

# TNI Board of Directors Meeting Summary July 11, 2018

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## 1. Roll Call

Directors	Present
Jordan Adelson	X
Aaren Alger	X
Steve Arms	
Justin Brown	
Bob Di Rienzo	X
Jack Farrell	X
Maria Friedman	X
Chris Gunning	X
Myron Gunsalus	X
Daniel Lashbrook	X
Judy Morgan	X
Cheryl Nolan	X
Patsy Root	
Debbie Rosano	
Scott Siders	
Alfredo Sotomayor	X
Dave Speis	
Lem Walker	X
Curtis Wood	
Past Chair	
Sharon Mertens	X
Staff	
Lynn Bradley	X
Carol Batterton	
Ken Jackson	X
Jerry Parr	X
Ilona Taunton	X
Janice Wlodarski	X

## 2. Approval of June 2018 Minutes

**Motion to Approve:** Judy Morgan

**Second:** Daniel Lashbrook

**Approved:** Unanimous

## 3. Implementing the 2016 Standard (Attachment 1)

An updated spreadsheet summarizing the activities that need to occur before the 2016 Standard can be implemented can be found in Attachment 1. This document will be updated every month for the Board to track progress on this topic. Good progress continues to be made.

#### 4. **Manufacturer Pre-packaged Reagents for Traceability**

The Board was notified of this issue in the June call. Lem Walker reached out to the manufacturer on June 25 and they responded that they would resolve the issue. The June minutes noted that this issue in general would be discussed in more detail at the July meeting.

As noted to Lem, the manufacturer was trying to retrieve their product from the laboratory, but was able to retain the lot number and had some of that with which to do quality testing. Nothing further has been reported back yet. We do not know if there was an attempt to recall the effected product.

Jack: There are two issues:

1. we can't trace product, or
2. we really can't determine the quality of materials or the materials that went into them.

And there is a bigger issue: Labs have standards they have to meet regarding measurement traceability. But Jack doesn't know if the vendors being used have those standard requirements. Laboratories should be evaluating vendors to make sure they are meeting those requirements. We need to be working with the vendors to make sure the product meets the standard/requirements.

Questions:

What should the Board do about it?

Does the AC need to do something?

Does a joint Task Force need to do something?

Are these companies accredited to an ISO standard or other quality management system?

Notifying laboratories about this issue is really important, as is giving assessors some guidelines, if they need them.

Should we make this an assessment forum topic for the next winter meeting? Yes. Placing an article in the next newsletter is also a good idea. Patsy would be a good author for the article (with Jack and Aaren).

#### 5. **China Update**

Jerry created a presentation that attempts to show how consensus standards, PT, ABs, and our training program all work together. This is very simplified presentation, not discussing LASEC, the PT Executive Committee etc., that are all internal processes. It would be good if the people that will be talking to the Chinese meet and edit and agree on the materials that will be sent to the Chinese. Robert Benz will schedule a call with the China group sometime in the near future.

Alfredo will also write up some suggestions on how we can work with the Chinese and share them offline before the teleconference.

#### 6. **Program Reports (Attachment 2)**

**Attachment 1  
2016 Standard Implementation Issues**

Action Item	Assigned To	Expected Completion Date	Status Update
<p><b>QAM Template Update</b> Create a template that will help laboratories prepare a QA Manual compliant with the new TNI Standard. Include multiple examples of documents, forms and procedures that might be helpful to laboratories.</p>	QS Expert Committee	12/31/17	Completed November 2017. Now on the website for \$115 for members.
<p><b>Post comparison document</b> A document detailing the changes between 2009 and 2016 was prepared in October. The website needs to be revised to allow individuals to access this document as well as the 2009 to 2003 comparison. Need to prepare document that summarizes changes between 2003 and 2016, since some are still using 2003.</p>	Jerry Parr and William Daystrom	1-22-18. No date determined for 2003-2016 document	2009-2016 document posted on website 1-22-18. New draft of 2003 to 2016 document completed and will be posted this week.
<p><b>Guidance Document - PTRL Issue</b> There is still an issue regarding the clarification and use of the PTRL. Include LASEC in final review of document. Small Lab Handbook will be helpful and could provide additional guidance.</p>	PT Expert Committee	05/25/18	The committee provided a draft on 5/4/18. Policy has reviewed and approved. Needs review by LASEC and AC.
<p><b>Update Standard Interpretation Requests (SIRs)</b> Review current interpretations from 2003 and 2009 Standard and map to new TNI Standard. Is an interpretation still relevant and if so, what is the section reference in the new standard? Keep legacy 2003/2009 SIR's active along with 2016. Relevant 2003, 2009 and 2016. Put folders on website. Long term review and consider whether SIRs trigger notes, annotations, or guidance. Archive old, obsolete SIRs.</p>	Expert Committees	08/10/18	Draft spreadsheet summarizing existing SIRs provided to Expert Committees
<p><b>SIRs</b> Set-up site for interpretation requests for the new TNI Standard.</p>	IT Administrator	03/01/18	Completed
<p><b>Can I Implement the New Standard Now?</b> LASEC? needs to prepare an answer to this question for a Training Workshop PPT slide. Consider preparation of guidance on how to move to the new standard - what do you need to add and when? What can you stop doing? Etc.</p>	LASEC	08/10/18	Assessment Forum for New Orleans will address this topic

Action Item	Assigned To	Expected Completion Date	Status Update
<b>Quality Systems Checklist - Laboratory Assessments</b> Checklist needs to be prepared for ABs to use during laboratory assessments.	Quality Systems	06/15/18	Checklist has been posted
<b>Quality Systems Checklist - Website</b> Revise the checklist web page to allow downloading either the 2009 or 2016 checklist	IT Administrator	06/15/18	Checklist has been finalized.
<b>LOD/LOQ Guidance</b> Will need LASEC and Policy review. Implementation date set after review by AC.	Chemistry Expert	06/15/18	Revised document has been sent to AC, LASEC, and Policy for review.
<b>Calibration Guidance</b> Needs LASEC and Policy review. Implementation date set after review by AC.	Chemistry Expert	06/15/18	Revised document has been sent to AC, LASEC, and Policy for review.
<b>New Standard Training Webinars</b> Make training on the new standard available to laboratories and ABs across the country. Roll out when we have an implementation date for 2016 standard.	CSDP EC	Fall 2018	4 webinars planned; one every 3-4 weeks beginning mid-August.
<b>Small Lab Handbook</b> Update Small Lab Handbook. Create a tool that will help laboratories prepare a QA Manual compliant with the new TNI Standard. Include multiple examples of documents, forms and procedures that might be helpful to laboratories. Work with Expert Committees to provide these examples. Policy committee review needed on current document.	QS Expert Committee	7/15/18	Final draft complete. Add Guidance documents as appendices.
<b>Implementability Issues</b> Review the final Volume 1 of the 2016 Lab Standard and the Volume 2 PT module as well. Each method/type module will be reviewed against the QS module to ensure no conflicts as well as implementability, and the administrative parts of the QS module (record keeping, document management, etc.) will be reviewed against Volume 2 for the same ends. Members without a specific module assignment are asked to review the entire Volume 1 for implementability and potential internal conflicts.	LASEC	03/05/18	Completed.
<b>Benefits of the New Standard</b> Prepare a document to show why the 2016 standard is an improvement over the 2009.	Expert Committees	6/7/2018	Complete

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## Attachment 2 PROGRAM REPORTS

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### CONSENSUS STANDARDS DEVELOPMENT

- The Asbestos Expert Committee has completed its “first pass” on drafting a proposed new version of V1M3. The module is being completely reorganized by technology, with separate sections on transmission electron microscopy; polarized light microscopy; and phase contrast microscopy. The old structure intermingled the techniques within sections for calibration, quality control, data acceptance etc., making it less “user-friendly” for a laboratory using just one of those techniques.
- The Chemistry Expert Committee has completed its guidance documents on Detection/Quantitation and Calibration and they have been submitted to LASEC for review and comment. The committee is preparing two 1-hour presentations on the guidance documents for inclusion in the assessment forum in New Orleans.
- The PT Expert Committee is focusing on completing its review of Standard Interpretation Requests. They are also in discussion with the Microbiology Expert Committee regarding some laboratories reporting greater-than values on their PT samples, since this will not be permissible with the new 2016 Standard. The PT Providers are being asked the methods where this is problematic. Looking ahead to the next standards development cycle, the issue of PT frequency will be revisited, and it will be a topic of discussion at the August meeting in New Orleans.
- The Laboratory Accreditation Body Committee has completed its review of the draft document, ISO 17011 with TNI language inserted. Additional items planned for review are the former 2003 NELAC Chapter 6 requirements that were dropped for the 2009 TNI Standard, to see if they need to be addressed, parking lot issues from the previous revision, and eight SIRs from the 2009 Standard as well as one from the 2003 NELAC Standard. Once the committee makes recommendations about how to handle those issues, it will be ready to publish an outline of proposed changes for comment from TNI members.
- Due to member conflicts, the WET committee is postponing its finalization of language to address the chemistry QA requirements in the revised module until the July meeting. Discussion of revisions to the scope of V1M7 as well as the IDOC/CDOC processes are getting underway. Plans to meet with ELAB or EPA, or both, about the WET PT issues at conference in New Orleans are evolving weekly, in the run-up to conference.
- The Microbiology committee is still planning a working lunch in New Orleans to discuss microbiology method code issues. They hope to include NELAP ABs and the EPA. The committee is starting work on the review of Technical Manager requirements as requested by the Quality Systems Expert Committee. The committee has started discussing an issue by email submitted by the PT Expert Committee: The new standard does not allow for greater than (>) value reporting. This will impact microbiology labs and the two committees need to start thinking about how to implement this change. The PT Expert Committee will be discussing this during their meeting in New Orleans. Guidance language may be drafted.
- The Quality Systems committee is continuing to review the 2016 Standard vs. ISO/IEC 17025: 2017 to prepare a crosswalk and to start moving language around to move the 2016 Standard into the new format. There was a lively discussion on Technical Director and the committee will be seeking more input on this topic before it will begin drafting language to update the Standard.
- The SSAS committee discussed Audit Sample Storage Conditions this month. This is an issue that has been raised and conversation will continue. The committee is reviewing DRAFT SOP 2-102 – SSAS Table Management. The committee will continue its previous discussions on expanding the SSAS Table and V1M1 Revisions in July.

## NEFAP Executive Committee

- Justin Brown and Paul Bergeron have been working on the first Mobile Laboratory Task force. A doodle was distributed and the first meeting will be planned in the next two weeks.
- The vote for NEFAP EC membership has been completed. The new membership includes:

**Geneva Bowman**, Other  
AIHA Laboratory Accreditation Programs

**Pam Hamlett**, Other  
US Air Force

**Jeff Buystedt**, FSMO  
City of Bend

**Janis LaRoux**, FSMO  
H&P Geochemistry

**Jeremy Driver**, FSMO  
Alabama Power

**Norman Rodriquez**, Other  
US EPA Region 3

**Jacob Gruzalski**, FSMO  
Environmental Standards

The new membership information has been forwarded to the Chair of the TNI Board for approval.

- Kirstin Daigle has been nominated as Chair and Tracy Szerszen as Vice Chair. Voting is being completed by email and will conclude this Friday.
- The committee will continue to focus on Marketing/Strategic Planning over the next few meetings. This effort will now be led by Justin Brown.
- The committee has delayed the review of the Field Activities Expert Committee (FAC) DRAFT Scope Guidance Document. It will be reviewed after New Orleans.
- The old FAQ document review will be added to the next meeting agenda.
- The committee received a complaint about FSMO assessment frequency. The Complaint Subcommittee has started working on this issue. The subcommittee was approved by the complainant – there were no conflicts of interest raised.
- The committee will assist in the preparation of the FAC presentation planned for Wednesday afternoon in New Orleans.

## Field Activities Expert Committee (FAC)

- Shannon and a subcommittee prepared a first DRAFT, putting the current Field AB Standard into the new ISO/IEC 17025:2017 format. The committee is reviewing this first attempt and is reviewing a similar document LAB has been working on. Comments are due mid-July to Shannon so the subcommittee can update the DRAFT.
- The FSMO Tools Subcommittee will likely not meet until the completion of the new Standard or if there are any additional tasks determined by the NEFAP Marketing/Strategy Subcommittee.
- The committee will start working on the presentation for the Wednesday session in New Orleans. They will seek input from the NEFAP EC.

## NELAP

### Accreditation Council

- Effective June 18, the Council passed a motion to adopt the 2016 TNI Environmental Lab Sector Standard, with stated intent to set an implementation date once all guidance documents are approved.
- The Council will respond to the PT Expert Committee with several comments on its guidance on PT Reporting Limits. The revised two chemistry guidance documents arrived the day before the July meeting, and are in review.
- For the current round of evaluations, thirteen letters will have been issued with six recognition renewals approved, including the new AB Oklahoma (making seven total approvals). Six applications are in various stages of review with one renewal recommendation pending approval by the NELAP AC. The remaining renewal letter goes out in October of this year.
- Paul Bergeron has been re-elected as Vice Chair of the Council, per the new General Operations SOP 3-100. The NELAP Decoupling Policy 3-102 has been approved and will be forwarded for Policy Committee review.
- As follow-up to the June Board meeting, the AC Chair has asked that AB representatives begin compiling lists of individual state requirements of laboratories that are not included in the standard, so that they can be shared with the various expert committees later this year.
- AB representatives will discuss LASEC's Lessons Learned document over the following several months, and provide written comments on the items where the NELAP AC is identified as having a role.

### Laboratory Accreditation System Executive Committee (LASEC)

- Planning for the Mentor Session and Assessment Forum session in New Orleans is nearing completion.
- LASEC continues reviewing the PTRL guidance document, and any additional comments received will be shared with the PT Expert Committee. They also received the Chemistry Guidance documents and will be reviewing those. LASEC discussed CSDEC's comments in response to the Lessons Learned document, and shared those with the NELAP AC. Once the AC's contributions are received, this document will be provided to the Board with LASEC's recommendations, if any.
- LASEC approved its Conflict of Interest SOP 3-113, which was provided to Policy Committee for review. Changes to address Policy's comments were approved at the June meeting, so that the final version will be presented to Policy Committee in July.

#### Standard Interpretation Request Quarterly Report

Total	Closed Out	At LASEC	At NELAP AC	At Expert Committee
323	303	1	9	2

*Note: We have started receiving SIRs for the 2016 Standard.*

## PROFICIENCY TESTING

- The NELAP AC has raised questions about the PCB footnote that was added in response to an Analyte Request Application (ARA) that was completed recently. Proposed wording from the NELAP AC was received and reviewed by the committee. After extensive conversations with NELAP ABs, PT Providers, PTPAs, the Chair of the Chemistry FoPT Subcommittee and PTPEC members and associates, the committee voted that the ARA cannot be accommodated to the submitter. There are

changes that can be updated during the next Standard update that would help and Nicole (Chair, PT Expert Committee) has been involved in the discussions. This ARA will be closed out without any changes being made.

- The FoPT Table Format Subcommittee has finished up the tables to include CAS numbers and an initial attempt at lining up nomenclature with LAMS. There were some analytes highlighted where the subcommittee would like LAMS to consider making a change. Maria has not received an update from Dan Hickman yet, so this topic was tabled to July. Craig is also hoping to meet with Rami to finish up the WET table. There is some concern that LAMS will need some updating to accommodate WET.
- The PTP/NEFAP Evaluation Workgroup: The subcommittee working on the combined language is incorporating Policy Committee comments and recommended changes before the next two Executive Committee meetings. The subcommittee is meeting on Thursday.
- The Microbiology FoPT Tables (DW and WW) were updated to reflect the changes being recommend by the Microbiology FoPT Subcommittee in response to the MPN Analyte Request Application (ARA). The subcommittee realized they missed something upon review and will be providing an additional update. Maria has requested analyte codes from Dan Hickman to finish up the tables and found out that the IT Committee is trying to decide how to add analyte codes. This will delay this request.
- The committee finished the update of SOP 4-102. The formatting will be finalized and the SOP will be sent to Policy for final approval.

## **ADMINISTRATION**

### **Advocacy**

- The Advocacy committee has identified the panelists for the discussion on “The Value of Accreditation” at their meeting in New Orleans. Panelists will be Stephanie Drier, Christine Sotelo, Curtis Wood, and Ron Coss. The panel discussion will be held on Friday, August 10, at 9:00 am.
- The committee approved the final version of a position statement on Quality Systems, which will be forwarded to the Policy Committee.
- The committee approved the article prepared by Jerry comparing the 2003 and 2009 TNI Standard to 2016. The article is ready to be posted on the website.

### **Policy Committee**

- Policy Committee has begun discussing the need for a TNI sexual harassment policy, and what the scope and content of this policy should encompass. They are also gearing up to implement the annual internal audits for each TNI committee, as required by the TNI Quality Management Plan. These will likely take place in the fall, so that the results can be presented at the TNI Annual Meeting, at conference in Milwaukee. The database needed for compiling the results of these audits is complete, except for being updated to include new policies and SOPs approved by Policy and the Board during the past year.
- Policy completed five-year reviews of the remaining four policies. Three policies received minor editorial changes, which are itemized for the Board, as noted below. Board approval is not required, unless particular items are considered worthy of additional attention. The fourth policy, Training POL 1-116, will need a substantial rewrite, due to the substantial expansion of TNI's educational delivery system. The updated policy will be provided to the Board for review when completed.



- *Open Meetings POL 1-110* – This needs format updating to correct the program to “Administration.” Since the new Board Attendance POL 1-126 references this document and is effectively subordinate to it, there is no need to add 1-126 as a reference. The review date will be noted in the “approved changes” box.
- *TNI Travel POL 1-112* – The program was updated to “Administration” and the Travel Procedures SOP 1-119 added as a reference. In the third paragraph of §I, everything but the first sentence is deleted, since this information is in the related SOP. The version number was increased to 1.2 and the review and effective dates changed accordingly.
- *Code of Ethics POL 1-125* – This policy addresses governance of TNI, whereas the TNI Code of Ethics document is intended for all members. Only minor edits are needed: The program is changed to “Administration”; in the first paragraph under §III, Governance, the word “oversight” is replaced with “overseeing” to maintain parallel construction; a superfluous “and” after the second bullet in the first set of bullets is deleted; “Form 990” becomes “IRS Form 990” for clarity; and the “approved changes” box was added with these edits and the date made noted.
- One Policy Committee SOP remains to be reviewed, likely at the July meeting. Other TNI committees will need to be reminded that five-year reviews of policies and SOPs initiated by those groups should be initiated.

## **Training**

- A number of new training courses are being worked on:
  - Sample Collection (Silky Labie – A final date for the course is still forthcoming based on a trip to Florida to help with the recording of this training.)
  - Good Laboratory Practice – Internal Audits (Matt Sica). This is a self-paced course that gives a great overview on internal audits and provides examples on how to organize an internal audit program. There was a hold-up with their recording, but it appears it is just about complete. Ilona is working on the posting/flyer information this week. The class should be up within the next week. This will be a pilot to determine whether more classes like this will be added.
  - There will be a full day course in New Orleans in August – Understanding Radiochemistry Testing and the TNI 2016 Standard – ASTM D7283 and EPA 906.0 (Liquid Scintillation Counting).
  - Marlene is planning a Microbiology Assessor training by webinar in September or October. The formal proposal has not been received yet.

## **NGAB**

- Ilona attended A2LA’s APLAC exit meeting.
- Ilona met with IAS (new NGAB applicant) to begin review of their application and attend their APLAC exit meeting. Ilona is working with Lynn to find a NELAP AB for the evaluation team.

## **NEMC**

- Hotel and conference registrations are continuing to come in ahead of last year’s numbers. The deadline for early registration is July 16.
- We currently have 151 oral presentations and 45 posters.
- Twelve abstracts have been received and accepted for the Technology Showcase.

- There are 54 confirmed exhibitors who have purchased a total of 61 tables. The vendor lunches are all full.
- We have around 550 registrations and the hotel room block is at 95%. The hotel added an extra 300 rooms to our block.
- The Science Communication training was cancelled because of lack of registrations.
- The radiochemistry training course has 19 attendees.
- The steamboat cruise has 170 attendees as of July 9.

**Membership**

- **Active Members:** 1041