

**Laboratory Accreditation System Executive Committee Meeting Minutes
August 7, 2019**

1) Welcome and Introductions

Judy Morgan welcomed everyone to the meeting and asked the committee members to introduce themselves. Attendance is recorded in Attachment A.

The outline of Judy's PowerPoint presentation is included in Appendix B. Highlights of the presentation and discussion items are summarized by topic here, and the presentation itself will be distributed to committee members separately.

2) Mentor Session and Assessment Forum for Jacksonville

Dorothy reported that Tuesday's Mentor Session titled, "Root Cause Investigations as a Follow-up to the Internal Audit Session", was packed for the morning session, but many people waited after the session's end for one-on-one conversations with the panel members, Dorothy, Nick and Andrea Teal. Apparently, they were reluctant to share their particular issues publicly. Apparently there was stiff competition for the afternoon session, but still, the people who did return in the afternoon were dedicated and appreciative.

Judy hosted the Assessment Forum the topic of "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". Speakers included Mitzi and Jeanne Mensingh as well as Judy herself. The session went well and the evaluation forms indicated that the topic was greatly appreciated and well presented.

3) SIR Update

Judy presented statistics on SIR submissions over the past year. Most new submissions now concern the 2016 Standard. She also described LASEC's new agreement with the Consensus Standards Development Executive Committee (CSDEC) to distribute to the expert committee chairs all of not-valid-SIR submissions relevant to their committees, on an information-only basis. The new Small Lab Advocate will also receive this list.

One commenter noted that it is important to ensure that the Non-governmental ABs include the posted SIRs during their lab assessments.

4) Follow-Up to LASEC's Lessons Learned Document and Responses from the NELAP AC and CSDEC

A small workgroup of three Chairs (LASEC, CSDEC and NELAP AC) and the three Program Administrators has been formed to revise the Standards Development SOP 2-100. This workgroup met in Jacksonville, and learned that the ANSI audit of the standards development program will likely lead to an even more in-depth revision of this SOP than originally envisioned, but in the end, the document should be much less complicated.

5) Open Discussion

Scott Siders raised the issue of changing the standard as a way of enforcing the timing of AB actions, such as delivering site reports and acting on lab requests for modifications to their certificates. As this has been an on-going discussion on committee teleconferences, participants were told that this is not a one-time complaint but rather perceived to be a systematic issue, and that LASEC is considering creating an issue paper and possibly conducting a survey to identify the scope of the problem.

Additional discussion points for this topic were as follows:

- Every AB has a complaint process available, and a lab should take such issues up with the state authorities, or even file a complaint with TNI, that if substantiated could trigger an interim evaluation.
- The NELAP AB operations are not within TNI control, but might be within control of the NELAP AC.
- During evaluations, if there is a repeat finding (such as consistent delays in processing such items), there will be a follow-up report required from the AB to ensure that the proposed corrective action is completed and effective.
- A trend analysis is needed.
- Delays such as are being discussed become a risk management issue for both laboratories and ABs.

No resolution was achieved and the meeting time was over.

6) Next Meeting

The next scheduled teleconference meeting of LASEC will be **Tuesday, September 24, 2019, at 1:30 pm Eastern time**. The SIR Subcommittee will meet on 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	Summy Cherukara	Cherukara.sumy@epa.gov	12/19 (first term)		EPA R2	No	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	No
5	Bill Hall	George.Hall@des.nh.gov	12/21 (first term)	SIRs	NH ELAP	NELAP AB	No
6	Harold Longbaugh	harold.longbaugh@houston.tx.gov	12/19 (first term)	SIRs	Houston Lab	Lab	Yes
7	Dorothy Love	dorothylove@eurofinsus.com	12/21 (second term)	Mentor Session	Eurofins Env't'l	Lab	Yes
8	Louise McGinley	louise.mcginley@tceq.texas.gov			TCEQ	NELAP AB	No
9	Michele Potter	michele.potter@dep.nj.gov	12/20 (first term)		NJ DEP	NELAP AB	Yes (phone)
10	Scott Siders	ssiders@pdclab.com	12/20 (first term)	Mentor Session	PDC Laboratories	Lab	Yes
11	Nick Straccione	nstraccione@emsl.com	12/19 (second term)	Mentor Session	EMSL	Lab	Yes

Associate Members

	Aaren Alger	aaalger@pa.gov			PA DEP	NELAP AB	Yes
	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	Yes
	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	gigwarren@gmail.com		SIRs	retired	Other	No
	Program Admin. Lynn Bradley	Lynn.bradley@nelac-institute.org					Yes

Attachment B – Outline from the Chair’s PowerPoint Presentation

Laboratory Accreditation Systems Executive Committee

Wednesday, August 7th, 2019, 1:30 – 3:00p

Our Mission

Manage TNI’s efforts in supporting a national program for the accreditation of environmental laboratories by:

- ❖ Supporting the NELAP Accreditation Bodies (ABs) and non-governmental ABs (NGABs) recognized to accredit to the TNI Environmental Laboratory Sector (ELS) Standard,
- ❖ Enabling stakeholders such as laboratories, proficiency testing providers and data users to effectively participate in the development of, adoption and implementation of, and compliance with the TNI standards.

Agenda

- 1:30 Welcome and Introductions
- 1:40 Update on Activities since New Orleans
- 2:00 Changes to the SIR Management SOP 3-105
- 2:15 Working with CSDEC/ NELAP AC to Update Standards Development SOP 2-100
- 2:30 The LOD/LOQ Guidance GUI 3-109
- 2:45 Discussion/Questions from the Participants, Other issues/discussion

Mentor Sessions

The Sessions:

- Encourage networking and collaboration
- Provide for knowledge sharing (guidance)
- Reduce barriers to:
 - ✦ getting accredited
 - ✦ maintaining accreditation

The Speakers include:

- State Accreditors
- Assessors
- Lab Managers
- Quality Assurance Specialists
- Instrument Specialists

TNI Mentor Session 2019

AGENDA

- 9:00 to noon – Presentations
- 9:00–10:00 Root Cause: Getting to the Bottom – Silky Labie
- 10:00-10:30 BREAK
- 10:30-11:00 Targeting Corrective Actions – Dorothy Love
- 11:00-11:30 Preventive Actions vs Corrective Actions – Trinity O’Neal
- 11:30-12:00 Q&A for Panel
- 1:00 to 3:00 –

- Workgroups with Panel input [note: divide into workgroups based on size of lab with at least one AB/Assessor per group] – different topics among the groups and in each activity period
- 1:00-1:45 WGs Activity Session 1 and report outs
- 1:45-2:00 Panel feedback
- 2:00-2:45 WGs Activity Session 2 and report outs
- 2:45-3:00 Panel feedback

Assessment Forum

Started in 2005

Goal:

- To provide an opportunity for laboratories and laboratory assessors to share information on how to improve the laboratory assessment process.

Topics:

- Feedback from the previous participants,
- Hot topics of the day
- Suggestions from individuals
- Member presentation interests

TNI Assessment Forum 2019

Thursday August 8th 9:00 – 12:00pm

Session Moderator/Team: Judy Morgan, PACE Analytical, Mitzi Miller - NV5,
Jeanne' Mensingh – Labtopia

9:00-10:00 "Can you Prove that Your Supplies Meet Your Needs?"

- Intro and Statement of Current issue: This is a recap or summary of Milwaukee and sets the stage for the second half

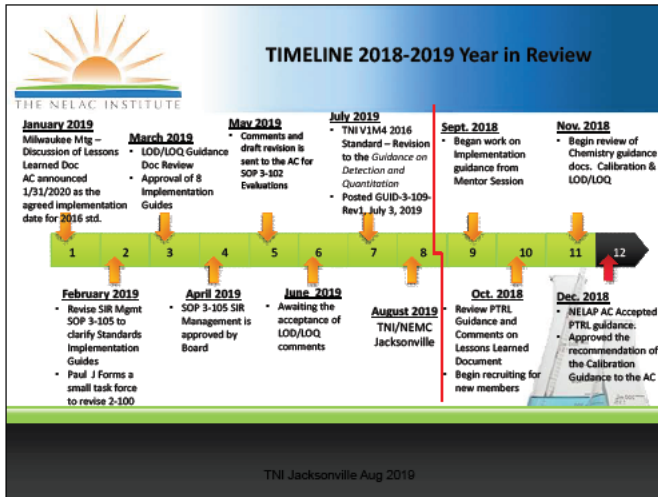
10:00-10:30 BREAK

10:30-11:00 Where do We go from here?

- Contracts - Requiring the quality needed
- What requirements should we use? What Specifications? Who are the authorities?
- When a supplier fails.....What is expected and what is an acceptable response?

11:00 - 11:45 Verification Checklist (Discussion of G34 and 17025)

- Examples of what is required
- Verification by lot#
- Verification at receiving
- New requirements under 17025:2017



Standard Interpretation Request (SIR) Update

- New submittals receive an acceptance decision within 3 days.

#	Year
• 44	• 2008
• 54	• 2009
• 49	• 2010
• 44	• 2011
• 31	• 2012
• 21	• 2013
• 36	• 2014
• 13	• 2015

Total Valid	year
• 8/4	• 2016
• 8/2	• 2017
• 19/14	• 2018
• 20/4	• 2019 ytd

LAS EC Plan for 2019

Progress Assessment (How are we doing?)

- ✓ Sustain SIR progress
- ✓ Supplement SIRs with Implementation Guidance for non-SIR questions
- ✓ Complete the review of Guidance for the Chemistry module
- ✓ Continue to Develop Policies and SOPs for NELAP
- Complete the outstanding items in the Lessons Learned document
- Collaborate with other committees as we plan for migration to the newly revised ISO17025 2017

Standard Interpretation Request (SIR) Process

SOP 3-105 – Standards Interpretation Request

- ◆ Must contain only one question;
- ◆ Must apply directly and clearly to a cited section of the Standard;
- ◆ Question is understood without supposition;
- ◆ Question is compelling, meaning the language used in the Standard(s) section cited in the SIR is not clear or where the language might have more than one interpretation;
- ◆ Cannot be to settle a dispute between the laboratory and the AB;
- ◆ Is not a “how to” question
- ◆ Is not a method interpretation question; and
- ◆ Where possible, the question should be framed in a manner that solicits a “Yes” or “No”.

Standards Implementation Guidance

- Implementation guidance is developed from two sources:
- Mentor Session
- SIR Process:
- A SIR may be classified as a clarification request needing implementation guidance to be developed, the LAS EC Chair or designee may forward the request to an appropriately appointed team who will answer the question.

Implementation guidance responses have the following attributes:

- categorized by subject matter or topic within the standard
- contain the original question
- may contain some additional background information

- Are supported by references to the appropriate sections of the all standards in use (if more than one is applicable.)
- shall be reviewed by at least one subject matter expert, external to LASEC
- Implementation guidance documents will be posted on the TNI website
- requester will be notified of the response, prior to posting
- shall include a disclaimer

Implementation Guidance – Example

TNI Standards Guidance

Disclaimer: This material represents the opinion of its authors. It is intended solely as guidance and does not include any mandatory requirements except where such requirements are referenced. This guidance does not establish expectations of being implemented universally, exclusively, in whole, or in part.

This guidance does not establish or affect legal rights or obligations and is not finally determinative of the issues it addresses. It does not create any rights enforceable by any party in litigation with TNI, its accreditation bodies, or affiliated institutions. Any decisions made by TNI regarding requirements addressed in this guidance will be made by applying the applicable standards, policies or procedures to the relevant facts.

Module: Quality Systems & Chemistry

Subject: Titrants - Documentation and Verification

Question 1	<p>Is it required to independently verify the concentration/strength of all laboratory titrant solutions?</p> <p>The laboratory must have a written policy on the use of prepared solutions. The policy shall address record keeping and documentation requirements for each type of solution.</p> <p>Considerations are as follows:</p> <ul style="list-style-type: none"> Titrants used directly in the calculation of the analytical result must be independently verified for concentration. Regardless of use, all prepared solutions affecting analytical quality and calibration must be traceable to the original chemical source to verify purity, concentration, suitability, specifications, etc. Traceability must be described in a policy or procedure.
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References:

TNI 2009 V1M4-1.7.3.5 <small>c)</small>	1.7.3.5 Reagent Quality, Water Quality and Checks a) In methods where the purity of reagents is not specified, analytical reagent grade shall be used. Reagents of lesser purity than those specified by the method shall not be used. Documentation of purity shall be available. b) The quality of water sources shall be monitored and documented and shall meet method specified requirements. c) The laboratory shall verify the concentration of titrants in accordance with written laboratory procedures.
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SOP 3-105 – Standards Interpretation Request SOP

Revised and approved April 2019

1.1 & 1.5 – Minor edits

3.4 added 2-100 as a reference document

4.0 revised a couple of definitions: Standard & Standard Interpretation to be consistent with the TNI Glossary

Added a definition for SIR Subcommittee

5.2.3 Clarification for SIR determination

5.3.4 Added the option for standard implementation guidance

5.4.3 Added the drafting of implementation guidance

5.5.4 Increased the TNI expert committee review time period from 30 to 45 days.

5.8 Added the process to ensure that applicable SIRs are tracked, reviewed and considered when a Standard Module is being revised.

SIRs can be complex!

June 2019

- Quarterly summary of all SIRs to committee chairs.
- Goal – additional transparency

- Provides a review process to verify the status of SIR determination
Will require an additional revision to SOP 3-105

List of 2019 Approved Implementation Guides From 2018 Mentor Session

- Failure to Implement CA Despite Confirmation of Completion
- Failure to Qualify Results
- Improper Calibration Curve Change
- Whistleblower or Trouble Maker
- Vendor Recall
- Wrong ID on Bench Sheet
- Sample Cooler Overlooked and Melted
- Samples Switched

LASEC working with CSDEC & NELAP AC to Update Standards Development SOP 2-100

SOP 3-106 Standards Review and Acceptance

- Revision pending from “lessons learned” during the review of the 2016 TNI Standard.

SOP 2-100 Standards Development

- A task force has been appointed to review 2-100 relative to solving the issues in the “lessons learned” document
- The goal of the task force is to improve the process, streamline the review, and reduce the overall time

SOP/Policies/Etc. in Review

SOP 2-100 Standards Development

- 8/5/19 – Meeting
- Talked through the challenges and barriers of the current process
- Current process and document is relatively complex
- First Action: Outline the necessary steps to the process, apply the issues from the “lessons learned” document and draft a new procedure.

LASEC Review of Standard Guidance Documents

- SUMMARY
- V1M4
- Guidance Document:
- Chemistry – Detection and Quantitation – Posted Rev 1 in July 2019
- Two other guidance docs:
 - PTRL
 - Calibration
- All guidance must meet specific requirements.
- If guidance is required as part of the standards approval process, the guidance must also be approved

LOD LOQ Guidance

Review: Divided the document into sections and performed a complete review

- Multiple comments on format, flow, and references

- Identified a conflict between the guidance and the standard
- A review summary was provided
- Revisions were made and the document is on the TNI website as Rev 1. (Posted in July 2019)

New Item for Consideration

LASEC – Recently apprised of concerns regarding the apparent challenges that are faced by some ABs relative to time commitments.

Any other issues?

Questions?

Discussions?