Laboratory Accreditation System Executive Committee Meeting Minutes Forum on Laboratory Accreditation, Milwaukee, WI, February 26, 2019

1) Welcome and Introductions

Judy Morgan welcomed everyone to the meeting. Attendance is recorded in Attachment A. The minutes from January 22 and 28 were approved.

2) Election of New Members

Bill Hall and Jack Farrell have both agreed to be nominated as committee members. Both of them served the maximum of two three-year terms as full members, after LASEC was combined with the Technical Assistance Committee. Both have spent a year as associate members and would like to return to full membership. Michele moved and Sumy seconded that they both be elected, and approval was unanimous.

Judy is negotiating with one additional AB staff person to apply for membership, but that application has not yet arrived.

3) Mentor Session and Assessment Forum in Milwaukee

Dorothy was unable to participate in this meeting, but Judy reported that many participants from the Mentor Session indicated that it was successful. The Assessment Forum struggled with a short-notice substitute for its first presentation (many flights were delayed or cancelled during the entire week). After that, the session flowed more smoothly with a discussion of certificates of analysis and examples of missing items that are needed by labs and should have been included. Judy noted that there's a need for a follow-up session, at the summer conference in Jacksonville, FL, and will discuss with Dorothy whether that should be a Mentor Session or a more targeted Assessment Forum to address procedures for verifying acceptability of vendor-supplied products and establishing criteria for their acceptance.

4) SIR Update

Judy reported that the SIR Subcommittee met immediately prior to this meeting, and discussed the struggle to create an Implementation Guidance (IG) document from SIR 290, which questions how to deal with different calibration factors at the two calibration points of a thermometer. She noted that the subcommittee has identified a way to shorten the references sections in the IG documents being created from the New Orleans Mentor Session, all of which are still in review by the subcommittee.

Participants were asked to review the draft IG from SIR 239, about tracking support equipment. The document was distributed with the minutes from the January 22 meeting, so that committee members would have an opportunity to think about it prior to the discussion at this meeting. That question and the draft answer are provided in Attachment B.

Comments made follow:

• the response does not actually address the question asked

- the assessor's insistence on having records listed on the worksheet for the specific analytical result is, in fact, for the convenience of the assessor, and not actually needed for traceability of the support equipment, since those can normally be referenced back to which batch of reagent (or pipettes or whatever) was in use on the day of analysis
- a clear distinction between "analytical equipment" and "support equipment" is needed, since support equipment has multiple "layers" in use at different phases of the analysis
- the response is clear enough; participants agreed they can "live with it"
- how far down the "rabbit hole" does traceability need to be referenced? Does the worksheet really need to note which balance was used to make up the reagent batch on that particular day (in the past), or is it adequate to be able to document that balances used in the actual analysis were calibrated on the day of analysis?
- the documentation for traceability should be "risk-based, and there is not one fixed rule to apply
- Lynn noted that somewhere, this SIR got mis-numbered and while all the documentation has 329 on it, it is actually 328. This does not alter the text but she needs to fix it in the tracking mechanisms.

Michele offered to edit the response and distribute that for comments, after the meeting. This will be available for consideration at the next LASEC meeting.

5) Revision of the SIR Management SOP 3-105

The current revision of this SOP was distributed, for reference. As a result of the Lessons Learned Item 9, this SOP needs to include something about tracking SIRs and being able to provide to the various expert committees a list of completed SIRs that must be considered when a module of the standard is being revised.

Judy also noted that the Implementation Guidance description needs to be expanded to describe that the goal of IG is to describe the best or most accepted practice(s) in the industry to meet the requirement being questioned.

NOTE: Lynn will attempt a draft revision of this SOP for the next meeting. Also, the Detection and Quantitation Guidance should be available then, and the draft revised AB Operations module V2M1 should be available for review and comment soon.

6) Follow-Up to Lessons Learned

Judy noted that the CSDEC Chair, Paul Junio, is convening a small task force to revise the Standards Development SOP 2-100, and both she and Aaren Alger, NELAP AC Chair, have been asked to participate. Bob Wyeth, former CSDEC Chair, is now the Program Administrator for the Consensus Standards Development Program, and will be taking over the responsibilities for interacting with ANSI that Ken Jackson formerly fulfilled.

3) Next Meeting

The next scheduled teleconference meeting of LASEC will be <u>Tuesday, March 26,</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	12/21 (extended)	Chair (all)	Pace Analytical	Lab/FSMO	Yes
2	Sumy Cherukara	Cherukara.sumy@epa.gov	12/19 (first term)		EPA R2	Other	Yes
3	Jack Farrell	aex@ix.netcom.com	12/21 (first term)	Mentor Session	Analytical Excellence	Other	No
4	Silky Labie	elcatllc@centurylink.net	12/20 (first term)	SIRs	ELCAT	Other	Yes
5	Bill Hall	George.Hall@des.nh.gov	12/21 (first term)	SIRs	NH ELAP	NELAP AB	Yes
6	Harold Longbaugh	harold.longbaugh@houstontx.gov	12/19 (first term)	SIRs	Houston Lab	Lab	No
7	Dorothy Love	dorothylove@eurofinsus.com	12/21 (second term)	Mentor Session	Eurofins Env't'l	Lab	No
8	Michele Potter	michele.potter@dep.nj.gov	12/20 (first term)		NJ DEP	AB	Yes
9	Scott Siders	ssiders@pdclab.com	12/20 (first term)	Mentor Session	PDC Laboratories	Lab	No
10	Nick Straccione	nstraccione@emsl.com	12/19 (second term)	Mentor Session	EMSL	Lab	No

Associate Members					
Aaren Alger	aaalger@pa.gov		PA DEP	NELAP AB	No
Kristin Brown	kristinbrown@utah.gov	SIRs	UT Bur. of Lab Improvement	NELAP AB	Yes
David Caldwell	david.caldwell@deq.ok.gov	Assmt Forum	OK DEQ	NELAP AB	No
Myron Gunsalus	ngunsalus@kdheks.gov		KS Lab Director	NELAP AB	No
Carl Kircher	carl.kircher@doh.state.fl.us	SIRs	FL DOH	NELAP AB	No
Mitzi Miller	mitzi.miller@moellerinc.com		Dade Moeller, Inc	Other	No
William Ray	Bill_Ray@williamrayllc.com		Wm Ray Consultants	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

Implementation Guidance from SIR 239 (Question in Bold, guidance in plain type)

Does TNI contend that all support equipment is required to be traced to individual results, or is there a distinction between analytical equipment, that is required to be traced to individual results, and support equipment, that is required to be calibrated and correctly maintained, but not necessarily traceable to individual results? If the former, then where exactly is the limitation on what is required to be traceable?

The ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project.