TNI Board of Directors Meeting Summary September 12, 2012

1. Roll Call

Directors	Present
Joe Aiello	
Aaren Alger	X
Steve Arms	X
Susan Boutros	
Judith Duncan	X
Zonetta English	X
Jack Farrell	X
Keith Greenaway	
Sharon Mertens	X
Judy Morgan	
Patsy Root	
Matt Sica	
Scott Siders	
Alfredo Sotomayor	X
Dave Speis	
Elizabeth Turner	X
Susan Wyatt	
Ex-Officio Directors	
Brenda Bettencourt	X
Brooke Connor	X
George Detsis	
Jordan Adelson	
Staff	
Lynn Bradley	X
Carol Batterton	X
Ken Jackson	
Jerry Parr	X
Ilona Taunton	X
Janice Wlodarski	X

2. Approval of July and August Minutes

July 2012

Motion to Approve with Changes: Dave Speis

Second: Jack Farrell Approved: Unanimous

August 2012

Motion to Approve with Changes: Judy Duncan

Second: Dave Speis Approved: Unanimous

3. Old Business

Board webinar: Webinar has been converted to a webcast and should be ready for viewing this week. Just need to email a link to everyone – will go out this week.

4. AB Task Force Interim Report (Attachment 1)

The AB Task Force would like the Board to review progress to date.

Since this plan deviates somewhat from what was originally envisioned by the Board and the Task Force, we'd like to have the Board's concurrence to develop another program as described in the attachment.

Motion for the ABTF to:

1) continue their efforts in this process and take into consideration the comments from the BOD today and 2) include the BOD in formal discussions to provide additional input and to help resolve any issues that the Board should be involved in: Jack Farrell

Second: Dave Speis **Approved:** Unanimous

5. Corrective Action Task Force (Attachment 2)

The Corrective Action Task Force has completed their efforts and has a report for the Board to review and endorse.

Motion to approve this report and pass along to the CSDP, the LASEC and NELAP to review and take action as appropriate: Jack Farrell

Second: Dave Speis **Approved:** Unanimous

Add, under the title, "Endorsed by the TNI Board of Directors" and the date. This will become an official document. A copy of the final report will be sent to Kirstin, Aaren, and Bob Wyeth for distribution to their respective committees/members.

6. APHL Position Statement

From: Michael Heintz Date: 9/6/2012

As a follow-up to the presentation Michael Wichman gave at the Environmental Measurement Symposium, we wanted to let TNI know that APHL's position statement concerning non-governmental accreditation of environmental laboratories is final and available on our website.

http://www.aphl.org/policy/positions/Documents/POL_2012Jul_APHL-Position-Statement_Nongovernmental-Accreditating-Bodies-for-Environmental-Laboratories.pdf

We understand there is still some disagreement within the broad environmental laboratory community on this topic, however we wanted to extend the courtesy of informing you that APHL's Board and membership approved the statement as a position of APHL. Please let us know if you have any questions, and I look forward to seeing you both again soon!

michael.heintz@aphl.org

Michael E. Heintz, MS, JD Senior Specialist, Environmental Laboratories Association of Public Health Laboratories, Inc. 8515 Georgia Avenue, Suite 700 Silver Spring, MD 20910 Direct: 240.485.2786

Does the Board need to take any action on this letter? No, but this view is extremely limiting and makes it difficult for TNI to find solutions for some of the issues that have been plaguing the program.

This could be a problem of APHL's not understanding (or not recognizing) the difference between accreditation and licensing. Anything that TNI could do to clarify this difference would be the only area that TNI works on. Let others react or move on this and we keep monitoring this. The accreditation vs. licensing issue is something we should be involved in.

Important that we keep abreast of what's going on with other organizations and recognize that other organizations are going to have differing positions about accreditation. We should continue to educate but can't, as an organization, take everything that is stated about accreditation "personally".

Judy Duncan will not be able to continue to serve on the APHL committee but it's important that we continue to have someone serve on the committee.

Only action to be taken on this: Jerry will draft a thank you letter to Michael Heintz for sharing this information with us and bringing us into the conversation.

7. Program Reports

See Attachment 3.

Attachment 1 Next Steps for Accreditation Body Task Force II: Non-Governmental Accreditation Bodies

Background:

In the initial report to the TNI Board, the Accreditation Body Task Force (ABTF) found that third party (non-governmental) accreditation is a viable option that has the potential to alleviate workload problems for NELAP ABs, and that there are no insurmountable impediments to its use.

The TNI Board agreed with the ABTF and voted to form a new task force to specifically address implementation of this recommendation. The TNI Board charged this group with developing a plan of action for allowing NGABs to grant NELAP accreditations. The new task force (ABTF II) had the following charter:

- 1) To propose an implementation plan to allow non-governmental ABs to grant accreditation in accordance with the TNI Environmental Laboratory Sector Standard;
- 2) To develop a concept for a national accreditation program that incorporates both governmental and non-governmental accreditations, and
- 2) To facilitate mutual recognition among all recognized accreditation bodies.

Discussion:

The ABTF II has concluded that an evaluation process similar to the current NELAP/NEFAP Evaluation SOP can be designed to approve NGABs as meeting requirements of the TNI standards to accredit laboratories. However, a major question remains as to what body will provide oversight and approval for the NGABs and how the NGABs will be incorporated into the current system. Not all state NELAP ABs can have mutual recognition with NGABs. In a survey conducted by the ABTF II in which 11 of 15 NELAP ABs responded, six states have indicated that they cannot allow an NGAB to be a member of the NELAP AC. Six states also responded that they would not be able to approve NGABs. Some state ABs believe that lab accreditation is an inherently governmental function and in fact, one state has indicated they would be required to withdraw from the NELAP AC if NGABs are allowed to participate. The NGABs have also indicated they cannot grant mutual recognition to labs accredited by NELAP ABs as it would jeopardize their ILAC recognition.

This development will require the ABTF II to take a somewhat different approach to approving NGABs that was originally envisioned. The ABTF II sees the establishment of a separate approval and oversight body for NGABs as the best and only path forward at this time. ABTF II believes that a program for approval and oversight of NGABs could have the following characteristics:

- An approval body composed of members of the current NELAP AC, LASEC, NEFAP, and/or others.
- An Evaluation SOP similar to NELAP and NEFAP SOPs which could be developed by the NELAP AC or others.
- NGABs judged competent to accredit labs to the TNI standard will be designated "TNI approved".
- States that can accept an NGAB accreditation may do so. Those who cannot are not required to.
- A forum for NGABs can be established to discuss consistency issues. Participation by the NELAP state ABs is voluntary.

The ABTF II believes this approach is worth pursuing because it will provide some relief to states that perform out of state accreditations for labs that do not have a NELAP program in their state. For states

TNI Board of Directors Meeting Summary September 12, 2012

that can accept an NGAB accreditation, there could be a reduction in out of state travel. NGABs will need to be transparent with their clients about how NGAB accreditations can be used.

Requested Action:

Since the above plan deviates somewhat from what was originally envisioned by the TNI Board and the task force, the ABTF II would like the Board's concurrence before recommending development of the program described above.

Attachment 2 TNI Corrective Action Committee Report to the TNI Board of Directors August 2012

Introduction

On August 8, the Board decided to undertake a formal corrective action process to determine what occurred in the development of the 2009 Standard, with the intent to suggest actions to improve this process for the current Standards being revised. The draft Quality Management plan states:

Corrective actions include a determination of the nature and extent of the problem, the root cause of the problem, and alleviation of the problem as soon as practical, including implementing appropriate corrective actions and actions to prevent recurrence, documenting all corrective actions, and tracking such actions to closure. Review of the effectiveness of implementation of the corrective action is performed by the QA Director or QA Manager, as appropriate, and reported to the BOD.

Subsequently, an ad hoc task force was formed, led by Sharon Mertens (then Vice Chair of the TNI Board, with representatives from the NELAP AC, PT Committee, CSD-EC, LASEC, TNI Board and TNI staff.

This report presents the methodology, findings or discussion items and recommendations of this committee. The appendix to this report includes suggested modifications to one of the Standards development SOPs, a flow chart that illustrates the proposed process changes we are recommending, and more details about the key findings that were discussed.

We believe that the next step, following Board approval, would be to hand this over to the Consensus Standards Development Executive Committee for implementation and to ask the LASEC and NELAP AC to review their respective processes and modify their procedures accordingly.

Methodology

The job of the task force was not to do a detailed review of each of the comments and/or concerns that came out of the 2009 Standard approval process, but rather to take a critical look at the process as a whole. Our goal was simple – to document the issues and recommend process improvements.

The committee was formed with members representing key stakeholders who were part of the development of the 2009 TNI Standard. The goal was to have a recommendation for the Board by early summer. With this in mind, it was felt that a smaller group could cover the necessary topics more quickly. The group met once or twice a month from early March to the present.

Table 1 –	Task Fo	orce Me	embers
-----------	---------	---------	--------

Name	TNI Organization
Sharon Mertens	BOD, LAB Expert Committee
Jerry Parr	Executive Director
Susan Wyatt	NELAP AC, TNI BOD
Kirstin Daigle	LASEC, PT Committee
Ken Jackson	CSD EC, TNI Staff
Jack Farrell	TNI BOD
Patsy Root	TNI BOD
Bob Wyeth	CSD EC

The group approached the task by identifying a list of key findings from the 2009 Standard development process. The detailed list is included as Attachment 1 to this report. Observations regarding the root cause of those findings and problem resolution, where there was any, came primarily from within the group itself although several in the group consulted outside resources and shared their findings with everyone.

Each of these findings was discussed in the task force meetings. Summaries of those discussions are also included in Attachment 1.

Overall, we agreed that the documented process was generally followed. Since TNI was a brand new organization, adopting a new Standard with a new process, we have to give a lot of credit to our systems, staff and volunteers for everything that did go right. Our focus could be on corrective action to improve the process itself, rather than its implementation. We quickly focused on four main areas where there are gaps or weaknesses in the system. These are described in the recommendations below.

The group reviewed all of the pertinent TNI SOPs. We also discussed the processes used by ISO and ASTM and drew upon ideas from those organizations that we thought could be helpful.

Recommendations

During the course of discussion, it became clear that there were just a few main areas where there were gaps or problems. The task force thought that the following need to be addressed.

- The process from the time the expert committee receives comments on the VDS to when the Standard becomes final should be modified.
 - Consider adding an additional step to allow those who made comments to review how the committee used those comments to make changes;
 - Consider an additional vote on the VDS by the membership after changes (based on comments) are made.
 - Consider forming a Standards Review Council to review any Standards for policy, content, consistency, etc. at an organizational level (similar to Policy Committee).
- Examine the process used by the NELAP EC and LASC to review the Standard.
 - Consider adding an earlier review to identify "show stopper" issues. This could occur before the WDS goes to VDS.
 - Explore better mechanisms to solicit input from the ABs (as customers) before and during standards development to ensure that their needs are understood by the expert committees. Be sure to include input from non-NELAP ABs, especially those that will become NELAP ABs in the near future.
- Develop better mechanisms to track issues that are deferred to future rounds of standards development to be sure that all worthy recommendations are addressed.
 - Sometimes recommendations have merits but cannot be addressed in the current VDS. These
 are tabled by the committee, presumably to be addressed later. We should have a more formal
 way of tracking these.
- Review SOPs 2-101, 3-103 and 3-106 for completeness and consistency. Update them to reflect any
 process changes that result from our recommendations.

Consider establishing a standardized review cycle for updates to the standard as ISO does. The suggestion would be every 5 years. Rewriting regulations more frequently is excessively burdensome on state ABs. We realize that it may take some time to establish such a cycle but this would be a good goal for the future.

A flow chart is included as Attachment 2 which illustrates the change in the process that we would recommend. We also reviewed section 5 of SOP 2-100 and are recommending changes in this document. These recommended changes are attached as Attachment 3. It is our understanding that the LASEC are reviewing their process SOP and will take these recommendations into consideration as a part of that.

The bottom line is that all of the committees, their members and others who were involved in the process, tried to do a good job in following the procedures that were established and putting out the 2009 Standard. However, the Standard was finalized and approved using a process that was new to the organization. There may have been mistakes or inconsistencies and certainly things that should be done better in the future.

While adding additional review as recommended would add time to the overall process, the goal to recognize inconsistencies and problems that could stall implementation before the Standard is finalized could actually make the overall process (i.e. time to implementation) easier and shorter.

Corrective Action Report - Attachment 1 Key Findings for 2009 TNI Standard

1. The consensus process was used well.

The Expert Committees followed SOP 2-100 diligently. More than 1000 comments were provided in 2006 and 2007 and all comments were considered carefully and a response to comments document was prepared that summarized all decisions.

The task force agreed with this finding.

2. Some commenters felt their comments were not heard; the standards development process used by the expert committees could be improved.

The current process has the TNI membership vote on a Voting Draft Standard. The expert committee then reviews the comment, and if ruled persuasive, changes the Standard. However, the commenter does not get a chance to vote again, or send in a rebuttal comment. Commenters are not notified of the outcome of their comment other than by reviewing the Response to Comments document. This practice is what most other consensus standards organization use.

The task force made the following observations –

- Some comments were tabled until the next version of the Standard (the expert committee can do this)
- Some comments were given in public forum but not submitted on the form. Others didn't use the form.
- This was our first time through the process as developed. People may have been frustrated because they didn't understand how it was supposed to work.
- Perhaps there needs to be a "sanity check" by the CSDB or an editorial board such as that used by ASTM and other standards development group.
- There is no obvious feedback mechanism to let members who submitted comments know why their comments were rejected (or, for that matter, accepted). It might be helpful to add another step in the process to allow the member ship to review changes that were made to the Standard after the committees consider comments.

3. Three SOPs govern the standards development, review and approval process and these SOPs were not prepared to work in concert.

The standards development process, started before the formation of TNI, assumed that once an expert committee had approved a standard, the work was done. With the formation of TNI in 2006, two additional steps were added to the process, a review for suitability to be performed by the Laboratory Accreditation System Executive Committee, and a vote to adopt into the NELAP program, performed by the NELAP Accreditation Council. Separate SOPs were developed for these other two steps. The current process does not allow for serious concerns about implementing the Standard to be considered until very late in the process.

The task force agreed that there are inconsistencies between these SOPs and at least 2 of them lack necessary detail with regards to work flow and timing. These SOPs should also be modified to reflect the recommendations of this group (if adopted). Therefore, the SOP revision should probably be the last step in this process.

4. Significant concerns from NELAP representatives were not given appropriate attention.

Several commenters submitted negative votes on particular issues that were ruled non-persuasive. The commenters generally did not indicate the serious nature of their concern, and given the

Correction Action Report - Attachment 1 cont. Key Findings for 2009 TNI Standard

feedback issues discussed in number 2 above, these issues were not escalated to the appropriate level until too late in the process.

Task force comments: At the time, there didn't seem to be any comments that were "show stoppers" from any ABs. Perhaps the LASEC review should be moved up in the process. The task force also spent time talking about the timing on the AC review. As the "customer", they may need to have a different kind of review, input, in addition to the regular membership review in standards development process. Perhaps some of these significant concerns were overlooked because of the sheer size of the job of reviewing the initial Standard. It should be easier in the future, when there are only a few changes to any particular Standard. Nevertheless, critical reviewers, such as ABs, should be reminded of the importance of their timely and thorough review. We should recognize that people, being people, can make mistakes. We need a system that is consistent, but we should build in contingencies, where we can, to allow us to address oversights or mistakes.

5. The NELAP Accreditation Council supports the consensus process, even if they disagreed with the language in the Standard.

Many concerns with the 2009 Standard were voiced by the Council, but every member voted to implement the Standard despite their concerns. This has resulted in the Standard not being implemented by some ABs.

The task force discussed the fact that this was the first time through the standards adoption process and most of the ABs were feeling the pressure to adopt a Standard, even with imperfections. This has been a learning process for all. The ABs are less likely to ignore potential problems and try to take the time needed to work through them.

6. The 2009 Standard was a significant change from the 2003 NELAC Standard. This resulted in over a thousand comments.

The committees were overloaded with comments and under pressure to complete their step of the process in a short time frame, and thus some comments may not have received the attention they deserved.

The task force agreed that the sheer volume of work on this first effort could have been overwhelming. As we were looking at the entire Standard, this could be expected. This situation shouldn't happen again.

7. Committees were not given clear expectations of what should or should not be in the Standard.

In 2005, when INELA decided on a new approach to the Standard, the committees were given responsibility for specific modules and volumes, and were directed to use ISO 17011 and 17025, but detailed guidance about both the organization and content of the Standard were not provided.

The task force agreed that the level of understanding of what was needed varied depending upon committee members and input from outside contributors. This can easily happen with volunteer committees. An editorial board or committee could provide overall guidance or be available to answer questions.

Corrective Action Report - Attachment 1 cont. Key Findings for 2009 TNI Standard

8. Many TNI Members were preoccupied with the combination of INELA and NELAC while the new Standard was being developed.

Most of the current leadership of TNI along with many other individuals were highly focused on the efforts that led to the formation of TNI in November 2006, and subsequently, on getting TNI up and running. This focus meant that the review of the Voting Draft Standard did not get the attention it deserved.

The task force had mixed feelings on this finding. In spite of all of the organizational changes that were going on at the time, there were a lot of comments and a lot of debate. Many things that could also have been "show stoppers" were fixed before they became problems. A few issues did slip through but there could have been a lot more.

9. ISO language was omitted by the Quality Systems committee in parts of the Standard because they felt it was not appropriate. Since the language was never put up for vote, and no one compared the TNI Standard to 17025, this was not caught until 2010.

The task force discussed the value of an editorial review to catch issues such as this. We discussed the ASTM and ISO process where there is a high level editorial committee that takes a "big picture" look at the Standards before they are put out for vote. This is different than the Uniformity of Standards review that we do and more like the review our policy committee does for SOPs and internal policies.

10. Each expert committee operated independently which resulted in a lack of coordination and uniformity between the Standards.

This was not a major factor but we recommend that the CSDB EC take a look at this to determine whether there is anything they can do to improve communication and coordination between the expert committees.

Corrective Action Report - Attachment 2 Development and Implementation of TNI Standards for NELAP

Development and Implementation of TNI Standards for NELAP

Pre-Draft Work Stakeholder comments addressed Committee solicits and groups comments and any parking lot items - there Input requested from LASEC and AC would have to be a public notification, website and/or email blast Working Draft Standard written Committee addresses and adds or edits according to parking lot items and comments received WDS presented publicly for stakeholder Stakeholder comments addressed comments WDS modified as a result of stakeholder comments Modified WDS presented publicly for Stakeholder comments addressed stakeholder comments VOTE -- Voting Draft Standard - Public Vote Committee takes in any comments from the vote and addresses Comments addressed publicly Stakeholder comments addressed Interim Standard written Standard presented to LASEC and AC for input Comments and edits from the Voting Draft Standard vote are incorporated into the Interim Standard Interim Standard sent to Standards Review Council Interim Standard revised based on feedback, if needed Review and approval by editorial board VOTE -- Interim Voting Standard -- last public vote Stakeholder comments addressed Committee takes in any comments from the vote and addresses Final Standard --Revisions made based on comments and Final Standard and Response to Comments document published. Final review for suitability by LASEC Adoption by NELAP AC

Corrective Action Report - Attachment 3 TNI Corrective Action Committee Proposed Modifications to SOP-2-100 (Procedures Governing Standards Development)

June 2012

5.2 Working Draft Standard

5.2.1 Before starting preparation of the Working Draft Standard (WDS), Expert Committees publish a notice of Intent to Prepare or Revise a Standard, which invites stakeholders to provide input.

Those stakeholder groups who may subsequently adopt the standard (e.g., the NELAP Accreditation Council; and the Laboratory Accreditation System Executive Committee) will also be asked for their input.

Formatted: Font: Not Bold

- During the approximately six-morth period preceding a TNI semi-annual meeting, the Expert Committees develop modules of a working draft standard. The Committee Chair may delegate the standard-writing process to the Committee Members or to any task group formed from the Committee Members, Affiliates and Associate Committee Members. All Committee Members, Affiliates and Associate Committee Members are afforded the opportunity to contribute to the standard-development process. All stakeholder input is gathered and considered in the standards-writing process. If the WDS will be an update of an existing TNI standard, any stakeholder input provided since the adoption of the original standard will also be considered.
- | 5.2.22 An official vote of the Committee Members, with at least two-thirds of the members in concurrence, is required for release of the working draft standard by an Expert Committee for publication. The working draft standard is published at least thirty (30) days prior to the TNI semi-annual meeting at which it will be discussed.
- 5.2.41 The working draft standard is discussed publicly at the TNI semi-annual meeting. At this time, any TNI member or any member of the public may propose changes from the floor for consideration by an Expert Committee, and may also submit to the committee written comments within fifteen (15) days following the meeting.
 - 5.2.5 Within ninety (90) days following the close of the above comment period after the TNI semiannual meeting, an Expert Committee may modify the working draft standard based on comments received during the public debate and those received within the fiteen (15) day timeframe following the TNI semi-annual meeting. The Committee Members vote to accept the Modified Working Draft Standard (MWDS). A two-thirds favorable majority vote of the Committee Members is required for passage.
 - 5.2.6 The MVVDS is published at least thirty (30) days prior to the next TNI semi-annual meeting at which it will be discussed.
 - 5.2.7 The MWDS is discussed publicly at the TNI semi-annual meeting. At this time, any TNI member or any member of the public may propose changes from the floor for consideration by an Expert Committee, and may also submit to the committee written comments within fifteen (15) days following the meeting.

5.3 Voting Draft Standard

5.3.1 Within ninety (90) days following the close of the above comment period after the TNI semi-annual meeting, an Expert Committee may again modify the working draft standardMWDS, from consideration of the comments received during the public debate and those received within the fifteen (15) day timeframe following the TNI semi-annual meeting. The Committee Members vote to accept the newmodified working draft standardMWDS. A two-thirds favorable majority vote of

Corrective Action Report - Attachment 3 cont. TNI Corrective Action Committee Proposed Modifications to SOP-2-100 (Procedures Governing Standards Development)

- the Committee Members is required for passage. The $\frac{\text{working draft standard} | \underline{\text{MVWDS}}}{\text{MVWDS}}$ then becomes the TNI Voting Draft Standard $\underline{\text{(VDS)}}$.
- 5.3.2 All Committee Members, Affiliates and Associate Committee Members may vote on their committee's modules of the Voting Draft Standard. Each Committee Member, Affiliate and Associate Committee Member has one vote. All voting is conducted by electronic ballot.
- 5.3.3 At least fifteen (15) days prior to voting, the Voting Draft Standard is published, together with an electronic ballot form. TNI shall indicate conspicuously on the ballot that negative votes should be accompanied by written comments related to the proposal and that negative votes unaccompanied by such written comments will be recorded as "hegative without comments" without further notice to the voter. Such ballots, however, will not be counted as either negative or positive. TNI is not required to solicit any comments from the negative voter.
- 5.3.4 At least fifteen (15) days after publication of the Voting Draft Standard, the voting period for ballots shall begin. The voting period shall last for thirty (30) days. Early voting will be permitted; i.e., all votes cast from the date of publication of the electronic ballot form up to forty-five (45) days after the date of its publication will be accepted. Each Committee Member, Affiliate and Associate Committee Member will vote on one of the following positions:
 - Affirmative
 - · Affirmative with comment
 - · Negative with comment
 - Abstain
- 5.3.5 A negative vote may be withdrawn at any time by written electronic submission to TNI. The voter shall instruct TNI if the withdrawn negative is to be changed to an affirmative vote or to an abstention.
- 5.3.6 In order for the Voting Draft Standard to pass, an affirmative vote of at least two-thirds of the Committee Members is required, and all written comments accompanying votes cast by Committee Members, Affiliates and Associate Committee Members must be considered and brought to resolution as described below (Sections 5.3.7, 5.3.8 and 5.3.9). Ballot items returned as negative without comment shall be recorded as negative without comment. Ballot items returned unmarked shall be considered as unreturned ballots.
- 5.3.7 All written comments accompanying negative or affirmative votes cast by Committee Members, Affiliates and Associate Committee Members shall be recorded and considered publicly during the next TNI semi-annual meeting. Each Expert Committee will meet in separate session to consider those comments received on its modules of the standard. These meetings will be open to the public. Following its discussion, each written comment shall be ruled persuasive or non-persuasive by a simple two-thirds vote of the Committee Members present. No written comment shall be dismissed because it does not provide alternative language or a specific remedy to the negative vote. The committee may, subject to the restrictions in 5.3.8, prioritize the comments and may place any comments on hold until the next revision cycle of the standard, if the comments are too numerous to be dealt with in the time-frame available until the TNI Standard is published. Any comment placed on hold must be addressed during the next revision cycle of the standard and must be recorded and considered as a comment at that time.
- 5.3.8 An Expert Committee may prioritize the comments received and may place a comment on hold until the next revision cycle of the standard if all of the following conditions are met:
 - The comment would introduce a concept that had not been subject to public review by being
 included in a related proposal as published in the Voting Draft Standard.

Corrective Action Report - Attachment 3 cont. TNI Corrective Action Committee Proposed Modifications to SOP-2-100 (Procedures Governing Standards Development)

- The comment would change the text proposed by the Expert Committee to the point that the
 Expert Committee would have to restudy the text of the Voting Draft Standard
- The comment would propose something that could not be handled properly within the time frame for processing the changes.

In making the determination whether to place a comment on hold, the Expert Committee may consider relevant factors, including but not limited to: the extent to which the comment proposes a change that is new and/or substantial; the complexity of the issues raised; and whether sufficient debate and public review have taken place. The negative commenter must be informed, in writing, of the reasons the comment has been placed on hold.

- 5.3.9 A persuasive negative vote or an objection received from a member of the public will require the Expert Committee to consider whether modification of the Voting Draft Standard is appropriate. The committee may modify the standard, if such modification will lead to removal of the cause for the negative vote. The modified standard must then be made available through publication on the TNI website, together with a Response to Comments document summarizing all persuasive and non-persuasive votes and their resolution, and any objections received from the public and their resolution, for all Committee Members, Affiliates, Associate Committee Members and the public to review. Within fifteen (15) days of this publication, any Committee Member may change his or her vote, providing written electronic notice to TNI. The vote is then re-tallied and, in order to pass, requires an affirmative vote of at least two-thirds of the combined affirmative and negative votes cast by Committee Members. Within fifteen (15) days the tally from the vote on the Voting Draft Standard is published as: number of affirmative votes; number of persuasive negative votes; number of non-persuasive negative votes; number of abstentions.
- 5.4 Interim Standard
- 5.4.1 If the Voting Draft Standard passes, it becomes the Interim Standard. If any module fails, it is returned to the Expert Committee for processing during the next revision cycle. All individuals who provided votes or who submitted public review comments that were ruled non-persuasive shall be so notified and shall be informed of their right to appeal. Any appeals registered with TNI must be considered in accordance with Section 6 of this Policy.
- 5.4.2 The Interim standard shall be presented for further input to those stakeholder groups who may subsequently adopt the standard (e.g., the NELAP Accreditation Council; and the Laboratory Accreditation System Executive Committee). As a result of this input the Expert Committees may further modify the Interim Standard.
- 5.4.3 The Interim Standard shall be submitted to the Standards Editorial Board Standards Review

 Council for review and approval. The Editorial Board may recommend further changes, which will be incorporated prior to the Board's approval.
- 5.4.4 If the Interim standard has been modified, the Committee Members vote to accept the modifications. A two-thirds favorable majority vote of the Committee Members is required for passage.
- 5.4.5 The Interim Standard undergoes the voting process described in Section 5.3.1 through 5.3.6 above.

Formatted: Font: Not Bold

5.45 TNI Standard

Corrective Action Report - Attachment 3 cont. TNI Corrective Action Committee Proposed Modifications to SOP-2-100 (Procedures Governing Standards Development)

- If the Voting DraftInterim Standard passes, it becomes the TNI Standard. If any module fails, it is returned to the Expert Committee for processing during the next revision cycle. All individuals who provided votes or who submitted public review comments that were ruled non-persuasive will be so notified and will be informed of their right to appeal. Any appeals registered with TNI must be considered in accordance with Section 6 of this Policy.
- 5.4.45.2 The TNI Standard is made available to all interested parties, including standards-adoption organizations.
- 5.4.25.3 If any appeal is upheld by the appeals panel, the affected module or section of the TNI Standard is withdrawn by the Expert Committee that developed that module or section for processing during the next revision cycle.

Attachment 3 PROGRAM REPORTS

CONSENSUS STANDARDS DEVELOPMENT

- Following TNI Board of Directors' approval to form two new quality systems expert committees
 (Radiochemistry and Microbiology), the Radiochemistry Expert Committee has already been formed
 by Bob Shannon, being based mostly on membership of the previous Quality Systems subcommittee.
 A charter has been written and the Committee has already held three meetings. Robin Cook is
 waiting to hear back from those who signed up for the Microbiology Expert Committee during the
 August Environmental Measurement Symposium to find out if they are still interested. It will be
 necessary to determine their interest groups to assure balance on the new committee.
- The recommendations of the Corrective Action Committee on standards development were accepted
 and discussed by the Consensus Standards Development Executive Committee (CSDEC) during the
 August Environmental Measurement Symposium. The CSDEC will now work on modifying SOP 2100 (Procedures Governing Standards Development) to incorporate the recommendations.
- The Proficiency Testing WDS for V1M1 (laboratory volume) and V2M2 (AB volume) was presented and discussed during the August Environmental Measurement Symposium. Based on the discussion, rather than repeat laboratory requirements in V2M2, that module will reference back to V1M1 by adding "The primary AB shall require applicant laboratories to meet the PT requirement as specified in V1M1". There was discussion on whether to continue PTs by technology rather than method (as required by EPAOW), but the consensus was to stay with technology. In V1M1 There was concern that a laboratory could not submit a PT result outside the routine PT schedule, and the Committee will revisit this and clarify the requirement of passing 2 out of 3 PTs. There was a preliminary discussion of V3 (requirements for PT providers) and a WDS for V3 is slated for discussion during the next Forum (January 2013).
- Subsequent to a meeting with EPA staff, the Chemistry Expert Committee (formerly the
 Environmental Measurement Methods Expert Committee) is editing the 40CFR Part 136 MDL
 procedure (Appendix B). It was agreed at the meeting, in order for EPA to make changes to
 Appendix B without many years of more data gathering (with no guarantee of a useful outcome), the
 best that could be done would be an edit of the MDL procedure that would be within the bounds that
 the number obtained could still be called a MDL. The Committee is also modifying its draft calibration
 standard following input received when it was presented as a WDS at the August Environmental
 Measurement Symposium.
- The Laboratory Accreditation Body Expert Committee will present its recommendations on third-party assessors to the TNI Board. It will be suggested to proceed in incremental steps, starting with a simple list of individuals or ABs that wish to be known as available for third-party assessor work. This straightforward task can be accomplished fairly quickly and will be helpful to ABs. Further steps may be undertaken later, depending on need and resources available. The use of surveillance assessments continues to be discussed, though most ABs do not favor changing the standard to 5 year reassessments with surveillance assessments (every 2 years at most) in between. It has been suggested using the drinking water 3-year requirement as a benchmark (compliance with federal regulation) while defining surveillance assessments so that use of modern electronic tools (videoconference, for example) to clarify what might be acceptable, and formalizing decision criteria about severity of findings for use in determining how exhaustive a surveillance audit should be.
- Modified SOP 2-100 (Procedures Governing Standards Development) and SOP 2-101 (Procedures for Expert Committee Operations) have been modified and are currently with the Policy Committee. Further modifications to SOP 2-100 are contemplated as a result of the Corrective Action Committee's recommended changes in the standards development process.

NEFAP

NEFAP Executive Committee

- The committee has not met since DC.
- The chair (Marlene Moore) will be resigning from the committee in January 2013, but will be involved in the Recognition Subcommittee instead. There are other members rotating off at this time too, so the committee is putting a Nomination Committee together to get ready for this transition.
- NEFAP is in the process of pulling together the first Recognition Subcommittee. Marlene is waiting to hear back from a few candidates.

Field Activities Expert Committee (FAC)

- The committee has not met since DC.
- Ilona will be working with Justin to begin work with a subcommittee to develop a Quality Manual template for FSMOs. This will be underway by the end of September.
- There is no report yet on the subcommittee that was developed to look at the best way to accredit mobile labs and stand alone analytical instruments used in the field. Overlap with NELAP will be considered. (Note: Something similar was mentioned in DC during the NEFAP EC meeting. Need to discuss which committee will take responsibility for this concern.)
- The chair and the NEFAP EC chair still need to meet to discuss the placement of the "NEFAP Training Oversight Subcommittee". This subcommittee needs to work on written procedures on how to determine training needs and review training proposals submitted for review. Ilona will work closely with this subcommittee to expedite this process.

NELAP

Accreditation Council

- WETT TIA approved, for implementation August 1, 2012
- Agreed to improve consistency through a quarterly forum of NELAP assessors discussing assessment practices (in lieu of an AC meeting) likely to begin December 3, 2012
- Workgroup of 4 AB representatives reviewed all outstanding/unapproved SIRs with intent of clearing
 out the backlog of "needs discussion" items. The plan is to quickly approve as many as possible,
 return those that are poorly articulated (with explanation of why for the Expert Committee), and
 eliminate those that are not actually SIRs or delayed so long that they're no longer relevant. LAS EC
 is aware of this plan and will receive the package once full AC approves the small group's
 recommendations. Thanks to our Webmaster for creating a spreadsheet to facilitate this process!
- As requested by the LAB Expert Committee, provided feedback on surveillance assessments (extending from 2 to 5 years the full reassessment time.) Consensus was that time savings for the few large labs is overwhelmingly outweighed by the extra time expenditures that would be needed for the many small labs, and the likelihood that state travel approvals may become difficult to obtain without the 2-year mandate also weighed into that decision. Our EPA liaison continues to see clarification of the position of EPA Office of Water about a change in the assessment cycle timelines
- Responded to survey from ABTFII concerning NELAP AB's ability to "approve an NGAB to grant NELAP accreditations and the ability to accept an NGAB into the Accreditation Council. Further clarified for ABTFII that continued insistence upon AC involvement in TNI sanction or approval of NGABs to use the NELAP standard would threaten the stability of the existing NELAP program.
- Continues working with TNI's Database Administrator as he seeks to minimize the number of method codes in LAMS as the MUR implementation requires a considerable increase in this number

Implementation Status as of August 20, 2012

AB	Standard in Effect	Status/Progress		
CA	2003 NELAC	Will shift to 2009 standard as staff can be trained and the checklist approved		
FL	2003 NELAC	Not penalizing labs that choose to implement 2009 TNI. May have rule in place by July 2013, or wait for next version of standard. Accepting PT reports per 2009 TNI standard		
IL	2003 NELAC	Will incorporate by reference into regulations the next TNI Standard by reference when it is adopted by the NELAP AC. (a 2012 revision is expected.)		
KS	2003 NELAC	Moving forward slowly		
LA DEQ	2003 NELAC	Not penalizing labs that choose to implement 2009 standard. Labs seeking national accreditation will be cited for non-compliance with the common requirements of the Louisiana Administrative Code, 2003 NELAC standard and 2009 TNI standard. Anticipating public comment period this fall on regulation update which includes provision for adoption of the 2009 standard.		
LA DHH	2003 NELAC	Moving to 2009 standard, likely by 2013. Regulation is written and approval expected by December 2012		
MN	2003 NELAC	Not penalizing labs that choose to implement 2009 TNI. May skip 2009 TNI standard if standards development continues expected pace		
NH	2003 NELAC	Not penalizing labs that choose to implement 2009 TNI. Rulemaking expected to begin mid-2013		
NJ	Assessing to 2009 standard at present	Previously written rule is now being processed. Should take a few months to reach "proposal" stage, and then an additional 6 months to become final		
NY	2003 NELAC	Will incorporate by reference into regulations the next TNI Standard by reference when it is adopted by the NELAP AC. (a 2012 revision is expected.)		
OR	2009 TNI	Transition effective October 1, 2011		
PA	2009 TNI	Began assessing labs to new standard in October 2011; official transition date was July 2011, but needed to get checklists in place, etc.		
TX	2009 TNI	Transition effective July 2011		
UT	2009 TNI	Completed transition in fall 2011		
VA	2003 NELAC	Regulation development begun. Where the standards differ, gives lab "benefit of doubt."		

Laboratory Accreditation System Executive Committee (LAS EC)

- Standards Interpretation Request (SIR) process:
 - Changes have been made to the summary spreadsheet to include two new columns: the original question and the reason a SIR was not accepted or canceled. The summary is now being made available to more people and inclusion of this information helps put things in one place.
 - All SIRs were reviewed for status and any needed letters and reminders were distributed. The spreadsheet matches what is on the NELAP AC voting site and what the expert committee chairs should have for response.
 - There was 2 requests received in August and both were directly responded to and not added as a SIR. One was a method related question (forwarded to TAC for possible training topic) and the other was a question that needed to be directed to the inquirer's AB.

- The committee is reviewing the SIR SOP and looking for opportunities for improvement.
- The NELAP AC formed a subcommittee to review any open SIRs between 6-150. They are
 hoping to work through these as a group to speed up the response process on the older SIRs.
 LAS EC discussed this process in DC and some concerns were expressed if responses are being
 reworded.
- SIR Update:

Total Number of SIRs	SIRs Closed Out	SIRs in NELAP AC Voting Process	SIRs To Be Responded To: Quality Systems Expert	SIRs To Be Responded To: PT Expert	SIRs To Be Responded To: LAB Expert	SIRs Being Redirected
212	125	67	8 (160, 161, 171, 191, 195, 203, 214, 215)	6 (168, 176, 181, 184, 193, 202)	4 (200, 216, 136, 165)	(105, 110)

Note: 2 SIRs were originally given to the NELAP AC for a response and are now in the process of review to be placed into an expert committee for a response.

Note: The following SIRs were finalized and William is posting them on the website and removing them from the SIR Voting Summary - 27, 42, 63, 64, 66, 70, 72, 73, 75, 76, 77, 78, 79, 95, 96, 97, 109, 130, and 135. He is also removing 153, 155, 156 and 157. These SIRs were responded to as non-SIRs.

The committee is still working on updating the Standards Review SOP.

Technical Assistance Committee

- The committee discussed in July the review needs of highly technical training that is being proposed through the Education Delivery System (EDS). They are working on some wording to use as a disclaimer and will forward this information to Jerry when completed. They decided the training needs to be reviewed, but that the trainer should take responsibility for the technical content.
- Training Summaries are still being worked on. They are looking for someone to help with Microbiology and Asbestos.
- The committee has determined that an SOP for Assessor Training Credits at the Assessment forum is no longer needed.
- The committee has started work on the Assessment Forum and Mentor Session for the Denver meeting.

PROFICIENCY TESTING

PT Program Executive Committee (PTP EC)

- The Chemistry FoPT Subcommittee is finishing up their review of NPW analytes. The final table will need to be updated, voted on and then passed on to the PT Program Expert Committee for review and voting. The committee is seeking additional members in preparation of starting the review of the Solids table.
- E-mail addresses for state contacts are still needed so they can be contacted about the changes to the FoPT website. An option has been added to the site where people can automatically sign-up for updates.

- The committee has received a formal complaint on the process of communicating PTPA information to all states. This complaint is being worked on.
- The PTPA database subcommittee has not met since the DC meeting, but plans are to finalize the
 content needed for the PTP EC review, prepare a budget for each option to collect the information for
 the PTP EC review and report back to the PTP EC. The PTP EC will then review the options and
 prepare a recommendation for the TNI Board. Jerry is following up with A2LA on a concern raised in
 DC.
- A subcommittee has been formed to update and finalize all program SOPs. Ilona will be working closely with this subcommittee to expedite this process.
- The committee has not met since the DC meeting.
- The PTP EC Chair will be a part of both PTPA Evaluation teams.

ADMINISTRATION

Advocacy Committee

- Target publication date for the next newsletter is October 15. Lara Phelps is the editor.
- The Advocacy Committee is working with Jerry to finalize a guidance document on how to use the TNI standard to comply with the 12 essential QC elements required in the MUR. The guidance document will be a handout for the one hour webinar.
- The Advocacy Committee is working on an SOP regarding development and approval of TNI position statements.

Accreditation Body Assistance Task Force II

 ABTF II has determined that a separate approval and oversight body will be needed in order to approve NGABs to grant accreditations under the TNI standard. The ABTF II is requesting concurrence from the TNI Board before proceeding with further development of this approach. A summary of the ABTF II's findings will be discussed at today's meeting.

Policy Committee

- No meeting in August.
- All SOPs and Policies have been reviewed for status and format.
 - o 25 have been approved by the board,
 - o 25 are pending review by the policy committee,
 - o 12 are in draft form at the committee level, and
 - o 6 have been assigned a title and document number, but have not been drafted

Training

- The second Brown Bag Webinar occurred on July 27th. It has already been posted as a Webcast.
- Met with WebEx to talk through start-up glitches and the information will be used to continue to improve the Webinar process.
- WebEx was used during the DC meeting to allow people who could not attend the meeting to
 participate and see presentations that were utilized during a meeting. It was also used in the ELAB
 meeting so Board members, who could not see the presentation screen in the room, could see it on
 their computer screen.
- Compiled training surveys and summarized results to trainers.

 Working with William on notifications when webcasts are purchased so that training certificates can be prepared.

Conference Planning

2013 Denver Forum (1/14-17, 2013)

- Preliminary schedule developed
- Conference registration and exhibit fees established
- Registration to open on October 16

2014/15 Meetings

- RFP has been issued and proposals coming in
- Louisville appears to be leading choice, a New Orleans is in the mix
- Considering having 2015 meeting in same location as NELAC 1 (Crystal City, VA) in lieu of 20 year anniversary date

2012 Environmental Measurement Symposium - Washington, DC

- Presentations, biographies and abstracts are posted. All presentations were converted to PDF format.
- Working with Jan to compile information for Conference Proceedings (papers, updated abstracts with correct titles, etc ...).

2013 Environmental Measurement Symposium - San Antonio, Texas

- Steering Committee has met and plans for the conference theme and Call for Presentations is well underway.
- Website has been re-done to prepare for 2013.
- All instruction sheets have been updated for posting and/or incorporation into descriptions on the website.
- The tracking summary has been redesigned to hopefully allow the use of only one spreadsheet in tracking needed items for the conference.
- Call for Presentations and Exhibit Program will open in November

Membership Report

• Active Members: 856