Laboratory Accreditation System Executive Committee Meeting Minutes June 26, 2018 1:30 pm Eastern

1) Welcome and Introductions

Judy Morgan welcomed everyone to the meeting. Attendance is recorded in Attachment A. Minutes from May 22, 2018, were approved later in the meeting, after a quorum was present.

Judy noted, for those who might need to depart the meeting early, that a Wednesday afternoon session at conference is planned to address the next revision of the TNI Standards that will be based on the 2017 revision of ISO/IEC 17025. She encouraged everyone to engage in this discussion.

2) Assessment Forum and Mentor Session Update

The Assessment Forum in New Orleans will be Monday morning, and will address new requirements in the 2016 TNI ELS Standard that can be implemented whenever the lab chooses, up until its primary AB requires them. The first portion will focus on the Quality Systems module, with shorter segments about radiochem and microbiology. After the break, the second session will focus on the two Chemistry Guidance documents. Presenters have been asked to allow ample time for Q&A.

The Tuesday morning Mentor Session will be based on a survey sent out in mid-June to all TNI members. As of the LASEC meeting date, sixty replies have been received, and a few more will likely arrive before the end date of the survey. Dorothy will present the methodology used and Michelle Wade will present a summary of the "oh, crap!" moments and actions taken that were reported in response to the survey. The second half of the session will be either panel discussions or small group sessions, based on the survey results.

3) SIR Subcommittee

This group met prior to the LASEC meeting, to review six SIR submissions that were previously determined not to be valid SIRs but flagged as potential candidates for Implementation Guidance (IG) documents. One of these will be returned into the SIR system, one was determined not to be suitable for IG (it applied to AB activities, not labs) and four will be turned into IG documents.

Participants further discussed the SIR that is being re-visited, since it concerns filtering samples in the receiving room and whether the receiving team should create and filter method blanks as well. This procedure essentially holds the laboratory responsible for actions that should have been taken at the time of sampling.

4) Lessons Learned

Our Lessons Learned document, with CSDEC's comments, was offered to the NELAP AC for its consideration and comments. Meanwhile, LASEC members should review the CSDEC's comments and share their thoughts with other committee members.

NOTE: The NELAP AC discussed the Lessons Learned document briefly at its July 2 meeting, and agreed to provide written responses for the items that LASEC identified as being applicable to the AC. AB representatives will discuss this topic at conference, although not in the public session, and create written responses that will need to be approved by the full membership before delivery back to LASEC. Once LASEC has both sets of responses, a presentation to the TNI Board will take place.

5) Standards Review

As of June 18, the NELAP AC has adopted the 2016 TNI Standard, with the proviso that an implementation date will be set once the guidance documents are available and approved.

The PT Expert Committee's Guidance on the PT Reporting Limit (PTRL) was again discussed. At its June 6 meeting, the NELAP AC offered several comments and its members have been asked to review this document in more detail. Judy asked that LASEC members look at the document again (it was attached to the June 26 meeting reminder) and share their comments so those can accompany the NELAP AC's comments back to the PT Expert Committee. Obviously, since the AC has comments, it would be inappropriate for LASEC to proceed with its planned recommendation, at this time.

The Chemistry Guidance documents were not available as of this meeting date. NOTE: The Chemistry Guidance documents arrived on Friday, June 29, and were distributed for review

6) Conflict of Interest SOP 3-113

Minor revisions requested by Policy Committee's review were presented and explained. Myron moved and David seconded that the edited SOP be approved. The vote was unanimously in favor of the motion, and this document will be returned to Policy Committee for approval at its July 20 meeting.

7) NELAP Decoupling Policy 3-102

NOTE: The NELAP AC initiated a vote on this policy at its June 2 meeting. No further LASEC action is anticipated, but if LASEC is involved with revising the NELAP Evaluation SOP 2-102, interim oversight may still be added to the next version of that document.

8) Preparation for Discussion of ISO 17025's 2017 Revision at Conference in New Orleans

As noted above, a full half day session will be devoted to this discussion at conference. Several participants affiliated with companies having Canadian offices or relationships with other Canadian entities (that will shortly be accredited to the 2017 version by ILAC signatory ABs) offered perspectives. Also, the Defense Department's program will migrate to the new revision well ahead of the TNI ELS revision and NELAP's adoption of it. NEFAP is beginning to revise its FSMO Standard based on the 2017 revision now.

The significant difference in this revision is not in what's been added, but rather in what has been removed. There is no longer a requirement for a "quality manual" and the laboratory is supposed to identify vulnerabilities to data quality through a risk assessment process, and address those risks in its documentation. This process replaces many requirements, formerly in the standard, that have been removed. One participant remarked that this new revision of ISO 17025 is "an operation manager's dream but a QA Manager's nightmare." An AB stakeholder noted that governmental ABs need specifics in the standard, since often labs that are required to be accredited will only perform the minimum needed, and noted that risk assessment is a tool, not requirements that can be enforced.

In an email to LASEC members, Dorothy later provided two comparison documents of the 2004:2017 versions of ISO 17025 plus a link to a video produced by Perry Johnson, presenting the 2017 standard (~100 minutes, https://www.youtube.com/watch?v=pzhMgywc6Us&feature=youtu.be).

NOTE: Lynn raised this issue with the NELAP AC at its July 2 meeting, and shared both crosswalks as well as the video URL with that group as well.

David moved and Carl seconded that the meeting be adjourned.

9) Next Meeting

The next scheduled teleconference meeting will be Tuesday, July 24, 2018, at 1:30 pm Eastern time. A reminder with agenda will be sent prior to the meeting.

Action Items are included in Attachment B. This is the last month this Attachment will be included. Existing items will be moved into, and future tracking will be done in, the Excel file that accompanies each meeting's minutes.

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	Kristin Brown, Vice Chair	kristinbrown@utah.gov	FinalYear 2018	SIRs/Assmt Forum	UT Bur. of Lab Improvement	NELAP AB	No
3	David Caldwell	david.caldwell@deq.ok.gov	FinalYear 2018	Assmt Forum	OK DEQ	NELAP AB	Yes
4	Sumy Cherukara	Cherukara.sumy@epa.gov	3 years, 12/19		EPA R2	Other	Yes
5	Myron Gunsalus	ngunsalus@kdheks.gov	FinalYear 2018		KS Lab Director	NELAP AB	Yes
6	Carl Kircher	carl.kircher@doh.state.fl.us	FinalYear 2018	SIRs	FL DOH	NELAP AB	Yes
7	Silky Labie	elcatllc@centurylink.net	3 years, 12/20	SIRs	ELCAT	Other	Yes
8	Harold Longbaugh	harold.longbaugh@houstontx.gov	3 years, 12/19	SIRs	Houston Lab	Lab	No
9	Dorothy Love	dorothylove@eurofinsus.com	3 years, 12/18	Assmt Forum	Eurofins Env't'l	Lab	Yes
10	Michele Potter	michele.potter@dep.nj.gov	3 years, 12/20		NJ DEP	AB	Yes
11	William Ray	Bill Ray@williamrayllc.com	FinalYear 2018		Wm Ray Consultants	Other	No
12	Scott Siders	ssiders@pdclab.com	3 years, 12/20	Assmt Forum	PDC Laboratories	Lab	Yes
13	Nick Straccione	nstraccione@emsl.com	3 years, 12/19	Assmt Forum	EMSL	Lab	No
Ass	ociate Members						
	Aaren Alger	aaalger@pa.gov			PA DEP	NELAP AB	No
	Jack Farrell	aex@ix.netcom.com			Analytical Excellence	Other	Yes
	Bill Hall	George.Hall@des.nh.gov		SIRs	NH ELAP	NELAP AB	No
	Mitzi Miller	mitzi.miller@moellerinc.com			Dade Moeller, Inc	Other	No
	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
75	Review revised draft of COI SOP in preparation for vote	All committee members	June 26, 2018	Revisions approved; return to Policy for final approval