

TNI Board of Directors Meeting Summary December 13, 2018

1. Roll Call

Directors	Present
Jordan Adelson	
Aaren Alger	X
Steve Arms	X
Justin Brown	X
Bob Di Rienzo	X
Jack Farrell	X
Maria Friedman	X
Chris Gunning	X
Myron Gunsalus	
Daniel Lashbrook	X
Judy Morgan	X
Cheryl Nolan	X
Patsy Root	X
Debbie Rosano	
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
Ken Jackson	X
Jerry Parr	X
Ilona Taunton	X
Janice Wlodarski	X

2. Approval of November Minutes

Motion to Approve: Patsy Root

Second: Maria Friedman

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. The three guidance documents are complete and waiting final approval from Policy.

Progress is being made on the PT provider issue discussed in November. This issue has been added to the spreadsheet. The PT Providers are resisting the Board decision made in November.

Aaren and Jerry met and are on the same page with regard to how to resolve the issue. At the January 7th NELAP Council meeting they will set an implementation date for Volume 1 of the 2016 Standard, as well as Section 5.9 of Volume 3 (integral part of Vol 1). As of that date, we would expect all PT Providers to be scoring to the new standard. Any AB that has not implemented by that date, or

has implemented before that date, they can continue with what they are doing. Jerry will write it the proposed resolution and turn it over to the PT Executive Committee this week. A report should be back to the Board by the January BOD meeting.

3. Lessons Learned from the 2016 TNI Standard (Attachment 2)

This (the attachment) is not so much a “lessons learned” document, but a back and forth discussion between 3 different committees. It is not presentable in this format.

The purpose of this document was to be a recap of those particular issues that got put down on paper to highlight the struggles of Advocacy and those involved. They recapped goal, suggested action and who takes lead, and then requested feedback. One of the more constraining issues is the ANSI criteria. The purpose of doc was to make sure that the issues that delayed the standard or caused major barriers at the time are addressed moving forward and that we do everything we can to prevent them from occurring in the future.

It was suggested that perhaps the ANSI requirements are hindering us putting a second system in place and maybe we are too worried about meeting the ANSI requirements. Have we considered the ANSI Process for continuous improvement for a Standard? No.

Since this document is not publishable in its current form, Judy would like to take some time and try pairing it down to a summary – a more cleansed version – of nonconformances, taking out the rhetoric and opinions, etc.

4. NGAB Developments

While the original plan was for the Advocacy committee to send out a survey, the Advocacy Committee now plans to invite NGABs to a panel discussion in Milwaukee to discuss ideas for expanding the use of NGAB accreditations in non-NELAP states and to discuss in general the expansion of this program.

5. ISO/IEC 17025: 2017

The Ad-Hoc group formed to study this issue had a second call on December with good discussion but no resolution. Jerry is preparing a “hybrid” document that merges parts of the new 17025 with the existing 2016 TNI Standard.

This hybrid document is almost done and will be sent out to this committee this week. The QSM plus Standard plus 17025 – will be resolved by second week in January.

6. California Update

California’s Environmental Laboratory Technical Advisory Committee has a meeting scheduled for December 13 where they will discuss a proposed “parallel accreditation” with a “California Quality Management System.” The California QMS is nothing but following the methods, the QC in Part 136, and some elements from the TNI standard, including Sections 5.3, 5.5-5.9 and excerpts from the quality manual section. Jerry has prepared comments that are under review by Carol and Steve to show how inappropriate this parallel system would be.

Several large commercial labs in California have volunteered to mentor some at-risk municipal labs that are in remote areas to show them how to comply with TNI.

7. Program Reports (Attachment 3)

**Attachment 1
2016 Standard Implementation Issues**

Action Item	Assigned To	Expected Completion Date	Status Update
<p>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.</p>	QS Expert Committee	12/31/17	Completed November 2017. Now on the website for \$115 for members.
<p>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.</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>Guidance Document - PTRL Issue There is still an issue regarding the clarification and use of the PTRL.</p>	PT Expert Committee	10/15/18	Committee has revised and sent to AC
<p>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.</p>	Expert Committees	08/10/18	Draft spreadsheet summarizing existing SIRs provided to Expert Committees
<p>SIRs Set-up site for interpretation requests for the new TNI Standard.</p>	IT Administrator	03/01/18	Completed
<p>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.</p>	LASEC	11/18	Article on this topic published in November newsletter.
<p>Quality Systems Checklist - Laboratory Assessments 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
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	1/15/2019	Committee has revised and sent to Policy Committee for final review.
Calibration Guidance Needs LASEC and Policy review. Implementation date set after review by AC.	Chemistry Expert	1/15/2019	Committee has revised and sent to Policy Committee for final review.
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	2/1/2019	Preliminary discussions only.

Attachment 2

Lessons Learned During Development of the 2016 TNI Environmental Laboratory Sector Standard

During its meetings in summer of 2017, LASEC discussed and created a list of “lessons learned” during the review of the 2016 standard for suitability, in accordance with SOP 3-106, Standards Review for Suitability. Many of the issues encountered are a result of TNI’s unique structure, where the ELS standard is essentially written for use by the National Environmental Laboratory Accreditation Program (NELAP,) and per TNI, the Laboratory Accreditation Systems Executive Committee (LASEC) is charged with reviewing the standard and making recommendations to NELAP about whether the standard is considered suitable and should be adopted.

These lessons are designed to facilitate LASEC’s role of reviewing new and revised standards, and then providing its recommendation about the standard to the NELAP Accreditation Council for its consideration. After struggles with implementation of the 2009 TNI standard, LASEC undertook to review the individual modules as they are developed, and not just the final complete standard once approved by TNI. While not yet perfected, and obviously requiring much more intensive effort over a longer period of time, this module-by-module review seems to be an improvement over the “once and final” review as happened with the 2009 standard.

Where appropriate, lessons will be incorporated into the LASEC Standards Review SOP 3-106, and also shared with the NELAP AC and CSDEC in the coming months, in hopes that those groups will also adapt their processes to facilitate review of the TNI ELS standard for suitability. If the process cannot meet ANSI requirements and still be modified to allow adequate review time for LASEC to perform its review, then we respectfully ask that the TNI Board of Directors reconsider whether and how to structure a meaningful review process that can be done within the parameters allowed by TNI’s consensus standards development certification.

CSDEC Response

The 2016 standard was developed under a version of SOP 2-100 that has now been replaced. The version of SOP 2-100 (Rev. 2.01) in current use was developed when the 2016 environmental standards development cycle was under way, and it was developed specifically to address problems already seen in developing the 2016 standards. Many of the concerns cited by LASEC are now addressed. This new revision of SOP 2-100 was developed by the following team: Sharon Mertens, TNI Chair; Jerry Parr, TNI Executive Director; Bob Wyeth CSDEC Chair; Aaren Alger, NELAP AC Chair; Judy Morgan, LASEC Chair; and Ken Jackson, CSDP Administrator. Following its development and approval by the TNI Policy Committee, this SOP was approved by ANSI. The new standards development cycle is in its very early stages, and it will follow Rev 2.01. It would be premature to abandon this in favor of a new revision at such an early stage of its operation, and because it would necessitate ANSI approval of a new revision.

The lessons identified are listed below as Goals, with proposed actions and responsible parties identified.

- 1. Goal:** The revised or added language should be clearly distinguishable from the original document, when revised standards modules are presented for review at every stage. When revising an existing standard module, redline/strikeout versions from the previously adopted and implemented standard should be provided for review. These can be done retroactively using “document compare” if necessary, but continuous tracking with comments provided in the margin is preferable. Additionally, a summary of changes should be provided.

Action: Modify §5.3.1 of SOP 2-100 if possible, but in any event, ensure that all expert committees are aware of this request at the outset of revision or development of a module.

Responsible Party: CSDEC

CSDEC Response

During development of the 2016 standard proposed changes in a redline/strikeout tracked format were provided for most of the modules. It will be assured that this is done consistently in future when standards are presented for review and for voting. Section 5.2.1 of SOP 2-100 Rev. 2.01 already requires expert committees to present a summary of changes *“with reference to the section/clause numbers of the standard, to show how the proposed standard will be an improvement over the existing standard.”* This is done prior to voting at every stage (VDS, MVDS, IS and MIS).

NELAP AC Comment

For maximized transparency and clarity, the ABs prefer information on specific changes because “minor” changes can have significant impact on enforceable requirements and, ultimately, on data quality. Specific (vs. “summary”) information also aids in more timely evaluation of the acceptability of changes. It is also noted that sometimes changes in a ‘summary’ form may be the clearest way to communicate, (for example as would have been appropriate for the revised MDL section in the 2016 Standard or when the changes are so significant that “track changes” would be more confusing than helpful) so this format may serve a purpose in some cases.

LASEC Comment:

Section 5.2.1 of SOP 2-100 does require a summary of changes to be made. This has not been consistent throughout the revision history of the standards. The change summary being requested is a document that is generated after the standard is changed and is described in section 5.7.2. This summary shows section deletions, revisions to language, section additions, while giving previous and revised (current proposed) language. The change summary is designed to reference the changed section and represent the previous and proposed language. The redline version of the standard should be for reviewers, while the change summary is for reviewers, interested parties, and any voting member to use to better understand the changes to the document and to be able to locate them in the document.

- 2. Goal:** A version of pre-notification of changes is now included in §5.2.1 of SOP 2-100. LASEC requests that that pre-notification includes a justification for any changes made/proposed. NELAP states may be required to include a justification when changing their regulations to implement a new standard. Please consider including an estimate of the economic impact of proposed changes with this pre-notification release, and possibly some form of Frequently Asked Questions (FAQ) clarification.

Action: Modify §5.2.1 of SOP 2-100 if possible, or address in a related document so that all expert committees are aware of this need for justification of changes from the outset of revision or development of a module.

Responsible Party: CSDEC

CSDEC Response

Section 5.2.1 already requires the pre-notification to include justification of the proposed changes for every clause of the standard. The Expert Committees' could only provide a limited perspective on economic impact, and the CSDEC believes this can best be determined by the regulators (the ABs) and the regulated community (the labs). It is unclear what is meant by FAQ clarification.

NELAP AC Comment

Rulemaking generally requires both the justification and *estimation* of economic impact to be presented. This information can be estimated by the Expert Committees proposing changes since

the committees are 'balanced' (have lab, other, and AC representation) and have resources to make these estimations if needed. These factors need to be considered at the outset of proposing changes because if the cost is not reasonable and/or is not justified by the benefits of the change, the proposed change should be halted in its early stages. On the contrary, when there are savings for labs without a compromise to quality, then those changes should be highlighted and communicated so that they can be embraced in the update process. We, the expert committees and the AC, must ensure that the changes represent not only an improvement to quality, consistency, and economics, but that the changes are necessary. As noted above, some changes while seemingly minor can cause significant time and economic hardship for very little benefit. At other times changes have unintended consequences. For this reason, it is important for the expert committees to weigh the impact of all changes against the benefit.

An example of "FAQ clarification" is the guidance document on the PTRL changes to the PT sections of the 2016 Standard. These requests should be needed only on rare occasions, but when needed, the Expert Committees are most suited to provide them. The purpose of any requested FAQ-style clarification documents is to aid both ABs and labs in consistent understanding of new or challenging content.

LASEC Comment:

Where there is economic impact positive or negative, the expert committee should be able to make an estimate. In the event that the committee does not feel qualified, they should reach out to the AC or LASEC for further guidance.

3. **Goal:** Improve the quality of response-to-comments tracking and track ALL comments received throughout the development of the standard, not just those at the voting stages. This will ensure that "show-stoppers" raised early in the process do not get overlooked and provide some ability to estimate the criticality of comments received and a way to assess impact of a comment to ensure that discussions result in adequate resolution.

Action: a) Add requirement for tracking response to comments at the "outreach and information collection stage (SOP 2-100 §5.2.1)

b) A standardized template has been created and shared among Program Administrators, that includes tracking of comments received in public discussions (outside of voting procedures, which are documented in SOP 2-100) so that early comments are ensured consideration during the standards development process. This template could become an appendix to SOP 2-100, but at minimum, all expert committee chairs must be made aware of it and encouraged to use the standardized format from the outset of standards development.

c) For comments submitted during the voting process, consider categorizing comments into editorial, technical and implementation (as ISO does) and require that the submitter provide a recommended language change. Without the recommended language change, the default decision is "no revision submitted."

Responsible Party: CSDEC

CSDEC Response

The use of a standard template for tracking comments received during the outreach and information collection stages will be implemented. This will include comments made from the floor in public discussions, where the commenter(s) will be asked to submit those comments in writing to assure they are on record for consideration by the committee. When commenter(s) do not present their remarks in writing the Expert Committee(s) will attempt to address these verbal issues, but they may be limited in their abilities to do so. If the commenter(s) contact information is available, the committee(s) may contact the commenter(s) in an effort to ensure their remarks are understood and considered. In the past all comments received during standards development have been documented in the expert committees' minutes, as have the consideration of those comments in developing the standards. As an example, development of the Chemistry Module (V1M4) involved very detailed

technical discussion at a pace the program administrator was often unable to follow in real time. In such cases, besides the administrator being on the calls to scribe the minutes, the calls were recorded to capture the nuances of the discussions and to subsequently add these to the minutes. This level of effort may not be necessary for all committee discussions, but efforts will be made to assure that detailed minutes are provided for all technical discussions, including consideration of comments received during the outreach and information collection stage.

Editorial comments are so-noted in the response-to-comments document. It may be difficult to draw a line between technical and implementation, and the CSDEC is unsure why this would be necessary. Commenters are already requested to provide proposed language (SOP 2-100 Rev. 2.01, Section 5.3.2), but ANSI rules prevent making this a requirement.

NELAP AC Comment

All changes to improve effective communication and handling of issues at the earliest opportunity are valuable to the process and beneficial to all stakeholders. Asking the commenter to provide suggested alternative language may be beneficial but should not be a requirement as the requirement may discourage some from participating.

LASEC Comment:

We understand that we cannot require that the submitter suggest language but we can encourage it. The purpose of this request was to ensure that we do not dismiss any comments prematurely regardless of when they are received.

- 4. Goal:** Create a standardized decision process regarding persuasive or non-persuasive determinations for comments, so that consistent procedures being used across committees. One way to ensure that the expert committee's understanding of each comment matches what the commenter intended to say is to contact the commenter for clarification, but if a requirement to submit alternative language is created [see 3(c) above], that would resolve this issue.

Action: Consider including criteria for decision-making in SOP 2-100 or in some related document.

Responsible Party: CSDEC

CSDEC Response

The Expert Committee members are those best equipped to determine if a comment is persuasive or non-persuasive, and it would be very difficult to apply a metric to this process. Many factors are involved in making the decision, and this frequently involves protracted discussion during committee meetings (those discussions are detailed in the minutes). The committees involved in developing the 2016 standard (Chemistry, PT, Microbiology, and Radiochemistry) have all reached out to commenters to discuss their comments, and this will continue to be done by all committees when a clear decision on a comment is not immediately obvious.

NELAP AC Comment

The AC agrees with CSDEC that a specific metric may not be easily definable or always beneficial. The most important issue, which may have been effectively resolved by improved practices, is that a committee should never dismiss or discount a comment as non-persuasive until it has been fully evaluated. Comments from Accreditation Bodies (ABs) who are representing the perspectives of public health, state and federal regulations, and EPA's expectations for data of known and documented quality should not be dismissed without an opportunity being offered for the AB to discuss and communicate the concerns either with the expert committee or the other members of the NELAP AC. Real-time discussion (meetings, phone) is likely the most time-efficient manner to approach this issue. Committees inviting commenters to call in to teleconference meetings when

discussion is needed has been an effective communication opportunity since all committee members can participate in the discussion with the commenter(s).

LASEC Comment:

Reaching out to commenters should be consistent and documented on the comment tracking spreadsheet. We believe that the decisions regarding the determination of persuasive/non-persuasive decisions can be adequately decided by the expert committee. However, when strong comments or concerns are submitted by an AB, the submitter should always have the opportunity to meet with the committee to discuss the issues. As an example, PT Expert has done this for many years and it allows for detailed insight regarding the comment and creates a more informed group to collectively decide the outcome.

- 5. Goal:** Identify or create a process or procedure for considering and responding to comments from committees. Within TNI and for the Environmental Laboratory Sector Standards, LASEC is assigned the role of reviewing standards and recommending adoption (or not) to the NELAP AC. Thus, LASEC's involvement in the process is not optional, and when LASEC determines that an implementation barrier exists, there **MUST** be a process for getting that feedback into the expert committee's deliberations that does not require waiting until the standard is completed, so that it needs to be re-opened for repeated revision.

Action: Identify or create a process or procedure for considering and responding to comments from committees. If the process cannot meet ANSI requirements and still be modified to allow adequate review time for LASEC to perform its review, then we respectfully ask that the TNI Board of Directors reconsider whether and how to structure a meaningful review process that can be done within the parameters allowed by TNI's consensus standards development certification.

Responsible Parties: CSDEC working with TNI Board, LASEC and NELAP AC

CSDEC Response

This difficulty was voiced by LASEC during the 2016 standards development cycle and it was the major point that prompted development of SOP 2-100 Rev. 2.01. The process now involves many opportunities for stakeholders and committees to be proactive in telling the expert committees up-front what they want in the standard, and also to respond up-front to the committees' proposals. The diligent and timely response by stakeholders and committees will be necessary for the effective implementation of this phase of the standards development. This is embodied in Section 5.2.1 of the SOP. The most significant stage is the following:

"Following input, the Expert Committees draft bulleted outlines of the essential items to be included in the standard, and publish them on the TNI website, requesting comments within 30 days of said publication. If this is a revision of an existing TNI standard, the Expert Committees also attach a summary of the changes, with reference to the section/clause numbers of the standard, to show how the proposed standard will be an improvement over an existing standard".

This means that every proposed change will be explained and justified. All that will be missing will be the actual wording of the standard that will be presented for vote, so there should be no surprises other than editorial ones when the standard is voted on. This review by LASEC and other stakeholder groups will be critical, and if it is now realized that the 30-day time frame is insufficient for LASEC review of this document, the time period will be extended on request. This will allow all stakeholders the extra time, and it will not be imposing more stringent requirements than ANSI has approved.

NELAP AC Response

The AC concurs with the goal and CSDEC response.

LASEC Comment:

We agree with the response.

6. **Goal:** Create a pathway through which significant comments and concerns can be addressed whenever they are identified during the standards development process. Despite best efforts, not all potential problems are recognized when the current process permits consideration of a comment addressing them. As presently designed, the process allows only for comments accompanying votes (at the designated voting stages of development) to be addressed, but there must be some way to address significant comments outside of this framework – the system needs to be tweaked to permit “show stoppers” to be addressed whenever they are identified, rather than proceeding through final approval with an identified problem that cannot be addressed because it was not identified at a time when SOP 2-100 allows for a comment identifying that problem.

Action: identify or create a process or procedure for considering and responding to comments from intended users of the standard whenever significant concerns are identified. If reviewers are making good efforts to meet identified timelines but fail to recognize a potential problem and comment on it at the times permitted by SOP 2-100, that comment deserves not to be ignored.

Responsible Parties: CSDEC working with TNI Board, LASEC and NELAP AC.

CSDEC Response

Section 5.2.1 of SOP 2-100 rev. 2.01 addresses this, as discussed under #5 above. This process is repeated prior to every iteration of a voting standard (VDS, MVDS, IS and MIS), and it is the responsibility of stakeholders and stakeholder groups to make their voices heard at this stage, in a diligent and timely manner, especially if a “show stopper” is identified. If an objection is raised after a standard has been voted in by the membership, the only option is for the expert committee to start again, otherwise the integrity of the voting process would be compromised.

NELAP AC Response

The reality we must address is twofold: (1) NELAP AC members have a responsibility first and foremost to represent their State, (from the perspective of what’s best for public health and the environment) in the decision-making process related to standard review and development; and (2) All NELAP AC members are stretched thin, and resources [time] for standards review and development is extremely limited.

With those perspectives & limitations, processes must (1) ensure that changes to the standards are necessary and limited in scope to only the necessary elements; (2) provide AMPLE time for ALL NELAP AC members to respond so that the quality of reviewing/commenting is not impacted by the pressure of a deadline. The process needs to address the reality that meeting a deadline is not more important than thorough review at the necessary stages.

LASEC Comment:

LASEC respectfully points out, that time constraints alone can prevent some stakeholders from meeting the comment time window. In the event that an issue is identified outside of the normal process there must be some process to acknowledge and address this if the issue is significant.

7. **Goal:** LASEC and the NELAP AC must have adequate time for review. With one meeting each month, the current 30-45 days is not sufficient to allow individuals to review even one standard module and discuss it in a committee meeting, and then formulate a comprehensive response or position, never mind to have the NELAP AC consider comments and recommendations from the LASEC about individual modules prior to voting and commenting on the modules. The bare minimum

time for such dual review to take place would be 90 days, and during the winter holiday season, that will likely be too short.

Action: Find a way to extend the review period during which comments may be submitted on the version of the particular standard being voted upon. This could be by providing additional review time prior to opening the vote, or by extending the voting period, or perhaps by accepting comments post-vote.

Responsible Parties: CSDEC, LASEC and NELAP AC

CSDEC Response

If section 5.2.1 is implemented as written, there should be no surprises at the voting stage. As discussed above, the review period for consideration of comments on the “bulleted list” will be extended as needed. It is suggested, at these critical times, LASEC meet more frequently than monthly, as is the case with a number of administrative and expert committees on a routine or as needed basis.

NELAP AC Response:

The NELAP AC cannot effectively review, discuss, involve all parties, and provide feedback on major items within a 30-45 day turn-around time. Any expectations for this kind of review require modifications, such as for advance copies so that the reviews can be done before the ‘clock’ starts. (Refer also to response for Goal #6.)

LASEC Comment:

LASEC respectfully points out that the option to meet more frequently does not address the timing issue. Expert committees are focused on a single portion of the standard, while LASEC may have multiple modules to review at any given time. In this circumstance the issue is simply the amount of time available, not the capability to meet or not. We are mindful of timeliness and appreciate the option to extend the review time, however, this option does not alleviate the time constraint of the voting period. We are asking for an evaluation of the voting period and an extension of the allotted time if necessary.

- 8. Goal:** Identify where and how LASEC’s process for recommending standards modules to the NELAP AC failed to identify in timely fashion the show-stopper issues in one particular module of the 2016 ELSS, and determine whether the possibility of a recommendation “with conditions” or returning the standard to the developing expert committee for revision at an earlier stage could have prevented the need for a second-round revision.

Action: LASEC to consult with NELAP AC and CSDEC, and hopefully identify one or more points in the review process where a different approach could have altered the course.

Responsible Parties: CSDEC, LASEC and NELAP AC

CSDEC Response

This was the one event that had not been predicted when SOP 2-100 was revised. However, if all parties are diligent and timely in their review as per section 5.2.1 this should not happen again.

NELAP AC Response

The next Standard will have a significantly higher degree of change than the change from TNI 2009 to 2016, so the next Standard will ‘test’ this process on a much larger scale. Significant caution

regarding the changes and the impact on labs and accrediting bodies will need to be considered for each portion of the revisions.

For the Quality Systems portion (moving into compliance with ISO 17025:2017), review and discussion and preliminary approval of small sections, rather than one big section, is recommended.

LASEC Comment:

LASEC agrees with the statement of caution and the approval approach described by the NELAP AC. While the goal is to provide a thorough and timely review of the standard modules and volumes as they progress through the system, we still need to be mindful that no system is perfect and should develop a plan for extenuating circumstances if/when they occur.

9. **Goal:** Provide CSDEC (or each expert committee?) with a list of SIRs to be carried into the revised standard, at the outset of revision or perhaps when the “outline” of proposed revisions is published. This process should also serve as a check and balance to ensure that all interim interpretations are considered for inclusion in the newest revision.

Action: LASEC to provide such a list for each module undergoing revision. Revise SOP 3-106 accordingly.

Responsible Parties: LASEC and CSDEC

CSDEC Response

The requirement to consider all SIRs is already in Section 5.2.2 of the SOP.

NELAP AC Comment

The AC concurs with the goal and CSDEC response.

LASEC Comment:

LASEC recommends modifying SIR tracking spreadsheet to allow recording of when a SIR is added and lists the applicable standard section. It also should allow recording that an SIR will not be added and the reason.

Attachment 3 PROGRAM REPORTS

CONSENSUS STANDARDS DEVELOPMENT

- Notices of Intent to Modify a Standard for SSAS V1M2 and EL V1M6 (Radiochemistry) were published on the TNI website. Also, PINS (Project Initiation Notification System) forms for the two modules were submitted to ANSI for their publication in Standards Action. The TNI publication and ANSI publication are both ANSI requirements to provide the public an opportunity to challenge the need for the standards.
- The Consensus Standards Development Program pilot study of the new internal audit process is under way. Each Expert Committee chair is working on the relevant checklist with the assistance of the program administrators. The CSD Executive Committee (CSDEC) checklist is also being prepared, and it will be a subject of discussion during this month's CSDEC conference call.
- The Chemistry Expert Committee, having submitted its guidance document for calibration to the Accreditation Council (AC), had received two further comments from the AC. These were discussed and hopefully resolved during the committee's December call, and the revised document was returned to Lynn.
- The PT Expert Committee has completed its review of the table of Standards Interpretation requests for their applicability to the 2003, 2009, and 2016 standards. Two new Committee Members were approved by the members: Matt Sica of ANAB (AB) and Rachel Bailey of Advanced Analytical Solutions (PT Provider). Bob Wyeth, as CSDEC Chair will be asked to approve the appointments.
- The Asbestos Expert Committee continues its work to revise V1M3 during its November conference call.
- The Laboratory Accreditation Body Committee has only a few "parking lot" issues remaining to consider for the revision of Volume 2 Module 1 and will then begin its review and approval of the "outline of proposed changes" for publication to request comments from TNI members and the public. Because of the ISO revisions to ISO 17011, the number of changes is exceptionally high – a situation that will also occur with the Quality Systems module based on ISO 17025, in the future. We still anticipate that the revision and request for comments can be published within a few months. We understand that the full text of the revised document can be made available behind the "Members Only" firewall as a draft, but will not be available to non-members of TNI. LAB has requested that CSDEC approve a 2-year 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. One full member is completing her second term and will remain as an associate; all other members will remain as full members. Two new member applications await vote at the next meeting. Thanks to Ken for preparing the first draft of LAB's Internal Audit this month. It has been reviewed and finalized by staff and the Chair. The committee will see it at the December meeting, and will propose any needed corrective actions after conference in Milwaukee.
- The WET Expert committee continues discussions about how best to revise the Demonstration of Capability language in the standard 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. WET may have identified a new member of the "other" stakeholder category. Since member terms were not staggered when this committee was formed, it is vital that enough new members be brought into the committee to provide continuity when the original members are forced to rotate off, and this "other" category has been the limiting factor. There are ample associate members eager to step up to full membership as soon as possible. Thanks to Ken for preparing the first draft of WET's Internal Audit this month. It has been reviewed and finalized by staff

and the Chair. The committee will see it at the December meeting, and will propose any needed corrective actions after conference 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 in January or February 2019 to discuss this. Bob Shannon and Ilona worked on completing the recordings for the QC packages that could not be finished in New Orleans. Recordings have been sent to William for posting the training. A DRAFT for the Milwaukee training is complete and plans are in place to record the pre-course material before the end of the year. The Radiochemistry Expert Committee has voted in a new Chair for 2019 – Terry Romanko from TestAmerica. The Committee will elect a vice-chair in January.
- The Microbiology Committee placed the Method Code issue on hold this month. Robin is reviewing current status and will place this back on the agenda in November. The Committee is continuing work on the review of Technical Manager requirements as requested by the Quality Systems Expert Committee. The Committee is now reviewing various State requirements. The Committee started reviewing new applications and plans to vote in new membership this week. The Committee is planning to ask Robin to stay on the Committee for at least one more year.
- The SSAS committee did not meet last month.
- 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 started reviewing applications and plans to vote in new membership during their first meeting in December.

NEFAP Executive Committee

- The NEFAP EC did not meet in November.
- The committee will continue work on the FAC DRAFT Scope Guidance document, the complaint regarding FSMO assessment frequency, and updates of SOPs.

Field Activities Expert Committee (FAC)

- The Committee worked hard this month outside of meeting time to start the review of the 2014 FSMO Standard versus the ISO/IEC 17025:2017 Standard. The assignments to insert all the 2014 FSMO language into the ISO/IEC 17025:2017 Standard were completed and compiled into one document. The committee started to review the text, but decided it would be easier to review the material outside of meeting time. Each assigned section leader will work on removing duplicate language and then reviews will be done of each section by the Committee. Scott Haas and Ilona are working on a tool to let people edit the same document when doing the reviews.
- The Scope Guidance Subcommittee: No update.
- 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.

Field Activities Task Force

- The Task Force continued review of possible new language prepared by Marlene Moore and Paul Bergeron for insertion into both the Field and Lab Standards. Task Force members suggested changes to the language and the committee worked on language to define mobile laboratories.
- The Task Force will be reaching out to the NGAB's to understand their role and look for ideas on handling mobile labs.
- Paul will draft a presentation of work to date for the Milwaukee meeting.

NELAP

Accreditation Council

- For the current round of evaluations, all renewal letters have been issued with eight recognition renewals approved. Six applications are in various stages of review and the final one application is due next week.
- Kristin Brown of Utah has been elected as the new Vice Chair of the Council. Her first official act will be to sign Aaren's new Certificate of Recognition, and then issuance of the first set of annual certificates will be complete.
- Kimberly Hamilton-Wims as stepped in as Program Manager for Louisiana DEQ, replacing Paul Bergeron.
- Council members have accepted LASEC's recommendation to approve the revised PTRL Guidance 3-114. They also approved a slightly modified Drinking Water FoPT table. Members have been asked to review both the Calibration Guidance GUI 3-110 and the LOD/LOQ Guidance GUI 3-109 in anticipation of a recommendation from LASEC to accept those documents being available for the January meeting. One minor change requested by a Council member was quickly addressed by the Chemistry Expert Committee and the revision returned; the changes affected only one paragraph and will not delay the review time.

Laboratory Accreditation System Executive Committee (LASEC)

- Planning for both the Mentor Session and the Assessment Forum in Milwaukee is well underway. These sessions are immensely valuable to the NELAP community, and next month's topics will be internal audits for the Mentor Session and assuring vendor quality for the Assessment Forum
- LASEC completed its review of the revised PTRL Guidance 3-114 and forwarded a recommendation to the NELAP AC to accept the document. Members have been asked to review the Calibration Guidance GUI 3-110 and the LOD/LOQ Guidance GUI 3-109 prior to the December meeting (rescheduled for December 18).
- LASEC will present its Lessons Learned document and recommendations to the TNI Board at this December meeting.
- LASEC has recruited several AB members and will bring back at least one former "other" member (who has been in associate status for a year), so they will have a full roster in January.

PROFICIENCY TESTING

- The committee continued discussion on the implementation of Volume 3 and 4 of the 2016 TNI Standard. Jerry attended the November PTPEC meeting to discuss the Boards statement regarding the implementation of the 2016 TNI Standard Volumes 3 and 4. Jerry commented that he was surprised the PT Providers were concerned about having to work with different state implementation dates. He was also surprised that the PTPA wanted the AB assessed before they approve the PT Provider for work performed under the 2016 Standard. Discussion points included:
 - The NELAP ABs have never been on the same Standard – they give a “blind” eye to some of the differences in order to continue to recognize secondary labs.
 - Jerry will look into the possibility for all PT Providers to use only the 2016 Standard. He will discuss this with the NELAP AC.
 - Another option would be to state the results are reported to the 2009 Standard but with the 2016 calculation requirements. A disclaimer could be something along the lines of: PT Provider accredited to the 2009 TNI Environmental Laboratory Standard, but PT Provider reports results per Section xxx of the 2016 TNI Environmental Standard. Jerry will discuss this with the NELAP AC too.
 - Moving to the 2016 Standard before a State requires it may put additional burden on the labs sooner than required. Many did not think this would be a problem for most labs. The bigger impact is on larger labs with Organics.
- Ilona prepared a DRAFT update to the PTP/NEFAP Combined Evaluation SOP and it will be sent today to the subcommittee working on this SOP. After review it will go to the group that met last month to discuss this issue (Alfredo, Jerry, Maria, Kirstin, Tracy and Ilona) for review. If all looks good it will be reviewed for finalization by the Executive Committees this month and then sent to the Policy Committee.
- Schedules have not allowed the Chemistry FoPT Subcommittee to meet to discuss the Radiochemistry Expert Committee recommendation on how to update Radiochemistry limits in the future. This will be tabled to January or February 2019.
- The Microbiology FoPT Subcommittee is finalizing 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. The Subcommittee finished up their voting process, but Jennifer Best (Chair) and Maria need to work through a few more details before updates will be ready for posting.
- The PTP SOP Subcommittee has a new Chair – Eric Smith. The subcommittee will assess status this Friday and put a plan together to finish up the SOPs still under review.
- 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.
- The PTPEC will be evaluating new membership this month.

ADMINISTRATION

Advocacy

- The Advocacy Committee will invite NGABs to a panel discussion in Milwaukee to discuss ideas for expanding the use of NGAB accreditations in non-NELAP states.
- Jerry will send the study plan for the 600 series method validation project to EPA with a request for clarification in several areas.
- The Quality Systems position paper has been revised and re-submitted to the Policy Committee for review.
- The Advocacy Committee will begin work to prepare a position paper on the Value of Accreditation.

Policy Committee

- Policy Committee is making progress in crafting the recommendation requested by the Board about whether and what changes might be needed to committee operations as a result of Eurofins' acquisition of TestAmerica. For now, it looks as if only one expert committee has members from both organizations, and one of those will become an associate, voluntarily.
- Policy also initiated its reviews of the three guidance documents accompanying the 2016 Standard. The review of PTRL Guidance GUI 3-114 was completed last week, with the document being returned for some minor reformatting. The Calibration Guidance GUI 3-110 and LOD/LOQ Guidance GUI 3-109 are considerably longer, so that verification of "no added requirements" will take more time, but all agreed that they are much improved over the initial drafts.

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 is waiting for DRAFT training from Silky.
 - Good Laboratory Practice – Internal Audits (Matt Sica) This course went live in October and response has been great. Ilona will be meeting with ANAB next Wednesday to discuss a part 2 of this class.
 - Marlene will be doing a Microbiology Assessor training January 14, 15 and 17, 2019. It will also be recorded for a Webcast.
 - 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 5th through March 5th for two hours early afternoon.
 - An Assessor On-Going Training for the 2016 TNI Environmental Laboratory Standard is planned for mid-February 2019. Registration is open.
 - 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. Ilona is now reviewing the training material and the pre-course material will be recorded within the next 2 weeks.

Milwaukee Meeting

- Currently only 85 individuals have registered, but this is comparable to 88 attendees on this date for Albuquerque.
- 93 individuals have hotel reservations with 384 room nights booked. We need to get to 560 to meet contractual requirements.
- We have 19 exhibitors.
- Both training courses are a go with 12 for Managing an Environmental Laboratory and 8 for Radiochemistry.

NEMC

- The Call for Abstracts has been mailed out and 6 abstracts have been received.
- The committee is working to identify keynote and plenary speakers.
- The committee did not meet in November.

NGAB

- Kirstin Brown and Ilona have begun the review of the IAS Technical Checklist. Kirstin will be witnessing an on-site in January.

Membership:

- Active Members: 1080
- There were 7 new committee applications received in November – three for LAB, one for Quality Systems, one for WET, one for PT Expert, and one for Microbiology.