Laboratory Accreditation System Executive Committee Meeting Minutes December 18, 2018 2:30 pm Eastern

1) Welcome and Introductions

Judy Morgan welcomed everyone to the meeting. Attendance is recorded in Attachment A. Minutes from November 27, 2018, were approved. This meeting time was rescheduled due to the normal date falling on December 25.

2) Assessment Forum and Mentor Session Update

Nick reported that the planning group met on December 13 and agreed on the tasks needed to be complete in order to finish pulling together the Mentor Session for conference in Milwaukee, This session will be the second half of Monday morning and all of Monday afternoon. Unfortunately, that overlaps with the LASEC meeting, but the schedule conflict is difficult to avoid. Scott, Michelle Wade and Pam Schlemmer will comprise the planning group and Jack will be available on-site to assist. Nick asked that **committee members please send their examples of internal audits – especially traceability and both good and not-so-good practices – to Dorothy by the end of the year.**

Judy has a planning call scheduled for the Assessment Forum later in the week of this meeting. She noted that the topic of oversight of vendor quality has not yet been openly addressed, so that this session may actually be ground-breaking. David and Carl agreed to help previously and Jack will help as he's available.

3) SIR Updates

The SIR Subcommittee planned to meet on Thursday, December 20. NOTE: Subcommittee members are asked to review the draft Implementation Guidance documents that Nick and Dorothy have reviewed prior to the January 22 subcommittee meeting, so that we can announce the approval of half of the results from New Orleans at conference.

4) Lessons Learned and Comments Presented to TNI Board

The Lessons Learned document, with comments from CSDEC, the NELAP AC and LASEC, was presented to the Board at its December 12 meeting. Instead of responding to the items where reviewers (LASEC and the AC) sought more clarity from the expert committees and more review time, the Board focused more on the interactive aspect of the comments, suggesting that clear recommendations were not yet articulated.

After the CSDEC meeting (following the Board meeting), Bob Wyeth suggested and the other two groups agreed to meet in a public session at conference to further discuss how to approach resolution to the difficulties that LASEC identified. This session will be either on Monday morning (10:30 am – noon) or during the LASEC session on Monday afternoon (1 - 3 pm) at conference.

To repeat from the November minutes, the issues still needing to be resolved with clarity are

- the request for a redline/strikeout version of revised standards,
- 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 90-day 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 Guidance Documents

The minor edit to the Calibration Guidance (requested by the NELAP AC) was included in LASEC's review. There were no adverse comments on the latest revision of this document, and LASEC approved a recommendation to the AC that the Calibration Guidance be adopted. This recommendation is in Attachment 2 below.

Judy had asked several colleagues to review the Detection and Quantitation Guidance, and multiple comments were made that should be addressed. After discussing some of these comments and the concern about passive voice, participants agreed to return the document to the Chemistry Expert Committee with an offer to do a revision and provide it to Chemistry for review and approval, if Chemistry did not wish to do another revision.

For these reasons, no recommendation can be made about the Detection and Quantitation Guidance at this time. NOTE 1: The AC plans to consider whether to proceed with setting an implementation date for the standard or to await a final version of this guidance at its January 7 meeting.

NOTE: The response from Chemistry was that LASEC would not have access to the reasoning behind how the guidance was crafted, and that Chemistry Committee should do the revisions, although much frustration was expressed about substantive comments at this late date. Unfortunately, the version reviewed by these individuals was not the latest revision, but thankfully, most of the items noted have already been addressed. The most difficult issue to address, however, is the transition from passive to active voice, and that remains outstanding. No final resolution has yet emerged, as Chemistry meets on January 2.

Lynn noted that the NELAP AC accepted LASEC's recommendation about the PTRL Guidance at its December 3 meeting. Policy Committee requested, at its December 8 meeting, that the bullets be numbered for ease of reference, and PT Expert Committee has undertaken that task. The final version will be provided to LASEC and the AC for final acceptance, once Policy's review is complete.

6) Farewell to Members Completing Final Terms

Judy thanked everyone for their service on LASEC, and especially those completing their second 3-year term. She expressed her gratitude that everyone rolling off of full membership intends to remain as an associate member, and also noted that Bill Hall and Jack Farrell will be re-applying to become full members.

In response, committee members thanked Judy for her leadership and support of the LASEC.

7) Next Meeting

The next scheduled teleconference meeting of LASEC will be <u>Tuesday, January 22,</u> <u>2019, at 1:30 pm Eastern time</u>. 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	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	Yes
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	No
5	Myron Gunsalus	ngunsalus@kdheks.gov	FinalYear 2018		KS Lab Director	NELAP AB	No
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	No
8	Harold Longbaugh	harold.longbaugh@houstontx.gov	3 years, 12/19	SIRs	Houston Lab	Lab	Yes
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	No
11	William Ray	Bill_Ray@williamrayllc.com	FinalYear 2018		Wm Ray Consultants	Other	Yes
12	Scott Siders	ssiders@pdclab.com	3 years, 12/20	Assmt Forum	PDC Laboratories	Lab	No
13	Nick Straccione	nstraccione@emsl.com	3 years, 12/19	Assmt Forum	EMSL	Lab	Yes
13	Nick Straccione	nstraccione@emsl.com			EMSL	Lab	-

Associate Members							
Aaren Alger	aaalger@pa.gov		PA DEP	NELAP AB	No		
Jack Farrell	aex@ix.netcom.com		Analytical	Other	Yes		
			Excellence				
Bill Hall	George.Hall@des.nh.gov	SIRs	NH ELAP	NELAP AB	No		
Mitzi Miller	mitzi.miller@moellerinc.com		Dade Moeller,	Other	No		
	_		Inc				
Gale Warren	ggw01@health.state.ny.us	SIRs	NY ELAP	NELAP AB	No		
Program Admin.							
Lynn Bradley	Lynn.bradley@nelac-institute.org				Yes		

Attachment 2

Approved by the NELAP AC as of December 7, 2018.

Recommendation of LASEC to NELAP AC Regarding Chemistry Calibration Guidance

APPROVED BY LASEC December 18, 2018

The Laboratory Accreditation Systems Executive Committee (LASEC) has reviewed the guidance document provided by the Chemistry Expert Committee, TNI Guidance on Instrument Calibration, GUID-3-110-Rev0, December, 2018.

LASEC finds this guidance to be acceptable and useful, and recommends that the NELAP Accreditation Council approve it as presented.