THE NELAC INSTITUTE

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

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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
- Unambiguous and transparent
- Enforceable
- Clearly defined responsibilities
- The Standard is adequate to allow for the production of data of known and documented quality

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   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 Revision	New SOP Revision	Date of change	Description of 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 CSDEC Program Administrator
	1.0	Sept. 2016	Revisions to address concerns of Policy Committee that were neglected in May 2016 revision

Flowchart for 5.2 – 5.4 (Final Review)