in the same manner or at the same time. Currently, states participating in NELAP have two choices for an accreditation standard, the 2003 NELAC standard or the 2009 TNI standard. A third standard, the 2016 standard, has been approved by TNI's Consensus Standards Development Program but has not been adopted into NELAP.

Note: These standards specify the requirements that environmental testing laboratories must meet to demonstrate their competence. They cover testing performed using standard methods, non-standard methods, and laboratory-developed methods. The standards are applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing activities. When a laboratory does not undertake one or more of the activities covered by these standards, such as sampling and the development of new methods, the requirements of those clauses do not apply. These standards are for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use them in confirming or recognizing the competence of laboratories.

Background

EPA, with the states as its implementation partners, maintains requirements for the certification of drinking water laboratories and also establishes accreditation requirements for laboratories that analyze lead (such as in paint) and asbestos. 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. Over thirty years ago, EPA recognized the problem

of uncoordinated, inconsistent and redundant state and federal laboratory accreditation programs. In a 1988 Report to Congress on the comparability of laboratory test procedures, the EPA recommended that it explore the feasibility of establishing a uniform national laboratory accreditation program.

The 2003 NELAC Standard

On February 16, 1995, state and federal officials voted to approve an interim Constitution and Bylaws – thus establishing the National Environmental Laboratory Accreditation Conference (NELAC), a standard setting organization. The major objective of NELAC was to develop accreditation standards, and in the period between 1995 and 2003 it did so. However, NELAC, in its original structure, did not meet the definition of a voluntary consensus standards body and thus the last NELAC standard was published in 2003. This standard was based on the 1997 version of the international standard ISO/IEC 17025, 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."

In addition, the 2003 standard:

- Added specificity to improve clarity and help with consistency for environmental testing,
- Required conformance to EPA mandated methods (where they exist,) but otherwise allows flexibility in meeting requirements,
- Represented the best professional practice of the environmental testing community,
- Allowed for multiple Accreditation Bodies to implement consistently,
- Contained an appropriate level of proficiency testing, and
- Included a data integrity component missing from ISO/IEC 17025.

The 2003 NELAC Standard has been used by NELAP-recognized Accreditation Bodies (ABs) since 2005, and as such, is very familiar to the ABs as well as the accredited laboratory community and other stakeholders. However, the 2003 NELAC standard contains language about the operation of an organization that no longer exists, contains administrative detail that does not pertain to the operation of an accreditation program, contains language from an obsolete version of ISO/IEC 17025, is very hard to read and understand by laboratories that have not been accredited, and is not recognized by the EPA as a consensus standard. The 2003 NELAC Standard is widely perceived as one of the barriers to increasing the participation of both laboratories and states in NELAP. Nonetheless, this standard is still in use by some states and is an acceptable standard for a state to use.

The 2009 TNI Standard

The NELAC Institute (TNI) was formed on November 6, 2006, 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.

The 2009 TNI standards were developed to respond to criticisms of the 2003 NELAC standard and represent a substantial improvement over the 2003 standard.

- It removed outdated language related to the National Environmental Laboratory Accreditation

Conference, an organization that no longer exists.

- It has incorporated the 2005 version of ISO/IEC 17025.
- It has incorporated ISO/IEC 17011, the international standard for accreditation bodies.
- It has a multi-volume modular approach that simplifies reading and understanding the requirements and minimizes the cost of the standard for laboratories.
- It has improved clarity on requirements, especially requirements related to method validation and demonstration of capability.
- It has a stronger emphasis on the technical competence of laboratory assessors.
- It is a true consensus standard[1].

A comparison of the 2003 NELAC Standard and the 2009 TNI standard can be found in Appendix 1.

The NELAP Accreditation Council adopted this standard for use in NELAP with an effective date of July 1, 2011. However, due to state governmental changes and political realities (such as a freeze on regulations by a new governor, for example), not all states were able to implement the standard as earlier agreed planned. The extent of such delays became obvious in early 2011, as new governors were installed into office and began to make changes in state operations. The NELAP Accreditation Council (AC) and each of its 14 NELAP ABs fully commit to maintaining reciprocal recognition regardless of which standard is in use by any individual AB. This is no different than when NELAC changed from the 2001 to the 2003 Standard, and TNI's Board of Directors has accepted the AC's proposal for a "rolling implementation." Expectations were that the change-over could be accomplished on a fixed date, but reality intervened, and a fixed date for implementation is simply not feasible.

The 2016 TNI Standard

The 2016 standard is the result of efforts to continually improve the requirements. This standard clarifies the proficiency testing requirements, improves the sections on method validation, instrument calibration and detection/quantitation limits for chemistry and contains completely rewritten sections for microbiology and radiochemistry. Appendix 2 summarizes the key differences between the 2009 and 2016 standards. It is likely that the implementation date for this standard will be 2019 or later, although some states (e.g., Florida) may do so sooner if they have changes to their regulations underway.

In summary, there are three national standards available. While each of these have different requirements, they all have the same quality system foundation, the same frequency of proficiency testing, and similar technical requirements. While each revision to a standard brings improvement, TNI believes these standards are all "equally effective" to be used as the basic framework for an accreditation program.

[1] The 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."*

Appendix 1: The 2009 TNI Standard

The 2005 version of ISO/IEC 17025 has some additional management and technical requirements that were not in the obsolete version of ISO/IEC 17025 contained in the 2003 NELAC standard. These new requirements, found in Module 2, are summarized below.

- Ensure personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system. (4.1.5 (k))
- Ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system. (4.1.6)
- Ensure the integrity of the management system is maintained when changes to the management system are planned and implemented. (4.2.7)
- Seek feedback, both positive and negative, from its customers to improve the management system, testing activities and customer service. (4.7.2)
- Continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. (4.10)
- Analyze quality control data and, where they are found to be outside pre-defined criteria, take action to correct the problem and to prevent incorrect results from being reported. (5.9.2)

In addition, TNI's Quality System and Proficiency Testing (PT) expert committees revised language from the 2003 NELAC standard, and in some cases added new language, that impose new laboratory requirements. For example,

- Section 4.2.1 of Module 1 requires PT samples to be analyzed every 5 to 7 months. The 2003 NELAC standard required PT samples to be analyzed approximately six months apart. The 2009 standard is not a change in the requirement, but increased clarity on "approximately six months."
- Section 5.5.13 of Module 2 provides the requirements for a daily check of support equipment such as balances, ovens and refrigerators. The 2003 NELAC standard (Section 5.5.5.2.1 of Chapter 5) used the phrase "prior to use on each working day." The 2009 TNI standard has revised this to read "each day the equipment is used" to clarify what was meant by "working." Again, this is not a new requirement.
- Section 5.6.4 of Module 2 now requires reagents to be traceable. This is a new requirement.
- In the 2003 standard, PT Providers were required to evaluate reported results to a PT Reporting Limit published in the TNI Fields of Proficiency Testing tables. This requirement forced many laboratories to create specific reporting limits just for PT sample analyses, which is contrary to the requirement that PT samples be analyzed as routine samples. The 2009 standard allows laboratories to report results to their normal reporting limit for that analyte/method/matrix, and the PT Provider must evaluate the result on that basis. This change will require laboratories to provide their LOQ when reporting PT results. For more details, read section 5.2 of Module 1 and section 10.3 of Volume 2, the requirements for PT providers.

The TNI expert committees that developed the 2009 standard carefully reviewed requirements in the 2003 NELAC standard relative to their importance to ensuring data quality and integrity. A number of requirements from the 2003 standard have been modified, or in some cases deleted, to provide more flexibility in meeting the requirements or to allow laboratories to stop performing non-essential activities.

For example,

- Section 5.4.2.3 of the 2003 NELAC standard required laboratories to have 23 specific items in their

Quality Manual and even specified what was to be on the cover page. Section 4.2.8 of Module 2 requires the Quality Manual to have a title and 8 specific items. It then lists 20 items that can be in the Quality Manual or simply referenced. There are no requirements for what must be on the cover page.

- Section 5.5.6.4 of the NELAC standard required an expiration date for standards, reagents, reference materials and media. The 2009 TNI standard (section 5.6.4 of Module 2) does not require a laboratory to fabricate an expiration date that is not provided by the manufacturer or required by a method.
- Section 5.5.4.2.2 of Chapter 5 in the NELAC standard required a laboratory to document a demonstration of capability (DOC) using a form found in Appendix C and that information to be maintained in an employee training file for each analyst. The requirements for the DOC were very much oriented towards laboratories performing chemical analyses. In the 2009 TNI standard, the requirements for DOC are found in Modules 3-7 and vary based on the scientific discipline (asbestos, chemical, microbiological, etc.). The requirements for what must be documented are not changed, but laboratories are not required to use a specific form, and the laboratory can decide where and how to store this information.

These three examples illustrate the increased flexibility allowed in the 2009 TNI standard. In each of these examples, a laboratory could continue their current practice and be in compliance with the 2009 standard. The table which follows summarizes all of the changes between the 2003 and 2009 standard.

Summary of Changes from 2003 NELAC to 2009 TNI Standard

Volume	Module	Section	Change	Discussion	Laboratory Impact
1	1	4.1	For laboratories applying for accreditation, last analysis of PT sample must be within 6 months of application.		Minor
1	1	4.1	Provision to allow PT samples to be obtained from a non-accredited provider	For this to occur, a) analyte would have to be approved by PT EC and NELAP AC and b) no existing PT providers are capable of providing sample.	No impact
1	1	4.2	Provision to allow PT samples to be obtained from a non-accredited provider	For this to occur, a) analyte would have to be approved by PT EC and NELAP AC and b) no existing PT providers are capable of providing sample.	No impact
1	1	4.2	PT sample analyses must be at least 5 and no more than 7 months apart	Clarification of "approximately six months"	Minor
1	1	4.2	Provision to allow for Experimental PTs	For this to occur, analyte would have to be approved by PT EC and NELAP AC	No impact
1	1	4.2	Corrective action PT samples must be 15 days apart.	2003 NELAC standard required 15 days from closing date of PT study. The 2009 TNI language uses analysis date, not study closing date.	Trivial
1	1	5.1	Clarifications on how PT samples are to be analyzed.	No change in intent from 2003 NELAC	No Impact
1	1	5.2	Report PT data to LOQ.	Significant change for labs that reported to PTRL.	More flexibility
1	1	5.3	Retain record of on-line submission of PT results		Trivial
1	2	4.1.5 (k)	ensure personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system	New ISO 17025 language	Minor
1	2	4.1.5 (h)	Delete requirement that TD has to certify personnel have education/technical knowledge to perform tests (NELAC 5.4.1 .5.h)	See Section 5.2.5 – Management shall authorize…	More flexibility
1	2	4.1.6	Ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system	New ISO 17025 language	Minor
1	2	4.1.7.2	Change requirement from 65 days to 35 days for reporting to AB when TD is absent		Minor

Volume	Module	Section	Change	Discussion	Laboratory Impact
1	2	4.2.3	Commitment to continually improving effectiveness of management system	New ISO 17025 language	Minor
1	2	4.2.4	Importance of meeting customer and regulatory requirements.	New ISO 17025 language	Minor
1	2	4.2.7	Ensure the integrity of the management system is maintained when changes to the management system are planned and implemented	New ISO 17025 language	Minor
1	2	4.7.2	Customer feedback required. Feedback may be a survey or a review of reports with customer	New ISO 17025 language	New Activity
1	2	4.10	The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.	New ISO 17025 language	Minor
1	2	4.11.3	Increased emphasis on implementation of corrective actions.	New ISO 17025 language	Minor
1	2	4.14	Follow-up required to verify corrective actions implemented	New ISO 17025 language	Minor
1	2	5.9.2	Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported.	New ISO 17025 language	No impact
1	2	5.10.3.1	Information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the uncertainty affects compliance to a specification limit;	New ISO 17025 language	Minor
1	2	4.2.8	Requirements for content of Quality Manual	Only 9 items required to be in Quality Manual; other items may be or may be referenced. No requirements for cover page.	More flexibility
1	2	4.2.8.5	No requirement for a "Methods Manual."	Labs must have SOPs for all test methods; they do not have to be consolidated into a "manual."	More flexibility
1	2	NA	Demonstration of Capability removed	DOC is in modules 3-7 and varies by scientific discipline.	More flexibility
1	2	4.11.7	Corrective action root cause analysis now clarified to apply to systematic errors		Clarification
1	2	5.5.13	Requires calibration of support equipment to be checked each day the equipment is used.	2003 NELAC had the phrase "prior to use on each working day"	Clarification
1	2	5.5.5	Removed requirements for date equipment was received, placed in service and condition when received		More flexibility

Volume	Module	Section	Change	Discussion	Laboratory Impact
1	2	5.6.4	Expiration dates for reagents in original containers not required unless provided by manufacturer		More flexibility
1	2	5.6.4	Expiration dates for prepared reagents and standards must be on container	2003 NELAC allowed dates to be in Quality Manual	New Activity
1	2	5.6.4	New traceability requirement for prepared reagents		New Activity
1	2	5.10.2	Date of test report not required to be present		More flexibility
1	2	5.10.2	Certification that the results meet all requirements or provide reasons and/or justification if they do not no longer required		More flexibility
1	2	5.10.2	"Report cannot be reproduced except in full" is now a *Note*	ISO 17025 language	More flexibility
1	2	5.10.2	Establishes default reporting requirements as "as received."		More flexibility
1	4	1.4	New language to allow for addition of anlaytes to a reference method.		More flexibility
1	4	1.5.2	Removed "must have procedures to relate LOD to LOQ"		More flexibility
1	4	1.5.3	Sets different requirements for validation of reference methods and non-reference methods for precision and bias.		More flexibility
1	4	1.6	Initial DOC required for all methods and analysts, except those in effect one year before applying for accreditation		New Activity
1	4	1.6	Form in Appendix C of 2003 NELAC not required to be used for DOC	Documentation must be maintained	More flexibility
1	4	1.6	DOC Documentation not required to be in personnel file		More flexibility
1	4	1.6	Initial DOC required if analyst does not perform method within 12 months		New Activity
1	4	1.6	QC sample used for DOC does not have to be from an outside source		More flexibility
1	4	1.6	4 replicates (e.g., the 2003 NELAC requirements) is one option for initial DOC but not required		More flexibility
1	4	1.6	It is the responsibility of the laboratory to document that other approaches to initial DOC are adequate.		More flexibility
1	4	1.6	Options from NELAC 5.5.2.6 still allowed: Single-blind sample, Initial DOC, or 4 LCSs		More flexibility

Volume	Module	Section	Change	Discussion	Laboratory Impact
1	4	1.6	Another option for on-going DOC added: A documented process of analyst review using QC samples. QC samples can be reviewed to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary.		More flexibility
1	4	1.6	On-going demonstration of proficiency does not have to contain all analytes for which lab/analyst is qualified; must calibrate for all (V1M4, 1.6.3)	See NELAC 2003 – Analyte was never used in this section	Clarification
1	4	1.6	“Read and understand” requirements for test methods and quality documents deleted (NELAC 5.5.2.6)	See M2 section 5.2.1 and 4.2.8.5. It may not have the words read and understand but requires education, training, experience and demonstrated skills.	More flexibility
1	4	1.7	Low standard must be at or below LOQ		New Activity
1	4	1.7	Minimum number of calibration standards changed from 2 to 3	0 may be used as a calibration point	More flexibility
1	4	1.7	Data must be qualified for failed surrogate recoveries.	2003 NELAC said "should."	New Activity
1	4	NA	2003 NELAC language relating to glassware cleaning removed.		More flexibility
1	5	1.5	Method validation required for non-reference methods	Specific for microbiology	New Activity
1	5	1.6	An acceptable approach for initial DOC described; other options possible	Specific for microbiology	More flexibility
1	5	1.6	Options for on-going DOC described; other options possible	Specific for microbiology	More flexibility
1	5	1.7	Beginning and ending filtration blank for MF now 1 per set per series, not 1 set per filtration unit	There was a micro task group which made signification clarifications to M5	Clarification
1	5	1.7	Additional specifics on media quality control		Clarification
1	5	1.7	TOC and ammonia/organic nitrogen added to micro water quality requirements		Minor
1	5	1.7	Recording of amount of media received no longer required		More flexibility
1	5	1.7	Determination of time required to reestablish equilibrium in incubators deleted		More flexibility

Volume	Module	Section	Change	Discussion	Laboratory Impact
1	5	1.7.5	Thermal preservation not required if if analysis begins within 15 minutes of collection or samples refrigerated within 15 minutes		More flexibility
1	5	1.7.5	Increased clarity on residual chlorine check	New language makes it very clear on when this check needs to be performed.	Clarification

Appendix 2: Summary of Changes between the 2009 and 2016 Standards

As summarized in the seven subsections below, TNI's Consensus Standards Development Program believes this 2016 Standard is a significant improvement over the 2009 standard in terms of clarity and consistency and represents the best professional practices for determining the competency of environmental testing laboratories. The table which follows this summary shows all of the changes between the 2009 and 2016 standard.

Module 1: Proficiency Testing

Volume 1, Module 1 of the 2009 TNI Standard was limited in detail and contained requirements preventing its implementation by some TNI Accreditation Bodies (ABs). Volume 1, Module 1 of the 2016 TNI Standard contains revisions to improve the organization, clarity and content of the standard allowing all TNI ABs to implement. The significant changes made to improve and provide a more comprehensive proficiency testing (PT) standard are listed below:

- The definitions in Section 3.0 were removed, added, or revised to minimize redundancy with normative references and to ensure consistency.
    - These definitions were removed as no longer being applicable:
        - Accreditation Body
        - Accreditation Field of Proficiency Testing
        - Analysis Date
        - Experimental Field of Proficiency Testing (Experimental FoPT)
        - Supplemental Proficiency Testing Study
        - TNI PT Board
    - The definition for Field of Proficiency Testing (FoPT) was slightly revised to clarify that TNI's PT Program Executive Committee establishes FoPT.
    - The definitions for PT Study, PT Study Closing Date, and PT Study Opening Date were revised to discuss both scheduled and supplemental PT studies.
    - A definition for Proficiency Testing Reporting Limit (PTRL) was added to reflect the change in Section 4.3.

- The Experimental Fields of Proficiency Testing requirements in Section 4.2.2 of the 2009 standard were removed as they have been incorporated as Fields of Proficiency Testing or removed from the PT Program.

- The content of Sections 4.0 and 5.0 were reorganized for clarity and flow of requirements. The Whole Effluent Toxicity (WET) specific requirements were incorporated separately from Chemical, Radiological, Asbestos and Microbiological to allow for these differences to be clearly highlighted.

- New Radiochemistry and Whole Effluent Toxicity (WET) requirements were added to Sections 4.0 and 5.0 to improve consistency within these disciplines, including reporting radiochemistry PTs as measured (zero, negative, or positive values) and with their associated measurement uncertainty and only requiring 1 PT/year for WET testing with the acceptance of DMR-QA PTs.

- Section 4.2.1 was added to require the laboratory to analyze PT samples in accordance with instructions provided by the PT provider.

- The reporting options and impacts relative to reporting by "method" or by "technology" were explained in Section 4.3.4 to help laboratories understand the risks of reporting by one or the other. The standard now notes that "if a laboratory reports PT results for multiple methods using the same analytical technology, an evaluation of not acceptable for one method will be applied to all methods reported with that technology".

- The PT requirements in Section 4.3.4 for EPA drinking water analytes specified in 40 CFR 141 were clarified, noting that PT results for these analytes are to be reported for each analytical method rather than by a single analytical method representative of a technology.

- Evaluating and reporting PT sample results down to the laboratory's Limit of Quantitation (LOQ) was changed back to evaluating and reporting PT sample results down to the prescribed Proficiency Testing Reporting Limit (PTRL). See Section 4.3. The 2009 TNI Standard allowed laboratories to report PT results as less than (<) their LOQ even if the analyte was present in a PT sample, and be scored "Acceptable", if the LOQ value reported with the less than (<) sign was within the acceptance range. This was a major obstacle for some TNI Accreditation Bodies and prevented their implementation of the 2009 TNI Standard. PTRL reporting, however, is sometimes difficult for laboratories to execute while still treating PT samples as routine environmental samples. So, the 2016 TNI Standard also includes allowances for laboratories to deal with these difficulties, including calibrating lower or reporting without qualification for results below their routine calibration curve.

- PT frequency requirements were changed in Section 5.1.1 from 5-7 months apart to a maximum of 7 months apart with a minimum of 7 days between PT studies instead of 15 days to allow laboratories to participate in PTs more frequently, if they desired, and to regain or obtain new fields of accreditation more quickly.

- The PT tracking requirement in Section 5.2.1 was changed from analysis date back to the PT Study closing date as the analysis date was onerous for both Accreditation Bodies and laboratories to track. Using the closing date provides a more streamlined process that is easier to maintain.

- The difference between an "Acceptable" PT score from a PT Provider and a "Successful" PT evaluation from an Accreditation Body was clarified in a Note in Sections 5.1.2 and 5.2.3 to ensure that laboratories understand that there is more to obtaining a successful evaluation than just reporting an acceptable result.

- Section 5.3.2 in the 2009 standard on historical records was deleted since the language in 5.3.1 (4.4.1 in the 2016 standard), *all records necessary*, addresses this requirement.

- The corrective action requirements in Section 6.0 for unsuccessful PTs were updated to include the submittal of the root cause investigation and corrective action documentation to the primary Accreditation Body within 30 days of request from the primary Accreditation Body. In Volume 2, Module 2, of the 2009 TNI standard, Accreditation Bodies were required to suspend a laboratory for not submitting a corrective action report within 30 days of request, yet Volume 1, Module 1, never contained this corresponding requirement for laboratories. This requirement eliminates that contradiction.

- The allowance for the analysis of another PT sample to reestablish successful PT history was removed from the corrective action requirements in Section 6.0. It is not a requirement for corrective action and was no longer needed with the change to the PT frequency noted above allowing labs to analyze PTs at any frequency within the 7-month maximum.

Module 2: Quality Systems General Requirements

- Added the following new definitions: Analyte, Data Integrity, In-depth Data Monitoring, Lot, Physical Parameter, and Reference Method.
    - Modules 3 thru 7 in the 2009 Standard used the word "parameter" to describe what is being measured, but the definition of this term did not reflect this purpose. The 2016 Standard added Analyte and Physical Parameter to clarify the difference and reflect common practice.
    - Section 5.2.7 discusses data integrity training and in-depth data monitoring, but these terms were not defined in the 2009 standard, which resulted in confusion among some laboratories.
    - ISO/IEC 17025 Section 5.4 discusses standard and non-standard methods, but these terms are not defined. The TNI standard uses the term reference method to differentiate this from the well-known Standard Methods in the US. Modules 3-7 describe various method validation activities to be carried out for reference methods and non-reference methods.
    - The definition of "lot" was added to help clarify the requirements in Modules 3-7 for various Quality Control (QC) checks.

- Revised the definitions for Demonstration of Capability, Limit of Detection, and Selectivity.
    - The revised definition for Limit of Detection is consistent with the definition of Method Detection Limit in 40 CFR Part 136.
    - The revised definition for Demonstration of Capability focuses on competence of the analyst.
    - The revised definition for Selectivity eliminated the inappropriate use of the word "parameter."

- As stated in ISO/IEC 17025, Notes are not enforceable; they are guidance. Many Notes were eliminated, or the word "Note" was removed thus making the language part of the standard.

- The ISO/IEC 17025 language stating that Notes are guidance only was added back in to Section 1.2.
- The Note in Section 4.1.7.1 relating to the technical manager and quality manager was removed and the text in the Note was added to the beginning of the section, thus ensuring this option is available to laboratories.
- The word "Note" was removed from the beginning of Section 5.5 and the language was revised to clarify that these calibration requirements do apply to environmental laboratories.
- The note in 5.8.7.3(b) relating to laboratory sample identification number (ID) was removed clarifying that ID numbers on sample containers are not permanent records to eliminate confusion.

- Section 4.2.8.1 on Data Integrity was revised to clarify that data integrity is not a "thing" to be monitored. Rather, Data Integrity is a system with various components.

- Added back language concerning non-standard methods and method validation in Sections 5.4.4 and 5.4.5 from ISO/IEC 17025. The 2009 Standard had moved some language from these sections into the Technical Modules 3-7, but in an inconsistent manner and some language from ISO/IEC 17025 was omitted. The 2016 standard faithfully contains all of the language in these sections in Module 2, including a missing subsection (5.4.5.3) that requires laboratories to assess the results from method validation studies to customer needs. Additional language was added to sections 5.4.4 and 5.4.5 to link these requirements to the method validation requirements in Technical Modules 3-7.

- Section 5.5.13.1 was significantly reorganized to:
  - Require the laboratory to establish specifications for calibration of support equipment,
  - Clarify that volumetric checks only apply to devices used for quantitative analysis
  - Add incubators to the list of support equipment requiring daily checks,
  - Allow laboratories to use a single-point calibration check for temperature measuring devices that are used over a range of 10°C or less, and
  - Clarified subsection (e) relative to verification checks for volumetric measuring devices.

- Added in missing sections 5.6.1 and 5.6.2 from ISO/IEC 17025. While these sections primarily apply to calibration laboratories, the language is applicable to some activities of testing laboratories.

- The language in Section 5.8.5 (a) on sample identification numbers was reworded slightly for clarity and expanded to include all sub-samples.

- Added in missing subsections from Section 5.10.4 of ISO 17025 relating to calibration certificates. Although this section does not apply to testing laboratories, the language was

included because of a requirement from the American National Standards Institute that all language from ISO/IEC 17025 be included in the TNI Standard.

Module 3: Quality Systems for Asbestos Testing

- Sections 1.4 and 1.5 on Method Selection and Validation were revised to be consistent with the 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.

Module 4: Quality Systems for Chemistry Testing

- Sections 1.4 and 1.5 on Method Selection and Validation were revised to be consistent with other modules.
    - The ISO/IEC 17025 language in these sections was moved back into Module 2.
    - The language in Section 1.4 about adding analytes to reference methods was revised for clarity.
    - The language in section 1.5.1 on validation of reference and non-reference methods was revised to link to Module 2.
    - New language was added to require laboratories to participate in PT studies.

- Section 1.5.2.1 on detection limits was significantly revised to be consistent with the EPA MDL procedure in 40 CFR Part 136 and to reflect best professional practice.
    - A detection limit study is required for methods and analytes except where it is not applicable (pH, color, temperature, odor and dissolved oxygen).
    - Consistent with the new EPA procedure, the study must include both spike and blank data and include results from multiple days.
    - Using the EPA procedure is an option.
    - On-going quarterly verification analyses are required.
    - Note: 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. This section uses the term to Detection Limit (DL) to clarify that when a lab uses the term MDL they are using the Part 136 procedure.

- Section 1.5.2.2 on Limit of Quantitation (LOQ) was significantly revised to allow the detection limit study in Section 1.5.2.1 to be used to verify the LOQ and to improve the procedure.
    - The verification criteria include both qualitative and quantitative criteria
    - The LOQ must be verified quarterly.
    - Documentation requirements were added.

- 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.

- Section 1.7.1 on instrument calibration has been extensively revised, describing various calibration options, discussing how to drop calibration points, and introducing a new quality control measure for evaluating calibration curves.
    - New section 1.7.1.1 (e) on removal of calibration points was added based on votes received in the comment period and reflects current data integrity practices designed to minimize inappropriate calibration practices.
    - The new section 1.7.1.1 (e) does allow replacement of calibration points under very limited circumstances.
    - New section 1.7.1.1 (f) was added to specify the minimum number of calibration standards to ensure a minimum of three degrees of freedom.
    - New section 1.7.1.1 (k) was added to require laboratories to use and document a measure of relative error. This language was added to prevent poor calibration practices based solely on correlation coefficient.
    - The language in subsection (h) (now subsection (p) was revised for clarity and to require a linear check be performed quarterly.
    - New section 1.7.1.1(m) was added to address specific issues surrounding the analysis of Aroclors.
    - New section 1.7.1.2 (c) was added to require the calibration check standard to be equal to or less than one half of the highest level.
    - Section 1.7.1.2 (c) (now section (d)) was revised to allow the second source verification standard or a laboratory control sample to be used for calibration verification.
    - The criteria for calibration verification in section (e) (now section (f)) were revised to allow for a second calibration check standard to be used in limited circumstances.

Module 5: Quality Systems for Microbiology Testing

This module was substantially revised to add clarity, reinforce the concept of minimum requirements and default to the use of the data. All prior Standard Interpretation Requests (SIRs) were addressed as part of the revision process.

- A definition of source water was added to section 1.3.

- The language in Section 1.4 on method selection was moved to Module 2.

- Section 1.6.3 added language to clarify that DOCs need to be appropriate for data use and program, so that they need to mirror what would be seen the specific program. For example, total coliform by MF for the DW program needs to have the same set of 10 aliquots as would be seen when doing P/A methods. A single sample with reporting a number is not sufficient for use in the Drinking Water program.

- The Quality Control section (1.7) was reorganized to separate the activities done before analysis from those done during analysis, along with many other changes.
    - The active voice is used throughout the section. This clarification was made to ensure labs know what is expected to be accomplished in the lab, by the lab.
    - Section 1.7.1 and 1.7.3 clarify that sterility checks and methods blanks are not the same. Sterility checks and performance checks are done on materials to be used during testing as part of the process. Blanks are for methods and techniques.
    - Sterility checks are to be done on all materials that are part of the process if the sterility of an item would affect the test.
    - 1.7.3 clarifies the individual requirements for reagent water and dilution water. This section also further clarifies that they are not the same.
    - 1.7.3 Reproducibility is clarified and made consistent across methods reporting qualitative results. If a lab must report a number, all analysts doing that test must be able to reproduce that number for each test. Previously this requirement only applied to plate methods, but it will now apply to all methods where a number is reported.
    - When verifying the selectivity of media, the process needs to be like for like. If this media is to be used in a qualitative test, the selectivity must be determined with a qualitative analysis. For tests where P/A is reported, P/A is sufficient for the selectivity check.
    - Thermometers can be verified at a single point as long as they are checked at that single point, such as in an incubator.
    - Volumetric equipment is clarified and acceptance criteria is provided.
    - Section 1.7.3.7 for Incubators and water baths has clarified the equilibrium and uniformity of temperature check. Also, there is some allowance for labs for staffing issues, such as weekends and holidays. Defined “under test” so that when needed labs may forgo the second reading of an incubator which is now empty because the tests have been completed and removed.
    - This section has removed the requirement for an annual Inhibitory Residue Test. It is now only required initially. Will not be required again unless the soap is changed.
    - 1.7.5.1 allows for some reasonable flexibility in sample acceptance for samples not quite down to temperature. Added a note to clarify that the intent is to get the samples to the lab as soon as practical rather than holding on to them until they have reached the acceptable temperature.
    - 1.7.5.2 has removed the need to monthly spot check for chlorine removal. However, language was added to clarify that this section is an exemption and not a requirement. The requirement is located in Module 2 and requires each sample be checked for proper preservation. As checking each sample is neither practical nor desirable as it can compromise the samples, this section spells out what the labs must do as an alternate to a comprehensive check. This section also has some language to clarify that the labs are not really looking for chlorine per se, but are checking the efficacy of the sodium thiosulfate. As chlorine is the most frequent

type of disinfection chemical there are still some references, but other types of disinfection are mentioned as well.

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.

Module 7: Quality Systems for Whole Effluent Toxicity Testing

There are no new changes to module 7 at this point. However, the committee wanted to mention that they recommended postponing the adoption of the 2012 version of module 7 because the 2009 version better met the criteria and requirements of WET testing.

The committee had two principal objections to the 2012 revision as written.

- First, the initial demonstration of capability for each individual analyst, as required in 1.6.2 of the 2012 version, is not representative of the way toxicity labs operate and is therefore inappropriate.

- Second, requiring toxicity labs to comply with the requirements of 1.7.1.6 of the chemistry module for its support measurements is excessive, since the purpose of WET testing is not to identify the individual components of the effluent mixture, but rather to establish whether that the effluent is sufficiently toxic that it warrants further investigation. These chemistry measurements are support measurements to the WET - which should be the primary focus (not the chemistry parameters).

The committee is currently working on addressing these two topics for a future revision.

Changes from the 2009 to the 2016 TNI Standard

Note: Sections number shown in brackets. i.e. [x.x], refer to the 2009 standard.

Volume	Module	Section	Change	Discussion	Laboratory Impact
1	1	1.3.2	TNI PT Board changed to PT Program Executive Committee	This reflects an organizational change in TNI that occurred in 2010.	No impact
1	1	[1.3.3]	Section deleted.	This section referred to an appendix that did not exist.	No impact
1	1	[3.1]	Deleted definition for Accreditation Body.	This term is defined in Volume 2.	NA
1	1	[3.2]	Deleted definition for Accreditation Field of Proficiency Testing	This is the same as Field of Proficiency Testing and was duplicative.	NA
1	1	3.2	The definition for Field of Proficiency Testing (FoPT) was slightly revised to clarify that TNI's PT Program Executive Committee establishes FoPT.		No impact
1	1	[3.3]	Deleted definition for Analysis Date	Analysis date is no longer used for tracking PT sample results. This was a problematic issue for laboratories in the 2009 standard.	NA
1	1	[3.4]	Deleted definition for Experimental FoPT	Experimental FoPT are no longer allowed. Such FoPTs were voluntary and thus subject to misinterpretation.	NA
1	1	3.8	Added definition of PT Reporting Limit	Definition added to conform to changes to section 4.2	NA
1	1	3.10	Revised definition of PT Closing Date to address both scheduled and supplemental PT studies		NA
1	1	3.11	Revised definition of PT Opening Date to address both scheduled and supplemental PT studies		NA
1	1	3.13	Revised definition of Study to include both scheduled and supplemental PT studies		NA
1	1	[3.18]	Deleted definition of Supplemental PT Study	This term is now included in 3.13	NA
1	1	[3.20]	Deleted definition of TNI PT Board	This group no longer exists. It has been replaced by the PT Program Executive Committee. See Section 1.3.2.	NA
1	1	4.0	New Section	Section 4.0, Accreditation Requirements, is a new section containing three subsections.	Increased clarity

Volume	Module	Section	Change	Discussion	Laboratory Impact
1	1	4.1	New Section containing General Requirements. The language in [5.1.2] regarding prohibited activities is now 4.1.5.	This section clarifies the types of PT samples required for accreditation referring to FoPT tables,	Increased clarity
1	1	4.1.6	New subsection indicating the actions described in 4.1.5 can be a cause for revocation.		Increased clarity
1	1	4.1.7	New section indicating these requirements can be super ceded by regulations.		None, unless some regulation supercedes
1	1	4.2	New section on Sample Handling, Preparation and Analysis	This section includes some of the language from [5.2.1]	Increased clarity
1	1	4.2.1	New subsection requiring laboratories to follow instructions from PT Provider	This was added to address issues surrounding diluting ampules to volume	Increased clarity
1	1	[4.2.2[	The Experimental FoPT requirements in Section 4.2.2 of the 2009 standard were removed as they have been incorporated as FoPT or removed from the PT Program.		No impact
1	1	4.2.2	The language from 5.1.1, minus the Note, was moved here.	The Note, reworded, was moved to section 4.3.4.	No impact
1	1	4.2.3	New section requiring laboratories to evaluate results to the PT Reporting Limit (PTRL).	This is a substantive change to [5.2.1]. The 2009 standard allowed reporting to the LOQ. TNI has developed extensive guidance to assist laboratories with this issue and it will be discussed in a training course scheduled for later summer 2018.	Significant issue for laboratories that test for organics.
1	1	4.2.4	New section to allow laboratories to report to their LOQ if their LOQ is less than the PTRL.		Minor
1	1	4.2.5	New section that allows laboratories to rescale their calibration curve or report unqualified data below the LOQ.	Because of the language in 4.2.2, this language was added to allow flexibility in meeting PTRLs.	Minor
1	1	4.3	New section on Reporting Requirements	Some of the language from [5.2] was moved here.	Minor
1	1	4.3.1	This is [5.1.1] with minor edits.	Removed experimental PTs	Minor
1	1	4.3.2	This is [5.1.2] with a sentence added about initial accreditation and other minor edits.		Minor
1	1	4.3.3	New subsection to link PT results to FoPTs.		Minor

Volume	Module	Section	Change	Discussion	Laboratory Impact
1	1	4.3.4	This new subsection takes the Note in [5.1.1], removes the Note thus making this section applicable, but then adds a Note relative to multiple methods that use the same technology		More flexibility
1	1	4.3.5	New subsection emphasizing the reporting to PTRL requirement in 4.2.3 and 4.2.4.	See 4.2.3 and 4.2.4.	Significant issue for laboratories that test for organics.
1	1	4.3.6	New subsection on radiochemistry PTs.	Clarifies reporting radiochemistry results as measured (zero, negative, or positive values) and with their associated measurement uncertainty.	Increased clarity
1	1	4.3.7	New subsection on reporting to PTRL.	This section discusses various reporting options based on results above or below the laboratory LOQ and/or PTRL.	Significant issue for laboratories that test for organics.
1	1	4.3.8	New subsection for solid PTs.	The section states results are not to be adjusted for moisture content.	Minor
1	1	5.0	Section [4] was renamed and renumbered to 5.0, PT Study Frequency Requirements for Accreditation. The section has been clarified and includes new sections on PT testing for Whole Effluent Toxicity.		Increased clarity
1	1	5.1	Section divided into 2 subsections with 5.1.1 for asbestos, chemistry, microbiology and radiochemistry and 5.1.2 for toxicity. A Note was added to indicate acceptable performance is more than getting acceptable scores.		Increased clarity
1	1	5.1.1	[4.1.1] reworded to allow 2 out of 3 passing for initial accreditation with a Note that indicates a third PT is not required if the first 2 pass. The 2 Notes in [4.1.1] were deleted. The requirement to have the 2 initial PTs to be at least 15 days apart has been reduced to 7 days. [4.1.3] was reworded to add a clause regarding semi-annual testing and defining this as no more than 7 months apart.	PT frequency requirements were changed from 5-7 months apart to a maximum of 7 months apart with a minimum of 7 days between PT studies instead of 15 days to allow laboratories to participate in PTs more frequently, if they desired, and to regain or obtain new fields of accreditation more quickly.	Minor
1	1	5.1.2	New subsection on Whole Effluent Toxicity testing.	These types of PT samples were not discussed in the 2009 standard.	Minor
1	1	5.2	Section divided into 2 subsections with 5.2.1 for asbestos, chemistry, microbiology and radiochemistry and 5.2.2 for toxicity. A Note was added to indicate acceptable performance is more than getting acceptable scores.		Increased clarity

Volume	Module	Section	Change	Discussion	Laboratory Impact
1	1	5..2.1	[4.2.1 a-c] reworded but with no change in the requirement other than the phrase “at least 5 months apart” was deleted and 15 days between PT samples was reduced to 7.		More flexibility
1	1	5.2.1	The PT tracking requirement in Section 5.2.1 was changed from analysis date back to the PT Study closing date as the analysis date was onerous for both Accreditation Bodies and laboratories to track.	Using the closing date provides a more streamlined process that is easier to maintain.	Easier process.
1	1	5.2.2	[4.2.1 d-e] reworded with more discussion about DMRQA for toxicity testing, but the discussion on correction action moved to 6.5.		Minor
1	1	5.2.3	New subsection that indicating that not analyzing PT samples in the required time frame counts as a failure.		Minor
1	1	[5.3.2]	This section in the 2009 standard on historical records was deleted since the language in 4.4.1 in the 2016 standard, *all records necessary*, addresses this requirement.		No impact
1	1	6.1 – 6.2	[6.1] reworded to focus on corrective action and root cause analysis. The language on supplemental studies removed.	Although the section no longer discusses supplemental PT samples to demonstrate compliance, there is no prohibition from doing so.	More flexibility
1	1	6.3	New section that requires the laboratory to provide their AB with a corrective action report when requested.	In Volume 2, Module 2, of the 2009 TNI standard, Accreditation Bodies were required to suspend a laboratory for not submitting a corrective action report within 30 days of request, yet Volume 1, Module 1, never contained this requirement for laboratories. This requirement eliminates that contradiction.	Minor
1	1	6.4	New section indicating failure to provide a correction action report is cause for suspension.		Minor
1	1	6.5	New subsection containing some of the language from [4.1 d] on documentation of corrective action for toxicity testing.	Note that sections 6.1 through 6.4 also apply to WET testing.	Minor
1	1	7.2	New section on submitting questions to an AB.		Minor
1	1	8.1 and 8.2	Two sentences reworded with no change in the requirements.		Minor
1	1	8.3	New section on suspension relative to not providing a corrective action report.	While [6.1] required corrective action for failed PT samples, it did not require this to be reported to the AB. The revised 6.3 requires the laboratory to provide such a report if	Increased clarity

Volume	Module	Section	Change	Discussion	Laboratory Impact
				requested. This new section provides an enforcement clause.	
1	2	1.2	Sentence added indicating ISO 17025 language is shown as italics.		No impact
1	2	1.2	Sentence added stating that Notes are guidance and do not impose requirements.	This language is contained in ISO 17025 but was inadvertently left out of the 2009 standard.	Increased clarity
1	2	2.0	References to ISO/IEC 17000 and the VIM added. These references contain basic terms of metrology and conformity assessment that are not essential to understand.	This language is contained in ISO 17025 but was inadvertently left out of the 2009 standard.	No impact
1	2	3.1	Added the following new definitions: Analyte, Data Integrity, In-depth Data Monitoring, Lot, Physical Parameter, and Reference Method.	Definitions do not impose requirements.	NA
1	2	3.1	Revised the definition for Demonstration of Capability.	Change the focus from results to analysis.	NA
1	2	3.1	Revised the definition for Limit of Detection.	The revised definition is now consistent with EPA's Method Detection Limit (MDL).	NA
1	2	3.1	Added a definition for Reference Method	Section 5.4 discusses standard and non-standard methods, but these terms are not defined. The TNI standard uses the term reference method to differentiate this from the well-known Standard Methods in the US. Modules 3-7 describe various method validation activities to be carried out for reference methods and non-reference methods.	NA
1	2	3.1	Revised the definition for Selectivity.	Deleted "or parameter" after the word analyte.	NA
1	2	4.1.7	Added the language in the Note to the beginning of this section.	The Note indicated that the quality manager and technical manager could be the same person, removing the word "Note" ensures this option is allowed.	Increased clarity
1	2	4.2.8.1	Changed in-depth periodic monitoring of data integrity" to "periodic in-depth data monitoring"	The focus is to look at data.	Increased clarity
1	2	4..2.8.5 f	Changed parameters to analytes	Reflects addition of analyte and physical parameter to glossary and deletion of analyte	No impact
1	2	5.2.5	Removed the word Note.	By removing this word, it makes it clear that references to issuing Calibration Certificates is not applicable to environmental testing.	Increased clarity

Volume	Module	Section	Change	Discussion	Laboratory Impact
1	2	5.4.4	ISO 17025 language added back in	This language as in Modules 3-7 in the 2009 standard and was moved back to this section to be consistent with ISO 17025.	No impact
1	2	5.4.1.1	New subsection relative to the Note in ISO language in 5.4.1.	The Note discusses items to be considered in validating a new method. 5.4.1.1 clarifies that these items must be considered.	Minor impact only to laboratories that develop methods.
1	2	5.4.1.2	Requires new methods to be documented in an SOP.	This is just a restatement of 4.2.8.5 (f).	No impact
1	2	5.4.5.1	This section is just a definition of the word “validation.”	This language is contained in ISO 17025 but was inadvertently left out of the 2009 standard.	NA
1	2	5.4.5.2	ISO 17025 language added back in.	This language as in Modules 3-7 in the 2009 standard and was moved back to this section to be consistent with ISO 17025.	No impact
1	2	5.4.5.3		This language is contained in ISO 17025 but was inadvertently left out of the 2009 standard.	Minor impact only to laboratories that develop methods.
1	2	4.5.5.4	New section linking 5.4.5 to section 1.3 of Modules 3-7.	Clarifies that all test methods must be validated according to the specific requirements in Modules 3-7.	Increased clarity
1	2	5.5	Removed the word “Note” from the Note at the bottom of this section and moved it to the beginning of the section.	Clarifies that 5.5.1 through 5.5.12 apply to environmental laboratories.	Increased clarity
1	2	5.5.13.1	Subsection completely revised with these changes: a) Laboratories shall establish specifications for calibration of support equipment. b) Records of repair and maintenance are to be kept. c) Clarified that support equipment only needs to be checked on days when it is being used. d) Removed the requirement to bracket calibrations for ovens and related equipment that is designed to be used at one temperature. e) Clarified the calibration requirements for volumetric equipment. f) Revised [5.5.13.1(a)] to reference “all other equipment.” g) Retained [5.5.13 (b)] relating to raw data records.	In general, these changes clarify the requirements and in some cases, relax the requirements.	Increased clarity
1	2	5.6.1	Removed two statements that stated 5.6.1 and 5.6.2 do not apply to environmental laboratories.	Section 5.6.2.2 state the conditions by which this section applies to testing laboratories.	Minor impact
1	2	5.8.5 (a)	Added the phrase “the sample containers that hold.”	Clarifies that is the containers to be uniquely identified.	Editorial correction

Volume	Module	Section	Change	Discussion	Laboratory Impact
1	2	5.8.7.3 (b)	Added “The placement of the laboratory ID number on the sample container is not considered a permanent record.”	Clarifies that the system used to track samples is a record to be kept, but not a sample label since the containers may be destroyed after analysis.	Increased clarity
1	2	5.10.4	ISO 17025 language added back in.	The beginning of the section indicates this section does not apply to environmental laboratories. The language was added back in because of the license agreement TNI has with the American National Standards Institute for the use of 17025 language.	No impact
1	2	5.10.10	Revised the citation to the items that can be exempted in reports.	Incorrect section citation.	No impact
1	3	1.4	Moved ISO 17025 language on method selection back into Module 2, section 5.4. Changed the word parameter to analyte.		No impact
1	3	1.5	Moved ISO 17025 language on method validation back into Module 2, section 5.4.		No impact
1	3	1.6	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. Changed the word parameter to analyte.		Increased clarity
1	3	1.7.7	Corrected the citation to an EPA document in two places.		Editorial correction
1	4	1.4	Moved ISO 17025 language on method selection back into Module 2, section 5.4.		No impact
1	4	1.4	The language about adding new analytes to reference methods was revised for clarity.		No impact
1	4	1.5	Moved ISO 17025 language on method validation back into Module 2, section 5.4.		No impact
1	4	1.5.1	Added subsections relating to the level of validation effort needed for reference and non-reference methods.		Editorial correction
1	4	1.5.1 (a)	Added subsection requiring laboratories to participate in PT programs.	This is already required per Module 1.	No impact
1	4	1.5.2.1	Complete rewrite of the Limit of Detection section with many new requirements relating to both the initial and on-going determination of the LOD.	These changes are consistent with the changes EPA made to the MDL procedure in 40 CFR Part 136 in 2017. TNI is developing additional guidance and training on this topic.	Significant change

Volume	Module	Section	Change	Discussion	Laboratory Impact
1	4	1.5.2.2	Complete rewrite of the Limit of Quantitation section with many new requirements relating to both the initial and on-going determination of the LOQ.	These changes ensure the LOQ verification is aligned with section 1.5.2.1. TNI is developing additional guidance and training on this topic.	Significant change
1	4	1.6	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. Changed the word parameter to analyte.		Increased clarity
1	4	1.7.1	Complete rewrite of the Instrument Calibration section with many new requirements relating activities such as: - dropping calibration points, - adjusting the calibration range, - replacing standards, - number of calibration standards, and - using a measure of relative error.	TNI is developing additional guidance and training on this topic.	Significant change
1	4	1.7.5 (b)	Changed “compound” to “analyte.”		Editorial correction
1	5	1.1	Changed the last sentence from “are being followed” to “will ensure that microbiological test results are fit for the intended use.”		Editorial correction
1	5	1.3.1	Added definition for Source Water.	Source water is mentioned in section 1.7.5, but was not defined and this has led to confusion.	NA (Definitions are not auditable.)
1	5	1.4	Moved ISO 17025 language on method selection back into Module 2, section 5.4.		No impact
1	5	1.5	Moved ISO 17025 language on method validation back into Module 2, section 5.4.		No impact
1	5	1.5.1 (b)	Added subsection requiring laboratories to participate in PT programs.	This is already required per Module 1.	No impact
1	5	1.5.1 (c)	Added subsection requiring laboratories to document any method validation.		Minor impact
1	5	1.5.2	Clarified the evaluation of precision.		Editorial correction
1	5	1.6	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. Other minor corrections.		Increased clarity

Volume	Module	Section	Change	Discussion	Laboratory Impact
1	5	1.7.3	Section was totally rewritten and reorganized. 1.7.3.1. contains the QC requirements for standards, reagents, materials and media, the QC requirement to be done **before** testing while section 1.7.3.2.2 contains the requirements for method blanks, to be done **during** testing.	There are many other changes to this section. TNI is developing training on this topic.	Significant change
1	5	1.7.3.3	Minor changes to clarify this section applies to tests that provide quantitative results.		Increased clarity
1	5	1.7.3.6 (b)	Minor changes to clarify this section in terms of describing media.		Increased clarity
1	5	1.7.3.6 (d)	Added "(i.e., working cultures)" to the subsection title.		Increased clarity
1	5	1.7.3.7 (a)	Removed "Plants, food and drink shall be prohibited from the laboratory work area."		
1	5	1.7.3.7 (b) (i)	This section revised for clarity and to indicate that verification of temperature measurement devices can be made at a single point.		Increased clarity
1	5	1.7.3.7 (b) (ii)	Subsection (a) on autoclave performance reworded to focus on the laboratory requirements by the frequent use of the phrase "the laboratory shall." The Note about PV = nRT was removed. A new subsection (b) was added about ovens used for sterilization.		Increased clarity
1	5	1.7.3.7 (b) (iii)	Changed the emphasis to "the laboratory shall." Added an acceptance criterion for volumetric checks.		Minor impact
1	5	1.7.3.7 (b) (iv)	Changed the emphasis to "the laboratory shall."		Increased clarity
1	5	1.7.3.7 (b) (v)	Changed the emphasis to "the laboratory shall." Clarified that incubators, water baths and ovens only need to be checked when in use.		Increased clarity
1	5	1.7.3.7 (b) (vi)	Clarified that the Inhibitor Residue Test is only required for detergent formulations.		Increased clarity
1	5	1.7.5.1 (a)	Clarified that samples delivered to the laboratory on the same day as collection should have evidence that cooling has begun.		Increased clarity
1	5	1.7.5.1 (a)	Clarified that potable water samples, including source water, must be checked for disinfectant unless all of several conditions are met.		Increased clarity

Volume	Module	Section	Change	Discussion	Laboratory Impact
			In subsection (iv), “chlorine residual” was changed to “disinfectant residual.”		
1	6	All	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.	TNI has an on-line downloadable 3.5-hour training course (webcast) on this Module.	Significant change