

**Summary of the TNI NELAP Board Meeting
April 20, 2009**

1. Roll call

The NELAP Board met at 12:30 PM CST on April 20, 2009. Those members in attendance are listed in Attachment 1. In addition to those indicated, Eileen Sanders and Kay Smith from Virginia DCLS also joined the call.

2. Minutes

Minutes from the 4-06-09 meeting were reviewed. The minutes were approved for posting.

Steve Arms noted that the WET FoPT table had been posted on the TNI website with the wrong effective date. It should be 4-1-09. He indicated that Jerry was aware and would fix the error.

3. Update on renewals

First round:

CA –CA response determined to be satisfactory. Recommendation to the NELAP Board is in preparation.

Second round:

IL- Dan Hickman granted a 30 day extension to the evaluation team to review the response. New due date is May 6.

LADEQ – Response to technical review satisfactory. Onsite will be scheduled.

OR – Draft report from the onsite is in preparation. Labs for shadow observations have scheduled.

TX – Onsite scheduled for this week, lab shadow scheduled for April 30.

New applications:

VA application has been submitted. Review will be delayed until staff hired or until May 1.

4. Update of Evaluation SOP

Lynn Bradley reported that the need to update the Evaluation SOP came up on the Regional Evaluators' call last week. The EPA regional evaluators' have an interest in being part of the revision process. Dan Hickman solicited volunteers to work on the update. Steve Stubbs volunteered. Lynn will recruit volunteers from the EPA regional staff.

Also, several evaluators have offered to share their checklists and other evaluation tools. Lynn offered to explore ways to make these tools available. It will be made clear that use

of these tools is not mandatory, but they will be offered as examples.

5. Question regarding multiple primary ABs

Aaren Alger reported that PA has had requests from labs located in non-NELAP states for primary accreditation when that lab already has another primary AB for other parameters. The reason expressed by the lab for wanting another primary was that the original primary AB could get the assessment done on the new field of accreditation in a timely manner. Aaren asked if the NELAP Board had a policy on multiple primary ABs.

After discussion, the Board concluded that the standard does not expressly prohibit multiple primary ABs, but members did not feel this was good practice. PA will tell the lab that they should get the new accreditation from the original primary AB.

6. SW 846

Joe Aiello indicated that he had called Dave Speis to determine the status of the ELAB meetings with the EPA office of solid waste. Dave wants the NELAP Board to wait until ELAB comes out with their recommendations on this issue before deciding on a solution. Steve Arms reported that ELAB had come out with some draft recommendation which he will forward to Carol to distribute to the group. While the ELAB recommendations may provide a long term solution, there will still need to be a short term solution, particularly if some states cannot drop the letter designation.

7. Assessor training in Virginia

The Virginia DCLS has requested input from the NELAP Board on whether DW certification officer experience can substitute for the required four onsite observations for NELAP assessors. There was concern expressed by the board that Drinking Water certification and NELAP accreditation are very different in approach. NELAP assessments are more quality systems based rather than technical. The board agreed that the onsite assessment observations required for NELAP assessor training have to be NELAP assessments.

8. Issues from the TNI Board

Dan reviewed the responses prepared by Jerry Parr to questions raised by EPA RS&T Directors and EPA regional lab staff regarding NELAP accreditations and communications with the NELAP Board. The responses are attached as an appendix. Dan asked for concurrence or comments from the Board on the proposed responses.

Item #1 – no objections

Item #2 – no objections

Item #3 - no objections

Item #4 - no objections

There was not time to consider item #5.

9. Next meeting

The next meeting of the NELAP Board will be May 4, 2009. Agenda items at the next meeting will include:

Update on renewals
SW 846
Standards Interpretations

Attachment 1

STATE	REPRESENTATIVE	PRESENT
CA	George Kulasingam T: (510) 620-3155 F: (510) 620-3165 E: gkulasin@dhs.ca.gov	Yes
	Alternate: Jane Jensen jjensen@dhs.ca.gov	
FL	Stephen Arms T: (904) 791-1502 F: (904) 791-1591 E: steve_arms@doh.state.fl.us	Yes
	Alternate: Carl Kircher carl_kircher@doh.state.fl.us	
IL	Scott Siders T: (217) 785-5163 F: (217) 524-6169 E: scott.siders@illinois.gov	No
	Alternate: TBA	
KS	Dennis L. Dobson 785-291-3162 ddobson@kdhe.state.ks.us	Yes

	Alternate: TBA	Yes
LA DEQ	Paul Bergeron T: 225-219-3247 F: 225-219-3310 E: Paul.Bergeron@la.gov	Yes
	Alternate: Cindy Gagnon E: Cindy.Gagnon@la.gov	
LA DHH	Louis Wales T: (225) 342-8491 F: (225) 342-7494 E: lwales@dhh.la.gov	No
	Alternate: Ginger Hutto ghutto@dhh.la.gov	
NH	Bill Hall T: (603) 271-2998 F: (603) 271-5171 E: whall@des.state.nh.us	Yes
	Alternate: Jeanne Chwasciak jcchwasciak@des.state.nh.us	
NJ	Joe Aiello T: (609) 633-3840 F: (609) 777-1774 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	No
	Alternate: Dan Dickinson dmd15@health.state.ny.us	

OR	Dan Hickman T: (503) 229-5983 F: (503) 229-6924 E: hickman.dan@deq.state.or.us	Yes
	Alternate: Raeann Haynes haynes.raeann@deq.state.or.us	
PA	Aaren Alger T: (717) 346-8212 F: (717) 346-8590 E: aaalger@state.pa.us	Yes
	Alternate: Bethany Piper bpiper@state.pa.us	
TX	Stephen Stubbs T: (512) 239-3343 F: (512) 239-4760 E: sstubbs@tceq.state.tx.us	Yes
	Alternate: Steve Gibson jgibson@tceq.state.tx.us	
UT	David Mendenhall T: (801) 584-8470 F: (801) 584-8501 E: davidmendenhall@utah.gov	Yes
	Alternate: Kristin Brown kristinbrown@utah.gov	
	Program Administrator: Carol Batterton T: 830-990-1029 or 512-924-2102 E: carbat@beecreek.net	Yes
	Evaluation Coordinator: Lynn Bradley T: 202-565-2575 E: Bradley.lynn@epa.gov	Yes

Quality Assurance Officer Paul Ellingson T: 801-201-8166 E: altasnow@gmail.com	No
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Issues for TNI

Based on Discussions prior to, during and after the Miami TNI Meeting a list of concerns facing the EPA Regions has been compiled. These items are to be forwarded to the TNI Board of Directors for discussion at the March 18th RS&T Director's Conference Call.

Item 1 – Need for an independent conflict resolution process for laboratories before going through a state's administrative process.

Discussion: If a Regional Laboratory (or any laboratory for that matter) has an issue with it's laboratory accreditation, it's only recourse is through the state AB's legal process. This should be avoided and TNI needs an interim step prior to the legal step.

Question(s): Can TNI insert an interim step to try and avoid going through a very expensive and cumbersome legal process?

Implementation of the accreditation program is delegated to state government agencies designated as Accreditation Bodies (ABs). This is no different now that from what has existed since the inception of the drinking water certification program. TNI has no authority to intervene in a state government's activities. This is also consistent with ISO 17011, section 4.2.2

"The accreditation body shall have authority and shall be responsible for its decisions relating to accreditation, including the granting, maintaining, extending, reducing, suspending and withdrawing of accreditation."

As part of the NELAP evaluations, the NELAP Board does consider whether or not an AB has conformed to TNI's accreditation requirements.

TNI has implemented a standards interpretation request procedure where laboratories can seek clarification on issues. However, this procedure is not designed to be used to resolve a dispute between a lab and an AB.

In 2009, TNI is planning to develop additional technical assistance for laboratories. One of the items under discussion is a listing of most frequent assessment deficiencies and options for how to respond to them. TNI is also revising the Quality Manual template and the Quality Systems committee is planning to have case studies showing options for implementing the requirements.

Finally, TNI understands the need for a less formal process that could be used early in the process of a dispute and TNI's Policy Committee is going to take on the task of developing a complaint resolution procedure. Preliminary discussions suggest that TNI might act as a facilitator to make sure that each side hears and understands the point of view of the other. It is reasonable for a laboratory to be able to discuss how the process works with an independent third party who can help to convey their point of view. The Region 3 evaluator sometimes acts as an intermediary in disputes between a laboratory and an AB and is

routinely provided copies of the laboratory's Assessment Appraisal Forms completed after each NELAP assessment. The Region 3 efforts will be considered as the Policy Committee considers this topic.

Item 2 - What recourse does an EPA Region have when the NELAP Board of Directors does not apply the Standard or implement the program appropriately?

Discussion: Regarding the Drinking water Program – conceivably, NELAP could conclude that an AB is running an appropriate drinking water laboratory program, while the parent Region comes to a different conclusion. A process for resolving this scenario before a Region proceeds to formally intervene.

Question: The Regions and TNI need to develop a process to resolve these potential disputes, what is the best way to approach this?

TNI and the Regions work together during the evaluations to resolve such disputes, but there is no process for the intervening period if some new concern arises. Any concerns about an AB not implementing the program correctly should be brought to the NELAP Board and will receive serious attention. As noted above, TNI's Policy Committee will work on development of a complaint resolution procedure and the TNI Board will discuss measures that might be taken to facilitate discussions early in the process of a dispute.

Item 3. Concerns about whether NELAP assessors have adequate technical training.

Discussion: There are recent instances where NELAP AB assessors have approved laboratories that are making modifications to the drinking water methods. This points to a lack of technical training in the drinking water methods. NELAP AB assessors are required to take assessor training that focuses on the accreditation process, but the technical training program is very lacking.

Question: What can be done to improve the technical training that assessors receive?

TNI agrees that assessors need to be competent to assess the technical areas they audit. TNI has taken, or plans to undertake the following actions:

1. The TNI On-Site Assessment Committee has developed a technical curriculum that will be provided to the Technical Assistance Committee for this committee to consider for future planning.
2. The Technical Assistance Committee is developing a plan for how such training would be provided, including a process by how TNI can approve trainers and/or training courses.
3. TNI will continue to hold day-long Assessment Forums in conjunction with our meetings held twice a year.
4. The new TNI standard requires assessors complete and attain a passing score on all technical disciplines that the assessor will assess. This is an increased requirement from the 2003 NELAC standard

At a special session at Pittcon in 2007 on the performance approach, that included representatives from TNI and the Office of Water, we requested EPA to provide information that clearly defined what they would expect an assessor to be looking for to decide whether or not a laboratory was modifying an EPA method. TNI requests EPA consider developing this guidance, especially for newer, complex methods.

Item 4 – The NELAP Board is allowed to vote to interpret the NELAC Standard without participation of all of TNI.

Comment [JP1]: We had a very good discussion on the role of regional evaluators and I think strategically, we need to see how to get them more engaged. I want to find out more about these monthly conference calls Carol mentioned and see if we can expand the scope.

Discussion: During the 2008 evaluation process the NELAP Board ruled regarding the interpretation of the 2003 NELAC standards related to assessor training requirements. These standards interpretations were then used as the basis for the evaluations that were conducted.

Questions: Why is this permitted? There is no transparency in this process. Too much authority is given to the NELAP Board. An EPA presence on the NELAP Board could prevent this. Is there any progress in getting an EPA presence on the TNI Board of Directors?

TNI's standard interpretation process generally involves a number of committees that have diverse stakeholder representation, including the Expert committee that developed the language and the Laboratory Accreditation System Committee. On occasion, such requests have come to the NELAP Board directly. TNI has agreed to revise the process as follows:

- The responses to all standards interpretation requests (SIR) will be reviewed by the Laboratory Accreditation System Committee (LASC) who will provide a recommendation back to the NELAP Board.
- Any agenda item brought to the NELAP Board independent of TNI's formal SIR process that has the appearance of a SIR will be identified by the TNI program administrator as an SIR and treated as such.
- TNI plans to expand the role of the QA Officer for NELAP to include an annual report to the TNI Board of Directors on the activities of the NELAP Board, and actions by the NELAP Board on SIR will be added to the list of items to report on.

The TNI and NELAP Boards have discussed adding an ex-officio (non-voting) representative from EPA and believe this is a good idea. We need to define roles and responsibilities. The NELAP Board also wants to ensure the person on the board would fully represent EPA.

Item 5: NELAC Chapter 6 vs. the new TNI Standard

Discussion: The new TNI standard (Volume 2) does not include all of Chapter 6 of the 2003 NELAC Standard (Accrediting Authority). It is understood that much of the remaining material governing the evaluation of ABs is in NELAP's SOP for the Evaluation of ABs. And that this SOP is only a TNI policy approvable by the NELAP Board.

Questions: Is all of Chapter 6 included in the TNI standard and Evaluation SOP? Can the NELAP Board of Directors change the Evaluation SOP and the policies within, and not have to have the concurrence of all of TNI?

The adoption of SOPs and policies by the NELAP Board includes input from the LASC, review by the TNI Policy Committee for consistency across TNI, and review by the TNI Board for organizational risk so there are several ways in which these documents have concurrence from TNI groups that have balanced representation.

One of the things that did not work in the old NELAC system, was that the Standard – particularly Chapter 6, contained a lot of prescriptive procedure and policies that did not belong in the standard and did not need to be created/voted on by all the membership. Items like timelines, what the certificate should include, how to fill out an application, and EPA's role in evaluations. The process for changing these in the standard was too lengthy. In addition, some of these just did not work and others are no longer in existence (e.g. NELAP Director). These were pulled out of the new standard for these reasons, and to be consistent with ISO 17011 which also recognizes the impracticality. The NELAP Board has implemented SOPs that address the primary required activities from the old Chapter 6. There are some items that may not need to be included in TNI policies and procedures (e.g., administrative procedures for handling appeals that are codified in state regulations).

Comment [JP2]: Joe pointed out this is not just a TNI problem also is in DW program. Kevin Kubik provided the perspective that he thought NY could have done the training by bringing Marlene in, but did not want to pay for it. Someone from Region 1 indicated this was two "lightning rods" one because of untrained assessor and one because of lack of transparency. This was probably the biggest issue we discussed, but I perceived very good acceptance of the proposed plan.

We have used LASC very successfully to review the standards and offer consensus opinion representing all stakeholders. If you look at TNI's bylaws, and also go back to the intent at the time of the formation of TNI, we intended LASC to be an advisory group to the NELAP Board. We plan to have LASC involved in all SOPs that relate to NELAP (including the SOPs from the consensus standard development and proficiency testing programs), and provide recommendations to both the group that developed the SOP, as well as the NELAP Board and, where appropriate the TNI Board.

Items in NELAC Chapter 6 that are not in the Evaluation SOP, but that may be needed when the new standard is implemented (e.g., timelines) will be developed as additional SOPs by the Accreditation Body committee, a consensus body with diverse stakeholder interests.

TNI will provide a crosswalk document to compare NELAC Chapter 6 to the new TNI standard and SOPs.

Other Actions by TNI

We will request the NELAP Board consider what actions would need to be taken if a primacy state accreditation or certification decision differs from that of an out-of-state NELAP AB for a laboratory located within the primacy state.

Comment [JP3]: This is a new issue developing in Regions 1 and 4. Gregg Carroll has been asked to write a policy memo on the same topic.