

Laboratory Accreditation System Executive Committee Meeting Minutes
October 24, 2017 1:30 pm

1) Welcome and Introductions

Judy Morgan welcomed everyone to the meeting. Minutes of June 27 and August 7, 2017, were approved by acclamation. Attendance is recorded in Attachment A.

2) Approval of Revised SIR Management SOP 3-105

This SOP was approved unanimously with the revisions from the May meeting, and is considered to have “provisional” status, meaning that it can be used as approved. Due to a rescheduling of the July Policy Committee meeting, it will not be possible to have Board endorsement (and thus attain “final” status) prior to conference, but the revised SOP is usable in its current status.

2) Updates

Implementation Guidance from WET Expert Committee Activities – Lynn noted that this committee has addressed some questions from the WET lab community that are being turned into Implementation Guidance. These will come to LASEC for final approval once completed and reviewed.

Assessment Forum and Mentor Session – There was no update on this activity. None of the draft Implementation Guidance documents from the Assessment Forum sessions in DC have been presented to LASEC yet. NOTE: the winter conference is only ten weeks away.

SIR Management SOP 3-105 – this revised SOP, incorporating updated language about Implementation Guidance, was endorsed by the Board at its October 11 meeting.

SIRs – the SIR subcommittee met and considered a detailed review of SIRs, as they relate to the 2016 Standard, as conducted by Jerry Parr. The purpose of his 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 SIR subcommittee is drafting a recommendation on how to proceed and will bring that recommendation to the full committee at the November meeting.

Standards Modules – voting closed on the Chemistry Module, V1M4. Ken Jackson explained at the October Board meeting that the issue raised about requiring preservatives in one section of the standard but not in another was an error. EPA removed the preservative requirement in its recent Method Update Rule, and the requirement should have been completely removed from V1M4. He believes this can be corrected as a “technical edit.”

3) Lessons Learned

A draft transmittal for the consolidated list of “lessons learned” during LASEC’s review of the 2016 standard for suitability was provided for committee consideration. (See Attachment C, below). Participants briefly discussed the document, and a few edits were suggested. Judy asked that other edits and comments be sent to her and Lynn

after the meeting. A revised version will be presented for approval at the November meeting.

These recommendations will be incorporated into the Standards Review SOP 3-106, where appropriate, and also shared with the NELAP AC and CSDEC once finalized.

4) Next Meeting

The next scheduled teleconference meeting will be Tuesday, November 28, 2017, at 1:30 pm Eastern time. 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 | Yes |
| 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 | Yes |
| 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 | No |
| 8 | Bill Hall | George.Hall@des.nh.gov | 3 years, 12/16 | SIRs,FAQs | NH ELAP | NELAP AB | Yes |
| 9 | Carl Kircher | carl.kircher@doh.state.fl.us | 3 years, 12/18 | SIRs, FAQs | FL DOH | NELAP AB | Yes |
| 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 | No |
| 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 | Yes |
| 14 | Nick Straccione | nstraccione@emsl.com | 3 years, 12/19 | Assmt Forum | EMSL | Lab | no |
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|-------------------|---------------|--|--|------|-----------------|----------|-----|
| 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 | |
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Attachment C – Lessons Learned Draft

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 b) 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 ___ 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.

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 75-90 days.

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

Responsible Parties: LASEC and CSDEC