

**Laboratory Accreditation System Executive Committee Meeting Minutes
November 28, 2017 1:30 pm**

1) Welcome and Introductions

Judy Morgan welcomed everyone to the meeting. Minutes of October 24 were approved by acclamation. Attendance is recorded in Attachment A.

2) Assessment Forum and Mentor Session

No one has seen any write-ups from the Mentor Session in August, in Washington, DC, but the evaluations showed that participants liked the workshop format and the networking opportunity it provided, beyond the substance and purpose of the session. Since this committee meeting, Lynn contacted Jerry Parr, and a conference call with him, Ilona, Dorothy, Nick and Judy is scheduled for December 8, to discuss possible topics for a follow-on session in Albuquerque.

Further discussion led to a suggestion to ask Jack and perhaps an A2LA representative to discuss the status of California's program and its use of third party assessors for the Assessment Forum session.

2) SIR Update

The SIR subcommittee did not meet. The draft recommendation on how to proceed with managing and implementing the detailed review of SIRs prepared by Jerry Parr, as they relate to the 2016 Standard, was distributed for consideration. The purpose of this review was to identify which SIRs should "carry forward" and apply to the 2016 Standard, and which ones were incorporated into the 2016 Standard or are otherwise obsolete. The draft was approved by acclamation as presented (see Attachment C) and Judy will send it forward to Jerry.

3) Lessons Learned

No further edits were received, after the October meeting, to the draft transmittal for the consolidated list of "lessons learned" during LASEC's review of the 2016 standard for suitability. (See Attachment D, below.) By acclamation, participants approved sending the document forward to the Executive Director (and, at his discretion, the Board of Directors,) the NELAP AC and CSDEC, as well as proceeding to incorporate appropriate portions into the LASEC Standards Review SOP 3-106.

4) Decoupling AB Certificates of Recognition from the Evaluation Process

The NELAP Accreditation Council has been discussing how to modify the evaluation process so that delays such as those encountered this year are not devastating. (At this point, twelve months into the cycle, only one evaluation is complete and only three site visits have been accomplished.) The Council was presented with a draft policy, based on its discussions in recent months, and requested that LASEC be invited to provide additional input, particularly where additional detail might clarify issues for someone not immersed in the actual evaluation process, such as new Accreditation Bodies and new third party assessors. No further discussion took place at this committee meeting, but

participants were asked to review the document and offer ideas for improvement by emailing both Judy and Lynn. (See Attachment E, below.)

5) Conflict of Interest SOP

TNI's Board of Directors has directed all executive committees to prepare SOPs based on the Conflict of Interest Policy 1-101. Lynn is willing to draft such a document but needs to know more about possible ideas to include. Sample documents or a discussion of committee members' thoughts will be needed before writing can begin.

6) Chemistry Module, V1M4

The voting on the revised V1M4 closed in October, and all comments have been addressed by the Chemistry Expert Committee. Ken Jackson provided the final language of the module for review by LASEC and the NELAP AC, and a draft recommendation from LASEC to the NELAP AC was distributed with the meeting agenda (see Attachment F,) along with the initially approved 2016 module and the revised section 1.5 that was just completed.

A vote to approve the recommendation was initiated, and absent members were invited to vote by email. As of COB Friday, December 1, there were nine "yes" votes and one abstention, so that the recommendation is approved. This recommendation will be presented to the NELAP AC at its December 4 meeting.

7) Next Meeting

The next scheduled teleconference meeting will be Tuesday, December 19, 2017, at 2:30 pm Eastern time. NOTE: This is a one-time reschedule due to the Christmas holiday week. A reminder with agenda will be sent prior to the meeting.

Action Items are included in Attachment B.

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, 12/18	Chair (all)	Pace Analytical	Lab/FSMO	Yes
2	JoAnn Boyd	jboyd@swri.org	3 years, 12/16	StdsRev	Southwest Research Inst.	Lab/FSMO	No
3	Kristin Brown, Vice Chair	kristinbrown@utah.gov	2 years, 2/17	SIRs/Assmt Forum/FAQ	UT Bur. of Lab Improvement	NELAP AB	No
4	David Caldwell	david.caldwell@deq.ok.gov	2 years, 12/17	Assmt Forum	OK DEQ	Non-NELAP AB	Yes
5	Sumy Cherukara	Cherukara.sumy@epa.gov	3 years, 12/19		EPA R2	Other	No
6	Jack Farrell	aex@ix.netcom.com	3 years, 12/16	Assmt Forum, StdsRev	Analytical Excellence	Other	No
7	Myron Gunsalus	ngunsalus@kdheks.gov	3 years, 12/18		KS Lab Director	NELAP AB	Yes
8	Bill Hall	George.Hall@des.nh.gov	3 years, 12/16	SIRs,FAQs	NH ELAP	NELAP AB	No
9	Carl Kircher	carl.kircher@doh.state.fl.us	3 years, 12/18	SIRs, FAQs	FL DOH	NELAP AB	No
10	Harold Longbaugh	harold.longbaugh@houstontx.gov	3 years, 12/19		Houston Lab	Lab	Yes
11	Dorothy Love	dorothylove@eurofinsus.com	3 years, 12/18	Assmt Forum	Eurofins Env't'l	Lab	Yes
12	Mitzi Miller	mitzi.miller@moellerinc.com	2 years, 12/17	FAQs	Dade Moeller, Inc	Other	No
13	William Ray	Bill_Ray@williamrayllc.com	3 years, 12/17		Wm Ray Consultants	Other	No
14	Nick Straccione	nstraccione@emsl.com	3 years, 12/19	Assmt Forum	EMSL	Lab	Yes

Associate Members							
	Aaren Alger	aaalger@pa.gov			PA DEP	NELAP AB	No
	Michelle Wade	michelle@michellefromks.com			Wade Consulting	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

Action Items – LAS EC

	Action Item	Who	Expected Completion	Actual Completion / Comments
64	Update SOP 3-106 with “lessons learned” once the 2016 standard is in place	LASEC	“parking lot issue” -- open	Particularly, add review of committee decisions about non-persuasive comments and examine timing of multiple reviews in light of SOP 2-100 restrictions
71	Review draft lessons learned paper (see Attachment C below)	LASEC	Prior to November 28 meeting	
72	Contact Jack and A2LA about possible Assessment Forum talks in Albuquerque	Judy	ASAP	
73	Meet with Jerry and Ilona to plan Mentor Session	Judy, Dorothy, Nick, Lynn	12/8/17	

Draft Response to Jerry Parr about Future Use of SIRs Disposition Spreadsheet – 10/30/2017

Jerry Parr provided LASEC with a detailed spreadsheet of all SIRs, grouped by module of the standard, including the status of the SIR and a recommendation about whether a) the SIR and its interpretation should carry forward to the 2016 modules or b) if the SIR is obsolete or c) if the approved interpretation has been completely incorporated into the relevant 2016 module. The spreadsheet was created for use in a training course for assessors, to ensure that interpretations are addressed as well as the language in the standard itself. *[NOTE: What follows is the committee's response to the spreadsheet.]*

LASEC's SIR Subcommittee reviewed the spreadsheet, and offers the following suggestions for moving forward.

- All interpretations that are still relevant and were not incorporated into the standard should carry forward, remaining on the website with the cited reference updated, if necessary, for the most recent revision of the module.
- Unapproved, un-completed SIRs would necessarily carry forward until the next revision cycle.
- Interpretations for all SIRs that were incorporated into the 2016 standard should be posted (archived) in a form accessible to the TNI community, clearly marked as having been addressed in the 2016 standard. Archiving matters since the interpretation may have additional information that helps with either implementing or assessing that particular section of the standard. The archived materials could be posted to the website somewhat like the Implementation Guidance documents.

Any completed SIRs that were not incorporated into the revised modules should have been, and TNI needs to make stronger efforts to ensure that all completed SIRs are incorporated into the next revision of standards modules. It would seem that the Standards Development SOP 2-100 is the appropriate place to document this requirement, rather than the LASEC SIR Management SOP 3-106.

Regarding the spreadsheet itself, before taking further action to alter SIR information on the website, the SIR subcommittee recommends that the individual expert committees be asked to verify the preliminary determination about whether each SIR was addressed or needs to be carried forward. Terminology such as "still valid" needs to be clarified – can the SIR not be incorporated or was it overlooked?

LASEC should have a review and confirmation responsibility for the final product of the expert committee review process. Then, for the future, expert committees should be required to evaluate what to do with SIRs pertaining to their modules, during each revision of the committee's module.

Thank you for the opportunity to review this spreadsheet.

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.

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

- 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 include 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

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

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

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

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.

- 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

- 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

- 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

Policy TITLE:	Relationship of NELAP AB Certificates of Recognition and the NELAP Evaluation Process -- DRAFT FOR COMMENT
Policy NO.:	3-YYY
REVISION NO:	0
Program	NELAP

Committee Approved Date:	
Policy Committee Reviewed Date:	
TNI Board of Directors Endorsed Date:	
Policy Effective Date:	(TNI fiscal year 2019)

I. PURPOSE AND APPLICABILITY

This policy describes the relationship between issuance of Certificates of Recognition and the three-year evaluation cycle for the National Environmental Laboratory Accreditation Program (NELAP) Accreditation Bodies (ABs.)

II. DEFINITIONS

Certificate of Recognition: the document that officially designates a NELAP AB as being “approved” to accredit laboratories to the standard adopted by the NELAP AC. A certificate is valid for three (3) years, so that the evaluation process occurs every three years for each AB.

Evaluation Team (ET): a team comprised of the LE, other State AB and/or EPA representatives, and any other technical evaluators approved by the NELAP AC to conduct a review of an AB for the purposes of granting NELAP recognition to the AB.

Lead Evaluator (LE): the chosen member of the ET who provides direction for the ET and is responsible for issuing the written final recommendation regarding AB recognition, based on input from the entire team.

NELAP Accreditation Body (AB): one of the AB organizations within NELAP. An AB is responsible for assessing a laboratory’s total quality system, on-site assessment, and PT performance tracking for fields of accreditation.

NELAP Accreditation Council (AC): the body within TNI’s NELAP program comprised of representatives of each NELAP AB and holding final authority for implementation of the program for the accreditation of environmental laboratories.

III. RELATED DOCUMENTS

NELAP Evaluation SOP 3-102 (*NOTE: may require minor revision to accommodate this policy*)

IV. CERTIFICATES OF RECOGNITION

Beginning with the start of The NELAC Institute's (TNI's) fiscal year 2019, in October 2018, all NELAP ABs in good standing will be issued a Certificate of Recognition. "Good standing" means that the AB's most recent evaluation was satisfactory and that its continued recognition was approved by the NELAP Accreditation Council (AC) at the conclusion of that evaluation.

New certificates will be issued annually to each AB in NELAP, contingent upon the most recent evaluation being satisfactory and assuming that the AB wishes to continue with the program. Previously, new certificates were issued only at the completion of the evaluation process, regardless of time elapsed since the previous certificate was issued.

V. NELAP EVALUATION CYCLE CHANGES RESULTING FROM THIS POLICY

The NELAP ABs are evaluated approximately once every three years, in accordance with the NELAP Evaluation SOP 3-102, by a team of peers led by a Lead Evaluator (LE) who is contracted to The NELAC Institute. Depending on the wishes of the EPA region in which the AB is located (the states are divided into ten EPA regions), this team may include EPA regional staff.

The timing and team composition for these evaluations has shifted since the inception of NELAP. The AC finds that, with one single LE and an alternate LE for instances where conflict of interest may be present, it is desirable and practical to formally schedule these evaluations on a regular basis over the three year cycle, rather than have each evaluation begin at some date dependent on the conclusion of a prior evaluation.

Thus, beginning with the evaluation cycle that starts in November, 2019, NELAP ABs will be scheduled to receive their renewal letters (requesting renewal applications) at intervals of two months, in the order in which their evaluations were concluded during the 2016-2019 cycle of evaluations. This interval will permit the LE to schedule the steps of the evaluation, as described in SOP 3-102, on a systematic basis, and will enable the individual ABs to proceed through the process on a more clearly defined schedule.

VI. CONTINUED MEMBERSHIP IN NELAP AC

As documented in SOP 3-102, the final step of an AB evaluation is the decision of the NELAP AC concerning whether to accept the recommendation of the evaluation team, for continued recognition, as presented by the LE. In the unexpected event that the evaluation is unsatisfactory, and the NELAP AC accepts a recommendation not to renew an AB's recognition, then the NELAP AC will determine a suitable amount of time to transition the AB's accredited labs to other NELAP ABs (probably two to four months) and, based on that determination, set an "end date" for the AB's then-currently-valid Certificate of Recognition. In this case, the Certificate issued to that NELAP AB would expire on the date determined by the NELAP AC, regardless of the "normal" annual expiration date on the Certificate when it was issued.

Policy Approved Changes

Prev. Policy No.	New Policy No.	Date of Change	Description of Change

Attachment F

**Recommendation of LASEC to NELAP AC
TNI ELS Standard V1M4, Chemistry module as revised and approved with final
vote ending October 15, 2017
APPROVED BY LASEC November 28, 2017**

The LASEC has reviewed the revised Chemistry Module (V1M4 Rev 2.2) as revised and approved by TNI member vote, closing October 15, 2017. LASEC has determined that all of the previously objectionable language has been revised in a way that met the NELAP AC's requirements (given the lack of adverse comments from the NELAP AC members on this current revision) and LASEC recommends that the NELAP AC find the revision to be acceptable. LASEC makes this recommendation with the caveat that the previously agreed-upon "guidance" for the Chemistry Module, that has yet to be reviewed, is determined to be suitable.

With this recommendation, LASEC is providing a redline version of the revised sections plus the previously rejected V1M4 Rev 2.1 for comparison.