

Summary of the NELAP Accreditation Council Meeting

June 10, 2011

1. Roll call

The NELAP Accreditation Council (AC) met at 12:30 pm EDT on June 10, 2011. Those members in attendance are listed in Attachment 1.

2. Continued Effort to Resolve the Recommendation from Laboratory Accreditation Systems Executive Committee (LAS EC)

There was no further discussion of this issue at the June 6 meeting. On May 27, 2011, Susan had proposed, and Aaren distributed by email, a motion as follows:

I move to delay implementation of a new accreditation standard until 1) the TNI LAS EC provides the NELAP AC with a side-by-side comparison of the 2003 NELAC Standard and the 2009 TNI Standard highlighting all deletions and additions with justifications for each change; 2) an unambiguous document control system with unique identification assigned to the standard and any supporting documentation so that the documents may be clearly referenced in rulemaking and publications prepared by TNI and the ABs; and 3) a complete set of standards (whether 2009 or later) that may be adopted, in its entirety, by the NELAP ABs.

An affirmative vote on this motion would, in effect, rescind the prior motion (from August 2009 adopting the TNI Standard and agreeing on implementation date of July 1, 2011, supported by the February 2011, agreement to rolling implementation of the TNI Standard). An affirmative vote on this motion would place the 2003 NELAC Standard as the accreditation standard for laboratories but does not preclude the NELAP ABs from implementing certain portions of the 2009 TNI Standard, where these items may be placed in operational SOPs and do not require a regulatory change.

Further Recommendation for Consideration:

1) I would recommend that the NELAP AC provide guidance to TNI concerning expectations for any new proposed standard and outline all supporting documentation needed from TNI prior to NELAP AC's consideration for adoption of new standards. My preferred documentation would include: a side-by-side comparison document as mentioned in the motion above; checklists for labs and ABs; training modules for labs and ABs; a summary of all comments received and the committee review and decision-making; and evidence of the incorporation of any relevant standards interpretations and TIAs. Why? We'll get useful information to begin or complete the rulemaking process. We'll have a thorough understanding of the impact to our programs and the labs.

2) I would recommend that the NELAP ABs agree to perform a gap analysis (internal audit) of their current program and the 2009 TNI Standard in preparation for providing the guidance to TNI committees (i.e. All ABs fill out the current AB Application Technical Checklist and report to the Chair of the NELAP AC.) Why? We'll have an idea of what we gain and what we lose by a delayed or rolling implementation.

Several ABs requested verbal discussion of this motion, and no second was put forward up until the beginning of this meeting.

Aaren requested that, before addressing the motion (above), that each AB indicate what its preferred course of action was, since votes on the May 16 motion that failed seemed to have been for a variety of reasons, so that it remained unclear, even after the vote, what solution might actually meet the needs of all or most ABs. Aaren requested that ABs indicate their preference of (1) staying with the 2003 NELAC standard, (2) using the 2009 TNI Standard except for the PT modules and Volume 3, and using the 2003 NELAC standard for PT, or (3) moving to the 2009 TNI standard. Results are tabulated below. None of the ABs present found option 2 desirable, all were openly opposed to splitting the standard.

STATE	option chosen	comments
CA	1	wants standard with minimal problems
FL	3	wants to move forward, will implement TNI standard when rule can begin
IL	1	prefers to stay with 2003 NELAC until expedited updating changes to TNI standard can be adopted
KS	1 or 3	writing rule now, may be able to adopt "by reference"
LA DEQ	1	is taking steps to write rule, but long time off
LA DHH		(absent)
MN	1 or 3	needs "tools" (checklists) in order to write new regulations, then wants to move to TNI standard
NH		(absent)
NJ	1 or 3	can go either way, does not want to split. Has rule drafted, not proposed yet
NY	1	wants 2003 NELAC due to specific PT concerns
OR	3	has final rule for TNI standard in place; would have to rescind otherwise. Can recognize 2003 NELAC accreditations
PA	1	wants to keep 2003 NELAC, feels parts of TNI standard are broken. ALSO, state rules require that it change to the TNI standard on the date set by NELAP (July 1, 2011), but checklists are not yet available – severe problem to implement new standard without tools such as checklists, that have traditionally been provided by other committees, not developed state-by-state
TX	3	ready to implement TNI standard now
UT	1 or 3	rule on hold pending AC resolution, wants "whole" standard, either one
VA	1	TNI standard has unresolved and unknown problems.
OK (participating)	3	has been using 2003 NELAC, applying to NELAP under TNI standard, can adapt to either

Additionally, Art Clark (EPA Liaison to the AC) stated that EPA will have concerns about inconsistency and lack of progress, if the AC elects to remain with the 2003 NELAC standard, even though he understands reasoning behind reservations about the 2009 standard. He noted that the Drinking Water program would accept either standard.

Susan reiterated her need for justification or rationale for the changes made from 2003 NELAC to 2009 TNI standard, stating that MN's rulemaking process requires documentation for "why" the change is being made. It was noted that justification for each change is really not forthcoming.

NOTE from PA here: The change to a standard based on the ISO/IEC 17025 and 17011 standards was agreed upon as a way to move NELAC towards a consensus-based standard, rather than the highly prescriptive, written-by-government-only NELAC standard, so that TNI could become consistent with (or more nearly approach) the requirements of OMB Circular 119A, that requires

use of consensus standards instead of purpose-built government standards, whenever possible.

Other perspectives began to emerge as the conversation shifted from the LAS EC's recommendation as presented to exploring how to meet the needs and concerns of ALL the NELAP ABs, and not just NY's difficulty with resolving the PT issue. If NY were to find it necessary to withdraw from the NELAP program, the states needing to "pick up the slack" could be severely overburdened.

NOTE from PA for non-NELAP audience – NY requires all of its labs to use the NY PT program, and the PT standard [Volume 3 of the TNI standard] is being implemented by PT Provider Accreditors as of July 1, 2011, and not with the "rolling implementation" that the NELAP AC has needed to adopt.

The discussion then focused on the motion proposed by Susan Wyatt. It received a second from Scott Siders.

Steve Arms noted that the 2009 TNI Standard does in fact have a unique identification number (although not an EPA-assigned number, as occurred with the NELAC standard, it is unique within TNI) – those numbers are:

EL V1 ISO 2009
EL V2 ISO 2009
EL-V3-2009
EL-V4-2009

It was pointed out that the TNI PT standard (the objectionable component, for NY) merely "clarifies" points in the 2003 NELAC standard that were easy to "interpret" or overlook previously.

An amendment to Susan's motion, to delay implementation of the TNI standard for 60 days, was proposed but not seconded. Several participants noted that the LOQ reporting requirement for PT results is problematic, no matter WHEN implementation occurs, and that if NY were to change its rules to accommodate the PT portions of the TNI standard, that problem would not vanish. Establishing and validating LOQs for reporting levels for all analytes having PTs will be somewhere between burdensome and overwhelming for all ABs.

After that discussion, Susan was asked if she wished to accept the amendment; her response was that she preferred to withdraw the motion entirely. Scott Siders was amenable to this action, and the withdrawal occurred.

Susan then proposed a new motion, which was seconded by Paul Bergeron. With further discussion and clarifications factored in, and appropriate approvals for those edits, the final form of the motion was as follows:

I move that the NELAP AC clarify its meaning of the "rolling implementation" by mutually recognizing accreditations issued in compliance with the 2003 NELAC standard or the 2009 TNI Standard for a period of at least two years to allow all Accreditation Bodies to adopt the standard into laws or regulations.

Some discussion followed, to clarify that it would be up to each AB to explain to its primary and secondary laboratories how that AB will be implementing the 2009 TNI standard (how

it will transition from the 2003 NELAC standard.) It was noted that non-NELAP states that rely upon NELAP accreditations will also be impacted by this motion, but that seemingly, this will be the most widely acceptable and implementable course. It does not penalize OR and TX for being ready to implement the TNI standards on July 1, nor does it overturn the August 2009 NELAP decision to implement the TNI standards on July 1, 2011.

It was noted that, if a new/updated TNI standard is proposed within the year (as expected), NELAP could actually have three standards in various phases of “rolling implementation.” This was not considered to be a “show stopper.”

A question arose about what NELAP accreditation certificates will say, concerning which standard the lab is actually accredited to, but general agreement affirmed that the current certificates do not specify the standard in place at the time accreditation is granted.

All present affirmed a prior consensus of the AC that AB operations will be evaluated to the 2009 TNI standard, regardless of which standard is operational for the laboratories.

Paul Bergeron called the question, Steve Arms seconded that call, and the vote was unanimous, to proceed to a formal vote on the motion. Twelve of the 15 ABs were still participating at that point, and 11 of them voted “yes.” Two expressed reservations which were addressed by affirming that the NELAP AC is still moving forward towards full implementation of the “new” 2009 TNI Standard; one “no” vote was cast, with that AB explaining that they preferred a defined end date to the implementation period as the reason for its negative vote. Because of the vagaries of existing and future changes to state politics, it had already been deemed that an “end date” for full implementation was not practicable.

The remaining 3 ABs are being polled by email, and per the AC’s voting SOP (TNI SOP 3-101), they have up to 2 weeks to cast their vote.

3. Next meeting

The AC will hold its next regular conference call on Monday, June 20, 2011, at 1:30 pm Eastern. The agenda items will likely include:

- Roll Call and Approval of Minutes
- Update on Renewals
- Resolution of outstanding votes
 - WET PT from June 6
 - Provisional Recognition SOP from June 6
 - Motion clarifying “rolling implementation” from June 10
 - If presented, any objections to David Caldwell (OK) assuming the Lead Evaluator role for PA’s evaluation (from June 6 discussion)
- Other items that may be identified prior to the meeting

Attachment 1

STATE	REPRESENTATIVE	PRESENT
CA	George Kulasingam T: (510) 620-3155 F: (510) 620-3165 E: gkulasin@cdph.ca.gov	yes
	Alternate: Jane Jensen E: jjensen@cdph.ca.gov	yes
FL	Stephen Arms T: (904) 791-1502 F: (904) 791-1591 E: steve_arms@doh.state.fl.us	yes
	Alternate: Carl Kircher E: carl_kircher@doh.state.fl.us	no
IL	Scott Siders T: (217) 785-5163 F: (217) 524-6169 E: scott.siders@illinois.gov	yes
	Alternate: TBA	
KS	Dennis L. Dobson 785-291-3162 E: ddobson@kdhe.state.ks.us F: (785) 296-1638	yes
	Alternate: Michelle Wade E: MWade@kdheks.gov	yes
LA DEQ	Paul Bergeron T: 225-219-3247 F: 225-325-8244 E: Paul.Bergeron@la.gov	yes
	Alternate: TBD	
LA DHH	Louis Wales T: (504) 219-4662 F: (504) 219-4661 E: louis.wales@la.gov	no
	Alternate: Donnell Ward E: donnell.ward@la.gov	no

MN	Susan Wyatt T: 651.201.5323 F: E: susan.wyatt@state.mn.us	yes
	Alternate: Stephanie Drier E: stephanie.drier@state.mn.us	yes
NH	Bill Hall T: (603) 271-2998 F: (603) 271-5171 E: george.hall@des.nh.gov	no
	Alternate: TBD	
NJ	Joe Aiello T: (609) 633-3840 F: (609) 777-1774 E: joseph.aiello@dep.state.nj.us	yes
	Alternate : TBD	
NY	Stephanie Ostrowski T: (518) 485-5570 F: (518) 485-5568 E: seo01@health.state.ny.us	yes
	Alternate: Dan Dickinson E: dmd15@health.state.ny.us	no
OR	Gary Ward T: 503-693-4122 F: 503-693-5602 E: gary.k.ward@state.or.us	yes
	Alternate: Raeann Haynes E: haynes.raeann@deq.state.or.us	no
	Scott Hoatson T: (503) 693-5786 hoatson.scott@deq.state.or.us	yes
PA	Aaren Alger T: (717) 346-8212 F: (717) 346-8590 E: aaalger@state.pa.us	yes
	Alternate: Dana Marshall E: dmarshall@state.pa.us	no

TX	Stephen Stubbs T: (512) 239-3343 F: (512) 239-4760 E: sstubbs@tceq.state.tx.us	yes
	Alternate: Steve Gibson E: jgibson@tceq.state.tx.us	yes
UT	David Mendenhall T: (801) 584-8470 F: (801) 584-8501 E: davidmendenhall@utah.gov	no
	Alternate: Kristin Brown E: kristinbrown@utah.gov	yes
VA	Cathy Westerman T: 804-648-4480 ext.391 E: cathy.westerman@dgs.virginia.gov	yes
	Alternate: Ed Shaw T: 804-648-4480 ext.152 E: ed.shaw@dgs.virginia.gov	no
	NELAP AC Program Administrator and Evaluation Coordinator Lynn Bradley T: 703-867-5966 E: lynn.bradley@nelac-institute.org	yes
EPA Liaison	Arthur Clark T: 617-918-8374 F: 617-918-8274 E: clark.arthur@epa.gov	no
	Quality Assurance Officer Paul Ellingson T: 801-201-8166 E: altasnow@gmail.com	no
	Oklahoma: David Caldwell Judy Duncan	David Caldwell
	Guests: none	