Laboratory Accreditation System Executive Committee Meeting Minutes February 27, 2018 1:30 pm Eastern

1) Welcome and Introductions

Judy Morgan welcomed everyone to the meeting. Attendance is recorded in Attachment A. Minutes from December 19, 2017, and January 24, 2018, were approved.

2) Committee Membership

Three applications for committee membership were received, from Silky Labie (Other), Michele Potter (AB) and Scott Siders (LAB.) The applications were distributed to committee members in advance of the meeting, and the three applicants were asked to call in fifteen minutes late, so that voting on their applications would be complete by time they joined the teleconference.

Dorothy moved and David seconded that all three applications be accepted. One question was asked, about whether the stakeholder balance of LASEC would be maintained, and since there is one applicant from each stakeholder category, the answer is yes. Approval of the motion was unanimous.

Welcome, Silky, Michele and Scott!

3) Assessment Forum and Mentor Session

Dorothy reported that the Mentor Session went well, with six break-out groups, and each one working to develop implementation guidance for a different section of the standard. Ilona has the notes from each group, and Dorothy will follow up with her about finalizing the work products. The groups did not present summaries, but rather just provided the notes from their discussions, which will have more detail and should be sufficient to create the implementation guidance. The evaluations for the Mentor Session were all outstanding.

For conference in New Orleans in August, Dorothy is thinking to use the break-out format since it is well liked, but with a handful of "oh, crap, what now" topics for discussion. She hopes to get solid examples through some form of survey, so that the products can be more like case studies.

Judy explained that the Assessment Forum was a different format, beginning with presentations and then switching to discussions about PT frequency and technical manager qualifications. She is thinking to use the forum in New Orleans as a working session to either create or fine-tune the list of items in the new standard that can be implemented early (before the ABs transition to the 2016 standard, even.) This is an already-existing assignment to LASEC, made in Albuquerque. NOTE: Lynn checked with Jerry Parr, and moving the deadline for LASEC to provide that list will be acceptable.

There was some discussion about whether such a list will actually be valuable, since all ABs will recognize one another's accreditations, regardless of which standard is in effect. However, the assignment still exists, for LASEC to create the list. Judy asked for

a small group to help with finalizing the decision about a topic for New Orleans, looking at suggestions from the evaluation forms, or perhaps considering presenting the chemistry guidance documents (with someone from Chemistry Expert Committee) as a training session.

4) SIR Subcommittee

This group met before the full committee meeting and approved an amended response to SIR 246 that more fully explains the rationale in comments about the response, to be posted to the NELAP AC's SIR voting site.

5) Standards Review

Everyone had reported back on the module review assignments, and Judy stated that she found no inconsistencies between her self-assigned chemistry module and the quality systems module. No one indicated that they had reviewed the entire Volume 1. The reports from individual reviewers are summarized below:

Module 1 – PT

Review shows consistency between V1M1 and V2M2. No edits needed.

<u>Module 2 – QS (this module was reviewed against Volume 2 for consistency)</u> Instead of CAB, the word laboratory is used, even in the italicized sections. §4.1.5 is an example.

Some discrepancies in definitions and possible missing items. For example, in V2M1, 3.1 and 3.7 are defined differently than they are in V1M2, section 3.1. The differences are subtle, but in one they are ISO language and the other TNI language.

Scope in V2M1 is not defined in V1M2 at all.

For the future, §8.1.1 in V2M1 and §7.0 in V2M3 both identify lists of the obligations of a CAB but I did not see those same items listed out in V1M2. Simple things like timelines for notification and what to notify the AB for did not seem as obvious in the QS module as they did in the AB modules. The AC has discussed this but apparently it never got transmitted to the committee for attention during the revision. Where there are things a lab needs to know that are only in the V2 document, the labs don't think they need to purchase or look at V2. We understand that this is not a "technical edit" but should be addressed in the next revision.

Module 3 – Asbestos

In Clause 1.6.2, there is a potential conflict between the IDOC requirements here and the allowance in 1.6.1(c) for the CDOC to suffice as the IDOC in certain cases, since only 1.6.1(a) is parenthetically referenced. The addition of the phrase "Unless exempted through clause 1.6.1(c)," prior to the rest of the sentence would eliminate this potential ambiguity or source of confusion. Section 1.7.6.2 refers to a Section D.6.2.2(b) that is an old 2003-version NELAC reference. This should be changed to Section 1.7.4.2(c) for this current Module 3.

Module 4 – Chemistry

No inconsistencies with the QS module were identified.

Module 5 – Microbiology

No inconsistencies with the QS module were identified.

Module 6 – Radiochemistry

In all but one instance where the standard references somewhere within the module the citation is simply the section number, e.g., 1.6.3. In section 1.5.2 the internal citation includes V1 M6. Changing it would bring consistency but otherwise not affect the standard. All references to other modules were correct.

Module 7 – Toxicity (WET)

No inconsistencies with the QS module were identified.

Judy asked that a recommendation be prepared for the NELAP AC, stating that LASEC recommends adopting the 2016 standard with the edits identified, and that it be voted by email so that the approved recommendation can be provided to the AC prior to its April 2, 2018, meeting.

NOTE: These inconsistencies were sent to CSDEC and the chairs of the committees where inconsistencies were found, as well as to Jerry Parr. Jerry indicated that only the reference in the Asbestos module should be changed now, and that the other technical edits should wait until the next revision of the standard. Once CSDEC confirms that decision (or issues a different one,) a formal recommendation about adopting the 2016 standard will be circulated to LASEC for email vote.

6) Conflict of Interest (COI) SOP Development

A draft SOP was distributed with the meeting agenda, containing the concepts discussed in the LASEC session in Albuquerque (see Attachment C.) Judy asked that committee members please review the draft and provide any comments, prior to the March 27 LASEC meeting.

Several suggestions were made by committee members. First, that the SOP be considered applicable to all committee actions except "routine administrative matters," such as minutes, SOPs and policies. Second, that we add an option in §5.3 to permit committee members to recuse themselves due to COI without disclosing the nature of that COI, and to have their vote on all relevant matters recorded as an abstention.

A revised draft will be circulated with these minutes, and committee members should be prepared to vote on the draft SOP at the March meeting.

6) Next Meeting

The next scheduled teleconference meeting will be Tuesday, March 27, 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.

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	Non-NELAP AB	Yes
4	Sumy Cherukara	Cherukara.sumy@epa.gov	3 years, 12/19		EPA R2	Other	Yes (phone)
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		ELCAT	Other	No
8	Harold Longbaugh	harold.longbaugh@houstontx.gov	3 years, 12/19		Houston Lab	Lab	Yes
9	Dorothy Love	dorothylove@eurofinsus.com	3 years, 12/18	Assmt Forum	Eurofins Env'ťl	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	Yes
13	Nick Straccione	nstraccione@emsl.com	3 years, 12/19	Assmt Forum	EMSL	Lab	Yes

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

Attachment B

	ACIION	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
72	Contact Jack and A2LA about possible Assessment Forum talks in Albuquerque	Judy	ASAP	
73	Meet with Jerry and Ilona to plan Mentor Session	Judy, Dorothy, Nick, Lynn	12/8/17	Planning underway
74	Provide sanitized copies of COI SOPs	Judy	Early February, 2018	None received; draft SOP prepared for review
75	Review revised draft of COI SOP in preparation for vote	All committee members	March 27, 2018	
76	Prepare recommendation to NELAP AC concerning adoption of 2016 standard, and conduct email vote	Lynn, Judy	March 23, 2018	For delivery to NELAP AC prior to its April 2, 2018, meeting

Action Items – LAS EC

Attachment C – Draft COI SOP

SOP TITLE:	LASEC Procedures for Addressing Conflicts of Interest
SOP NO.:	3-ZZZ
REVISION NO:	0

Committee:	LASEC	Approved Date:	
Program:	N/A	Approved Date:	
Policy Committee Re	eviewed Date:		
TNI Board of Directors Endorsed Date:			
SOP Effective Date:			

1.0 Purpose and Applicability

This Standard Operating Procedure (SOP) gives guidelines for preparing SOPs used by The NELAC Institute (TNI) to conduct activities supporting its mission. The guidelines described here apply to all SOPs used by TNI programs and administration.

TNI activities and services shall be administered and offered in an impartial and objective manner, uninfluenced by the private interests of individuals acting for or on behalf of TNI. Therefore, all TNI members or any person acting on behalf of TNI shall not be involved in actions representing actual or apparent conflicts of interest without disclosure as described in this policy.

2.0 Summary

This SOP details the procedure that LASEC shall follow in addressing potential COI for activities which affect other TNI committees or programs, or activities outside of the TNI organization.

3.0 Related Documents

Pol 1 – 101, Conflicts of Interest Policy 1-102, Ethical Conduct of TNI Members Policy 1-107, Membership Code of Ethics

4.0 Definitions

Conflict of Interest (COI)	A condition or circumstance that makes a person unable or potentially unable to act or deliver services impartially resulting from activities or relationships with other persons, or a condition or circumstance that makes a person obtain or potentially obtain an unfair competitive advantage.

5.0 Identifying Conflicts of Interest

- 5.1 LASEC is composed of a members representing three categories of stakeholders, as identified in the TNI Bylaws Accreditation Bodies, Laboratories, and Other. Within these categories, the committee membership represents as much diversity as possible, particularly for the "Other" category.
- 5.2 Because of the diversity of the committee's membership, it is understood that each person may have a particular bias on an issue. This is why TNI imposes the requirement for "balance" in committee membership.
- 5.3 The Chair will ask individual committee members to declare conflicts of interest (COIs) when the LASEC takes action (*i.e.*, votes) on any matter affecting other TNI committees or programs, or activities outside of the TNI organization. When a person has doubt as to whether a conflict of interest may exist, the person shall declare the presumed conflict so it can be properly evaluated.
- 5.4 Once potential or perceived COI are identified, then the committee along with the individual(s) so affected will decide whether or not further action, such as recusal from participating in the formal discussion (i.e., after the initiating motion is made) and the vote itself, is appropriate or necessary.
- 5.5 Such actions as approving minutes, memberships, or SOPs and Policies that impact only the committee internal operations will not normally trigger the requirement to examine potential COIs.
- 5.6 Any TNI member or agent who undertakes any TNI activity for which an actual or potential conflict of interest exists without declaring such a conflict in advance is in violation of this procedure and may be subject to disciplinary action, up to and including dismissal from the committee.

6.0 When the Committee Cannot Reach Consensus on Whether a COI Warrants Recusal

6.1 The Executive Committee of the TNI Board of Directors is the final evaluator of any disputes regarding a conflict of interest claim that has not been resolved by a program.

7.0 References

None known