

# TNI Board of Directors Meeting Summary

## January 9, 2019

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### 1. Roll Call

Directors	Present
Jordan Adelson	X
Aaren Alger	X
Steve Arms	X
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	X
Lem Walker	
Curtis Wood	
Past Chair	
Sharon Mertens	X
Staff	
Lynn Bradley	X
Carol Batterton	X
Ken Jackson	
Jerry Parr	X
Ilona Taunton	X
Janice Wlodarski	X

### 2. Approval of December Minutes

**Motion to Approve:** Judy Morgan

**Second:** Dave Speis

**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. Progress is being made on the PT provider issue with resolution expected later this month.

### 4. Change in Committee Membership Requirements

As discussed in the October Board call, due to the Eurofins acquisition of TestAmerica, the Board asked the CSPD Executive Committee discuss how this could impact TNI committee operations since our current SOPs only allow one individual from an organization to serve on a committee. The committee is recommending SOP 2-102 be revised to allow more than one individual to serve and

developed the language below. Conforming changes will also need to be made to any other SOPs that discuss committee membership.

*Organizations may have more than one Committee Member on an Expert Committee. An organization is a company, state government, EPA Program/Office/Region, or other federal agency.*

*As TNI and all Committees are striving for diversity within all Committees, membership should preferentially reflect volunteers who are representative of all sectors of the accreditation community. While balance/lack of dominance by any stakeholder group must be ensured, Committee Chairs and the CSDEC Chair will further ensure, through the membership nomination and approval process that the overall interests of all members of the accreditation community can be maintained.*

*The CSDEC Chair and applicable expert committee chair(s) on January 1 of each year (the beginning of any new terms or conclusions of terms for current members), will review expert committee membership rosters to ensure balance/lack of dominance, general make-up of the committees and appropriate representation by the overall accreditation community.*

Discussed: No more than 2 members from the organization may participate on the same committee unless special permission has been obtained from a higher committee (BOD).

## 5. General Data Protection Policies and Procedures

The Policy committee has approved a personal data Policy 1-127 and SOP 1-123 to get TNI in compliance with the General Data Protection Regulation in Europe. (This is something our vendors are asking for.) Concurrent with this effort, our IT Administrator has established an on-line description of this policy for TNI in general and for NEMC in particular. You can preview these here:

<https://nelac-institute.org/content/privacy.php>

<https://nemc.us/privacy.php>

These webpages are very extensive and detailed and have been reviewed thoroughly by TNI's Executive Director, Lynn Bradley and Suzanne Rachmaninoff. Such policies are cropping up in most organizations. The Policy and SOP were created to accompany these web pages and require review and approval by the Board.

**Motion to Endorse the Policy 1-127:** Jack Farrell

**Second:** Curtis Wood

**Approved:** Unanimous

**Motion to Endorse SOP 1-123:** Dave Speis

**Second:** Jack Farrell

**Approved:** Unanimous

## 6. Quality Systems Position Statement (Attachment 2)

The Policy Committee has approved the position statement developed by Advocacy. See Attachment 2. As required by SOP 1-118, this document does require review and approval of the Board.

There was discussion about where to use "Quality System" or "Quality Management System" – we will keep it to "Quality System" because this is what is in the Standard.

Other comments: Blue box at the top – the last word is covered up. Just need to fix that. Also inconsistent spacing issue to fix.

**Motion to Endorse Quality Systems Position Statement:** Steve Arms

**Second:** Myron Gunsalus

**Approved:** Unanimous

## **7. California Update**

California released their revised proposed rule on December 18. TNI has provided minor comments addressing the legal name of TNI, reporting results from satellite and mobile laboratories, and verification of pesticide identities. The revised proposed rule retains the use of the 2016 TNI Standard except for one PT sample per year and the qualifications of the technical manager. A public hearing is scheduled for January 15.

## **8. Program Reports (Attachment 3)**

**Attachment 1  
2016 Standard Implementation Issues**

<b>Action Item</b>	<b>Assigned To</b>	<b>Expected Completion Date</b>	<b>Status Update</b>
<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.</p>	Jerry Parr and William Daystrom	06/15/18	2009-2016 document posted on website 1-22-18. New draft of 2003 to 2016 document completed.
<p><b>Guidance Document - PTRL Issue</b></p>	PT Expert Committee	10/15/18	Committee has revised and sent to 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	11/18	Article on this topic published in November newsletter.
<p><b>Quality Systems Checklist - Laboratory Assessments</b> Checklist needs to be prepared for ABs to use during laboratory assessments.</p>	Quality Systems	06/15/18	Checklist has been posted

Action Item	Assigned To	Expected Completion Date	Status Update
<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>Calibration Guidance</b> Needs LASEC and Policy review. Implementation date set after review by AC.	Chemistry Expert	1/15/2019	Policy Committee has approved
<b>LOD/LOQ Guidance</b> Will need LASEC and Policy review. Implementation date set after review by AC	Chemistry Expert	1/31/2019	Reviews still underway.
<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	11/7/18	4 webinars completed
<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.	QS Expert Committee	7/15/18	Posted 10/7/18.
<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
<b>PT Provider Issues</b> Resolve issues surrounding scoring to the 2016 Standard and evaluation of PT Providers to Volume 3.	PTPEC	2/1/2019	

## Attachment 2 Quality Systems Position Statement

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### The NELAC Institute (TNI) Position Statement The Quality Systems Approach to Accreditation

All Environmental Laboratories, Field Sampling and Measurement Organizations, Proficiency Test Providers, Proficiency Test Provider Accreditors and Accreditation Bodies should conduct their operations according to and be evaluated and accredited using a quality systems approach. As defined in the TNI standards, a Quality System is “A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required quality assurance (QA) and quality control (QC) activities.” (EL-V1M2-ISO-2016-Rev2.1: *Quality Systems General Requirements*)

#### INTRODUCTION

Virtually all environmental measurement activities in the United States originate with the federal, state or tribal statutes and regulations. Historically, these regulations have focused on efforts to ensure consistency and technical competence among organizations that conduct these activities by requiring adherence to specified testing protocols. While this approach can serve environmental data needs in a narrow context, the broader need for data of known and documented quality, customer service and quality improvement demands a more comprehensive approach to quality in the environmental testing community.

#### BENEFITS OF A QUALITY SYSTEM

A quality system benefits the environmental laboratory or sampling organization, its customers and the end-users of environmental data by helping to ensure the organization has the managerial, human, physical and technical resources to consistently produce data of known and documented quality in support of decisions that affect the environment and public health. An effective quality system provides confidence as to the consistency, effectiveness and efficiency of the organization. It establishes the overarching principles that guide all other quality assurance and quality control practices, which, when integrated with the applicable technical and analytical specifications, will meet the needs of all interested parties. Furthermore, organizations that support, oversee, or accredit environmental laboratories or sampling organizations will also benefit in similar fashion by instituting a quality system.

An effective quality system can be implemented by an organization of any size. Ultimately, having such a system will reduce errors that can jeopardize compliance. The result of adopting the principles and practices of a quality system such as the TNI Standard is improved standardization of operations and data quality with increased confidence in the safeguarding of public health and the environment.

Once an organization implements a quality system, it is then a fairly easy step to become accredited to the TNI Standard. Taking this next step will provide the following benefits to organizations and oversight bodies:

- Formal recognition of testing competence from an authoritative independent body;
- National recognition for data produced that is of a known and documented quality;
- Continued compliance with requirements through external assessment of the laboratory's implemented quality system;
- Identification and management of risks for laboratory capability and products/data through internal assessments performed by the laboratory;
- A marketing advantage for commercial laboratories; and
- Consistency among accreditation bodies.

#### RECOMMENDATIONS

- TNI's standard is an essential element of an accreditation system which provides the laboratory, field sampling and measurement organization, proficiency test providers, Proficiency Test Provider Accreditors, client, regulator, or accreditation body with confidence in an organization's data.
- TNI will continue to promote the adoption of its quality system standards and principles by all environmental testing organizations regardless of accreditation status.
- TNI will continue to encourage state regulatory agencies and laboratory clients to require testing organizations to adopt quality systems.
- TNI will continue to create tools and training to facilitate documentation and implementation of quality systems.

#### ACKNOWLEDGEMENTS

TNI Quality Systems Committee

TNI Advocacy Committee

#### RESOURCES

The Benefits of Laboratory Accreditation, Judy Morgan, Environmental Science Corporation, January, 2009; Presented to the Forum on Laboratory Accreditation in Miami, FL

How NELAC Accreditation Improves Laboratory Operations, Nan Thomey, Presented at the TCEQ Trade Fair, May 2010

TNI EL-V1M2-ISO-2016-Rev2.1: Quality Systems General Requirements, February 22, 2016

<b>Position Statement Number:</b>		<b>REVISION NO:</b>	<b>0</b>
Advocacy Committee Approval Date:	12-6-18	Policy Committee Review Date:	1/4/2019
TNI Board of Directors Endorsed Date:		Effective Date:	

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## Attachment 3 PROGRAM REPORTS

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### CONSENSUS STANDARDS DEVELOPMENT

- The Laboratory Accreditation Body Committee has completed its draft revision of Volume 2 Module 1 and will seek approval of CSDEC to publish its “outline of proposed changes” to request comments from TNI members and the public. Since LAB has sought input at committee sessions during conference over the previous two years, we anticipate a smooth process going forward. The full text of the revised document can be made available behind the “Members Only” firewall as a draft, but only the “outline” describing omissions from the 2005 version of ISO/IEC 17025 and the additional TNI language placed within the 2017 version will be available to non-members of TNI. CSDEC approved a full-term extension of Carl’s term as Chair of LAB, so that he can finalize this revision and remain to oversee any implementation issues and SIRs that might be generated once the revised Volume 2 is implemented. Two new member applications await a vote, but the most recent meeting did not have a quorum.
- The WET Expert committee continues discussions about how best to revise the Demonstration of Capability language in the standard continue and are making good progress. Informal interactions among committee members, ELAB and EPA’s DMR-QA Coordinator continue at a slow pace, with no potential solutions yet emerging. There are no plans to have any meeting or conversations in Milwaukee.
- The Radiochemistry Committee is ready to start presenting the recommended calculation updates for Radiochemistry FoPTs to the Chemistry FoPT Subcommittee. They are waiting for a meeting date February to discuss this. The Milwaukee training is complete and the pre-recorded class material has been sent along with handouts for the course.
- The Microbiology Committee placed the Method Code issue on hold. The Committee is continuing work on the review of Technical Manager requirements as requested by the Quality Systems Expert Committee and is now working on language. The Committee has compiled 7 possible candidates and will be voting in new membership tomorrow. The Committee and CSDP EC have approved Robin’s membership extension for another year.
- The SSAS committee continued its work on its SSAS Table Management SOP that is partly based on the FoPT Limits SOP used for laboratories. A public meeting is being planned for February 27<sup>th</sup> for standards development. They will be discussing all three modules being updated. The mailing list is just about complete and invitations will go out before the end of January. Sheri and Tom are working on the agenda and handouts for this webinar. Sheri Heldstab was voted in as Vice-Chair.
- Quality Systems is continuing work on Technical Manager language. There has been a lot of input and a lot of strong opinions. The Committee is currently looking at options to leave the educational requirements as they are, but look for exceptions that might be exercised that include specific types of training. The Committee has started the review of applications and will be voting in new membership this Monday. There will be a new Chair and Vice-Chair for this committee too.

### NEFAP Executive Committee

- The Committee reviewed the update to the Combined Evaluation SOP and is finishing up the approval by email. The PTPEC approved the SOP with the addition of some time frames to the section describing the process if an Executive Committee does not have everything they need to endorse the recommendation. This final change had to be approved by the NEFAP EC too. Voting



will be complete by Friday and a final version will be sent to the Policy Committee for final review on 1/14/19.

- Kirstin met with the Field Activities Expert Committee (FAC) to share written comments on the Scope Guidance document early December. The NEFAP EC reviewed the comments and will provide the FAC with some additional thoughts for consideration.
- The NEFAP Nomination Committee SOP has been updated to address Policy Committee comments and to remove the previous requirement that committee members cannot be from the same organization. It is now being voted on by email. A final version will be sent to the Policy Committee on 1/14/19.

### **Field Activities Expert Committee (FAC)**

- The Committee is working on removing duplicate language after the 2014 FSMO Standard was inserted into a copy of ISO/IEC 17025:2017. A final check will be complete this Friday to confirm all language was successfully moved from the 2014 FSMO Standard. Scott Haas and Ilona are continuing to work on a tool to let people edit the same document when doing the reviews. They have looked at Dropbox, SharePoint, and email. On Jerry Parr's recommendation, they will be looking at DMS this month. If DMS proves to be a good tool, they will be able to share their process with the other expert committees preparing to work on standard updates.
- The Committee will work on 2019 Committee membership after the meeting in Milwaukee, so they can take advantage of the face-to-face time to develop the new Committee. New membership will be voted in on 2/4/19.

### **Field Activities Task Force**

- The Task Force is continuing to review new language prepared by Marlene Moore and Paul Bergeron for insertion into both the Field and Lab Standards.
- The Task Force reached out to the NGAB's to understand their processes for accrediting field work and mobile laboratories. More information needs to be gathered through conversations with the NGABs. Paul and Nick will be looking at the information about state accreditation collected by the Mobile Laboratory Subcommittee that was in existence before the Task Force. They will look at taking the information and summarizing it in a similar format to the Summary Table they currently working from.

## **NELAP**

### **Accreditation Council**

- For the current round of evaluations, all renewal letters have been issued with eight recognition renewals approved. Seven applications are in various stages of review.
- At the Monday, January 7, meeting, Council members will consider accepting LASEC's recommendation to approve the revised Chemistry Calibration Guidance 3-110 and discuss whether or not to set an implementation date without having yet approved the Chemistry LOD/LOQ Guidance 3-109.
- Voted on Monday. January 31, 2020 is the date set for implementation date. Can be implemented ahead of time. If an AB is unable to move to the new standard, technically nothing happens. This is

the same as we've always done. Honoring each other's agreement. Do an article similar to the one for the 2009 Implementation. This was in the newsletter 3 or 4 years ago. Lynn.

### **Laboratory Accreditation System Executive Committee (LASEC)**

- Planning for both the Mentor Session on internal audits and the Assessment Forum on monitoring vendor-supplied products are well underway. The committee is making good progress in creating Implementation Guidance documents from the summary of the Mentor Session in New Orleans.
- LASEC completed its review of the Calibration Guidance GUI 3-110 and forwarded a recommendation to accept it to the NELAP AC. The LOD/LOQ Guidance GUI 3-109 remains under review.
- LASEC discussed the Board's reaction and comments to Judy's presentation of the Lessons Learned document, as did CSDEC, and a meeting among LASEC, CSDEC and the NELAP AC is planned for Milwaukee to discuss the unresolved differences in perspective among the groups.

### **PROFICIENCY TESTING**

- The committee will be continuing discussion on the implementation of Volume 3 and 4 of the 2016 TNI Standard. The topic was not discussed during the December meeting because the PTPEC was waiting for an update from Jerry. Jerry provided an update by email with Draft language for the NELAP AC to consider in approving a process to move forward. The language will be reviewed at the January 17<sup>th</sup> meeting for finalization. Ilona noted a little more detail may be needed and she will follow-up on this before the PTPEC meeting. The process proposed involves determining a date that all PT results will be calculated using the 2016 Standard. This date will be based on the NELAP AC implementation date.
- The PTP/NEFAP Combined Evaluation SOP was reviewed by the small group that met in November to discuss a possible issue with how NGABs are approved (Alfredo, Jerry, Maria, Kirstin, Tracy and Ilona). There was support for the changes and it was sent to each of the Executive Committees and discussed during the December meetings. Each Executive Committee started the voting process to approve the SOP and voting will be complete this Friday. The final version will be sent to the Policy Committee for review by 1/14/19.
- The Chemistry FoPT Subcommittee has started to review and comment on the FoPT Limits SOP. They are also planning a meeting in February to begin reviewing the Radiochemistry Expert Committee recommendation for determining limits.
- The Microbiology FoPT Subcommittee has finalized the changes to the Microbiology sections of the FoPT tables. There will be separate listings of MPN-Multiple Tube and MPN-Multiple Well PTs. Originally these PTs were combined into one and now they will be separate. Maria will make the final updates to the table and footnote and the PTPEC will finalize these tables in January.
- The PTP SOP Subcommittee is continuing work on the FoPT Limits SOP.
- The PTPEC will take on the task to compare Volume 4 of the 2009 and 2016 TNI Standard to determine what additional SOPs may need to be written and which just need updating. This review will be started in January.
- The PTPEC determined an effective date of 7/1/19 for the DW FoPT Table that was approved by the NELAP AC this last month.

## ADMINISTRATION

### Advocacy

- The Advocacy Committee has received a positive response from NGABs for the panel discussion in Milwaukee. The NGABS will discuss ideas for expanding the use of NGAB accreditations in non-NELAP states.
- The Advocacy Committee assisted Jerry with review and comment on the third set of draft of rules for the California ELAP program. Comments are due January 19.
- The Advocacy Committee will work with Jerry to help host a lunch meeting in Milwaukee for first-time attendees from state agencies in non-NELAP states.

### Policy Committee

- As requested by the Board last fall, Policy Committee is presenting its recommendation for minor revision to the various TNI committee operations SOPs to permit more than one member per organization for any particular committee, in order to accommodate Eurofins' acquisition of TestAmerica. Unless the Board objects to this concept, SOP revisions will be undertaken for CSDEC, NEFAP and the general TNI committee operations SOPs.
- Policy is also presenting, for the Board's review and approval, two new documents, Personal Data Protection POL 1-127 and Personal Data Collection and Use SOP 1-123, that establish the parameters for TNI's new Privacy Policy. This policy was created in response to some members' complaints about excessive emails from their contact information provided to TNI, especially around the NEMC meetings, and allows for an "opt-out" of having contact information provided outside of TNI itself.
- Policy approved the revised Calibration Guidance GUI 3-110 upon verifying that "no added requirements" are included in the document. Review of the LOD/LOQ Guidance GUI 3-109 will take more time, since there may still be revisions pending completion of LASEC's review. Policy also approved the Advocacy Committee's Quality Systems Position Statement POS-1204, the second position statement for the organization.

### Training

- Current Classes 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. Ilona spoke to Silky and dates in March are being looked at. Silky is working on a DRAFT of the training.
  - Good Laboratory Practice – Internal Audits – Part II (Matt Sica) Ilona met with ANAB and an outline for a second class focusing on technical internal audits was developed. Matt will begin working on this training with a goal of seeing a DRAFT in Spring.
  - Marlene will be doing a Microbiology Assessor training this month - January 14, 15 and 17, 2019. It will also be recorded for a Webcast. Preliminary course information is going out today. There are 34 attendees registered for this class.
  - A new Management Training series will begin during the Winter meeting and conclude early March. Part of the course will be taught on Thursday at the TNI winter meeting (3 parts – remaining 2 will be taken by webinar). The series is a total of 5 parts that will be offered by

webinar/webcast. The series is purchased as one class. The class will be held every Thursday starting February 5<sup>th</sup> through March 5<sup>th</sup> for two hours early afternoon. There are currently over 50 people signed up for this webinar.

- An Assessor On-Going Training for the 2016 TNI Environmental Laboratory Standard is planned for mid-February 2019. There are currently 10 people registered for this class.
- The Radiochemistry class in Milwaukee will include a portion of the class being recorded ahead of time. Class participants will be required to review the recording prior to Milwaukee. This will allow the class to be completed in time for people's travel plans. The pre-course has been recorded and the link will be sent out to registered attendees today.

### **Milwaukee Meeting**

- Currently ~160 individuals have registered.
- 140 individuals have hotel reservations with 510 room nights booked. We need to get to 560 to meet contractual requirements.
- We have 20 exhibitors.
- Both training courses are a go with 20 for Managing an Environmental Laboratory and 11 for Radiochemistry.

### **NEMC**

- Abstracts are due by January 28, 2019.
- The committee is working to identify and finalize keynote and plenary speakers.

### **NGAB**

- Kirstin Brown and Ilona have begun the review of the IAS Technical Checklist. Kirstin will be witnessing an on-site this month. We are hoping to complete the checklist in February and visit IAS in March or April.

### **Complaints**

- A complaint was received regarding Oregon's cannabis program. Oregon is currently in the TNI Evaluation process. Ilona is following up on this with Alfredo to see if he did speak to Stephanie in Oregon.

### **Membership**

- Active Members: 1106
- There were 7 new committee applications received – two for LAB, two for Quality Systems, one for WET, one for PT Expert, and two for Microbiology. Some applications were for multiple committees.