

Laboratory Accreditation System Executive Committee Meeting Minutes February 24, 2015

1) Welcome and Roll Call

Judy Morgan welcomed everyone to the meeting. Those in attendance are recorded in Attachment A. We did not have a quorum, so minutes from January 27 and February 4 will be held until the March 24 meeting for approval.

2) Updates

Assessment Forum and Mentor Session

Barbara was unable to attend this committee meeting but shared the evaluation forms by email with committee members. The Assessment Forum got impressive feedback and was well attended and well received with lively participation. Several suggestions for future topics or different slants on past topics were offered. The attorney who participated in one of the panels was excellent and would make an excellent keynote speaker for a future conference.

The Mentor Session was good but had multiple competing sessions that limited attendance, unfortunately.

Members of the Assessment Forum subcommittee are Jack Farrell, Kristin Brown, David Caldwell, George Detsis, Barbara Escobar and Carol Schrenkel. Members of the Mentor Session subcommittee are Jack Farrell, Betsy Kent/Chair and Carol Schrenkel.

SIRs and Implementation Guidance

The session at conference spent considerable time discussing a SIR that was slated to become Implementation Guidance but as that process went forward, it became apparent that the question really did warrant an interpretation instead. SIRs 276 and 281 have been sent to the Chemistry Expert Committee for an interpretation.

The SIR subcommittee met immediately prior to this meeting and reviewed SIRs 230 and 277. SIR 277 is being returned to the Chemistry Committee for clarification, while SIR 230 will be posted to the AC voting site.

Members of this subcommittee are Kristin Brown, Bill Hall, Carl Kircher, Judy Morgan/Chair and Gale Warren, with staff support provided by Lynn.

Discussion of Standards Review Criteria for SOP 3-105

This discussion at conference is summarized in the February 4 minutes. Judy noted that it was both helpful and lively, and highlighted the difficulty of as well as the necessity to balance flexibility with prescriptiveness. "Auditable" is probably the best single word to describe what makes a standard "suitable", but it will also be important to consider whether the economic cost of any new requirements is justified by the benefits gained.

An updated revision to the LASEC Standards Review for Suitability SOP 3-105 awaits completion and approval of the CSDEC Standards Development SOP 2-100, which is imminent.

Request from NELAP AC to Develop Policies for On-Site Assessment and for Documenting Accreditation of Prep Methods

During the NELAP AC session at conference, five priority policies were identified. One of these will be addressed in the NELAP Mutual Recognition Policy 3-100, which LASEC approved at its January meeting. Two other policy areas still need further clarification within the AC itself, but two were sent to LASEC to begin policy development, as outlined below:

On-site assessment – to what extent must all methods be assessed, and what level of detail is required. The AC earlier agreed to honor EPA OGWDW's request that all drinking water methods be assessed individually, but other fields of accreditation need to be addressed with at least minimum requirements. The starting resource may be the 2003 NELAC Standard, Chapter 3, Appendix C §4, and possibly information in Modules 1 and 3 of the TNI ELSS Volume 2.

Prep methods – how ABs document the accreditation of these. Some accredit the “prep” separately, others include the prep with the method accreditation; some way for all ABs to be able to verify that prep methods were assessed needs to be agreed upon. This area is considered to be defined enough that it can be referred to LASEC for the drafting of a policy document.

The committee agreed with Lynn's recommendation to ask the Laboratory Accreditation Body Expert Committee to prepare a draft for the “on-site assessment” policy, as both committees have discussed previously.

Several issues about the “prep method policy” were brought up in discussion, as items that may need to be resolved or clarified during its development -- defining “method/technology” and whether prep methods would require separate PTs will likely need to be addressed. Thus, additional input from the AC will be needed since the Council initially sought only some way to document how prep method accreditations are done in different ABs.

Myron agreed to work with David and Carl to draft a document outlining these thoughts by March 6, in time for Judy to use it in a conversation with the NELAP AC at its the March 16 meeting, to begin the discussion of how narrow or in-depth the policy might be.

LAB Expert Committee Update

Carl and Lynn noted that LAB learned at conference that a 5-year systematic review of Modules 1 and 3 of Volume 2 of the TNI Standard needs to be undertaken, and as part of that, LAB will consider revising and consolidating those modules into one. This revision would not be complete in time for inclusion in the 2015 Standard but rather would await adoption with the 2020 revisions.

Calibration Interim Standard Review

The Chemistry Expert Committee asked that LASEC please consider a further revision to language in the standard noting that program requirements may not permit qualification of data even though the standard itself does – the section where the AC had negotiated a clarification or editorial revision to language in the original standard. The Chemistry Committee asked LASEC for feedback on the proposed revision, which was made in response to a comment deemed persuasive.

The following language shows additions from the persuasive comment in red:

V1M4§1.7.1.f.iii

If samples are analyzed using a system on which the calibration has not been verified, the results shall be qualified. Data associated with an unacceptable calibration verification may be reported **with qualification** ~~under the following special conditions~~ unless prohibited by the client, a regulatory program or regulation. **Data associated with calibration verifications that fail under the following special conditions shall still be qualified, but may use a different qualifier to indicate usability of the data.**

After considerable discussion and noting that SDWIS data cannot be qualified and Clean Water Act data cannot be reported as qualified either, participants agreed that making mention in the standard of using any “different qualifier” for data reported to those two programs may be read by labs as permitting the reporting of qualified data, which would not be acceptable. Further, introducing the undefined term “usability” adds additional confusion. Participants agreed to recommend the following as substitute/replacement (blue text added):

V1M4§1.7.1.f.iii

If samples are analyzed using a system on which the calibration **fails verification** ~~has not been verified~~, the results shall be qualified. Data associated with an unacceptable calibration verification may be reported **with qualification** ~~under the following special conditions~~ unless prohibited by the client, a regulatory program or regulation. **Data associated with calibration verifications that fail under the following special conditions shall still be qualified, but may use a different qualifier to indicate usability of the data.**

LASEC and the NELAP AC have previously noted that, without the reminder that program requirements override the standard, even though that was noted in a different module, labs have believed that reporting qualified data for water analyses was acceptable. We also believe that a prohibition on qualifying data would result in questionable data merely being not qualified and reported anyway; and some anecdotal evidence suggests this may have happened.

Judy noted that the NELAP AC should be advised of what has happened with the earlier agreed-upon revision.

Update of LASEC Charter

An updated charter with current member roster was circulated, but without a quorum present, approval will be delayed until the March 24 meeting. Edits to the first and second objectives were requested and agreed upon, along with a minor revision to the Considerations section. A copy of the revised draft charter is attached to these minutes as Appendix C.

The Charter should be updated annually to ensure that goals and objectives are current and aligned with the TNI Strategic Plan.

Status of Standards Review Processes -- Quality System Modules

LASEC learned at conference that previous obstacles have been resolved to the extent that we can begin our review of Modules 2, 3 and 7 from the 2012 revisions to Volume 1, as accomplished by the Quality Systems Expert Committee. These three modules are not presently being updated or re-revised by any other committee. Carl noted that he has reviewed all three modules against the "Response to Comments" document and feels that all the changes made due to persuasive comments do satisfactorily address the comments. Judy asked for additional volunteers and the following assignments were made or accepted after the meeting:

Module 2, Quality Systems: George Detsis

Module 3, Asbestos: Judy to ask Mitzi Miller, Lynn asked Gale Warren. NOTE: Gale has already completed her review but will ask a fellow NY assessor to review this module as well.

Module 7, Toxicity Testing (WETT): Judy will have an ESC Labs staff person review, and Christelle Newsome had earlier agreed to review this module (and affirms that she will do so.)

3) Next Meeting

The next meeting of the LAS EC will be on Tuesday, March 24, 2015, at 1:30 pm Eastern. Teleconference information and an agenda with any other materials will be sent the week before.

Action Items are included in Attachment B.

Attachment A

PARTICIPANTS --TNI LABORATORY ACCREDITATION COMMITTEE

	NAME	EMAIL	TERM, End Date	INTEREST	AFFILIATION	S/H CATEGORY	PRESENT
1	Judy Morgan, Chair	JMorgan@esclabsciences.com	3 years, 12/15	Chair (all)	Environmental Science Corp.	Lab/FSMO	Yes
2	JoAnn Boyd	jboyd@swri.org	3 years, 12/16	StdsRev	Southwest Research Inst.	Lab/FSMO	No
3	Kristin Brown	kristinbrown@utah.gov	2 years, 2/17	SIRs/Assmt Forum/FAQ	UT Bur. of Lab Improvement	NELAP AB	Yes
4	David Caldwell	david.caldwell@deq.ok.gov	2 years, 12/17	Assmt Forum	OK DEQ	Non-NELAP AB	Yes
5	George Detsis	george.detsis@eh.doe.gov	3 years, 12/17	Assmt Forum	US DOE	Other	Yes
6	Barbara Escobar	Barbara.Escobar@pima.gov	3 years, 12/15	Mentor, AssmtFrm, FAQ	Pima County, AZ	Lab/FSMO	No
7	Jack Farrell	aex@ix.netcom.com	3 years, 12/16	Assmt Forum, StdsRev	Analytical Excellence	Other	No
8	Bill Hall	George.Hall@des.nh.gov	3 years, 12/16	SIRs,FAQs	NH ELAP	NELAP AB	No
9	Betsy Kent	bkent@rcid.org	3 years, 12/15	Mentor Sessions	Reedy Improv. District, FL	Lab/FSMO	No
10	Carl Kircher	carl_kircher@doh.state.fl.us	3 years, 12/15	SIRs, FAQs	FL DOH	NELAP AB	Yes
11	Mitzi Miller	mitzi.miller@moellerinc.com	2 years, 12/17	FAQs	Dade Moeller, Inc	Other	No
12	William Ray	Bill_Ray@williamrayllc.com	3 years, 12/17		Wm Ray Consultants	Other	Yes
13	Kim Sandrock	Kim.Sandrock@state.mn.us	3 years, 12/15	Training	MN ELAP	NELAP AB	No
14	Carol Schrenkel	CSchrenkel@suburbantestinglabs.com	3 years, 12/16	Mentor, Ass. Forum		Other	No
	Elizabeth Turner	eturner@ntmwd.com		Ex Officio	Small Lab Issues	North TX Mun. Water District	No

Associate Members							
	Aaren Alger	aaalger@state.pa.us			PA DEP	NELAP AB	No
	Carol Barrick	cabarrick@msn.com , Carol.Barrick@mosaicco.com			FCC Environmental	Lab/FSMO	No
	Myron Gunsalus	ngunsalus@kdheks.gov			KS Lab Accred.	NELAP AB	Yes
	Carol Haines	haines.carol@epa.gov		Stds Rev, ad hocs	EPA Region 10	Other	No
	Christelle Newsome	cnewsome@c2nassociates.com			C2N Associates, Inc.	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

Action Items – LAS EC

	Action Item	Who	Expected Completion	Actual Completion / Comments
24	Consolidate “clarifications” for approval and circulate to LAS members	Judy	September 2014	Nine “implementation guidance” documents approved 10/28/14 – awaiting posting to website
26	Formally re-transmit SIR SOP 3-105 and Standards Review SOP 3-106 to Policy Committee for final approval	Lynn	August 2014	Both SIRs plus the NELAP Standards Review and Approval SOP 3-103 are now final
28	Draft language to provide to Chemistry Committee about “remove and replace” for points in a calibration curve, in the Calibration IS.	Judy, with input from committee members	October 1 – draft circulated 10/25/14	Language sent. Awaiting full “response to comments” document from CEC
30	Talk with CSD EC Chair and Program Administrator about process revisions. Specific issues are: 1 -- permit adequate time for LAS EC to review upcoming standards revisions 2 – build in that time at a stage when changes can still be accomplished to address problematic language 3 – consider whether to handle TNI committee reviews of developing standards in some parallel process that may allow either additional time or additional weight for those comments, or both	Judy/Lynn	Prior to October LAS meeting , hopefully at Strategic Planning session	Conversations held. Small workgroup appointed by CSD EC, includes both Judy and Aaren, to address needed revisions to both the CSD and LAS SOPs governing standards development and review. Workgroup to review CSDEC revisions, and approve final draft SOP during February.
32	Review/revise POL 3-100 for recommendation to AC	Workgroup led by Judy	Fall 2014	Approved by LASEC for AC review
36	Ask Christelle if she can review the WETT module (V1M7)	Lynn	December 2014	Christelle agrees to participate in review and awaits further info after January meeting
38	Collect AB reviews of new Implementation Guidance documents and complete former SIR 262 draft	Judy and workgroup	January 2015	2 documents approved for posting, will be sent to webmaster.

				Former SIR 262 to be discussed at conference.
39	Talk with Aaren and Carl about possible NELAP policy concerning third party assessor qualifications	Judy	January 2015	At conference?

Appendix C

THE NELAC INSTITUTE COMMITTEE CHARTER

1. Committee Name: Laboratory Accreditation System Executive Committee (LAS EC)	2. Version: First Revision since combining LAS EC with the Technical Assistance Committee	3. Date: TBD
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4. Mission Statement:

The mission of this committee is to manage TNI's efforts in supporting a national program for the accreditation of environmental laboratories by supporting the NELAP Accreditation Bodies (ABs) and enabling stakeholders such as laboratories, proficiency testing providers, and regulatory agencies to effectively participate in the development of, adoption and implementation of, and compliance with the TNI standards.

5. Program Administrator: Lynn Bradley

6a. Committee Members and term expiration date:	6b. Subcommittee	7. Stakeholder Group:
Judy Morgan, Chair, 2015	SIRs	Lab
JoAnn Boyd, 2016		Lab
Kristin Brown, 2017	SIRs, Ass'm't Forum	NELAP AB
David Caldwell, 2017	Assessment Forum	Non-NELAP AB
George Detsis, 2017	Assessment Forum	Other
Barbara Escobar, 2015	Mentor, Ass'm't Forum	Lab
Jack Farrell, 2016	Assessment Forum	Other
Bill Hall, 2016	SIRs	NELAP AB
Betsy Kent, 2015	Mentor Sessions, Chair	Lab
Carl Kircher, 2015	SIRs	NELAP AB
Mitzi Miller, 2017		Other
William Ray, 2017		Other
Kim Sandrock, 2015		NELAP AB
Carol Shrenkel, 2016	Mentor, Ass'm't Forum	Other
Elizabeth Turner, Ex Officio		Small Lab Advocate
Jerry Parr, Ex Officio		Executive Director

8. Objectives: *(insert rows as necessary for additional objectives)*

- Work in cooperation with the NELAP Accreditation Council (AC) to assist in implementing this program [successfully within the stakeholder community](#).
- Work with the Consensus Standard Development Program Executive Committee to ensure that accreditation standards developed for this program are suitable for use by review of standards and by consideration of [stakeholder community](#) AB and laboratory needs early in the development process
- Review new or revised standards after approval for the purpose of recommending them to the

NELAP AC for adoption
<ul style="list-style-type: none"> • Manage involvement and assistance of Expert Committees and the PT Executive Committee as appropriate for standards interpretations, guidance documents and related tools
<ul style="list-style-type: none"> • Develop tools and templates to assist laboratories and accreditation bodies with implementing accreditation programs.
<ul style="list-style-type: none"> • Support TNI's Educational Delivery System in providing training programs relevant to the needs of the NELAP stakeholder community.
<ul style="list-style-type: none"> • Ensure that laboratory assessors have a forum to discuss common issues (Assessment Forum)
<ul style="list-style-type: none"> • Develop a mentoring program to assist both laboratories and accreditation bodies with implementing accreditation programs (Mentor Sessions)
<ul style="list-style-type: none"> • Provide a voice and solution strategies for small organizations' issues and concerns (small laboratories, especially)
<ul style="list-style-type: none"> • Provide a peer review mechanism for documents.
<ul style="list-style-type: none"> • Develop and recommend to the NELAP AC policies and procedures, standards interpretations, guidance documents, and any related tools to implement NELAP

<p>9. Success Measures:</p> <ul style="list-style-type: none"> • Process Standards Interpretation Requests in timely fashion, consistently applying SOP 3-105 • Reviewing and providing recommendations to NELAP AC on TNI standards, policies and SOPs as needed or requested • Maintaining active liaison with the Small Laboratory Advocacy Group (SLAG) through active involvement of TNI's Small Laboratory Advocate • Providing Assessment Forums at TNI conferences, both winter and summer • Providing Mentor Sessions at TNI conferences, both winter and summer • Respond in timely manner to requests from TNI Educational Delivery System
<p>10. Key Milestones: <i>(significant events and corresponding dates)</i></p> <ul style="list-style-type: none"> • Develop and maintain the Standards Interpretation Request SOP 3-105 (revision complete by July 2013) • Assessment Forum and Mentor Session (August 2015, Chicago) • Assessment Forum and Mentor Session (January 2016, Tulsa) • Continue timely processing of Standards Interpretation Requests and development of Standards Interpretation Guidance documents • Review of Voting Draft, Interim and Final Standards Modules within timeframes established by Standards Review SOP 3-106
<p>11. Considerations: <i>(assumptions/constraints/obstacles/risks)</i></p> <ul style="list-style-type: none"> • TNI's Small Laboratory Advocate is an <i>Ex Officio</i> member • Available time at summer meetings to include Mentor Sessions and Assessment Forum
<p>12. Available Resources:</p> <ul style="list-style-type: none"> • Other TNI Committees (Expert and Support) for changes to the modules • Volunteer committee members • Existing national and international consensus-based standards • EPA Cooperative Agreement • TNI Website • Participating organizations • Other entities as the committee sees fit, that pertain to our mission
<p>13. Additional Resources Required:</p> <ul style="list-style-type: none"> • Web-based teleconferencing services • Effective and accessible member database

14. Anticipated Meeting Schedule: *(specify meeting format and frequency)*

- Monthly Committee Teleconferences (Fourth Tuesday of each month by teleconference at 1:30 pm Eastern)
- Additional teleconference scheduled as necessary for subcommittees and ad hoc working groups
- Committee meetings during semiannual TNI Forums, separate from Assessment Forums and Mentor Sessions