

**Accreditation Body Committee Meeting
January 13, 2009
Forum on Laboratory Accreditation
Miami, FL**

Committee Members Present:

Jeff Flowers, Chair
Linda Geddes
Lynne Bradley
Joe Aiello
Sharon Mertens
Dan Dickinson
Steve Arms
Jane Wilson, Program Administrator

Introduction and Background

Jeff welcomed the participants and provided an overview of the session. The Accreditation Body (AB) committee members gave self introductions.

Jeff reviewed the mission of AB committee from the committee charter. He emphasized the consensus element of the TNI standards process and its importance in the success of the TNI standards.

Committee strategies were reviewed, which are primarily to assist the NELAP Board and the Laboratory Accreditation System Committee (LASC) on issues related to the AB standard developed by the committee.

The accomplishments of the AB committee include the finished AB module, continued mutual recognition of ABs currently in NELAP, and achieving a recommendation to adopt the AB standard from LASC (with responses to LASC comments). The AB committee is currently developing two tentative interim amendments (TIAs) to respond to LASC comments. The draft TIAs are subject to public comment through Jan 21st.

The AB committee is also working to develop an affiliate/associate system of alternate state recognition, which represents a progressive model of attainment toward full NELAP accreditation. States participating in the system would be granted additional rights or recognition as their laboratory accreditation program matures. The committee may ask the NELAP Board to consider a new membership category.

Tentative Interim Amendments

Jeff reviewed the situations for which TIAs are appropriate and the requirements of TNI's procedures governing standards development for TIAs. CSDB has determined the emergency nature of the two proposed TIAs. It was noted that TIAs cannot extend

beyond 2 years. In that time period the standard must be revised via the normal consensus process.

Jeff reviewed the proposed TIAs content (currently posted on TNI website). He explained that LASC review identified some ABs that cannot meet the ISO 17011 requirements included in standard in two places. The TIAs are relevant to the process for sign off of AB assessments and internal audits.

Jeff reviewed the comments that have been received on the TIAs to date:

- The TIAs would allow the assessor to be both judge and jury
- The TIAs are counter to ISO 17011 and would affect the ability to cite compliance to the international standard
- Some ABs may need to drop NELAP if the TIAs aren't adopted
- Let the states with a problem figure it out how to address their specific situation
- Cannot change the ISO language directly and need to structure the TIAs differently (this was addressed by placing the proposed additional language into notes)
- Labs are expected to change to implement the new TNI standards, why not ABs as well
- Let standard be adopted as is and let states identify what they can and can't do

The wording of the TIAs limits the scope of the TIAs to the “responsible government authority,” so the onus is on the state government, rather than incorporated entities like A2LA.

The attendees discussed the following oral comments to the TIAs:

- Concern was expressed that the wording allows for everyone to do it with one person and maybe it should be limited to those ABs that cannot do it.
- It was asked whether all the NELAP states were consulted as to whether they can comply. The comments came from LASC, not NELAP. It would help to know if any of the states with a problem can find a way to comply. There is concern about the implied non-compliance with 17011 introduced by the TIAs.
- How can TNI tell a sovereign state government what to do? NELAC has always been a compromise organization for the states that do participate. This issue was not discussed in NELAP and was raised by AB members of LASC.
- The AB committee did discuss this very issue during development of the standard and the requirement was left in.
- It's up to the NELAP Board to determine how to deal with the situation. LASC just raised the question – NELAP board needs to determine how to deal with it.
- NELAP should discuss the issue prior to going to the TIA process. The AB committee initiated the TIA process as they were trying to be sensitive to the timelines needed to implement the TNI standards. NELAP can discuss during their Miami meeting.
- The current NELAC standard does not have this issue.

- The full context of the ISO 17011 language also addresses issues of impartiality and conflict of interest, and that those sections may provide the needed flexibility to AB programs that have insufficient staff to allow signoffs by separate individuals.
- The TIA process was discussed. There is no specific allowance for withdrawing the TIAs. The options appear to be a negative vote by the committee, or amendment of the TIAs after consideration of the public comment. The committee can reject the current version and start over as well.

Associate/Affiliate Program

Jeff reviewed a table of the activities that would be available to both levels of alternate recognition. The Associate level would be closer to being a full NELAP body. The terms associate and affiliate are those used by ILAC in their programs. The intent is not to downgrade anyone who is already an AB, just for new states who are looking forward to becoming an AB. Ann Marie Allen from MA has had meetings on this topic before. It will be up to the NELAP Board to make the decision – it is a long term project not related to implementation of the new TNI standards. Joe Aiello will be presented at the NELAP meeting and comments will be taken.

Attendees discussed the following oral comments to the Associate/Affiliate program:

- The objectives of the program were discussed. It was noted that some states probably will never become full ABs. This program is intended to provide a route to some level of recognized participation for those that do.
- This is a NELAP membership structure, not a TNI membership structure. The TNI organization should be able to express that it is more significant than the 12 states that are full ABs. Showing state participation in AB subcategories would be one way of doing it.
- Tony Anderson discussed the NACLA accreditation cooperative. NACLA is not active in the environmental area. It recognizes ABs to 17011 in several sectors. He has been talking to Jerry Parr about doing some cooperative work. When NACLA was formed, NELAC was already in place and NACLA didn't address the NELAC community. NACLA recognizes ABs the way NELAP recognizes ABs. NACLA doesn't have different levels of participation recognition.
- Having a broader TNI program might also help with international acceptance.
- The target is the inclusion of states that utilize TNI or its standards in some manner. TNI itself has many more states than NELAP. There is a need to be cognizant of the states that do not want to be automatically categorized as some kind of NELAP member. There would have to be some kind of application to verify the activities that the AB is undertaking.
- Need to add reciprocity to the list of AB activities.
- Would audits be needed to verify program processes for affiliates/associates? Can that be the drinking water assessment audit? It's not a quality systems audit, but it could have some value in granting status. It could be a self certification to keep cost down or it could be limited to drinking water programs.

- Are these efforts being directed to the wrong entity (states) – may resources should be directed toward small labs. TNI is doing this as well.
- Would this program potentially result in mutual recognition between non-NELAP states and would that decrease the incentive to becoming a full AB?
- Maybe TNI just needs the current information about who is using TNI processes/standards and to continue to do outreach to the potential state participants.

As follow up, the AB committee can talk to Ann Marie and get a sense of what has taken place so far. Feedback will also be provided by the NELAP Board.

Future AB Committee Plans

The committee intends to continue its work to develop SOPs and policies to allow for implementation of the TNI standards as requested by LASC. It also plans to continue work on the AA program.

The committee meets the third Tuesday of the month at 12:00 pm ET.