Laboratory Accreditation Systems Executive Committee

Monday

August 7th, 2017

9:00 – 10:00

TNI Washington DC August 2017

LASEC Members

Member	Affiliation	Category
Judy Morgan, Chair	Pace Analytical	Lab/FSMO
Kristin Brown Vice Chair	UT Bur. of Lab Improvement	NELAP AB
JoAnn Boyd	Southwest Research Inst.	Lab/FSMO
Harold Longbaugh	City of Houston	Lab/FSMO
Dorothy Love	Eurofins - Lancaster	Lab/FSMO
Nicholas Straccione	EMSL	Lab/FMSO
Bill Hall	NH ELAP	NELAP AB
Carl Kircher	FL DOH	NELAP AB
Myron Gunsalas	KDHE Lab Accred.	NELAP AB
David Caldwell	OK DEQ	Non-NELAP AB
Jack Farrell	Analytical Excellence	Other
Sumy Cherukara	US EPA	Other
Mitzi Miller	Dade Moeller, Inc	Other
William Ray	Wm Ray Consultants	Other

Member	Affiliation	Category
Ex Officio		
Elizabeth Turner	Small Lab Issues	North TX Mun. Water District
Associate Members		
Aaren Alger	PA DEP	NELAP AB
Gale Warren	NY ELAP	NELAP AB
Michelle Wade	Wade Consulting	Other

Program Administrator
Lynn Bradley

14 Members – Equally balanced among 3 categories: Lab/FMSO, NELAP AB, Other
Eight Associate members
One Ex-Officio – Elizabeth Turner, Small lab advocate.

TNI Washington DC August 2017

Agenda

- Updates on Recent Activities
  - Mentor Sessions
  - Assessor Forum
  - 2017 Timeline – Year in Review
  - Standard Interpretation Request (SIR) update
  - Standards Review Update
  - Lessons Learned – 2016 Standard Review
  - Other issues/discussion

Mentor Sessions

Coordinated by: Dorothy Love

☐ **The Sessions**:

  ➢ Encourage stakeholder 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 Washington DC August 2017

TNI Mentor Session 2017

TNI Mentor Session: Regulatory Overview and Staff Training

Monday August 7th 1:00 – 5:00

Where: Independence FGHI

Session Moderator: Dorothy Love, Eurofins Lancaster Laboratories

- 1:00 Regulatory Programs
- 1:45 Training Your Staff on Why We Do What We Do – Dorothy Love, Eurofins Lancaster Laboratories
- 2:15 Workgroup Session A – Compliance Samples, Sharing Best Practices
  - ✓ Managing Regulatory Requirements in Your Lab
  - ✓ Receiving Communication from the Client

- ✓ Tracking Compliance Samples in the Lab
- ✓ Ensuring Timelines are Met
- ✓ Addressing Qualified Data
- ✓ Reporting to the Client / Agency
- ✓ 3:00 BREAK

3:30 Workgroup Session B – Standards Implementation Issues

- ✓ Sections 4.1.6 and 4.2.4 – Staff Communication
- ✓ Section 4.1.7.1 (c) – QA Officer Impartiality
- ✓ Section 4.14.5 – Internal Audits – Covering the Scope of Tests

TNI California August 8, 2016

TNI Mentor Session 2017

TNI Session – Tuesday August 8th

- ➢ TNI Mentor Session: Standard Implementation Issues (Continued)
  - 9:00am – 12:00pm
- ➢ Independence FGHI
- ➢ Session Moderator: Dorothy Love, Eurofins Lancaster Laboratories
  - – Section 4.1(k) – Relevance of Activities
  - – Section 4.5 – Subcontracting
- ➢ 10:00 BREAK
  - – Sections 5.4.1, 5.4.3, 5.4.4, and 5.4.5 – Lab Developed Methods
  - – Section 5.8 – Sample Handling; Sample / Container Tracking
  - – Section 4.6 – Vendor / Supplier Approval

Assessment Forum

- Started in 2005

- Forum Schedule: Typically 8:00 to 5:00

- Attendees: 80 - 100

- Topics:
  - feedback from the previous participants,
  - hot topics of the day,
  - suggestions from individuals
  - member presentation interests

Standard Interpretation Request (SIR) Update

- New submittals receive an acceptance decision within 3 days.

SIR History

#	Year
5/2	2017 YTD
8/4	2016
13	2015
36	2014
21	2013
31	2012
44	2011
49	2010
54	2009
44	2008

THE NELAC INSTITUTE

TIMELINE 2016 - 2017

January 2017
Houston Meeting Discussed On Site Assessment and Prep Policies

March 2017
- Begin Planning for Assessment Forum and Mentor Session

May 2017
- Begin revision for 3-105 Standard Interpretation Requests to clarify the creation of Implementation Guidance
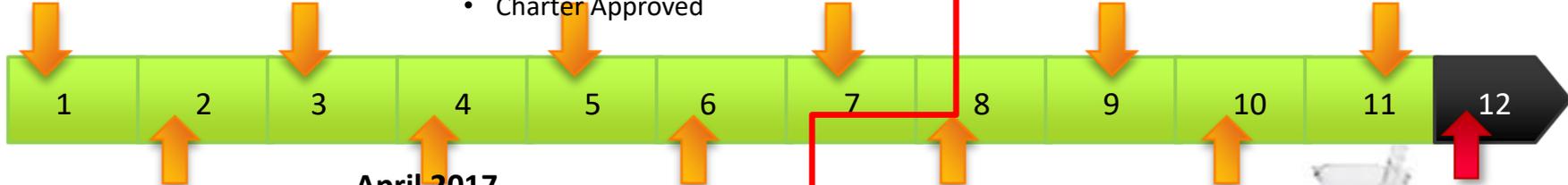- Charter Approved

July 2017
Prepare for August Meeting.

Sept. 2016
- AC Identified issues with V1M1 and V1M4

Nov. 2016
Resolved 2 of 4 issues with V1M4

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |

February 2017
- Began revisions on OSA and Prep Policies to combine into one
- Begin revisions on New Charter

April 2017
- Submit OSA and Prep Policies to AC
- Approved New Charter for submittal to Board
- Begin Review of 3-106 Review of Accreditation Standards for Suitability
- 3-106 Consider "Lessons Learned"
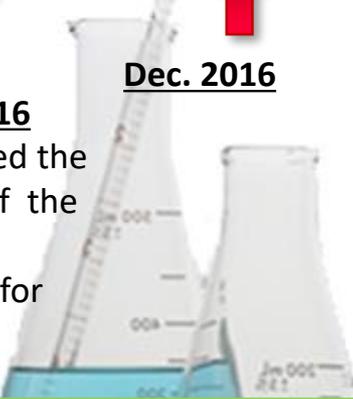
June 2017
Review draft revisions to V1M4

August 2016
TNI CA

Oct. 2016
Recommended the acceptance of the technical clarifications for V1M1.
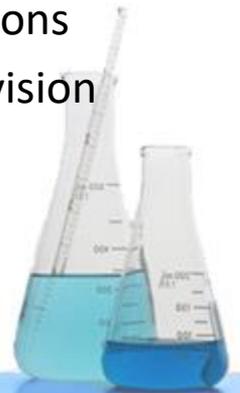
Dec. 2016

LASEC Review of the TNI 2016 Standard

SUMMARY

V1M4 -

➤ Editorial Changes - corrected

1. Consistency issues with the definition of MDL – Changed term to Detection Limit (DL)

2. Lack of clarity on whether MDLs must be calculated for each instrument – 1.5.2.1.1 c) clarified DLs are analyzed on multiple instruments

3. 1.7.1 - Sentence on instrument calibration removed - It did not describe a requirement and was perceived to cause confusion

➤ Technical Changes – New Language has been proposed in the most recent draft

• 1.5.2.2 Requirement that LOQ = 3*MDL – Revision will allow for exceptions

• 1.5.2.2.2 Conflict between initial and ongoing verifications of LOQ – Revision must include criteria for ongoing verification.

LASEC Review of the TNI 2016 Standard

➢ V1M1 PT – 3 issues were identified. Resolution achieved through minor editorial changes.

➢ Reviewed all standards documents

  ✓ Made formal recommendations to NELAP AC regarding acceptance of revised modules/documents for 2016 TNI Standard

  ✓ Updated SOPs for review and acceptance of standards *(LASEC Review for Suitability SOP 3-106, NELAP Standards Acceptance SOP 3-103)*

SOP/Policies/Etc. in Review

SOP 3-106 Standards Review and Acceptance

- Revision may be necessary based on "lessons learned" during the review of the 2016 TNI Standard.

LAS EC Plans - 2017

➢ Sustain SIR progress

- ✓ Create Implementation Guidance according to SOP 3-105 for non-SIR questions

➢ Monitor and Comment on New Revisions to Standards Modules

➢ Revise review process SOPs as needed

➢ Continue to Develop Policies and Procedures for NELAP AC

Review/Discussion

□ Lessons Learned from the review of the 2016 TNI Standard

Lessons Learned

Background for Standards Review

- Followed the SOP 2-100 *Procedures Governing Standards Development*

- The review and recommendations process followed SOP 3-106 *Review of Accreditation Standards for Suitability*

Lessons Learned

1. **Revised language:** Redline/strikeout versions, from the previously adopted and implemented standard, should be provided for review. These can be done retroactively using "document compare" if necessary, but continuous tracking with comments provided in the margin is preferable

2. **Pre-notification:** It would be helpful to have the expert committee provide information on proposed changes prior to the start of revision (this is discussed in the Standards Development SOP 2-100, section 5.2). Would like to have justification for any changes made/proposed.

3. **Recommendations:** LASEC's process for recommending standards modules to the NELAP AC, and the possibility of a recommendation "with conditions" (such as guidance) was tested with the Chemistry module.

   - The process did not work as well as initially anticipated. Perhaps a closer examination of where the process broke down will help with improvements.

Lessons Learned

4. **Individual Comments:** A standardized procedure for developing and maintaining the "response to comments" document needs to be developed by CSDEC that addresses:

   - An explanation of the decision process (comments are persuasive or non-persuasive)

   - A way to ensure that the expert committee's understanding of each comment matches what the commenter intended to say, so that comments are not dismissed because they are misunderstood.

   - A way to assess impact of a comment to ensure that discussions result in adequate resolution

5. **Committee Comments:** There MUST be some provision for considering and responding to comments from committees, since this is the stated purpose of LASEC's involvement in the process – recommending adoption (or not) to the NELAP AC.

Lessons Learned

6. **Significant Comments/Concerns:** At present, only comments accompanying votes (at the designated voting stages of development) are addressed.

    - There must be some way to address significant comments outside of this framework – the system needs to be tweaked.

7. **Time:** Need adequate time for review (30-45 days is not sufficient)

8. **SIRs/TIAs:** Provide a list of SIRs and TIAs that were carried into the new document (would also serve as a check and balance to ensure that interim interpretations are included)

9. **Comments:** Improve the quality of response-to-comments tracking and track ALL comments received throughout the development of the standard, not just those at the voting stages. This will ensure that "show-stoppers" do not get overlooked and provide some ability to estimate the criticality of comments received

TNI Washington DC August 2017

Any other issues?

Questions?

Discussions?

TNI Washington DC August 2017