Laboratory Accreditation System Executive Committee Meeting Minutes March 25, 2019

1) Welcome and Introductions

Judy Morgan welcomed everyone to the meeting. Attendance is recorded in Attachment A. The minutes from February 26 were approved.

2) Mentor Session and Assessment Forum for Jacksonville

Dorothy reported that the Mentor Session topic will be "Root Cause Investigations as a Follow-up to the Internal Audit Session" in Milwaukee, with both presentations and breakout groups. She expects that the presentations will give examples with corrective actions and illustrating different approaches, and indicated that serious work on the session will begin in May. Jack offered to present about AEX's procedure for meeting Florida's requirements for root cause analysis.

Judy discussed the Assessment Forum topic, which will be "Service Providers and Suppliers: Exploring the need for establishing consistent criteria for providers of critical consumables, supplies, and services in compliance with Section 4.6 of ISO 17025 and the TNI standard, Purchasing Services and Supplies". This too is a follow-up to the Milwaukee session, and may turn into a longer activity than just the single session. As an example, she noted that ASTM has requirements for Certificates of Analysis, although those are not always met by providers of standards, and that some labs are reluctant to challenge their suppliers who do not provide full information. Carl, Jack and David agreed to help develop this interactive session.

3) SIR Update

Participants were asked to review the revised draft IG from SIR 239, prepared by Michele, about tracking support equipment. Discussion focused on having all information available within the lab versus having it all in one place for the convenience of assessors.

The outcome of the discussion was to add an introductory paragraph, restating the principle of the standard to create data of known and documented quality, and explain that the analysis should be able to be reconstructed through an audit trail. Then Michele's edits would follow, but with the paragraphs reversed so that the more detailed explanation is the final paragraph. Lynn agreed to do this edit, then send it to Judy and then to Quality Systems to ask for a committee member to review it to ensure that no new requirements are added, and then bring it back to the full committee (or possibly the SIR subcommittee) for final approval.

Judy reported that the SIR Subcommittee met immediately prior to this meeting, and finally agreed on the content of the Implementation Guidance (IG) document from SIR 290, which questions how to deal with different calibration factors at the two calibration points of a thermometer. The subcommittee also agreed that eight of the IG documents created from the New Orleans Mentor Session are ready to post, subject to a final review by all subcommittee members, to be completed within one week of the meeting.

4) Detection and Quantitation Guidance

A final revision of this document was returned for review in early March, and this is the first committee meeting since it became available. Judy noted an error in Figure 1 that will be quickly reported to the Chemistry Expert Committee: in the top line (bullet?) of Figure 1, the text in guidance conflicts with the cited section of the standard. Lynn noted that one NELAP AC reviewer has raised a substantial question about a different section of the guidance. Thus, all agreed that a detailed review of this document is again needed.

Each active committee members was asked to review one of the three sections, cross-checking cited sections of the Chemistry module (V1M4, 2016 Standard, also attached) and generally reading for accuracy and ease of comprehension. Results of your review should be returned to Lynn and Judy (or to the full committee) no later than April 15. Review assignments are as follows:

- Intro and Section 1 Overview Sumy, Jack and Silky
- Section 2, Initial Determination Bill, Harold and Dorothy
- Section 3, Ongoing Verification and Appendix Michele, Nick and David
- Judy and Carl will review the full document.

5) Revision of the SIR Management SOP 3-105

A revised version this SOP was distributed, based on discussions at the February committee meeting, and the two sections being revised were discussed – describing the goal of Implementation Guidance documents and tracking SIRs so that we can provide to the various expert committees a list of completed SIRs that must be considered when a module of the standard is being revised.

Jack moved and Dorothy seconded that the revised SOP 3-105 be approved, and all present voted in favor. We noted that additional revisions may be needed when the expected revision of the Standards Development SOP 2-100 is completed.

6) Next Meeting

The next scheduled teleconference meeting of LASEC will be <u>Tuesday</u>, <u>April 23</u>, <u>2019</u>, 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

TERM,

INTEREST

AFFILIATION

S/H

NAME

EMAIL

PRESENT

| | NAME | EMAIL | IEKWI, | INTEREST | AFFILIATION | 5/H | PRESENT |
|------|-----------------|----------------------------------|--------------|----------|------------------|----------|---------|
| | | | End Date | | | CATEGORY | |
| 1 | Judy Morgan, | _ | 12/21 | Chair | Pace Analytical | Lab/FSMO | Yes |
| | Chair | Judy.Morgan@pacelabs.com | (extended) | (all) | | | |
| 2 | Sumy | Cherukara.sumy@epa.gov | 12/19 | | EPA R2 | No | No |
| | Cherukara | | (first term) | | | | |
| 3 | Jack Farrell | aex@ix.netcom.com | 12/21 | Mentor | Analytical | Other | Yes |
| | | | (first term) | Session | Excellence | | |
| 4 | Silky Labie | elcatllc@centurylink.net | 12/20 | SIRs | ELCAT | Other | No |
| | | | (first term) | | | | |
| 5 | Bill Hall | George.Hall@des.nh.gov | 12/21 | SIRs | NH ELAP | NELAP AB | Yes |
| | | | (first term) | | | | |
| 6 | Harold | harold.longbaugh@houstontx.gov | 12/19 | SIRs | Houston Lab | Lab | Yes |
| | Longbaugh | | (first term) | | | | |
| 7 | Dorothy Love | dorothylove@eurofinsus.com | 12/21 | Mentor | Eurofins Env't'l | Lab | Yes |
| | | | (second | Session | | | |
| | | | term) | | | | |
| 8 | Michele Potter | michele.potter@dep.nj.gov | 12/20 | | NJ DEP | AB | No |
| | | | (first term) | | | | |
| 9 | Scott Siders | ssiders@pdclab.com | 12/20 | Mentor | PDC | Lab | No |
| | | | (first term) | Session | Laboratories | | |
| 10 | Nick Straccione | nstraccione@emsl.com | 12/19 | Mentor | EMSL | Lab | Yes |
| | | | (second | Session | | | |
| | | | term) | | | | |
| | | | | | | | |
| | | | | | | | |
| Ass | ociate Members | | | | | | |
| | Aaren Alger | aaalger@pa.gov | | | PA DEP | NELAP AB | No |
| | Kristin Brown | kristinbrown@utah.gov | | SIRs | UT Bur. of Lab | NELAP AB | No |
| | | | | | Improvement | | |
| | David Caldwell | david.caldwell@deq.ok.gov | | Assmt | OK DEQ | NELAP AB | Yes |
| | | | | Forum | | | |
| | Myron Gunsalus | ngunsalus@kdheks.gov | | | KS Lab Director | NELAP AB | No |
| | Carl Kircher | carl.kircher@doh.state.fl.us | | SIRs | FL DOH | NELAP AB | Yes |
| | Mitzi Miller | mitzi.miller@moellerinc.com | | | Dade Moeller, | Other | No |
| | | | | | Inc | | |
| | William Ray | Bill_Ray@williamrayllc.com | | | Wm Ray | Other | No |
| | | | | | Consultants | | |
| | Gale Warren | ggw01@health.state.ny.us | | SIRs | NY ELAP | NELAP AB | No |
| | gram Admin. | | | | | | |
| Lynı | n Bradley | Lynn.bradley@nelac-institute.org | | | | | Yes |
| | | 1 | 1 1 | | ı | 1 | i . |