

Implementing the 2009 TNI Standard: Accreditation Bodies

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On July 1, 2011, the 2009 TNI standard, *Volume 2: General Requirements for Accreditation Bodies Accrediting Environmental Laboratories*, will become effective for all Accreditation Bodies (ABs) 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- It removes outdated language related to the National Environmental Laboratory Accreditation Conference, an organization that no longer exists.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 ISO/IEC 17011, the international standard for accreditation bodies.
- It has a Volume/Modular approach that simplifies reading and understanding the requirements.
- 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 standard¹.

Accreditation Bodies need to begin to take steps to be ready to implement this new standard on July 1, 2011. TNI has provided training on the new standard, and the new process for evaluating ABs, SOP 3-102. This article provides guidance to ABs and NELAP evaluators on the implementation of the new standard on the topics of reciprocity, AB evaluation, and proficiency testing.

Rolling Implementation and Reciprocity

Due to state governmental changes and political realities (such as a freeze on regulations by a new governor, for example), not all states will be able to implement the new Standard on July 1, 2011, as earlier agreed planned. The extent of such delays became in early 2011, as new governors were installed into office and began to make changes in state operations.

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.”*

The NELAP Accreditation Council (AC) and each of the 15 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.

For ease of reference, the status of each AB is listed below.

State AB	Status
CA	No problem with reciprocity. Unknown when TNI standard can be implemented, but is beginning the process
FL	Essentially no impact, no problem with reciprocity. FL forms to implement new standard are in rulemaking, held up by cessation of rule promulgation in FL.
IL	No problem with reciprocity. Expects to implement TNI standard by the end of 2011.
KS	No problem with reciprocity. Due to change of administration, unclear when implementation of TNI standard can begin.
LA DEQ	No problem with reciprocity. Will implement TNI standard in August 2011
LA DHH	No problem with reciprocity. Moving to TNI standard on July 1.
MN	No problem with reciprocity. Ready to implement TNI standard on July 1.
NH	No problem with reciprocity. Rules are written but now delayed one year. Will assess labs against whichever standard the lab has in use.
NJ	No problem with reciprocity. Has a "name change" underway. Has not proposed rules for implementing TNI standard, may delay
NY	No problem with reciprocity. Rewriting regulations now, expects July 1 implementation of Modules 1 and 3; PT issues will delay implementation of PT module 2.
OR	No problem with reciprocity. Preparing now for July 1 implementation of TNI standard.
PA	No problem with reciprocity. PA rules reference the AC-adopted standard.
TX	No problem with reciprocity. Preparing to transition to TNI standard on July 1.
UT	No problem with reciprocity. On track for July 1 implementation of TNI standard.
VA	No problem with reciprocity. Cannot adopt TNI Standard now, but can initiate new regulations in 2012.

As discussed in a companion guidance document², all laboratories should be moving forward to implement the quality system and technical requirements in Volume 1. Many of the new requirements are not addressed in the 2003 NELAC standard and thus would not be subject to assessment by those ABs that have not implemented the new standard by July 1. In other areas, the new TNI standard allows more flexibility than the 2003 standard, and those ABs that have not implemented the new standard will have to enforce the requirements on NELAC 2003. Nonetheless, TNI's encourages ABs to provide some leeway to laboratories that have moved on to implement the 2009 TNI standard.

Some laboratories that hold primary accreditations in multiple states may end up in a situation where one AB is enforcing the 2003 NELAC standard and another AB is enforcing the 2009 TNI standard. This

² Implementing the New TNI Standard: Laboratories, April 2011

situation has occurred in the past, and is no different than multiple and sometimes conflicting requirements associated with laboratories having to meet varying requirements of two different versions of the same method. Although this is a temporary situation, most laboratories that have multiple primary accreditations are very accustomed to meeting multiple and conflicting requirements and should be able to manage the situation during this transition period.

Because the ABs have committed to reciprocity and because TNI's Laboratory Accreditation System Executive Committee (LASEC) believes laboratories are capable of effectively managing this transition, the LASEC believes no further action is needed for this issue.

Evaluation of ABs

All ABs should be evaluated to the 2009 TNI standard, using SOP 3-102. Some ABs (for 2011 this will likely be Kansas, New Hampshire, and New York) likely will not have moved to the new TNI standard by the time their 2011 evaluation occurs. The process for evaluation is the same in both cases, and consists of:

- completeness and technical reviews of the application package,
- an on-site evaluation,
- an observation of the AB conducting an on-site laboratory assessment,
- an evaluation report with findings, and
- a decision by the TNI NELAP Accreditation Council regarding recognition or denial of recognition.

The technical reviews are very comparable in terms of looking at items such as management systems, human resources, and the assessment process. However, there are differences in the detailed requirements between the two standards and an accreditation body operating under the current NELAC standard, and assessing laboratories to that standard, will have findings from the technical review, on-site evaluation, and laboratory assessment observation.

TNI's Laboratory Accreditation System Executive Committee recommends that the Accreditation Council adopt the following statement for use within NELAP during the transition period:

An acceptable corrective action for any finding associated with the evaluation of an Accreditation Body that is solely attributed to a new requirement in either Volume 1 or Volume 2 of the 2009 TNI standard will be a plan from the Accreditation Body (AB) to implement by rule the new TNI standard. When the 2009 standard is implemented, the AB will provide a report to the NELAP Accreditation Council documenting their conformance to the new standard.

Thus, conformance to all requirements in Volume 2 are not mandated if an AB is unable to implement these changes due to legislative or rulemaking issues beyond their control.