

Laboratory Accreditation System Executive Committee Meeting Minutes
Forum on Laboratory Accreditation, Washington, DC
August 7, 2017 9:00 am

1) Welcome and Introductions

Judy Morgan welcomed everyone to the meeting and invited committee members to introduce themselves. Attendance is recorded in Attachment A.

2) Assessment Forum and Mentor Session

The first session, on Monday afternoon, will include a presentation by Judy on regulatory requirements as an introduction, and then will address three areas where California labs are requesting “clarifying language” to provide the substance for implementation guidance on particular portions of the 2016 standard. The Tuesday morning session will address five more areas selected for implementation guidance.

3) SIRs

Judy provided statistics on the number of Standard Implementation Requests (SIRs) submitted and accepted as valid. She also explained that the SIR Management SOP 3-105 was updated to include the terminology “implementation guidance” as approved for guidance development by TNI’s Policy Committee, and also to include the components of implementation guidance as well as the language required for the disclaimer to accompany each document when posted to the TNI website.

4) Timeline of LASEC Activities

Judy presented a graphic showing the past year’s activities of LASEC. This graphic is included in the presentation shared with committee members, that will also be posted to the meeting website at some point. The biggest item, by far, was review of the modules of the 2016 TNI Environmental Lab Sector Standard.

5) Plans for 2017

Judy briefly discussed the committee’s plans for the remainder of the year, as outlined below:

- Sustain SIR progress
 - Create Implementation Guidance according to SOP 3-105 for non-SIR questions (including from this conference’s Assessment Forum sessions)
- Monitor and comment on New Revisions to Standards Modules
 - Chemistry module underway, with WET module and Volume 2 AB Operations module starting
- Revise review process SOPs as needed
- Continue to develop policies and procedures for NELAP AC

6) Lessons Learned

During recent meetings, LASEC has discussed and created a list of “lessons learned” during the review of the 2016 standard for suitability. These lessons will be incorporated into the Standards Review SOP 3-106 and also shared with the NELAP AC and CSDEC in the coming months. The lessons identified are listed below, along with participant comments (in italics) offered during the discussion.

1. **Revised language:** 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.
2. **Pre-notification:** It would be helpful to have the expert committee provide information on proposed changes prior to the start of revision (this is discussed in the Standards Development SOP 2-100, section 5.2). Would like to have justification for any changes made/proposed.
Now included in SOP 2-100
Pennsylvania noted that state regulations are required to justify changes
Consider including economic impact of proposed changes
Provide a summary of changes (along with redline)
Consider whether some form of Frequently Asked Questions (FAQ) would be helpful
3. **Recommendations:** LASEC’s process for recommending standards modules to the NELAP AC, and the possibility of a recommendation “with conditions” (such as guidance) was tested with the Chemistry module.
 - The process did not work as well as initially anticipated. Perhaps a closer examination of where the process broke down will help with improvements.
4. **Individual Comments:** A standardized procedure for developing and maintaining the “response to comments” document needs to be developed by CSDEC that addresses:
 - An explanation of the decision process (comments are persuasive or non-persuasive.)
Need better and more consistent processes across committees for making persuasive/non-persuasive decisions
 - A way to ensure that the expert committee’s understanding of each comment matches what the commenter intended to say, so that comments are not dismissed because they are misunderstood.
 - A way to assess impact of a comment to ensure that discussions result in adequate resolution.
LAB and WET revisions will include tracking of comments made in public sessions and any other means. Other Program Administrators are considering doing the same.
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.”

Some committees assign comments to individual members to address, and those decisions are brought back to the full committee for consideration.

5. **Committee Comments:** There MUST be some provision for considering and responding to comments from committees, since this is the stated purpose of LASEC’s involvement in the process – recommending adoption (or not) to the NELAP AC.

When a committee determines that an implementation barrier exists, there MUST be a process for getting that feedback into the expert committee’s deliberations.

6. **Significant Comments/Concerns:** At present, only comments accompanying votes (at the designated voting stages of development) are addressed.
 - There must be some way to address significant comments outside of this framework – the system needs to be tweaked.
7. **Time:** Need adequate time for review (30-45 days is not sufficient.)
8. **SIRs/TIAs:** Provide a list of SIRs and TIAs that were carried into the new document (would also serve as a check and balance to ensure that interim interpretations are included.)
9. **Comments:** 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” do not get overlooked and provide some ability to estimate the criticality of comments received.

7) Additional Items Raised by Participants

Participants noted that the process of going from the 2009 TNI standard to the 2016 version is an improvement over the process of going from the 2003 NELAC Standard to the 2009 TNI standard. One commenter noted that “continuous improvement” has also provided some “preventive actions.”

One participant asked if there is any way to address the voting on standards modules by TNI members, since so few members actually cast votes. The only response offered, thus far, is that we do not know the reason for this, and without knowing why, it will be difficult to address the lack of member participation in the voting process. Determining the “root cause” will be problematic.

Judy noted that TNI needs some provision for addressing “outliers” during review of the standards modules – items that are recognized as needing revision, but not within the defined timelines of the Standards Development SOP 2-100. These would include substantive items that can reasonably be expected to create difficulties with adoption and implementation, but probably not the merely “nice to have” tweaks to the documents.

8) Next Meeting

The next scheduled teleconference meeting will be Tuesday, September 22, at 1:30 pm Eastern time. An agenda and any needed documents will be provided in advance of 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 (phone)
6	Jack Farrell	aex@ix.netcom.com	3 years, 12/16	Assmt Forum, StdsRev	Analytical Excellence	Other	Yes
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	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	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 (phone)

Associate Members							
	Aaren Alger	aaalger@pa.gov			PA DEP	NELAP AB	Yes
	Michelle Wade	michelle@michellefromks.com			Wade Consulting	Other	Yes
	Gale Warren	ggw01@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	Share “lessons learned” with CSDEC and work to further improve the process	Judy/Lynn		Begin after final committee discussion in September 2017
72				
73				