Implementing the 2009 TNI Standard: Laboratories

July 1, 2011

On July 1, 2011, the 2009 TNI standard, *Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis*, became effective for laboratories accredited under TNI's National Environmental Laboratory Accreditation Program (NELAP). This new standard represents a substantial improvement over the current 2003 standards used by NELAP today.

- It removes outdated language related to the National Environmental Laboratory Accreditation Conference, an organization that no longer exists.
- It has incorporated the current version of ISO/IEC 17025.
- It has a Volume/Modular approach that simplifies reading and understanding the requirements.
- It has improved clarity on technical requirements, especially requirements related to method validation and demonstration of capability.
- It is a true consensus standard[1].
- It has removed requirements that are non-essential for data quality.

The 1995 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)

[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."*

- 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 expert committee revised language from the 2003 NELAC standard, and in some cases added new language, that impose new laboratory requirements. For example,

- 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 new 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.

The TNI Quality System committee 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 new 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 a employee training file for each analyst. The requirements DOC were very much oriented towards laboratories performing chemical analyses. In the new 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.

The table below summarizes all the changes made to the Quality System requirements in the 2003 NELAC standard.

Detailed Summary of Changes from 2003 NELAC to 2009 TNI Standard

Volume	Module	Section	Change	Discussion	Laboratory Impact
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
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

Volume	Module	Section	Change	Discussion	Laboratory Impact
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	None
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		
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
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	Minor
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	Certification of results no longer required		More flexibility
1	2	5.10.2	Establishes default reporting requirements as "as		More flexibility

Volume	Module	Section	Change	Discussion	Laboratory Impact
			received."		
1	4	1.4	New language to allow for addition of analytes to a reference method.		More flexibility
1	4	1.5.2	Removed “must have procedures to relate LOD to LOQ”	LOD must be less than 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
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

Volume	Module	Section	Change	Discussion	Laboratory Impact
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."	Minor
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	Minor
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
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