

**Laboratory Accreditation System Executive Committee Meeting Minutes**  
**January 22, 2019 1:30 pm Eastern**

1) Welcome and Introductions

Judy Morgan welcomed everyone to the meeting. Attendance is recorded in Attachment A. Minutes from December 18, 2018, were approved.

2) Assessment Forum and Mentor Session Update

Dorothy reported that the Mentor Session on internal audits is coming together nicely. The agenda is in Attachment B.

Judy negotiated a final planning call for the following day, for the Assessment Forum. The draft agenda is in Attachment C.

3) SIR Updates

The SIR Subcommittee met before the full committee meeting. Two of the four members who had agreed to review the Implementation Guidance (IG) drafts returned their work by the deadline, and those have been distributed to SIR Subcommittee members for review. The remaining nine drafts need replacement reviewers. Judy agreed to review six of those and Silky volunteered to review the remaining three. Thank you both!

Unfortunately, none of these will be approved in time for conference, but reviews are moving again.

The subcommittee reviewed two IG drafts from SIR submissions. One of these, from SIR 282 about substituting a matrix spike for a lab control sample, turned out to have a history going back to the early NELAC standards, and apparently, lab practices are not always aligned with what seemed to be appropriate guidance. With this divergence of opinions, that item is being reclassified as a SIR and will be sent to the Chemistry Expert Committee for interpretation.

A second IG draft was prepared by Paul Junio, after Quality Systems Expert Committee struggled to prepare a response to the SIR question as an interpretation. Paul joined the subcommittee yet again to discuss this draft, and while he and the subcommittee believe the draft is adequate, Judy asks that the full committee review the draft IG and provide feedback before it is posted. This IG draft is being sent to members for review, along with the minutes.

4) LASEC Session at Conference

For this session on Monday afternoon, immediately after lunch, Judy will give the committee update at the outset, along with plans for the coming year.

The remainder of the session will be devoted to a conversation with CSDEC and the NELAP AC about the outstanding items from the Lessons Learned document. When

this was presented to the TNI Board at its December 12 meeting, Board members requested more specifics about what should be changed, so this conversation will be focused on identifying how to best meet the needs of the entire TNI community about reviewing and providing feedback (comments) on developing standards as well as the needs of the Accreditation Council for implementing those standards.

The issues still needing to be resolved with clarity are

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

#### 5) Chemistry LOD/LOQ Guidance Document

The NELAP AC determined not to wait for approval of this guidance, and has set its implementation date for the 2016 Standard as January 31, 2020. As with prior standard changes, this will be a “rolling implementation” with ABs that need to write regulations before implementation making the conversion when they are able to do so.

The annotated version of this Detection and Quantitation Guidance that was shared with LASEC in December has been transmitted to the Chemistry Expert Committee, which was less than pleased, particularly when they realized that the comments were made on an earlier version of the guidance. Still, Chemistry remains adamant that LASEC should not undertake a revision since LASEC members were not privy to the discussions that underlie the decisions made when the guidance was created.

The Chemistry Committee session on Wednesday afternoon will discuss this guidance document and hopefully come to terms with the fact that some revisions still need to be made. Judy agreed to be prepared to itemize the comments from the annotated version that were not addressed in the next revision. It remains unclear whether the conversion to active voice can be accomplished.

#### 6) Next Meeting

The next meeting of LASEC will be at conference in Milwaukee, **January 28, 2019, at 1 pm Central** time. Teleconference capability will be available, and the teleconference information will be sent separately.

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	<a href="mailto:Judy.Morgan@pacelabs.com">Judy.Morgan@pacelabs.com</a>	3 years, 12/21 (extended)	Chair (all)	Pace Analytical	Lab/FSMO	Yes
2	Sumy Cherukara	<a href="mailto:Cherukara.sumy@epa.gov">Cherukara.sumy@epa.gov</a>	3 years, 12/19		EPA R2	Other	No (furlough)
3	Silky Labie	<a href="mailto:elcatllc@centurylink.net">elcatllc@centurylink.net</a>	3 years, 12/20	SIRs	ELCAT	Other	Yes
4	Harold Longbaugh	<a href="mailto:harold.longbaugh@houstontx.gov">harold.longbaugh@houstontx.gov</a>	3 years, 12/19	SIRs	Houston Lab	Lab	Yes
5	Dorothy Love	<a href="mailto:dorothylove@eurofinsus.com">dorothylove@eurofinsus.com</a>	3 years, 12/21	Assmt Forum	Eurofins Env'tl	Lab	Yes
6	Michele Potter	<a href="mailto:michele.potter@dep.nj.gov">michele.potter@dep.nj.gov</a>	3 years, 12/20		NJ DEP	AB	Yes
7	Scott Siders	<a href="mailto:ssiders@pdclab.com">ssiders@pdclab.com</a>	3 years, 12/20	Assmt Forum	PDC Laboratories	Lab	No
8	Nick Straccione	<a href="mailto:nstraccione@emsl.com">nstraccione@emsl.com</a>	3 years, 12/19	Assmt Forum	EMSL	Lab	No
	(2 AB members pending)						

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

## **Attachment B – Mentor Session Agenda**

### **Internal Auditing Tools of the Trade**

#### 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

#### 1:30 to 3 and 3:30-5 – 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 (Pam to develop, Nick to present)
- 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.

## Attachment C – Draft Assessment Forum Agenda

### 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
  - o Audience Examples
  - o Review of “good” and “bad” certificates
- Example of Preparation of a Standard – 30 min -
- Considerations for Compliance – Checklist or Bulleted requirements -
  - o What supplies need this level of scrutiny?
  - o What are “critical” consumables, supplies and services?
  - o What should the expectation be for the documentation from the supplier?
  - o 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?) - All