Laboratory Accreditation System Executive Committee
Meeting Minutes
Monday, June 6, 2011, 12:00 EDT

1. Committee members present are listed in Attachment A.

2. Minutes from April 25, 2011 meeting were not available. They will be distributed for the next meeting.

3. On April 29th, the LASEC voted unanimously via email to forward the recommendation to the NELAP AC. The document in Attachment B was forwarded to Lynn Bradley, Administrator of the NELAP AC.

   It was discussed that the TNI Board and the PT Committee were not in agreement with the recommendation to implement the 2009 TNI Standard with the exception of the PT modules. Maintaining the 2003 NELAC Chapter 2 PT requirements was not favorable.

   The DOD and some State AB's want to implement the TNI Standard, but the NELAC AC has not yet adopted the recommendation or any other.

4. Kristen Brown inquired on the status of the Quality Systems Checklist. Ilona indicated that the QS committee has been working on it and she will inquire with Silky.

5. Next meeting Monday, June 27, 2011 at noon

Attachment A

PARTICIPANTS

TNI LABORATORY ACCREDITATION SYSTEM EXECUTIVE COMMITTEE

Member	Affiliation	Contact Information
Ann Marie Allen - present	Massachusetts, Non-nelap AB	T: 978-682-5237 x333 E: ann.marie.allen@state.ma.us
Aaren Alger – absent	Pennsylvania DEP	T: 717-346-8212 E: aaalger@state.pa.us
Jo Ann Boyd – present	Southwest Research Institute, Lab	T: 210-522-2169 E: jboyd@swri.org
Carol Barrick - present	Mosaic, LLC, Lab	T: 813-361-6911 E: carol.barrick@mosaicco.com
Kristin Brown- absent	Utah Bureau of Lab Improvement, AB	T: 801-965-2540 E: kristinbrown@utah.gov
George Detsis - present	Department of Energy, Government	T: 301-903-1488 E: george.detsis@eh.doe.gov
Dan Dickinson - absent	New York DOH, AB	T: 518 485-5570 E: dmd15@health.state.ny.us
June Flowers – Chairperson present	Flowers Chemical Laboratories, Inc., Lab	T: 407 339-5984 x212 E: june@flowerslabs.com
Terri Grimes - absent	Pinellas County Utilities, Municipal Lab	T: 727-5822302 E: tgrimes@co.pinellas.fl.us
Marvelyn Humphrey – absent	USEPA Region 6, EPA	T: 281-983-2140 E: humphrey.marvelyn@epa.gov
Roger Kenton - present	Eastman Chemical Company, Lab	T: 903-237-6882 E: rogerk@eastman.com
Judy Morgan - absent	Environmental Science Corporation, Lab	T: 615-773-9657 E: jmorgan@envsci.com
Mitzi Miller - present	Dade Moeller & Associates	T: 509.531.0255 E: mitzi.miller@moellerinc.com
Julia Sudds – present	E.S. Babcock & Sons, Inc. Lab	T: 951.653.3351 E: jsudds@babcocklabs.com
Ilona Taunton – present	TNI Assistant Executive Director	T: 828-894-3019/828-712-9242 E: ilona.taunton@nelac-institute.org

Attachment B

Implementing the New TNI Standard: Accreditation Bodies

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 standard[1].

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 planned. The extent of such delays became apparent in early 2011, as new governors were installed into office and began to make changes in state operations.

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[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 as of February 2011 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 document[2], 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 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 situation has occurred in the past, and is no different than multiple and sometimes

[2] Implementing the New TNI Standard: Laboratories, April 2011

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 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.

Proficiency Testing

The 2009 TNI Standards for Proficiency Testing have generated a number of concerns in several areas. The PT Expert Committee is working to publish a new Working Draft Standard by May, 2011. Concerns received by the committee are as follows:

1) A clause that allows for the use of a non-accredited PT provider when an accredited one does not exist.
2) Use of analysis date vs closing date.
3) Inclusion of experimental PT.
4) LOQ reporting.
5) PTs for Whole Effluent Toxicity (WET) testing.

These concerns are described in more detail in an attachment to this document. Several ABs have indicated serious concerns over adoption of the proficiency testing requirements as they currently exist in the 2009 TNI standard. TNI's PT Expert Committee has agreed to redraft the standard to address these concerns. Significant changes to the standard on these issues are expected to exist in draft form before July 1, 2011, but not be adopted by the Accreditation council until later in 2011 or early 2012.

Chapter 2 of the 2003 NELAC standard contains the current PT requirements and these requirements have been implemented by all ABs.

> In light of the concerns over the 2009 standard and the plans underway to revise the standard in the near future, the Laboratory Accreditation System Executive Committee (LASEC) recommends that the Accreditation Council continue to use the PT requirements contained in Chapter 2 of the 2003 NELAC standard until such time as the revised standard has been adopted for use in NELAP. This recommendation will maintain reciprocity and will alleviate concerns over laboratories, PT providers, and ABs in changing their systems to meet requirements that might be changed again in the near future.

Attachment A

Implementation Issues Surrounding Proficiency Testing

The 2009 TNI Standards for Proficiency Testing have generated a number of concerns in several areas. The PT Expert Committee is working to publish a new Working Draft Standard by May, 2011. This document summarizes the concerns and the plans to address the concerns. Concerns received by the committee are as follows:

1) A clause that allows for the use of a non-accredited PT provider when an accredited one does not exist.
2) Use of analysis date vs closing date.
3) Inclusion of experimental PT.
4) LOQ reporting.
5) PTs for Whole Effluent Toxicity (WET) testing.

These issues were discussed at a public meeting of the PT Expert Committee in Savannah, Georgia on February 2, 2011. The sections below summarize the comments from stakeholders and discuss how the committee plans to address each concern.

Use of non-accredited PT providers:

The committee proposed to provide an exemption for doing the PT until there is an accredited PT provider. Other changes include a clause in the AB volume that will be removed and the same exemption language will be inserted in other affected clauses.

Comments from the Savannah meeting were:

- This takes care of an unreasonable burden on the lab to find a PT from any available provider.
- The PT is one tool to determine lab competency. Can the lab have another method to demonstrate competency? This is required by 17025 so this should be in the QS standard. There is a difference between analyst competency and lab competency. There is a difference between a field of accreditation and an accreditation FOPT, which is not per method. There is an expectation that the lab will demonstrate competency.
- May need to define the terms “available” and “unavailable”.

Use of Analysis Dates versus Closing Dates:

The committee reviewed the background on the reasoning to switch to analysis date in the TNI standard. Part of the issue was the required time frame in between successive PT studies and how to best specify dates that would allow for meaningful PT results. The Accreditation Bodies (ABs) don’t want all PTs to be run during a single good calibration cycle, but use of analysis date created a complicated tracking issue for ABs. The committee has debated the specified timeframes between PTs, particularly when there is a failure, and how the labs can effectively redo the PT study in the most efficient manner. A related issue is requiring labs to run PTs at least 5 months apart. There needs to be a separation in time and the committee will have to look at how to best specify this.

Comments to the proposal were as follows:

- It sounds like the language would allow for a quarterly and a supplemental PT to be run at the same time but not reported at the same time. ABs do not want to receive PT reports for corrective action prior to the final result on the original PT. The proposed language is a compromise. Each PT will have a closing date for tracking purposes.
- It was proposed that there be separate specifications for the regular PTs from the quick response PTs. That way closing date could be used for regular PTs and analysis date for the quick response PTs. Shipping date might also be another parameter to consider.
- Are we hung up on dates and taking away from focus on laboratory competency.
- There has been a transition toward using analysis dates. One AB's database system allows it to be looked at either way.
- One motivator to go back to closing dates was that the lab could be out of sync using the analysis dates rather than the close date. The lab could go beyond the 7 month window for performing the PT by using analysis date but the PT would be acceptable by using the closing date. This keeps it simpler for the labs as well.
- Addition of the six month limit on PT age for initial accreditation is good, so that labs do not get accredited based on a really old PT result.
- It was asked if there are requirements for performing PTs during the time of pending application? If labs stop doing PTs, they are out of compliance as soon as they become accredited. The application should require them to be doing PTs on the TNI timeframes.

WET Requirements

The expert committee proposal is to add the requirements for WET that were in the NELAC 2003 standard into the TNI standards. A guidance document will also be developed. The WET PT can be for the DMRQA program, although this is not specifically mentioned. No other PT studies are available right now. The current FoPTs will also be reviewed to make sure they are relevant. Studies are open for 90 days. The DMRQA samples come from TNI providers and are TNI compliant. They differ from WP samples only in timeframe of the study. This will be documented with a TIA.

Comments to the proposal were as follows:

- It was asked whether the requirement is one PT per calendar year or one every 12 months. The PT is currently only being offered by DMRQA on their schedule.
- A typo was noted on the corrective action requirement. The committee may also look at using root cause analysis rather than corrective action.

LOQ Reporting

The committee has identified all the clauses where LOQ reporting is referenced. The lab should report PT samples the same way as environmental samples. The same clause for the analysis of PTs is used for the reporting section. The NELAC 2003 standard had very vague, non-specific language on this issue and in contrast, the TNI standard is very specific. Much of the discussion related to reporting of less than (<) values versus reporting a zero (0) value for a result. Some ABs and other entities are treating "0" as a numeric value rather than a non-detect. The committee proposed to keep the LOQ reporting concept in the standard, but potentially revise Volume 3 to require PT providers to flag results that are reported with values less than the LOQ

to better enable ABs to monitor this issue. The committee believes that results reported less than the LOQ will be a very small percentage of all results reported.

Comments on this topic from the Savannah meeting were as follows:

- How do providers calculate the study mean when < values are reported? Those values are not included. Calculations can only use actual values.
- There may be some regulatory agencies that require "0" to be reported. The lab may be required to report both ways. Sometimes that is allowed for permit compliance documentation as an option. It would be helpful to understand which states require this if this change would impact them. A lab would have the option of reporting it a specific way for a client, but not the PT reporting.
- There may be AB systems in which "<" value is not accepted and the lab must report a "0".
- Does the committee need to consider this change further to know if there are any PT programs that would be impacted by the "0" issue.
- Many labs are not commercial and may be reporting only to drinking water or wastewater programs. Also radiochemistry has negative values and 0 is an acceptable value. There may be a need for specific language for these disciplines.
- ABs wanted to make sure labs can deal with PTs that are much higher or lower than their normal range of measurement. Is this a PT module issue, or a QS module issue? Should this be assessed as part of the lab's quality system? A lab would not calibrate to a lower range just for analysis of the PT sample. High range samples can be diluted.
- This could be dealt with in the FoPT tables rather than the standard by adjusting some of the concentration ranges.
- No flagging of the value (asterisk) is required when reporting a result less than the lab's reporting limit. The AB can specify a special report that would identify this.
- With the allowance for less than (<) values, there will be more acceptable results. ABs also need to look at the normal operating range of the lab. Two parts to the assessment – score given by the PT provider, and the assessment done by ABs.
- If the lab is purchasing PTs that are fit for their use, there would be fewer < values. There are not PTs for every situation. Most PT providers can provide the special report to ABs with the asterisk.
- Can a copy of the report received by AB with asterisk also go to the lab? This does complicate the process, as the PT provider is generating multiple reports and making sure everyone gets what they want.
- Clients would tend not to look at what the asterisk means and then call lab about it.

Experimental PTs

Experimental PTs were included in Volume 1 because at the time, TNI had experimental PTs in FOPT tables. These have now been removed. The committee introduced two proposals on this subject. One removed the language regarding experimental PTs completely. The other introduced a new term for consideration – "Criteria Development Analytes". The purpose of the CDA would be the voluntary gathering of data to set control limits. The CDAs would have separate tables and would not be used for accreditation.

It was also noted that there is a need for a procedure for adding/removing analytes from the FoPT tables. These decisions are made by the PT Executive Committee. If the experimental PTs are deleted, there would have to be a defined procedure for adding/deleting. The question is whether the PT expert committee should add language to standard to provide the framework for that procedure.

Comments to the proposal were as follows:

- PT Executive Committee should be the owner of an SOP addressing the addition/deletion process. The PT standard should not get into how they are determined, etc. as it is easier to change an SOP than the standard.
- Having tables that the users understand is important. Having the process in the standard would allow for it to be uniform and would enable the Executive Committee to act on it.
- It shouldn't be in the standard since it relates to policy decisions.
- There is a need to differentiate the accreditation FoPTs and non-accreditation FoPTs (e.g., FAC lead, SSAS etc.)
- FoPT tables are referenced in the standard, so the tables become requirements upon acceptance.
- Introducing a new term will add additional confusion.
- Avoid another document if possible, so there would not be another document for the labs to keep track of. This would be a policy for the PT Executive Committee, so it would not impact the labs.
- There needs to be a total paradigm shift in how TNI generates a new value. What is the context of considering a new request for an addition to the FoPT tables.

Attachment C

Action Items – LASC

	Action Item	Who	Expected Completion	Actual Completion / Comments
	Update SIR SOP based on comments received from Policy Committee. Jerry suggested Ilona to work on this.	Ilona	12/31/10	
	Update Charter and post on website	Carol		Complete
	Review AB Evaluator SOP and provide comments to ABC.	Subcommittee to meet	10/1/10	Complete
	Approve Evaluation SOP and send to NEALP AC	LASEC	10/25/10	Complete
	Provide comments on Provisional Recognition SOP to June	LASEC members	11/8/10	11/29/10 Complete
	Make a recommendation on Provisional recognition SOP to AB committee and NELAP AC	Subcommittee to make recommendation	11/29/10	12/20/10 Complete
	Make a recommendation to NELAP AC for TNI Standard Implementation	LASEC Via email	4/29/11	Complete