

TNI Board of Directors Meeting Summary February 13, 2019

1. Roll Call

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

2. Approval of January 2019 Minutes

Motion to Approve January Minutes: Curtis Wood

Second: Justin Brown

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.

4. Committee Reports from Milwaukee (Attachment 2)

Committee reports taken at the Forum conference in Milwaukee, WI are provided here for information purposes.

5. **BRISEA and UCEEf**

On February 6, Jerry Parr met with Yuhong Jiang of BRISEA (Bridges over the Sea) and Danielle Blake of UCEEf by teleconference. BRISEA is a technology transfer company working primarily in China and UCEEf appears to be their educational outreach arm. Both companies are in New Jersey. This initial discussion started with NEMC and their interest in bringing attendees from China. But then we also discussed TNI's accreditation program and standards. After the call, Jerry provided them with more information about NEMC, a briefing package on our accreditation programs, and an article on our lab standard. Jerry and Yuhong plan to meet for lunch on March 18 while they both are at Pittcon. Lara Phelps and Anne Jurek (the session chair for the session that day) will also attend this lunch.

6. **Strategic Planning for 2020-2025**

We last did strategic planning in October 2014 and it is time to consider this again. In looking at a September-October time frame, these are dates that will not work well:

- October 23-25 (FSEA)
- October 31 (Halloween at Jerry's)

Based on demographics of the Board, staff and Executive Committee chairs, the best locations from a travel perspective are the DC, Baltimore, Philadelphia area, or the Chicago/Milwaukee area. ACIL is meeting October 8-11 in Nashville and WEF is meeting October 21-25 in Chicago, so somewhere around those dates and locations might also be good.

There are three developments that came up in Milwaukee that are all strategic issues to think about:

- 1) develop qualification program for third-party assessors,
- 2) develop standard for suppliers of consumables, and
- 3) form a training committee to help coordinate training activities

We should put out a preliminary Doodle poll to eliminate dates that don't work for people, as well as whether having the meeting on all weekdays or if carry over to Saturday would be acceptable or not. There would be funding for travel support for directors to come to the meeting, but need to find out how many can fund their own travel, etc.

7. **California Update (Attachment 3)**

After reviewing minutes from a subcommittee report that is working on an alternate standard, and conversations with Christine Sotelo, her attorney, and the TNI Executive Committee, TNI issued a cease and desist demand to the California Water Board, which triggered an immediate response. The demand letter and California actions are in Attachment 3.

ELAP plans to present their final proposed rule to the Water Board on May 22 in Sacramento and Christine has requested Jerry Parr, Lara Phelps, Vanessa Soto Contreras, and Trinity O'Neal to be present.

A development this morning: Michele Wade emailed Jerry a photograph of a copy of our Standard that was provided to the committee that was labeled "internal use for the committee only, not for distribution."

Several avenues were considered for how to address this issue. Final thoughts were to send a letter to the individual about a number of copies, over and above the one that was supplied to the committee for free, that have been erroneously distributed and request a response regarding this situation. If there is no response, then TNI may contact the Chief Executive of their organization.

Jerry will first check with TNI legal counsel to see what our responsibility is regarding the improper distribution of the standard. Jerry will update the Board at the next meeting.

- 8. Program Reports (Attachment 4)**
- 9. Next Meeting: March 13, 2019; 1:00pm EST/12N CST**

**Attachment 1
2016 Standard Implementation Issues**

Action Item	Assigned To	Expected Completion Date	Status Update
QAM Template Update 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.	QS Expert Committee	12/31/17	Completed November 2017. Now on the website for \$115 for members.
Post comparison document 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.	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.
Guidance Document - PTRL Issue	PT Expert Committee	10/15/18	Committee has revised and sent to AC
Update Standard Interpretation Requests (SIRs) 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.	Expert Committees	08/10/19	Draft spreadsheet summarizing existing SIRs provided to Expert Committees. Ilona is updating with missing SIRs.
SIRs Set-up site for interpretation requests for the new TNI Standard.	IT Administrator	03/01/18	Completed
Can I Implement the New Standard Now? 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.	LASEC	11/18	Article on this topic published in November newsletter.
Quality Systems Checklist - Laboratory Assessments Checklist needs to be prepared for ABs to use during laboratory assessments.	Quality Systems	06/15/18	Checklist has been posted

Action Item	Assigned To	Expected Completion Date	Status Update
Quality Systems Checklist - Website Revise the checklist web page to allow downloading either the 2009 or 2016 checklist	IT Administrator	06/15/18	Checklist has been finalized.
LOD/LOQ Guidance Will need LASEC and Policy review. Implementation date set after review by AC.	Chemistry Expert	2/28/2019	All remaining issues addressed in Milwaukee and final document should be available soon.
Calibration Guidance Approved and ready to post	Chemistry Expert	12/1/18	
New Standard Training Webinars 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
Small Lab Handbook 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.
Implementability Issues 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.
Benefits of the New Standard Prepare a document to show why the 2016 Standard is an improvement over the 2009.	Expert Committees	6/7/2018	Complete
PT Provider Issues Resolve issues surrounding scoring to the 2016 Standard and evaluation of PT Providers to Volume 3.	PTPEC	2/28/2019	This should get resolved on PTPEC call on 2/21.

Attachment 2

Summary of TNI Committee Reports to the Board of Directors Forum on Laboratory Accreditation, Milwaukee, WI, January 30, 2019

This is a summary of committee activities during the public meeting sessions plus anticipated meeting times needed for the Environmental Measurement Symposium in Jacksonville, FL, in August, 2019.

NELAP Accreditation Council

Aaren Alger – ¼ day

The Council announced the implementation date for the 2016 TNI Environmental Laboratory Sector (ELS) Standard, January 31, 2020. The Chair explained how this will be a “rolling implementation”, as in times past, where Accreditation Bodies (ABs) will implement the new standard as soon as they are able to do so, but with some needing to conduct rule-making, there will be ABs that experience delays in transitioning to the 2016 Standard. Each AB will continue to recognize the accreditations of other NELAP ABs, regardless of which standard is being enforced by that AB. A new Vice Chair has been elected, Kristin Brown of Utah, and the Council has been discussing acceptable options for revising the Technical Director qualifications in the next revision of the standard.

Laboratory Accreditation Systems Executive Committee

Judy Morgan – ¼ day plus; ½ day/AF, ¾ day/MS

Accomplishments of 2018 and plans for 2019 were presented and then, the rest of the session was devoted to discussion of LASEC’s Lessons Learned document and the feedback from CSDEC and the NELAP AC. Resolution of several sticking points now seems possible, and LASEC will work with those two groups and the TNI Board to finalize consensus resolutions to the difficulties encountered with the 2016 Standard. The Assessment Forum drew about 50 people to participate in learning and discussing ways to improve oversight of vendor supplied materials. The Mentor Session on Internal Audits also had good attendance and enthusiastic participation.

Environmental Laboratory Advisory Board

Sharon Mertens – ½ day

ELAB did meet, despite the government shutdown having ended late on the previous Friday. The ELAB Designated Federal Official participated by telephone, but there were no updates since preparation was hampered by the shutdown. Three main topics were discussed: acrolein/acrylonitrile preservation and a related data request; creating a task force to address 600 series methods; and an improved EPA method for Polychlorinated biphenyls (PCBs) that needs to be validated. They plan to have a response to EPA Office of Ground Water and Drinking Water’s guidance on Method Detection Limits prepared for the Agency in spring of 2019, and will be discussing the adoption of the most current drinking water method. Some activity around Whole Effluent Toxicity PTs is likely to continue, as well.

NEFAP

Kirstin Daigle – ¼ day or possibly ½ depending on progress in the spring

Participants identified action items to support the Field Activities Committee’s efforts in revising the Field Sampling and Measurement Organizations (FSMO) Standard, and worked to plan the summer meeting. The possibility of NEFAP as an add-on to NELAP accreditation was raised along with considering how such a “recognition” might work. The Mobile Lab Task Force is now formally created and continuing its efforts to harmonize accreditation and recognition of mobile labs across both standards.

Field Activities Expert Committee

Kevin Holbrooks – 1/2 day

FAC shared its completed working draft of a new FSMO standard, with the existing TNI language placed into the 2017 revision of ISO/IEC 17025. They hope to have a reviewed version of this updated document available for the summer meeting in Jacksonville.

Proficiency Testing Expert Committee

Nicole Cairns – ¼ day

This was a quiet meeting, with minimal feedback on the 2016 standard because no one is yet implementing it. The committee will plan its next activities at an upcoming meeting, and addressing Defense Department issues will definitely be considered in that conversation.

Microbiology Expert Committee

Robin Cook – ½ day

The committee discussed a SIR that was returned for revision, and will circulate the revised draft response for email vote. They also discussed language for the Technical Manager qualifications in this session as well as in the Quality Systems Expert Committee session. Microbiology will undertake to edit the method code table and seek comments on that revision when it's complete.

Quality Systems Expert Committee

Paul Junio – ½ day

QS discussed revisions to the Technical Manager qualifications for various expert committees, and have decided not to “patch” the current language but rather to begin from scratch. They will poll the NELAP AC to learn what requirements are encoded in state regulations or statutes that would be show-stoppers for such a revision. Jessica Jenson is succeeding Paul as chair of this committee, and the Board Chair, Alfredo Sotomayor, thanked Paul for his service.

Whole Effluent Toxicity Expert Committee

Lynn Bradley – ¼ day

With several other committee members participating by teleconference, Michele Potter led participants in discussions of changes to language in the WET module (V1M7) for initial and ongoing demonstrations of capability, and also the Technical Director qualifications language, which was shared with Quality Systems by Bob Wyeth. Participants also discussed the current status and their hopes for the ongoing interactions with ELAB and EPA about changes to proficiency testing – both in conducting PT studies and in evaluating acceptance criteria.

Laboratory Accreditation Body Expert Committee

Carl Kircher – ½ day

LAB presented its detailed changes to the TNI language as incorporated in the 2017 version of ISO/IEC 17011, to become the new V2M1 for TNI's ELS Standard. A few of the comments received will be incorporated immediately, prior to publication of the outline of changes, while others will need more consideration and are postponed for consideration with the full range of comments submitted once the outline is published.

Chemistry Expert Committee

Val Slaven – ½ day

Chemistry had a productive session. Three new members were introduced and the most recent LASEC comments on and questions about the Detection and Quantitation Guidance were all discussed and resolved. Val hopes to have committee review of the revised document to LASEC within a week.

Radiochemistry Expert Committee

Terry Romanko – ½ day plus 1 day for training

This committee had a quiet session, working on finalizing its checklist, discussing its Technical Director qualification revisions after the Quality Systems meeting, and discussed PTs. Terry is the new Chair, and Alfredo offered thanks to Bob Shannon who is stepping down as chair of this committee. Terry offered last-minute registrations for the Thursday radiochemistry training, topic of alpha spectrometry, for those whose travel plans were impacted by weather and have to stay over an unexpected day.

Asbestos Expert Committee

Bob Wyeth – ¼ day

This committee's meeting was cancelled since its revised draft module is not completed as was expected. They hope to have it ready for Jacksonville.

Stationary Source Audit Sample Committee

Ilona Taunton – ¼ day

SSAS used its session to work on two SOPs that are in development.

Consensus Standards Development Executive Committee

CSDEC did not meet and offered no input about whether to meet in Jacksonville or not.

Information Technology Committee

Mei Beth Shepherd – no meeting

IT discussed where to locate the links to Advocacy documents in the drop-down menu, and whether or how to better manage the SIR postings on the website. Jerry confirmed that the SIR webpage is getting about 30 hits per day, so people are actually using this.

Advocacy Committee

Steve Arms – ½ day

In response to the Board's tasking of Advocacy with exploring ways to integrate Non-governmental ABs (NGABs) into the national scheme, they held a panel discussion with NGAB representatives. The NGABs had hoped for more labs to apply for their accreditations than is actually happening, and a few ideas for next steps were identified. After that, Advocacy followed its normal agenda of identifying issues it needs to address from the current conference, conference planning, and identifying newsletter articles for the April newsletter as well as an editor for the fall newsletter.

PT Program Executive Committee

Maria Friedman – ½ day

The primary discussion topic was how to implement V3 (the PTP standard) to meet the NELAP AC's implementation date of January 31, 2020. They crafted a plan that still needs full PTPEC discussion and approval, but made good progress. Eric Smith is the new chair of the SOP subcommittee and they have a new member, Rachel Ellis of NJ.

Executive Director's Report

Jerry Parr

Bob Wyeth has been contracted to take over the ANSI relationship maintenance as well as staffing the CSDEC and Chemistry committees. The other two committees that were staffed by the late Ken Jackson were addressed at the following day's staff meeting – Asbestos and PT Expert – and those will be maintained by Ilona for a few months until Bob has a chance to learn what's needed about ANSI and its consensus standard program, and then Bob will assume staff responsibility for those two committees as well.

Expert Committee Chairs are asked to provide feedback to their respective listings of SIRs for their modules (the "SIR spreadsheets"). These are being updated and will be re-distributed, but the two committees that have completed their review of the original spreadsheets will have only minimal updating needed.

Jerry also discussed the status of the Department of Defense's Quality System Manual (QSM) Version 5.2. He explained that TNI needs to examine the "gray boxes" in the QSM to see if any are worthy of inclusion in the TNI Standard. He seeks to learn why DOD rejected V1M1 of the 2016 TNI ELS Standard and instead prepared its own PT module that also includes an additional section for radiochemistry that will be used by the Department of Energy. Several commenters indicated that DOD is now adapting to the 2017 revision of ISO/IEC 17025 (that will become Version 6.0), since all of its ABs are ILAC signatories and thus required to move to the 2017 revision within two years of its approval and may move away from using the TNI Standard. TNI will follow-up with Jordan Adelson.

Note: After conference, Jerry did contact Jordan and Jordan indicated the individuals who spoke up were mistaken. Everything in 6.0 will be open for comment, but there are no plans to move away from TNI.

Attachment 3 California Memo to ELTAC Committee with TNI Letter



State Water Resources Control Board

TO: Ronald Coss, Chairperson
Environmental Laboratory Technical Advisory Committee (ELTAC)
Subcommittee on Quality Management System

FROM: Darrin Polhemus, Deputy Director
DIVISION OF DRINKING WATER

DATE: February 8, 2019

SUBJECT: The NELAC Institute (TNI) Laboratory Standards Copyright and License Agreement

At the December 13, 2018 meeting an ELTAC subcommittee was formed to create a quality management system based on TNI Standards and applicable to all laboratories.

Subsequently, during the January 28, 2019 subcommittee meeting members voted to develop a laboratory standard **"...working within the TNI framework..."** and utilizing **"TNI by reference."** The subcommittee includes ELTAC members Mindy Boele and Huy Do and from the public Bill Ray, Josie Teller, Paul Monroy, Sushmitha Reddy, Dr. Yuli Tsi, and Amber Baylor.

TNI requested the Water Board to remind the subcommittee that the TNI Standards are protected by copyright law. Any unauthorized use such as copying, scanning or distribution is prohibited. Release of the TNI Standards to ELTAC subcommittee members who have not officially purchased the document from TNI is a violation of copyright law. TNI Standards License Agreement (see attachment) states, in part:

"...purchasers shall not merge, adapt, translate, modify, rent, lease, sell, sublicense, assign or otherwise transfer any of the Standards, or remove any copyright notice appearing on any of the Standards."

The subcommittee needs to adhere to the TNI Licensing Agreements while conducting subcommittee work on the quality management system. TNI Standards or sections of the TNI Standard cannot be distributed to the public. In addition, quality management standards the subcommittee ultimately creates cannot just be an edited or rewritten version of the copyrighted TNI Standards text.

ELAP will make available, during normal business hours, a controlled copy of the TNI Standards at all Regional Water Quality Control Board and Division of Drinking Water District Offices beginning February 22, 2019. To find an office, visit the Water Board webpage www.waterboards.ca.gov

Attachment: TNI Standards License Agreement, TNI Letter to ELAP

FELICIA MARCUS, CHAIR | EILEEN SOBECK, EXECUTIVE DIRECTOR

1001 I Street, Sacramento, CA 95814 | Mailing Address: P.O. Box 100, Sacramento, CA 95812-0100 | www.waterboards.ca.gov

ELTAC Subcommittee on QMS

- 2 -

February 8, 2019

cc: Kimberly Niemeyer, Attorney III, Office of Chief Counsel, SWRCB
Stephen Clark, Chair, Environmental Laboratory Technical Advisory Committee
Christine Sotelo, Chief, Environmental Laboratory Accreditation Program, SWRCB
Robert Brownwood, Assistant Deputy Director, Division of Drinking Water, SWRCB
Jerry Parr, Executive Director, The NELAC Institute
ELTAC Subcommittee Members



February 7, 2019

Ms. Christine Sotelo, Chief
Environmental Laboratory Accreditation Program
State Water Resources Control Board
P.O. Box 100
Sacramento, CA 95812-0100

Dear Ms. Sotelo:

At the January 28, 2019 Environmental Laboratory Technical Advisory Committee (ELTAC) subcommittee meeting (which is under your sanction), the subcommittee voted to utilize **"TNI by reference"** to create a California Quality Management System. According to the meeting notes, the membership of this subcommittee includes Ronald Coss, Mindy Boele, Huy Do, Bill Ray, Josie Teller, Paul Monroy, Sushmitha Reddy, Dr. Yuli Tsi, and Amber Baylor. In that meeting, the subcommittee voted to develop a laboratory standard **"...working within the TNI framework..."** I would also like to point out these meeting notes indicate the subcommittee could **"rephrase things."**

TNI would like to remind the Water Board that the 2016 TNI Laboratory Standard is protected by copyright law. Any unauthorized use such as copying, scanning or distribution is prohibited. Release of the TNI Standards to ELTAC subcommittee members who have not officially purchased the document from TNI would also be in violation of copyright law and our records show at least one member of this subcommittee has not purchased the standard.

In addition, by purchasing the TNI Standards from TNI, the purchaser also agrees to the TNI Standards License Agreement (see attachment) which states, in part:

"...purchasers shall not merge, adapt, translate, modify, rent, lease, sell, sublicense, assign or otherwise transfer any of the Standards, or remove any copyright notice appearing on any of the Standards."

According to *The Copyright Handbook* by Stephen Fishman, rephrasing the language so to the casual reader it is clear one work was derived from the other is generally ruled by the courts as "substantial similarity" and is also a violation of copyright.

TNI owns the rights to this standard. TNI never authorized this subcommittee to edit our standard. Therefore, this subcommittee may be in violation of our copyright. This letter is to demand you

immediately direct this subcommittee to cease and desist any efforts at using the TNI standard to create a "Quality Management System for California" in violation of copyright laws and License Agreement. TNI further demands you require any subcommittee member who have not purchased the standard to either do so immediately or destroy any printed or electronic copies of our standard they may have.

Please respond to this letter by February 11, 2019.

A handwritten signature in black ink, appearing to read "Jerry Parr", is positioned above the typed name.

Sincerely,
Jerry Parr
Executive Director

cc: TNI Executive Committee

TNI STANDARDS LICENSE AGREEMENT

Network Use Version

This License Agreement is between The NELAC Institute, (TNI), and you, the individual or entity that purchased a TNI Standard.

IMPORTANT - READ CAREFULLY BEFORE DOWNLOADING OR COPYING TO YOUR COMPUTER ANY FILE(S) CONTAINED HEREWITH.

THE STANDARD(S) AND OTHER INFORMATION PROVIDED HEREWITH ARE COPYRIGHT PROTECTED. BY DOWNLOADING ANY FILE PROVIDED HEREWITH TO YOUR COMPUTER, YOU ARE ACCEPTING AND AGREEING TO THE TERMS OF THIS LICENSE AGREEMENT. IF YOU ARE NOT WILLING TO BE BOUND BY THE TERMS OF THIS LICENSE AGREEMENT, PRIOR TO DOWNLOADING OR COPYING TO YOUR COMPUTER ANY FILE(S), YOU MUST DECLINE ACCESS TO SUCH MATERIALS.

1. GRANT OF LICENSE: Subject to the provisions contained herein and to the payment of all applicable fees, TNI grants you a nonexclusive, non-transferable license to the materials contained herewith (the Standards). Your licensed rights to the Standards are limited to the following:

(a) This License Agreement does not convey to you an interest in or to the Standards, but only a limited right of use revocable in accordance with the terms of this License Agreement. This License Agreement covers the following Standards:

Environmental Laboratory Sector

Volume 1 - Management and Technical Requirements for Laboratories Performing Environmental Analysis (comprising 7 modules)

Volume 2 - General Requirements for Accreditation Bodies Accrediting Environmental Laboratories (comprising 3 modules)

Field Sampling and Measurement Organization Sector

Volume 1 - General Requirements for Field Sampling and Measurement Organizations

Volume 2 - General Requirements for Accreditation Bodies Accrediting Field Sampling and Measurement Organizations

TNI grants you a non-exclusive, non-transferable, personal, limited license to use the standards according to the terms of this License Agreement.

(b) The Standards may be stored at a single location in digital form accessible by employees of your organization at that location. Your employees shall have the right to electronically display the Standards on their own computer and may print a copy of the Standards. You shall not merge, adapt, translate, modify, rent, lease, sell, sublicense, assign or otherwise transfer any of the Standards, or remove any copyright notice appearing on any of the Standards.

(c) You acknowledge and agree that the Standards are proprietary to the Copyright holders identified on the front page of the Standards, and are protected under U.S. copyright law and international copyright treaties. You further acknowledge and agree that all right, title and interest in and to the Standards, including all intellectual property rights, are and shall remain with the Copyright holders.

2. LIMITED WARRANTY:

(a) TNI warrants for your benefit alone that TNI and the Copyright holders can license the Standards and all copyright and trademarks related thereto or therein.

(b) THE EXPRESS WARRANTIES SET FORTH IN THIS SECTION 2 CONSTITUTE THE ONLY WARRANTIES WITH RESPECT TO THE STANDARDS AND THE COPYRIGHT HOLDERS MAKE NO OTHER REPRESENTATION OR WARRANTY OR CONDITION OF ANY KIND, WHETHER EXPRESS OR IMPLIED (EITHER IN FACT OR BY OPERATION OF LAW) WITH RESPECT TO ANY OF THE STANDARDS, INCLUDING, WITHOUT LIMITATION, WITH RESPECT TO THE SUFFICIENCY, ACCURACY OR UTILIZATION OF, OR ANY INFORMATION OR OPINION CONTAINED OR REFLECTED IN, ANY OF THE STANDARDS. THE COPYRIGHT HOLDERS EXPRESSLY DISCLAIM ALL WARRANTIES OR CONDITIONS OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NO OFFICER, DIRECTOR, EMPLOYEE, MEMBER, AGENT, REPRESENTATIVE OR PUBLISHER OF THE COPYRIGHT HOLDER IS AUTHORIZED TO MAKE ANY MODIFICATION, EXTENSION, OR ADDITION TO THIS LIMITED WARRANTY.

3. INDEMNIFICATION:

The Copyright holders, or any of their respective directors, officers, employees, agents, representatives or members (the Indemnified Parties) shall have no liability for, and you shall defend, indemnify and hold each of the Indemnified Parties harmless from and against, any claim, loss, demand, liability, obligation and expenses (including reasonable attorneys' fees) based upon or arising out of any injury or damage, or any product liability claim, including but not limited to, any personal or bodily injury or property damage, arising out of, pertaining to, or resulting in any way from, the use or possession of any of the Product by you and/or any of your directors, officers, employees, representatives, agents or contractors.

4. LIMITATION OF LIABILITY:

a) You acknowledge that each of the Copyright holder's obligations and liabilities with respect to the Standards are exhaustively defined in this Agreement. You are responsible for the consequences of any use of any of the Standards (whether or not such use was consistent with the license granted hereunder) created therefrom. Whether or not the Copyright holders have been advised of their possibility, neither the Copyright holders nor TNI nor any of its representatives or agents, directors, officers, employees, agents, representatives or members, shall be liable, whether under contract, tort (including negligence) or otherwise, for any indirect, special, punitive, incidental or consequential loss, damage, cost or expense of any kind whatsoever and howsoever caused, that may be suffered by you or any of your directors, officers, employees, agents, representatives or contractors or any third party.

b) If at any time an allegation of infringement of any rights of any third party is made, or in the Copyright holder's is likely to be made, with respect to any of the Standards, the Copyright holders may, at its option and at its own expense (i) obtain for you the right to continue using the Standard, (ii) modify or replace the Standards or any portion thereof so as to avoid any such claim of infringements, or (iii) refund to you the License Fee. the Copyright holders shall have no liability to you if any claim of infringement would have been avoided except for your refusal to use any modified or replacement Standard supplied or offered to be supplied pursuant to this Section 4(b) or to otherwise cease using the Standard. Notwithstanding anything contained in this Agreement, and except as set forth in Section 4(b) hereof, the Copyright holders liability to you for damages pursuant to this Section 4(b), if any, shall not exceed the amounts of the License Fee paid by you for the Standards subject to any such claim.

c) Section 4(b) state the entire liability of the Copyright holders with respect to the infringement or alleged infringement of any third party rights of any kind whatsoever by any of the Standard.

5. TERMINATION: This Agreement may be terminated immediately by TNI upon breach of any provision of this Agreement by you. Upon any termination of this Agreement, you shall immediately discontinue the use of the Standards and shall within ten (10) days certify in writing to TNI that the Standards have been deleted from your computer and have been eliminated from your premises.

6. GOVERNING LAW; ATTORNEY'S FEES: This Agreement shall be governed by the laws of the State of Texas without reference to its conflict of laws provisions and you further consent to jurisdiction by the state and federal courts sitting in the State of Texas.

7. MISCELLANEOUS: This Agreement constitutes the complete and exclusive agreement between TNI and you with respect to the subject matter hereof, and supercedes all prior oral or written understandings, communications or agreements not specifically incorporated herein. This Agreement may not be modified except in writing duly signed by an authorized representative of TNI and you. If any provision of this Agreement is held to be unenforceable for any reason, such provision shall be reformed only to the extent necessary to make it enforceable, and such decision shall not affect the enforceability (i) of such provision under other circumstances, or (ii) of the remaining provisions hereof under all circumstances. Headings shall not be considered in interpreting the Agreement.

8. EXPORT: You may not load or export or re-export any of the Standard or any underlying information or technology except in full compliance with all United States and other applicable laws and regulations.

BY ACCESSING THE STANDARD, YOU ACKNOWLEDGE THAT YOU HAVE READ THE TERMS OF THIS LICENSE AGREEMENT AND AGREE TO BE BOUND BY ITS TERMS.

Attachment 4 PROGRAM REPORTS

CONSENSUS STANDARDS DEVELOPMENT

- Discussions continued regarding the “Lessons Learned” document and the AC comments. No further direct response is planned but rather the CSDEC will meet with the LASEC and the AC in Milwaukee to remediate the standards adoption process and revise SOP 2-100 as necessary. Committee also completed inputs to the annual report and discussed activities for 2019.
- The CSDEC Procedures for Expert Committee Operations (SOP 2-101) prohibits more than one person from the same company from serving on an expert committee. The recent announced merger of Eurofins and TestAmerica has prompted the CSDEC to re-visit this issue, especially since it is known the Board of Directors has also raised concerns. Different versions of proposed changes have been discussed within the CSDEC and the Policy Committee. At the request of the Board of Directors, a final version, which limits membership to two individuals from a single organization, has been prepared and accepted by the Policy Committee. A final vote on this modification to the SOP will be voted on by the CSDEC at their February meeting.
- The CSDEC and the expert committees have performed a pilot study of the new internal audit process and found the SOP and the subsequent process to be implementable. While the committees completed their efforts in 2018 and early 2019, audit findings currently await input into the database.
- The Chemistry Expert Committee call was cancelled for January. The guidance document for LOD/LOQ, however, received further comments from the LASEC. These comments were discussed in Milwaukee and proposed language will be added to the document to hopefully resolve questions posed by the LASEC.
- The Asbestos committee reported making good progress in its review and revision of the standard. The committee will be electing a vice chair and will continue to seek new membership. The CSDEC chair has asked to committee to re-submit their Notice of Intent to Modify the Standard relative to criteria established by the LASEC/AC.
- At the Laboratory Accreditation Body Committee meeting in January, the committee finalized and approved its draft revision of Volume 2 Module 1. Then, at its session in Milwaukee, the Chair reviewed all of the TNI language as placed into the 2017 revision of ISO/IEC 17011. A few edits emerged from that conversation, and once the full committee approves those edits, the LAB will seek approval from CSDEC to publish its “outline of proposed changes” to request comments from TNI members and the public. Since the 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.
- The WET meeting in January continued the conversation about how best to revise the Demonstration of Capability (DOC) language, and the session at conference had some helpful discussions about DOC as well as the desired Technical Director qualifications language.
- During its session in Milwaukee, the PT Expert Committee discussed the various activities that it may undertake for the coming year. The Chair will take these ideas and suggestions back to the full committee to prioritize them for the coming year.

- The Radiochemistry Committee is ready to start presenting the recommended calculation updates for Radiochemistry FoPTs to the Chemistry FoPT Subcommittee. A meeting has been set-up for March 12, 2019. The committee has started work on defining Technical Manager requirements and has some great ideas on combining education and experience that they will share with the Quality Systems Committee.
- The Microbiology Committee is continuing work on the review of Technical Manager requirements as requested by the Quality Systems Expert Committee and is working on language. SIR 331 has been returned to the committee with comments from the NELAP AC. There were numerous “no” votes from the NELAP AC, so the committee is being asked to reconsider its response in light of new comments. A DRAFT of the internal audit has been completed. Ilona and Robin will complete the audit before the end of the month.
- Quality Systems is continuing work on Technical Manager language. There has been a lot of input and a lot of strong opinions. The unanimous consensus in Milwaukee is that the Committee should start over with new language – using ISO/IEC 17025:2017 language as the starting point instead of the previous Standard. The new Committee chair is Jessica Jensen and the new Vice Chair is Kathi Gumpfer. The Committee reviewed all its SIRs and will update its review into the new SIR review summary table.

NEFAP Executive Committee

- See update under PTPEC for Combined Evaluation progress.
- The NEFAP EC will take on the task of completing the Scope Guidance Document. This will give the Field Activities Committee more time to work on updating the Standard.
- The NEFAP Nomination Committee SOP was sent to the Policy Committee for review and finalization.
- A Nomination Committee Chair was chosen for 2019: Jeremy Driver (Alabama Power Company).
- The Committee will begin discussing accreditation options for FSMO's. An interesting discussion was started in Milwaukee when someone asked if they could add an FSMO accreditation to their NELAP accreditation. This could work currently for an NGAB accrediting to the TNI Environmental Standard.
- The Marketing/Strategic Planning Subcommittee chairs are working on how to evaluate good markets for NEFAP.

Field Activities Expert Committee (FAC)

- The Committee had a great working session in Milwaukee and now has a starting DRAFT of the FSMO Standard that includes both language from the 2014 TNI Standard and language from the ISO/IEC 17025:2017 standard. The next step is to remove duplicate language and then start working on the Standard.
- The Committee hopes to have an outline of the new Standard complete by April in order to receive public comments by webinar and email.
- The Scope Guidance Subcommittee: The work on the guidance document will be completed by the NEFAP EC.
- The Committee will be working on finalizing new membership by end of February.

- The first DRAFT of the Internal Audit has been completed. Ilona and Kevin (Vice-Chair) are working to complete it before the end of the month.

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 is finishing up their summary table to understand the various processes for accrediting field work and mobile laboratories.

NELAP

Accreditation Council

- As was announced in Milwaukee, the Council set the implementation date for the 2016 TNI Standard as January 31, 2020. This will be a rolling implementation, as in times past.
- For the current round of evaluations, all renewal letters have been issued with nine recognition renewals approved. Six applications are in various stages of review. Efforts to refine the NELAP Evaluation SOP 3-102 for the next round of evaluations are beginning with the NELAP evaluators.

Laboratory Accreditation System Executive Committee (LASEC)

- Both the Mentor Session on internal audits and the Assessment Forum on monitoring vendor-supplied products, at conference in Milwaukee, were well-attended and considered successful. The committee continues to progress with reviewing Implementation Guidance documents from the summary of the Mentor Session in New Orleans.
- Much of LASEC's session at conference was devoted to conversation about the Lessons Learned document with CSDEC and the NELAP AC. Some follow-up interactions will be needed, but good progress is expected.
- LASEC representatives participated in the Chemistry Committee's session at conference in order to resolve the latest set of comments on the Detection and Quantitation Guidance document

SIR Update

Total	Closed Out	LASEC Review	NELAP AC Voting	Expert Committee
333	316	3	7	7

PROFICIENCY TESTING

- The committee is continuing discussion on the implementation of Volume 3 and 4 of the 2016 TNI Standard. The committee is working on DRAFT language to put on PT Provider reports so they can start reporting to the 2016 Standard requirements before they receive their 2016 certificate. Once this DRAFT language is finalized, Maria will finalize a letter to the NELAP AC recommending that all PT data reported after 1-31-2020 be evaluated using the 2016 Standard scoring.

The DRAFT language being reviewed by the PTPEC is:

"This report is scored by the criteria in the TNI V3 2016 standard instead of by the criteria in the TNI V3 2009 standard to which the PTP is accredited. This is a planned change and is endorsed by the

TNI PTPEC for transition to the new standard. 'Name of ptp' is transitioning to TNI V3 2016 upon the expiration of its current certificate and scope on 'date'."

- The PTP/NEFAP Combined Evaluation SOP is being reviewed by the Policy Committee for finalization. Maria Friedman and Tracy Szerszen are working on a final draft of the Application and Shawn Kassner and Ilona Taunton are working on an evaluation checklist. Once these items are complete, the Combined Evaluation Work Group will be ready to decide when to start taking applications.
- The PTPEC finalized the Microbiology FoPT DW and NPW tables updated with the separate listings of MPN-Multiple Tube and MPN-Multiple Well PTs. Maria will be sending these to the NELAP AC for approval.
- The Chemistry FoPT Subcommittee has started to review and comment on the FoPT Limits SOP. They are also planning a meeting on March 12th to begin reviewing the Radiochemistry Expert Committee recommendation for determining limits.
- The PTP SOP Subcommittee is beginning work on SOP 4-107 – Management of FoPT tables.
- 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 was discussed in Milwaukee with Shawn Kassner.
- Membership: Maria has been voted in as Chair of the PTPEC for 2019. Rachel Ellis was voted in as a new member of the committee and confirmation has been sent to the TNI Board Chair. Jennifer Duhon, Patrick Garrity, and Michella Karapondo have been approved for a second term. The Committee is looking for a vice-chair.

ADMINISTRATION

Advocacy

- The Advocacy committee will follow up on the NGAB panel at Milwaukee with a questionnaire to the NELAP ABs. The committee will pose questions to the ABs to determine how the states may or may not be able to use NGABs in their accreditation programs.
- Target date for publishing the next newsletter is April 12. Martina McGarvey is the editor.
- After TNI's LAMS is updated, the Advocacy Committee will reach out to non-NELAP states with an annual report and summary of TNI's upcoming activities.
- The Advocacy Committee plans to continue working on a position paper "The Value of Accreditation" and to review the job description and other requirements for the Small Laboratory Advocate position.

Policy Committee

- Policy Committee began reviewing the Combined NEFAP/PTPEC Evaluation SOP 7-101, early in January, but has not met since then.

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.
 - The Microbiology Assessor training January 14, 15 and 17, 2019 had 37+ participants.
 - A new Management Training series has started and will be complete by 3/5/19. There are 110 participants between the webinar and the onsite training.
 - An Assessor On-Going Training for the 2016 TNI Environmental Laboratory Standard is in progress. The class will finish up this Friday with 27 participants.
 - The Radiochemistry class in Milwaukee has been completed and work is now in progress to turn this into a recorded webcast.

NEMC

- The date for submission of abstracts was extended to allow federal employees additional time. To date, 89 abstracts for oral presentations and 23 for posters have been received.
- Hotel registration will open within the next two weeks and conference registration opens in April.
- The hotel site visit is scheduled for February 25.

NGAB

- Kristen attended an onsite assessment of a laboratory by IAS. Ilona and Kristin hope to complete the Technical Checklist in February and do the on-site evaluation of IAS in late March/early April.

Membership

- Active Members: 1093
- There were 7 new committee applications received.