Laboratory Accreditation System Executive Committee Meeting Minutes
May 24, 2016 1:30 pm Eastern time

1) Welcome and Roll Call

Judy Morgan welcomed everyone to the meeting. Those in attendance are recorded in Attachment A. Minutes from March were not approved due to the lack of a quorum, and the committee did not meet in April.

3) SIRs

The SIR Subcommittee met and approved "recycled" two SIR responses from the PT Program Executive Committee, SIRs 26 and 80. These two very old SIRs are related and now have the same answer, and will be sent to the NELAP AC for approval. However, the fundamental issue causing confusion is not about the standard but rather about the implementation of the PT program, and cannot be resolved with the SIR process. The Chair and PA will work with other TNI committees and Program Administrators to seek resolution at a different level of TNI.

2) Assessment Forum and Mentor Session

Barbara reported good progress on planning for the summer conference sessions.
Dorothy will lead the Mentor Session on Monday morning August 8, about writing and reviewing SOPs. Several additional presenters are needed for this activity.

The first half of the afternoon Assessment Forum session, Monday August 8, will be a "technical assistance" session on hot to be TNI compliant. Jack Farrell and Christine Sotelo (CA program manager) will lead the session. They still need a California lab to participate in the session leadership, as well as representatives of very small labs (2-3 people.) They have access to some individuals from ~10 person labs who can contribute.

The second half of that afternoon session will be a panel presenting "audit findings of myth and legend", led by Kristin with a few other presenters.

The Tuesday morning, August 9, Assessment Forum session will be presented by the relatively new TNI Whole Effluent Toxicity Expert Committee, about assessing WET labs. The first half will be an overview of WET testing with particular information about west coast differences, plus a session on traceability. The second half will be on assessing WET labs – common findings, terminology and will also provide a checklist for WET methods (adapted from Virginia's checklist.) The WET committee members will do most of the presentations, and the second half is expected to be highly interactive. If needed, plans are to continue the discussion about assessing WET labs into part of the WET committee session on Tuesday afternoon.

3) Status of Standards Review

Lynn noted that the NELAP AC has accepted our LASEC's recommendations concerning the asbestos (V1M3), radiochemistry (V1M6) and aquatic Toxicity (V1M7, WET) with a vote initiated at the AC's April meeting.

Since committee members had been asked to review and provide comments on the remaining standards documents (PT/V1M1&V2M2, QS/V1M2, LOD/LOQ, Chemistry/V1M4, and Microbiology/V1M5) in the preceding weeks, draft recommendations to the NELAP AC were provided with the meeting reminder. Although a quorum was not present on the teleconference,

participants agreed to an email vote on each of these recommendations, initiated by motions presented during the meeting itself.

The comments received on each document and the draft recommendations to the AC are provided in Attachments C-G of these minutes. The motions to approve and forward the recommendations to the AC, and the votes cast, are summarized in the table below:

Document	**Motion to approve draft recommendation to NELAP AC**	**YES votes @ teleconf**	**YES votes by email thru 5/30**	**TOTAL YES VOTES (14 possible)**
PT (V1M1 & V2M2	Dorothy moved/Carl seconded	5	2 yes, 1 abstain	7
QS (V1M2)	Carl moved/Dorothy seconded	5	3	8
LOD/LOQ	Barbara moved/Dorothy seconded	6	2	8
Chemistry (V1M4)	Barbara moved/Kristin seconded	6	2	8
Micro (V1M5)	Carl moved/Dorothy seconded	5	2	8
NOTE: one person had to leave mid-process and voted by email on remaining items				

All recommendations are thus approved and will be forwarded to the NELAP AC for its consideration. In addition, the comments provided on the LOD/LOQ document and on the Chemistry Standard will be forwarded to the Chemistry Expert Committee.

5) LASEC Standards Review for Suitability SOP 3-106

Edits to this SOP were finalized, to address Policy Committee concerns along with concerns raised by the Program Administrator of the Consensus Standards Development Program and its Executive Committee (CSDEC.) This draft was circulated for consideration at the May meeting. There is no mechanism in the approved Standards Development SOP 2-100 for LASEC (or any other committee) to comment as a committee. All comments need to be provided by individual members of LASEC participating as either full or associate members of an Expert Committee, or else during the voting process, where, after the Voting Draft Standard, those comments are supposed to be limited to items changed to address comments previously ruled to be "persuasive."

As was done with the standards recommendations, an email vote was approved by consensus. Carl moved and Myron seconded that the draft be accepted, and five "yes" votes were cast during the teleconference. An additional three "yes" votes were cast by email, as of May 30, and thus the motion passes and the revisions to SOP 3-106 are approved. The next step is review and approval of the revisions by Policy Committee and endorsement by the TNI Board of Directors for final approval. The approved draft is in Attachment H to these minutes.

7) On-Site Assessment and Prep Method Policies for the NELAP AC

Updated documents for these items were not available. Kristin is willing to keep her assignment of the prep method policy, but cannot commit to a date for completing it due to competing priorities, and Kirstin has been non-responsive for a number of months now. Judy will seek out new "volunteers" to work on these documents.

8) Next Meeting

LASEC will meet on Tuesday, June 28, at 1:30 pm. Teleconference information and an agenda will be sent ahead of time. 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	JoAnn Boyd	jboyd@swri.org	3 years, 12/16	StdsRev	Southwest Research Inst.	Lab/FSMO	No
3	Kristin Brown, Vice Chair	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	No
5	Karen Costa	Costa.Karen@epa.gov	3 years, 12/17		US EPA	Other	No
6	George Detsis	george.detsis@eh.doe.gov	3 years, 12/17	Assmt Forum	US DOE	Other	No
7	Barbara Escobar	Barbara.Escobar@pima.gov	3 years, 12/18	Mentor, AssmtFrm, FAQ	Pima County, AZ	Lab/FSMO	Yes
8	Jack Farrell	aex@ix.netcom.com	3 years, 12/16	Assmt Forum, StdsRev	Analytical Excellence	Other	No
9	Myron Gunsalus	ngunsalus@kdheks.gov	3 years, 12/18	KS DHE	KS Lab Director	NELAP AB	Yes
10	Bill Hall	George.Hall@des.nh.gov	3 years, 12/16	SIRs,FAQs	NH ELAP	NELAP AB	No
11	Carl Kircher	carl.kircher@doh.state.fl.us	3 years, 12/18	SIRs, FAQs	FL DOH	NELAP AB	Yes
12	Dorothy Love	dorothylove@eurofinsus.com	3 years, 12/18		Eurofins Env't'l	Lab	Yes
13	Mitzi Miller	mitzi.miller@moellerinc.com	2 years, 12/17	FAQs	Dade Moeller, Inc	Other	No
14	William Ray	Bill_Ray@williamrayllc.com	3 years, 12/17		Wm Ray Consultants	Other	No
Ex Officio							
	Elizabeth Turner	eturner@ntmwd.com		Ex Officio	Small Lab Issues	North TX Mun. Water District	No

Associate Members							
	Aaren Alger	aaalger@pa.gov			PA DEP	NELAP AB	No
	Carol Barrick	cabarrick@msn.com, Carol.Barrick@mosaicco.com			FCC Environmental	Lab/FSMO	No
	Kirstin Daigle	Kirstin.daigle@testamericainc.com			TestAmerica	Lab	No
	Carol Haines	bio.haines@gmail.com		Stds Rev, ad hocs	Retired from EPA as of 5/1/15	Other	No
	Harold Longbaugh				Houston Lab	Lab	No
	Christelle Newsome	cnewsome@c2nassociates.com			C2N Associates, Inc.	Other	No
	Carol Schrenkel	CSchrenkel@suburbantestinglabs.com	3 years, 12/16	Mentor, Ass. Forum		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
Guests							

Attachment B

Action Items – LAS EC

	Action Item	Who	Expected Completion	Actual Completion / Comments
42	Craft wording for recommendation about PT modules	Judy/Mitzi	After comments from IS voting are reviewed and addressed?	Recommendation to AC approved as result of motion at May 24 meeting
56	Review LOD/LOQ module and submit comments by March 4	All committee members	In time for March 22 meeting	March 22, 2016 Recommendation to AC approved as result of motion at May 24 meeting
57	Revise Provisional SOP 3-106 per Policy Committee recommendations	Judy	April 1	Completed and approved at May 24, 2016 meeting
58	Transmit requests for items to be included in guidance for Calibration and LOD/LOQ documents	Lynn	April 15	Approved at May 24 meeting, transmitted May 31, 2016
59	Review Quality Systems (V1M2) module and submit comments by April 8	All committee members	In time for April 19 meeting	Comments received and recommen-dation to AC approved as result of motion at May 24 meeting
60	Review Micro (V1M5), Chemistry (V1M4) and PT (V1M1/V2M2) modules	Request by email to all committee members, send in lieu of April meeting	By May 13, so in time for May 24 meeting	Comments received and recommend-ation to AC approved as result of motion at May 24 meeting

Attachment C

PT Modules

Two LASEC members are voting members of the PT Expert Committee, and from that participation, they find the approved modules to be suitable and implementable.

The PT Expert Committee Chair has provided the following statements about how the 2016 revisions to V1M1 and V2M2 address the NELAP AC's objections to the 2009 versions of those modules

Vol 1

The 2016 version of Vol 1 Mod 1 addresses major concerns of the AB Council. The laboratory reporting for proficiency testing has been restored to the TNI PTRL reporting. We have also addressed the issue of tracking PT results by analysis date and switched this back to the close date of the study. The waiting time between PTs has been reduced to 7 days from 15 days.

Vol 2

The 2016 version of Vol 2 Mod 2 has been expanded the definition of an Accreditation Body to include non-governmental AB's. We modified the AB requirements for suspension and revocation to allow the AB's to follow their established rules for these activities. The note addressing clarifications for accreditation has been re-written to be much clearer. To avoid inconsistencies between Vol 1 and 2, all laboratory requirements exist only in Vol 1. ABs will be assessing the labs to Vol 1.

NOTE: Volumes 3 and 4 pertain to PT Providers and PT Provider ABs. Those volumes are not yet final. Voting is completed but the PT Expert Committee is reviewing comments provided during the voting period.

Recommendation of LASEC to NELAP AC
TNI Standard V1M1 and V2M2, Proficiency Testing, approved April 2016
APPROVED BY LASEC _____

The LASEC has reviewed the Proficiency Testing Modules (V1M1 and V1M2) as revised and approved in 2016,

and recommends that the NELAP AC adopt these modules as presented.

The problems with the 2009 versions of these modules have been resolved, as follows:

Vol 1

The 2016 version of V1M1 addresses major concerns of the AB Council. The laboratory reporting for proficiency testing has been restored to the TNI PTRL reporting. Tracking PT results by analysis date has been switched this back to the close date of the study. The waiting time between PTs has been reduced to 7 days from 15 days.

Vol 2

The 2016 version of V2M2 has been expanded the definition of an Accreditation Body to include non-governmental ABs. The AB requirements for suspension and revocation have been expanded to allow the ABs to follow their established rules for these activities. The note addressing clarifications for accreditation has been re-written to be much clearer. To avoid inconsistencies between Vol 1 and 2, all laboratory requirements for PTs now exist only in V1M1. ABs will be assessing the labs to Vol 1.

Attachment D

2016 Revisions to the Quality Systems Module V1M2

A markup was provided for review that notes all changes since the 2009 version. There was a 2012 revision, not offered for review, that was further updated for the 2016 revision. Only one committee member provided comments on this module.

Carl comments on V1M2

…I think you wanted us LASEC members to review the 2012-version Volume 1 Module 2 TNI Standard. I had to refer to each subsequent respective Technical Module to verify the inclusion and laboratory conformance requirements of any more stringent test method and regulatory requirements. Yes, I did find these requirements, so I can conclude that this V1M2 is "implementable" (plus whatever other adjectives we are supposed to attach to this) and can be sent to the NELAP AC.

Addendum added during May 24 meeting – Dorothy reviewed this module and suggested that the definition for "Limit of Detection" should be changed to "Method Detection Limit" to match the terminology change underway in the Chemistry module.

Recommendation of LASEC to NELAP AC
TNI Standard V1M2, Quality Systems, approved March, 2016
APPROVED BY LASEC _____

The LASEC has reviewed the Quality Systems Module (V1M6) as revised and approved in 2015, and

recommends that the NELAP AC adopt this module as presented.

Attachment E

Comments Received on Detection & Quantitation standard (sent to LASEC 2/19/16 with request for comments by March 4, for consideration at March meeting, but we didn't get to it then)

Dorothy:
I reviewed the LOD/LOQ Standard proposed revision and am OK with the content. In regard to a guidance document I would recommend developing a flow diagram that will show the process. For example one path for MDL and one for LOQ noting where the initial and continuing checks fall and basics about how they are performed and analyzed (per instrument, etc.). Reading through the document it is tough to picture exactly how everything is to flow.
Bill Ray:

I am OK with the language except about the part when an MDL is not necessary. The list does include some examples but should state that an MDL is not practical if any of the assumptions or conditions of the procedure are not met. For example based on the most used process in 40CFR Part 136 Appendix B

All gravimetric and titrimetric tests – reason – there is no variability at zero concentration so the assumption that the variability at a low level concentration mimics that of zero concentration is not met.

All gravimetric tests – reason – the measurement device, the balance, is not calibrated using solutions of known concentration of analyte. They are calibrate using standard weights.

All tests using senses (known as organo-leptic tests) – reason - the measurement device (nose, eyes, tongue) cannot be calibrated and the variability of one "device" is not mimicked by another.

pH is the unique case here simply because there is no such thing as a zero concentration. Pure water has an H^+ concentration of 10^{-7} or a pH of 7. A pH of zero represents 10^0 or 1 mole concentration something definitely not zero and the log of 0 is infinity.

Proposed Recommendation Statement:
Recommendation of LASEC to NELAP AC
TNI Standard for Detection and Quantitation, §1.5.1-1.5.2 of V1M4, Chemistry Module, approved by Chemistry Expert Committee January 20, 2015
APPROVED BY LASEC _____

The LASEC has reviewed the Detection and Quantitation sections of the Chemistry Module (V1M4) as revised

and approved in 2016, and recommends that the NELAP AC adopt this module as presented.

There are several issues noted that should be addressed in the requested guidance document. See below for

draft of transmittal to Chemistry committee.

Requests for Inclusion in LOD/LOQ Guidance

We do recommend developing a flow diagram that will show the process. For example, reading through the document, it is tough to picture exactly how everything is to flow, for example the one path for MDL and another one for LOQ noting where the initial and continuing checks fall and basics about how they are performed and analyzed (per instrument, etc.)

The guidance should explain how the decision about when an MDL is not necessary should be made. Not in examples (which tend to become requirements) but maybe a decision tree about how an MDL is not practical if any of the assumptions or conditions of the procedure are not met. An example, based on the most used process in 40CFR Part 136 Appendix B, follows:

All gravimetric and titrimetric tests – *reason* – there is no variability at zero concentration so the assumption that the variability at a low level concentration mimics that of zero concentration is not met.

All gravimetric tests – *reason* – the measurement device, the balance, is not calibrated using solutions of known concentration of analyte. They are calibrate using standard weights.

All tests using senses (known as organo-leptic tests) – *reason* - the measurement device (nose, eyes, tongue) cannot be calibrated and the variability of one "device" is not mimicked by another.

pH is the unique case here simply because there is no such thing as a zero concentration. Pure water has an H^+ concentration of 10^{-7} or a pH of 7. A pH of zero represents 10^0 or 1 mole concentration something definitely not zero and the log of 0 is infinity.

It would be helpful if the guidance can address the following questions:

1.5.2.1.2 In the event that verification fails, the laboratory shall perform a new MDL study within 30 calendar days.

Or what? Can samples be run within this 30 day window. Should it say 'shall be performed prior to samples being analyzed"?

1.5.2.3 If no analysis was performed in a given year the verification of the MDL/LOQ is not required, but a new initial MDL/LOQ verification shall be performed prior to analysis of client samples

Will there be guidance for the situations in which samples were only run once or twice during the year?

Please note that LASEC did not consider whether technical edits to the standard could resolve the need for guidance on these issues, but if Chemistry Expert Committee considers that approach to be preferable, we would surely consider having these points clarified that way rather than in the guidance itself.

Attachment F

Chemistry Module V1M4
This module was sent for review on April 26, asking for any comments by May 13. No comments were received. The entire V1M4 incorporates the already-reviewed Calibration Standard as well as the Detection and Quantitation Standard, plus a few changes of lesser magnitude.
Should there be a committee member who has reviewed this module, the following recommendation could be proposed for adoption.

Recommendation of LASEC to NELAP AC
TNI Standard V1M6, Chemistry, approved April 16, 2016
APPROVED BY LASEC _____

The LASEC has reviewed the Chemistry Module (V1M4) as revised and approved in 2016, and recommends that the NELAP AC adopt this module as presented.

Attachment G

Microbiology Module V1M5
This module was sent for review on April 26, asking for any comments by May 13. No comments were received.

Should there be a committee member who has reviewed this module, the following recommendation could be proposed for adoption.

Recommendation of LASEC to NELAP AC
TNI Standard V1M5, Microbiology, approved October 22, 2015
APPROVED BY LASEC _____

The LASEC has reviewed the Microbiology Module (V1M5) as revised and approved in 2015, and recommends

that the NELAP AC adopt this module as presented.

Appendix H

SOP TITLE:	**Review of Accreditation Standards for Suitability**
SOP NO.:	3-106
REVISION NO:	1.0

Committee:	n/a	**Approved Date:**	~~n/a~~
Program Executive Committee:	Laboratory Accreditation Systems Executive Committee	**Approved Date:**	May 26, 2016
Policy Committee Reviewed Date:			[Enter date here]
TNI Board of Directors Endorsed Date:			[Enter date here]
SOP Effective Date:			May 24, 2015

1.0 Purpose

This SOP describes the process for review of accreditation standards, or portions thereof, for suitability for use in TNI NELAP accreditation programs.

2.0 Summary

This SOP details the steps in the review process and the elements that must be considered for an accreditation standard to be recommended for adoption by TNI NELAP Accreditation Council (AC) and its component Accreditation Bodies (ABs).

3.0 Definitions

3.1 Standard -- a document that has been developed and established within the consensus principles of TNI and that meets the approval requirements of TNI procedures. The term "standard" refers to a revised section, module, or volume as well as to the complete package of modules once adopted and implemented, such as the Environmental Laboratory Sector Standard. NOTE: these are listed in sequential order for clarity of the relationships among the versions of a developing standard.

- Voting Draft Standard (VDS) – a standard that has been released in draft form by the Expert Committee and presented for voting.

- Modified Voting Draft Standard (MVDS) – a revised version of the Voting Draft Standard that has been released in draft form by the Expert Committee following response to comments from the voters, and which will again be presented for voting.

- Interim Standard (IS) – a standard that has been approved by the Expert Committee Consensus Body, but is subject to further review by stakeholders, and may be modified and again presented for voting.

- Modified Interim Standard (MIS) – A revised version of the Interim Standard that has been released by the Expert Committee following response to comments by voters, and which will again be presented for voting

- TNI Standard – a standard that has been approved by the Expert Committee Consensus Body.

3.2 Suitability -- The list of terms offered for describing "suitability," as agreed upon by LASEC follows.

- Auditable
- Implementable
- Understandable
- Improvement over previous version
- Clearly written -- only one possible interpretation of the language
- Enforceable
- Clearly defined responsibilities

- Economically advantageous to labs and/or ABs

3.3 Standards Review Council – a voluntary group representing stakeholders from Expert Committees, Accreditation Bodies, Laboratories and others, knowledgeable of the TNI process and the Standard that insures consistency in format of a module or volume of a standard with the Guidelines for Standards Development, editorial and/or grammatical corrections, clarity of content and overall consistency with other modules and volumes of the standard.

4.0 Related Documents

SOP 2-100	Procedures Governing Standards Development
SOP 3-101	NELAP AC Voting Procedure for General Business and Laboratory Accreditation Matters
SOP 3-103	NELAP Accreditation Bodies Standards Review and Acceptance

5.0 Procedure

5.1 General Requirements

It is the responsibility of the LASEC to provide a consensus recommendation regarding whether or not a standard should be implemented by TNI's NELAP recognized accreditation bodies in their accreditation programs.

5.1.1 The LASEC is invited to participate in and/or comment upon standards being developed or modified by Expert Committees from the on-set of the process and intermittently throughout the process. The LASEC reviews all standards provided by TNI Expert Committees and develops a recommendation relevant to the standards' suitability for use in TNI's NELAP, using the definition of suitability in section 3.2 above. This review will evaluate the standard relative to the current standard in use by the program or its potential applicability as a new standard and will consider any implementation issues affecting accreditation bodies, laboratories or others. The LASEC will review the new standard for any significant barriers or conflicts that would prevent the standard from being implemented in a timely and cost-effective manner. Specific review steps are as follows:

5.1.1.1 When a decision has been confirmed to develop and/or modify a standard, a notification is published on the TNI website and the LASEC Chair will also be notified by the respective Expert Committee.

5.1.1.2 The LASEC will meet to discuss the need for a new or revised standard. If it is decided that a new or revised standard is justified, LASEC will consider any items that should be included in the standard, or any needed changes if it is an existing standard. The LASEC will then meet with the Expert Committee by open meeting, webinar, or other form of public communication to present and discuss its recommendations.

5.1.1.3 Following the Expert Committee's publication of a list of proposed items to be included in the standard, the LASEC will review the

document for apparent issues or implementation concerns and notify the Expert Committee of any issues.

5.1.1.4 If warranted, the respective Expert Committee may revise their development/modification plans for the standard. LASEC representatives may serve as associate members of the Expert Committee.

5.1.1.5 The LASEC may choose to again meet with the Expert Committee to further discuss and refine the list of proposed items to be included in the standard.

5.1.1.6 The LASEC may also comment on the proposed standard or standard modification through its members participating in the voting process. The LASEC will consider whether the Standard is adequate to allow for the production of data of known and documented quality.

5.1.1.7 The LASEC will examine each volume and subsequent modules and document any findings or deviations, including but not limited to:

5.1.1.7.1.1 agreement or conflict related to the Standard as a whole; comments, feedback, and suggestions from peer groups within TNI;

5.1.1.7.2 known accreditation practices;

5.1.1.7.3 successful and consistent implementation; and

5.1.1.7.4 any identified possible or obvious barriers.

5.1.1.8 The final outcome is the LASEC's determination of suitability for the stakeholder group(s) affected. Comments regarding limitations to suitability and implementation of a standard should also reflect the bulleted items in section 3.2 above.

5.1.2 On-going Review During Standards Development

5.1.2.1 The LASEC may provide interim recommendations that could require a change to a TNI standard. Recommendations will be provided, as identified, to the Expert Committee chair with a copy to the Consensus Standards Development Executive Committee (CSD EC.) This includes changes to any of the following: VDS, MVDS, MIS, or IS. This will be done through individual LASEC members submitting comments during the voting process, or through their participation as associate members of the Expert Committee.

5.1.2.2 If a Modified Interim Standard is presented, LASEC may meet with the Expert Committee to discuss any concerns with the modifications made to the Interim Standard as a result of persuasive comments. If agreement is not reached, the Expert Committee will subject the MIS to further voting. This process will continue until both parties believe the standard will be acceptable as a Final TNI standard.

5.1.3 Each standard or modification to a standard being considered for development, regardless of its stage of development, will be discussed at meetings of the LASEC. A standards tracking spreadsheet maintained by the CSD EC and the Expert Committees may be used as a "read only" document by the LASEC to determine progress of any proposed developments or modifications. As appropriate, the LASEC will discuss how the new standard differs from the current standard, if one exists, and the advantages and disadvantages of the new standard, and whether any potential barriers to implementation are foreseen.

5.1.3.1 The LASEC may request the Chair of the Expert Committee (or designee) that developed the standard to make a presentation of the standard.

5.1.3.2 The LASEC Chair may establish a subcommittee to help review the standard.

5.2 Final Reviews with Recommendations to the NELAP AC

Although the LASEC monitors and comments upon each developing standard or revision, its reviews of the Interim Standard (IS) and the final approved modules and the complete TNI Standard package will include development and presentation of recommendations to the NELAP AC. The possible recommendations are described in section 5.3 below.

5.2.1 If there is an IS, LAS EC will seek to obtain a copy at least 30 days in advance of the official comment period. Upon its review of an IS, the LASEC will formulate a recommendation prior to the end of the official 30-day comment period for the IS, and present that recommendation as a draft to the AC, for the consideration of the AC and the individual NELAP Accreditation Bodies (ABs) in their separate reviews and comments on the IS. The content of this draft recommendation will be one of the possibilities described below. The AC may offer comment or other feedback on the draft recommendation, or discuss it with the LASEC in a joint meeting, if time permits.

5.2.2 If there is no IS after approval of the VDS, then the recommendations will be made only once, for the final TNI Standard.

5.2.3 Upon approval of the "final" TNI Standard, the LASEC will again review the document, encompassing any changes might have been made through the process of a Modified Interim Standard and re-vote, as well as any feedback received from the AC. Any comments should address one of the bulleted items in section 3.2 above. Based on that review, the LASEC will present a formal recommendation to the NELAP AC, again based on the possibilities described in section 5.3 below. This recommendation concerning the final version of the TNI Standard will normally be issued within sixty (60) days of final approval of the standard.

5.2.4 In the event that multiple sections, modules and volumes of the Environmental Laboratory Sector Standard (ELSS) are undergoing revision and planned to become a comprehensive update of the ELSS, then, in addition to formulating a recommendation for each section, module, or volume of the ELSS, the LASEC will review the final complete, consolidated package one final time and issue a comprehensive formal recommendation to the AC concerning the entire comprehensive document.

5.3 Possible Recommendations from LASEC to the NELAP AC

5.3 1 Adoption with No Conditions

5.3.1.1 This recommendation will be made if the section, module, volume or complete standard represents an improvement over the current standard; has no perceived obstacles to implementation by accreditation bodies; and requires no new policies, procedures, guidance documents or other related documents that need to be prepared.

5.3.1.2 The LASEC may recommend the AC adopt all standards in a given sector, one or more standards within a sector, or one or more modules in a standard.

5.3.2 Adoption with Conditions

5.3.2.1 This recommendation will be made if the standard or portion thereof
- represents an improvement over the current standard,
- has no significant obstacles to implementation by accreditation bodies, but
- requires new policies, procedures, guidance documents or other related documents that need to be prepared.

5.3.2.2 When this recommendation is provided, the LASEC will also prepare a list of the policies, procedures, guidance documents or other related documents that need to be prepared; which group LASEC recommends should develop the documents; and an estimated date for completion.

5.3.2.3 The LASEC may recommend the AC conditionally adopt all standards in a given sector, one or more standards within a sector, or one or more modules in a standard.

5.3.3 Adoption after Changes to the Standard are Made

5.3.3.1 This recommendation will be made if a standard
- represents an improvement over the current standard,
- has no perceived obstacles to implementation by accreditation bodies, but
- changes are required for implementation.
- this recommendation will be made only as a last resort, if an insurmountable issue belatedly emerges during the final review and recommendation process

5.3.3.2 The LASEC will send detailed correspondence to the Expert Committee and the CSD EC that specifically state the reason(s) for the inability to implement the newly developed or modified standard along with recommendations from the LASEC to mitigate the issue(s).

5.3.3.3 The Expert Committee may begin the process of modifying the IS per SOP 2-100 and ultimately present a Modified IS (MIS) for vote, after which LASEC will reconsider its recommendation.

5.3.3.4 The LASEC may recommend the AC adopt all standards in a given sector, one or more standards within a sector, or one or more modules in a standard.

6.0 References

SOP 2-100	Procedures Governing Standards Development
SOP 3-101	Voting Procedure for General Business and Laboratory Accreditation Matters
SOP 3-103	Accreditation Bodies Standards Review and Acceptance

7.0 SOP Approved Changes

Prev. SOP	New SOP	Date of	Description of Change

Revision	Revision	change	
SOP 5-102	1.0	4/22/2014	Change of program and updated per SOP 2-100 Rev. 2.0
Renumbered SOP 3-106	1.0	7/26/14	Revised to accommodate Policy Committee review
	1.0	May 2015	Revised to accommodate outcome of ANSI audit and related changes to SOP 2-100
	1.0	May 2016	Revisions to address concerns of Policy Committee and CSDEC Program Administrator