Laboratory Accreditation System Executive Committee Meeting Minutes August 28, 2018 1:30 pm Eastern

1) Welcome and Introductions

Judy Morgan welcomed everyone to the meeting. Attendance is recorded in Attachment A. Minutes from July 24 and August 9, 2018, were approved by acclamation, with no edits requested.

2) Assessment Forum and Mentor Session Update

The Tuesday morning Mentor Session was well attended, even though a few attendees needed to be elsewhere after the break. Dorothy presented a summary of the 70+ survey responses and Michelle Wade discussed when and how the incidents were related and connected them to the standard. The second half of the session, after the break, was break-out sessions with two case studies, followed by a small panel responding to the case study summaries presented by the workgroups. Additional time would have been helpful, but the format worked well. The summary write-up is being distributed to the committee along with these minutes, and is included in the presentation from the Mentor Session, in the conference website.

Please contact Dorothy if you have topics or ideas for the Mentor Session in January during the Milwaukee conference.

Monday morning's Assessment Forum addressed early implementation possibilities for the new 2016 TNI ELS Standard. An introductory overview was followed by presentations about the Quality Systems, radiochemistry and microbiology modules, then after the break, the focus shifted to the Chemistry module and in particular, the two Chemistry Guidance documents.

Jerry has requested that the Assessment Forum in January focus on V1M2's requirements about ensuring the quality of lab services and supplies.

3) Other Updates

There was no SIR Subcommittee meeting in August. Feedback on the Lessons Learned document has not arrived from the NELAP AC yet. The NELAP AC has abandoned its effort to create a policy about selecting methods for review during on-site assessments, but will continue discussions within the Council to ensure consistency among ABs.

5) Chemistry Guidance Review

The Chemistry Guidance documents were again discussed, since few email comments were received from committee members. Judy made<u>specific assignments for review as</u> <u>follows, with responses requested by September 14</u>, and absent members will get an email asking them to commit to reviewing one of the documents.

- Calibration Guidance GUI 3-110 Harold and Myron
- Detection and Quantitation GUI 3-109 Dorothy and Sumy

General comments discussed were that the Calibration document needs improved formatting, as it is difficult to read. In section 2/2, references and citations may be confusing, since labs not performing SW-846 analyses may not know what the "MICE Line" is, or realize that AZ DHS is a non-NELAP state accreditation body. Also, the 2009 standard should be referenced with consistent wording and some details are missing from the formulas, such as inconsistent use of "R" or "r" for both relative error and correlation coefficient. Judy committed to completing her review of the Calibration guidance; she will use comment bullets, and then consolidate those comments into a Word document for distribution.

General comments on the Detection and Quantitation guidance are that it is well written, and that the FAQ appendix has one answer for multiple questions. One participant noted that EPA/OQWDW circulated a memorandum stating that they do not allow instrument pooling for MDL studies, and that needs to be included in the guidance.

For both documents, inclusion of the language from the standard is helpful, but since the italics suggest that it is ISO language (as that's how the TNI standard is written), there needs to be some clarification, somehow, that the standard language included in the guidance is NOT from the ISO text.

Additional comments will be expected at the September 25 meeting.

4) Further discussion about ISO 17025:2017

After discussions at conference in New Orleans, it remains unclear what the future direction of the TNI standards (both NELAP and NEFAP/FSMO) will be. Conversations are on-going and NELAP ABs have each been provided with a controlled copy of ISO 17025:2017 for review and conversations with enforcement attorneys about whether the shift to a risk assessment/management paradigm can be used in a regulatory setting. One participant noted that a lot of the TNI normative language may need to be carried forward into the next revision.

5) Next Meeting

The next scheduled teleconference meeting will be Tuesday, September 25, 2018, at 1:30 pm Eastern time. A reminder with agenda will be sent prior to the meeting.

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	No
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	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	Yes
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	No

Asso	ociate Members						
	Aaren Alger	aaalger@pa.gov			PA DEP	NELAP AB	No
	Jack Farrell	aex@ix.netcom.com			Analytical	Other	No
					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
Prog	Program Admin.						
Lynn Bradley		Lynn.bradley@nelac-institute.org					Yes