

**Laboratory Accreditation System Executive Committee Meeting Minutes
Forum on Laboratory Accreditation, Milwaukee, WI, January 28, 2019**

1) Welcome and Introductions

Judy Morgan welcomed everyone to the meeting. Attendance is recorded in Attachment A. Judy provided a PowerPoint summary of the committee's accomplishments and plans, which is shown in outline form in Attachment B. There were no questions about the presentation.

2) Discussion of Lessons Learned Document and Comments from CSDEC and NELAP AC

The Lessons Learned document, with all comments, is provided in Attachment C, below. The discussion points made are summarized here, by section number.

1 – Request for redline strikeout version of the changes if possible.

This would make review more efficient. A summary of changes might miss a minor word change that has big impacts, so that all changes need to be reviewed.

2 – Request for both justification of changes and for estimate of economic impact.

The Notification of Intent to Modify the Standard should address the justification for change, but no one seems quite sure how to estimate the economic impact. An estimate of economic impact is critical, since a high cost without substantial improvements to data quality would not be worthwhile and should be halted, while a cost savings to labs without compromising quality should be pursued. States that must do rulemaking to adopt a new standard, in particular, need this information.

Rearranging section numbers for convenience means significant database changes to the ABs prior to implementation, and may require costly revisions by outside experts. These changes should be minimized. The asbestos standard was discussed as an example, where re-organizing the standard by technology will have economic impact and add excessive review time for minimal efficacy improvements.

One participant recommended including categories of changes needed for implementation to the LASEC review process – rulemaking, impact on AB workload, economic impact (on labs and ABs, separately), negative impacts, and possibly others (this would be SOP 3-106, Standards Review for Suitability). Participants agreed that these categories should be addressed iteratively, at all stages of standards development.

All changes should be questioned with “does it improve the standard?” This raised the question of why TNI is considering a next revision, when the 2016 ELS Standard is not yet implemented; this was answered with ANSI's requirement for a 5-year review, and the existence of updated ISO/IEC standards on which the TNI standards are based. There is a Board Task Force deciding whether a new

NELAP Volume 1 standard should be developed, now; the next review data for the 2016 standard will be 2021. For now, individual pieces of Volume 1 are being examined (Technical Director language, for instance). Still, TNI needs to consider the timeline for a major revision seriously, such as upgrading to the 2017 revision of ISO/IEC 17025.

Also, one participant noted that the FSMO standard really needs updating.

3 – Improve tracking of comments, not only during the voting process but throughout the standards development process. Ask for submission of proposed language with comments.

Apparently, TNI cannot insist upon submission of proposed language with a negative comment. It should be possible for expert committees to receive comments at any point during the standards development process, although the identified “open for comment” stages are still when the bulk of comments should be submitted. A tracking spreadsheet has been developed and shared among the Program Administrators for tracking comments throughout the entire standards development process.

4 -- Standardize a decision process for ruling comments persuasive or non-persuasive.

5 – Create a process for considering and responding to comments, whether from individuals or committees.

CSDEC may now be open to considering how to improve this process, so that the decisions are more consistent and show-stoppers do not get overlooked. However it is done, it should be documented and the process known to all. Some expert committee chairs want to restrict comments to written submissions only, so that they can be thoroughly documented; others suggested not holding verbal comments to the same response-needed standard as written ones, but still tracking them. All serious comments need to be addressed.

Webinars are available as public meetings to take comments on proposed standards. These can be recorded and reviewed in order to document the comments received during the webinar.

6 – Allow for comments to be addressed outside of the formal comment periods, when major issues are identified. This is not to encourage chaos, but rather to allow for identification of items that might have been overlooked during the review period.

7 – Allow adequate review time for LASEC and the NELAP AC; the 30-45 days allowed now is not sufficient.

8 – Allow show-stoppers to be addressed whenever identified.

It appears that the process in the current version of SOP 2-100 is not restricted by ANSI requirements, so that reasonable timelines are allowed as the organization sets those timeframes, and also that the restriction about not re-opening an issue once it was not addressed in the comments on the Voting Draft Standard is not an ANSI requirement.

9 – Formalize a process for the review and addressing of existing SIRs. This is currently required but no process or procedure is defined for doing it.

TNI needs a process to verify that each SIR was included in the latest revision and where, or else to document why it was not included. The incorporation of SIRs into the standard modules must produce implementable and auditable language. As SIRs, not all ABs can include those “interpretations” in their assessments.

Jerry Parr will again circulate a complete, up-to-date list of all SIRs to expert committees, and the committees will be asked to provide information on whether/how the SIRs were addressed, or not. (NOTE: this needs to be incorporated into SOP 3-105, SIR Management.)

Later during the conference and at the first CSDEC meeting post-conference, CSDEC announced that it will create a workgroup composed of LASEC, NELAP AC and CSDEC members to revise the Standards Development SOP 2-100.

3) Next Meeting

The next scheduled teleconference meeting of LASEC will be **Tuesday, February 26, 2019, at 1:30 pm Eastern time**. A reminder with agenda will be sent prior to the meeting.

The SIR Subcommittee will meet that day at 12:30 pm Eastern time.

Attachment A

PARTICIPANTS --TNI LABORATORY ACCREDITATION SYSTEMS EXECUTIVE COMMITTEE

	NAME	EMAIL	TERM, End Date	INTEREST	AFFILIATION	S/H CATEGORY	PRESENT
1	Judy Morgan, Chair	Judy.Morgan@pacelabs.com	3 years, 12/21 (extended)	Chair (all)	Pace Analytical	Lab/FSMO	Yes
2	Sumy Cherukara	Cherukara.sumy@epa.gov	3 years, 12/19		EPA R2	Other	(phone)
3	Silky Labie	elcatllc@centurylink.net	3 years, 12/20	SIRs	ELCAT	Other	Yes
4	Harold Longbaugh	harold.longbaugh@houston.tx.gov	3 years, 12/19	SIRs	Houston Lab	Lab	(phone)
5	Dorothy Love	dorothylove@eurofinsus.com	3 years, 12/21	Mentor Session	Eurofins Env'tl	Lab	(in Mentor Session)
6	Michele Potter	michele.potter@dep.nj.gov	3 years, 12/20		NJ DEP	AB	Yes
7	Scott Siders	ssiders@pdclab.com	3 years, 12/20	Mentor Session	PDC Laboratories	Lab	(in Mentor Session)
8	Nick Straccione	nstraccione@emsl.com	3 years, 12/19	Mentor Session	EMSL	Lab	No
	(2 AB members pending)						

Associate Members							
	Aaren Alger	aaalger@pa.gov			PA DEP	NELAP AB	Yes
	Kristin Brown	kristinbrown@utah.gov		SIRs	UT Bur. of Lab Improvement	NELAP AB	Yes
	David Caldwell	david.caldwell@deq.ok.gov		Assmt Forum	OK DEQ	NELAP AB	Yes
	Jack Farrell	aex@ix.netcom.com			Analytical Excellence	Other	Yes
	Myron Gunsalus	ngunsalus@kdheks.gov			KS Lab Director	NELAP AB	No
	Bill Hall	George.Hall@des.nh.gov		SIRs	NH ELAP	NELAP AB	No
	Carl Kircher	carl.kircher@doh.state.fl.us		SIRs	FL DOH	NELAP AB	Yes
	Mitzi Miller	mitzi.miller@moellerinc.com			Dade Moeller, Inc	Other	No
	William Ray	Bill_Ray@williamrayllc.com			Wm Ray Consultants	Other	No
	Gale Warren	gqw01@health.state.ny.us		SIRs	NY ELAP	NELAP AB	No
	Program Admin. Lynn Bradley	Lynn.bradley@nelac-institute.org					Yes

Attachment B – Outline of PowerPoint Presentation

Slide 1 -- Laboratory Accreditation Systems Executive Committee

- Monday
- January 28th, 2019
- 1:00 – 3:00

Slide 2 -- LASEC Members (list)

Slide 3 -- Our Mission

Manage TNI's efforts in supporting a national program for the accreditation of environmental laboratories by:

- ❖ Supporting the NELAP Accreditation Bodies (ABs) and non-governmental ABs (NGABs) recognized to accredit to the TNI Environmental Laboratory Sector (ELS) Standard,
- ❖ Enabling stakeholders such as laboratories, proficiency testing providers and data users to effectively participate in the development of, adoption and implementation of, and compliance with the TNI standards.

Slide 4 -- Agenda

- Update on Committee Activities
 - Mentor Sessions
 - Assessor Forum
 - 2018 Timeline – Year in Review
 - Standard Interpretation Request (SIR) update
 - Plans for Implementation of the 2016 Standard (Standards Review Update)
 - Other issues/discussion

Slide 5 -- Mentor Sessions

- The Sessions:
 - Encourage networking and collaboration
 - Provide for knowledge sharing (guidance)
 - Reduce barriers to:
 - ✦ getting accredited
 - ✦ maintaining accreditation
- The Speakers include:
 - State Accreditors
 - Assessors
 - Lab Managers
 - Quality Assurance Specialists
 - Instrument Specialists

Slide 6 -- TNI Mentor Session 2019

AGENDA

Scope:

- Overview of Internal Audits and Tools for Meeting the Requirements
- Pre-audit documentation
- In-audit documentation
- Post-audit documentation

10:30 to noon – Presentations

- Scott/Michelle – overview 10:30 – 11:30
- Dorothy – how to do double duty – 11:30-12

Slide 7 -- TNI Mentor Session 2019

1:30 to 3:00 and 3:30-5:00 – Workgroups/Presentations [note: divide into workgroups based on size of lab with at least one AB/Assessor per group]

- WG Activity 1 – Create an internal audit checklist for a designated section of the standard
- Presentation on How to Effectively Use Checklists
- WG Activity 2 – Give each group a checklist and have them develop the questions or auditing techniques that will enable evaluation of the items on the list; report out and feedback/discussion
- WG Activity 3 – Provide each group with examples of “proof of compliance” for checklist items where some are weak in meeting the expectation and some are strong. Have the group determine which are which and evaluate the weak examples as to how it could be strengthened.
- WG Activity 4 – Report or Audit Closure documentation; share what is needed to accomplish this.

Slide 8 -- Assessment Forum

Started in 2005

Goal:

- To provide an opportunity for laboratories and laboratory assessors to share information on how to improve the laboratory assessment process.

Topics:

- feedback from the previous participants,
- hot topics of the day
- suggestions from individuals
- member presentation interests

Slide 9 -- TNI Assessment Forum 2018

Tuesday January 29th 1:00 – 5:00pm

Session Moderator/Team: Judy Morgan, PACE Analytical

Jack Farrell, AEX, David Caldwell, OKDEQ

Purchasing Services and Supplies - Section 4.6 of ELSS Volume 1 Module 2

- Overview of Session – 10 min
- Examples of Procurement Failures – Deficiencies and Consequences – 30 mins
- Case Study - Colitag Contamination – 10 min
- Requirement Review – 20 min
- Open Discussion and Certificate Review - 50 min

Audience Examples | Review of “good” and “bad” certificates

- Example of Preparation of a Standard – 30 min
- Considerations for Compliance – Checklist or Bulleted requirements - What supplies need this level of scrutiny? | What are “critical” consumables, supplies and services? | What should the expectation be for the documentation from the supplier? | How do you make sure you are getting what you need to meet the analytical and quality criteria?

Next Steps – 5 min discussion (Mentor session?, Another Assessment Forum?)

Slide 10 – shows timeline (unable to copy into outline)

Slide 11 -- Standard Interpretation Request (SIR) Update

- New submittals receive an acceptance decision within 3 days.

Slide 12 -- Standard Interpretation Request (SIR) Update

SOP 3-105 – Standards Interpretation

- ◆ Each SIR submission must contain only one question;
- ◆ The question must apply directly and clearly to a cited section of the Standard;
- ◆ The question is understood without supposition;
- ◆ The question is compelling, meaning the language used in the Standard(s) section cited in the SIR is not clear or where the language might have more than one interpretation;
- ◆ Where possible, the question should be framed in a manner that solicits a “Yes” or “No”;
- ◆ The question has not been posed or phrased to settle a dispute between the laboratory and the AB;
- ◆ The question is not a “how to” question; and
- ◆ The question is not a request for a method interpretation.

Slides 13 -- Implementation Guidance

Implementation guidance is developed from two sources:

- Mentor Session
- SIR Process:

A SIR may be classified as a clarification request needing implementation guidance to be developed, the LAS EC Chair or designee may forward the request to an appropriately appointed team who will answer the question.

Implementation guidance responses:

- categorized by subject matter or topic within the standard
- contain the original question
- may contain some additional background information
- Are supported by references to the appropriate sections of the all standards in use (if more than one is applicable.)
- shall be reviewed by at least one subject matter expert, external to LASEC Implementation guidance documents will be posted on the TNI website
- requester will be notified of the response, prior to posting
- shall include a disclaimer

Slide 14 – Implementation Guidance

TNI	Consensus Standards Development	Laboratory Accreditation	Proficiency Testing (PT)	Field Activities (NEFAP)	Stationary Sources (SSAS)	Training & Meetings
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TNI Standards Guidance

Disclaimer: This material represents the opinion of its authors. It is intended solely as guidance and does not include any mandatory requirements except where such requirements are referenced. This guidance does not establish expectations of being implemented universally, exclusively, in whole, or in part.

This guidance does not establish or affect legal rights or obligations and is not finally determinative of the issues it addresses. It does not create any rights enforceable by any party in litigation with TNI, its accreditation bodies, or affiliated institutions. Any decisions made by TNI regarding requirements addressed in this guidance will be made by applying the applicable standards, policies or procedures to the relevant facts.

Module: Quality Systems & Chemistry

Subject: Titrants - Documentation and Verification

Question 1	<p>Is it required to independently verify the concentration/strength of all laboratory titrant solutions?</p> <p>The laboratory must have a written policy on the use of prepared solutions. The policy shall address record keeping and documentation requirements for each type of solution.</p> <p>Considerations are as follows:</p> <ul style="list-style-type: none"> • Titrants used directly in the calculation of the analytical result must be independently verified for concentration. • Regardless of use, all prepared solutions affecting analytical quality and calibration must be traceable to the original chemical source to verify purity, concentration, suitability, specifications, etc. Traceability must be described in a policy or procedure.
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References:

TNI 2009 V1M4-1.7.3.5 c)	<p>1.7.3.5 Reagent Quality, Water Quality and Checks</p> <p>a) In methods where the purity of reagents is not specified, analytical reagent grade shall be used. Reagents of lesser purity than those specified by the method shall not be used. Documentation of purity shall be available.</p> <p>b) The quality of water sources shall be monitored and documented and shall meet method specified requirements.</p> <p>c) The laboratory shall verify the concentration of titrants in accordance with written laboratory procedures.</p>
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Slide 15 -- LASEC Plans – 2019

- Sustain SIR progress
- Supplement SIRs with Implementation Guidance for non-SIR questions
- Complete the review of Guidance for the Chemistry module
- Continue to Develop Policies and SOPs for NELAP
- Complete the outstanding items in the Lessons Learned document
- Collaborate with other committees as we plan for migration to the newly revised ISO17025 2017

Slide 16 -- Current List of IGs in Review

From Mentor Session

- Failure to Implement CA Despite Confirmation of Completion
- Failure to Qualify Results
- Improper Calibration Curve Change
- Whistleblower or Trouble Maker
- Vendor Recall
- Wrong ID on Bench Sheet
- Sample Cooler Overlooked and Melted
- Samples Switched

Slide 17 -- LASEC Review of Standard Guidance Documents

SUMMARY

V1

Three Guidance Documents:

- Chemistry – Calibration – Reviewed, approved, recommended - Adopted
- Chemistry – Detection and Quantitation - Reviewed
- PTRL Guidance - Reviewed, approved, recommended - Adopted

All guidance must meet the requirements of SOP 1-105 Process for Creating Guidance

Slide 18 -- SOP/Policies/Etc. in Review

SOP 3-106 Standards Review and Acceptance

- Revision pending from “lessons learned” during the review of the 2016 TNI Standard.

Slide 19 -- Lessons Learned

- Summary of challenges identified during the review of the 2016 Standard
- 9 “Lessons” listed in the document
- LASEC → CSD → AC → LASEC
- A few issues left to resolve.....

Slide 20 -- Lessons Learned

The issues still needing to be resolved with clarity are

1. the request for some evaluation or estimate of economic impact of the revision,
2. the issue of handling specific comments that might be identified outside of the defined comment periods (show-stoppers especially),
3. the process for making persuasive/non-persuasive decisions about comments,
4. the need for a longer minimum comment period during reviews and at the voting stage, and
5. the need to document that all relevant SIRs have been reviewed and considered during the revision process.

Slide 21 -- Any other issues? Questions? Discussions?

Attachment C – Lessons Learned Document, 12/10/18

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, PTEExpert 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.