SUMMARY OF THE TNI POLICY COMMITTEE MEETING

JULY 10, 2009

The Policy Committee of The NELAC Institute (TNI) met on July 10, 2009 at 11:00 AM (ET) by teleconference.

Chairperson Mr. Alfredo Sotomayor, of the Wisconsin Department of Natural Resources, led the meeting. A list of committee members is given in Attachment A. A list of the action items generated during this meeting is included in Attachment B. The meeting agenda is given in Attachment C.

REVISION OF NELAP VOTING SOP 3-101

Mr. Sotomayor clarified that the standard operating procedure (SOP) dealt with general business and matters related to laboratory accreditation, not recognition of accreditation bodies (ABs), contrary to what he had stated in his electronic message.

This SOP would apply to the decision that the National Environmental Laboratory Accreditation Program (NELAP) Board would be making regarding the approval of the TNI Standards. The SOP was revised to allow the NELAP Board to make a decision on accreditation matters on the meeting in which a motion is presented. The SOP still allows two weeks to vote to NELAP Board members that are not present on the meeting a motion is made. The change is designed to streamline the voting process.

After some discussion, the Policy Committee agreed to forward the revised SOP to the TNI Board of Directors, requesting an editorial change to clarify the extent of the two week period afforded to NELAP Board members that were absent during a full quorum vote. The Policy Committee requested inserting a period after the first mention of the words "NELAP Board" in paragraph 4.3.3.1, and asked that the resulting second section be modified to: "NELAP Board members who are absent during the meeting in which a Full Quorum Vote is made have <u>up to</u> two weeks to place a vote electronically, by FAX, or hard copy on an official ballot provided by the NELAP Board chairperson."

The Policy Committee also agreed to forward the revised SOP with the suggested modification to the TNI Board of Directors for electronic voting with a deadline of July 17, 2009.

PENDING ITEMS SUMMARY

The committee reviewed a list of items it was still considering or had been asked to consider in the recent past. Mr. Sotomayor will assign tentative priorities to the list and will forward them to the committee for review and input. Mr. Sotomayor was asked to contact the Advocacy Committee member previously approached to determine the person's current interest in being a Policy Committee member.

Mr. Sotomayor informed the committee that he had attempted a very rough draft of a conflict resolution SOP, but it needed more work before it could be considered by the committee. The conflict resolution SOP would describe a process that would not supersede or impede the legal systems that Accreditation Bodies (ABs) have for addressing complaints. The process would exclude complaints regarding accreditation or recognition decisions, but was intended to be available to any TNI Program or member.

Other items the committee will need to consider are: developing a policy on use of electronic mail, completing a set of administrative policies, some of which have been delegated to the Finance Committee, and drafting an SOP on the operations of the TNI Board. The committee will also have to consider policies and SOPs that may result from restructuring the institute, at least for the inclusion on the National Environmental Field Activities Program (NEFAP) and will need to propose changes to the bylaws.

One of the items reviewed related to an ongoing comparison between the <u>Manual for the Certification of Laboratories Analyzing Drinking Water</u> and the new TNI Standards. Messrs. Bob Wyeth and Jerry Parr informed the committee that the Environmental Laboratory Advisory Board (ELAB) was actively working on this item and both felt that it could be removed from the list of the Policy Committee working items. Mr. Wyeth related that he had attended some of the meetings dealing with the comparison and noted that ELAB had made substantial progress on the issue.

The committee discussed its possible involvement in requesting a review of the NELAP Program. The NELAP Quality Assurance Officer (QAO), Mr. Paul Ellison, may be tasked with this effort. The committee also discussed briefly EPA's involvement in and the appointment of an ex-officio member from EPA to the NELAP Board.

Mr. Sotomayor noted that the TNI Program's compliance with the SOP on the Control of TNI Documents needed to be reviewed. He thought that the programs needed some facilitation to implement the SOP and he would explore alternatives for doing that.

Mr. Wyeth asked the committee to consider adding a working item related to "guidance documents". This led the committee to discuss the next set of agenda items.

RECENT QUESTIONS FOR THE COMMITTEE

Reviewing Guidance

The committee had been approached in the past about providing templates for guidance documents. At that time, the committee reasoned that the subject matter and the intended audience for those documents would require different formats or delivery media, and had concluded that creating a template for guidance documents was not efficient.

Subsequently, the committee was asked whether it should have a role in reviewing guidance documents produced by programs. The committee was reluctant to do this. However, Mr. Wyeth was concerned that without input from the Policy Committee, programs could be creating guidance documents that could impose requirements on the regulated community and that should be included in standards. Mr. Sotomayor added that guidance documents should not be used to

create policy or to specify procedures to be followed in a standard manner; those would best be included in policies and SOPs, and would be subject to the Policy Committee's review. Ms. Silky Labie had some reservations about the creation of guidance documents because some ABs treated them as requirements, while others did not. Mr. John Applewhite noted that guidance documents could be beneficial in limiting the universe of possibilities for the implementation of a requirement and for preventing "outlier" interpretations. Mr. Parr noted that ILAC recognized and had guidance documents as part of its records catalogue.

The committee concluded that it would be beneficial to create a TNI policy that would specify the proper creation and use of guidance documents. The committee agreed to add drafting the policy to its working items. The committee also agreed to meet on Tuesday, August 11, in San Antonio for a working lunch to create a working draft or strawman proposal that could be presented later that day during the Consensus Standards Development Program (CSDP) session that Mr. Wyeth would moderate. [NOTE: The Policy Committee's meeting in San Antonio will take place on Monday, August 10, during lunch.]

Status of Policy Governing Standards Development

Ms. Jo Ann Boyd asked, on behalf of the CSDP on the status of the "Policy Governing Standards Development", specifically, the one including the revisions made to the Tentative Interim Amendment sections. Mr. Parr and Mr. Sotomayor stated that the revised document had been reviewed by the Policy Committee and endorsed by the TNI Board. [Note: The committee reviewed and endorsed the document on January 12, 2009. The TNI Board concurred with the endorsement on March 11, 2009.]

Need for Policy on Distribution of Minutes

Mr. Sotomayor was asked to consider whether a policy should be created to address the distribution of minutes to Committee and Associate Members. At issue was whether drafts of the minutes had to be circulated to Associates all the time. He agreed that TNI committees should strive to be inclusive and transparent, but that there could be instances where some issues might require review and discussion by a smaller group, especially if conflicts of interest could arise.

The committee agreed not to create a policy on the distribution of draft minutes and felt that their dissemination would be decided at the discretion of each Committee's chair. The access and availability of all final minutes is covered by TNI's SOP on Document Control.

NAME OF NEW STANDARDS

The committee was asked to consider whether the new standards should be called "TNI Standards" or "NELAP Standards". It seemed that some ABs could have an easier time incorporating or using the standards if they were identified as NELAP or NELAC Standards.

Mr. Parr noted that Pennsylvania had been successful in incorporating "TNI" to designate the standards in its last set of regulation revisions. Mr. Sotomayor noted that Supplement 1 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water had amended the definitions and abbreviations section of Appendix C to read: "The NELAC

Institute (TNI) was created in November 2006 as an outgrowth of NELAC. References to "NELAC" are replaced with TNI." He also felt that the standards had been created by TNI, not NELAP and that naming the standards with a specific program designation did not reflect their use by organizations outside of NELAP.

The committee agreed that retaining "TNI" as part of the standards' name was accurate and desirable. To differentiate between the different types of TNI Standards now available, the committee suggested referring to them with their sector designations.

The committee requested that Mr. Sotomayor provide the suggested names for the standards to the Laboratory Accreditation System Committee (LASC) for their consideration and discussion. After input from the LASC, the Policy Committee would offer a recommendation to the TNI Board.

RECENT INITIATIVES

Mr. Sotomayor informed the committee that the TNI Board of Directors had started to consider possible alternative structures for TNI that would include emerging sectors such as the National Environmental Field Activities Program (NEFAP) and the Stationary Source Audit Program (SSAP), as well as others that might improve the efficiency of operations. He will share with the committee plans as they become more solid and at that time seek committee input.

The committee did not have time to discuss details of the NEFAP draft proposals. Mr. Sotomayor will forward some documents to the committee outlining some options for NEFAP. The Policy Committee wanted to work cooperatively with the architects of NEFAP, while at the same time not stifling or preventing their progress. The committee felt that having a NEFAP member in the Policy Committee would help in this effort and requested that Mr. Sotomayor contact Ms. Marlene Moore to discuss the possibility.

NEXT STEPS

The committee will meet again in San Antonio on August 11, 2009. The list of action items in Appendix B summarizes all other next steps. [NOTE: The Policy Committee's meeting in San Antonio will take place on Monday, August 10, during lunch.]

ADJOURNMENT

The meeting was adjourned at 12:25 PM (ET).

COMMITTEE MEMBMERS TNI POLICY COMMITTEE JULY 10, 2009

Member	Affiliation/Representing	Contact Information
Alfredo Sotomayor, Chair	Wisconsin Department of Natural Resources TNI Board	T: 608-266-9257 E: Alfredo.Sotomayor@Wiconsin.gov
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Jo Ann Boyd	Southwest Research Institute Laboratory Accreditation System	T: 210-522-2169 E: jboyd@swri.org
Silky Labie	Environmental Laboratory Consulting and Technologies Consensus Standards Development	T: 850-656-6298 E: labie@comcast.net
Steve Stubbs (Absent)	Texas Commission on Environmental Quality	T: 512-239-3343 E: sstubbs@tceq.state.tx.us
	National Environmental Laboratory Accreditation	
Robert Wyeth	Columbia Analytical Services	T: 716-860-9108 E: rwyeth@caslab.com
	At Large	

TNI POLICY COMMITTEE MEETING JULY 10, 2009

ACTION ITEMS GENERATED AT THIS MEETING

Item No. Meeting Date	Action	Date to be Completed
1. 07/10/09	Mr. Sotomayor will forward SOP 3-101 to the TNI Board of Directors, with the indicated editorial changes, for their concurrence electronically by July 17, 2009.	07/13/09
2. 07/10/09	Mr. Sotomayor will contact a member of the Advocacy Committee to select a member for the Policy Committee.	08/10/09
3. 07/10/09	The committee will produce a draft policy on the creation and use of TNI guidance documents.	08/11/09
4. 07/10/09	Mr. Sotomayor will forward recommendations on the name of the new standards to the LASC for discussion and input.	07/13/09
5. 07/10/09	Mr. Sotomayor will contact Ms. Moore to explore appointing a NEFAP representative as a Policy Committee member.	07/15/09
6. 07/10/09	Mr. Sotomayor will forward documents describing NEFAP to the Policy Committee.	07/15/09

UNCOMPLETED ACTION ITEMS FROM PREVIOUS MEETINGS

Item No. Meeting Date	Action	Date to be Completed
	NOTE: All uncompleted action items from previous meetings have been moved to a spreadsheet. The minutes will reflect their discussion and completion as they happen.	

The NELAC Institute (TNI) Policy Committee

July 10, 2009

11:00 AM – 12:25 (ET)

AGENDA

11:00	Welcome Back, Welcome Back
11:05	Pending Items Summary
11:30	Recent Initiatives
	Restructuring of TNINEFAP
11:40	Revision of NELAP Voting SOP 3-101
11:55	Recent Questions for the Committee
	Reviewing Guidance Status of Policy Governing Standards Development Need for Policy on Distribution of Minutes
12:05	Name of the New Standards
12:20	Next Steps
12:25	Adiournment