

Implementing the New TNI Standard

On July 1, 2011, the 2009 TNI standard, *Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis*, will become effective for all 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- It removes outdated language related to the National Environmental Laboratory Accreditation Conference, an organization that no longer exists.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 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 standard¹.
- It has removed requirements that are non-essential for data quality.

Over the next year, laboratories need to begin to take steps to be ready to be in compliance with this new standard by July 1, 2011. TNI has been providing a series of workshops around the country to help laboratories come into compliance. This article addresses one of the key issues about implementing the new standard, that of the schedule for implementation. This schedule has three components, those new requirements that can be implemented any time before July 1, 2011, one requirement that must wait until July 1, and revised requirements that can be implemented after July 1.

Requirements that can be implemented before July 1, 2011

The 1995 version of ISO 17025 has some additional management and technical requirements that were not in the obsolete version of ISO 17025 contained in the 2003 NELAC standard. Some examples of these new requirements, found in Module 2, are summarized below.

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.”*

- 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 new 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 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.

All of the examples above are requirements that could be implemented by a laboratory any time before July 1, 2011 as meeting these requirements do not conflict with any requirement in the current 2003 NELAC standard.

Requirement to be implemented on July 1, 2011

From a thorough review of the standard by TNI's Laboratory Accreditation Standard Executive Committee, there is one change that must be implemented on July 1, 2011. This change relates to

reporting of PT data. Currently, PT Providers evaluate reported results to a PT Reporting Limit published in the TNI Fields of Proficiency Testing tables. This requirement has 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 new 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.

Requirements that can be implemented after July 1, 2011

The TNI expert committees that developed the new 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 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.

These three examples illustrate the increased flexibility allowed in the new TNI standard. In each of these examples, a laboratory could continue their current practice and be in compliance with the new standard. And, this may be the approach to take if the system is working well. If a laboratory wants to change their system (e.g., quit using the Appendix C form), they could do so. However if such a change were implemented before July 1, 2011, it would be a finding according to the 2003 NELAC Standard.

Implementation Plan

Over the next nine months, there are a number of actions a laboratory should take.

- First and foremost, get a copy of Volume 1 and read it. This article only provided a few examples of the changes. TNI is developing a comprehensive list of all changes that should be published by January 2011.
- If you can, plan to attend one of the TNI workshops where much more detail will be provided.
- Begin implementing those new requirements that do not conflict with the current NELAC standard.
- On July 1, 2011, begin reporting PT data to your normal LOQ.
- After July 1, 2011, consider changing your quality system to take advantage of some of the increased flexibility in the new TNI standard.