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| SOP TITLE: | Review of Accreditation Standards for Suitability |
| SOP NO.: | 3-106 |
| REVISION NO: | 2.0 |

| | Initial Approval | Revision Date | Review Date |
|--|-------------------------|----------------------|--------------------|
| Program: Laboratory Accreditation Systems Executive Committee | April 22, 2014 | July 23, 2020 | |
| Policy Committee Review | | October 7, 2016 | |
| TNI Board of Directors Endorsement | | NA | |
| SOP Effective Date | May 24, 2015 | July 23, 2020 | |

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's NELAP Accreditation Council (AC) and its component Accreditation Bodies (ABs).

3.0 Definitions

- 3.1 Expert Committee – a committee whose duties include the development and maintenance of consensus standards. The number and scope of Expert Committees is not limited and will be determined by the TNI Consensus Standards Development Executive Committee with the approval of the TNI Board of Directors. The Expert Committees are consensus bodies for TNI ANSI standards development activities.
- 3.2 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.
- Draft Standard (DS) – A standard (volume, module or section of a module or standard) that has been approved by the Expert Committee and presented for comment.
 - TNI Standard – A document that has been developed and established within the consensus principles of TNI and that meets the approval requirements of TNI procedures, and has been approved by the Expert Committee. While the TNI Standards are composed of volumes and modules, reference to the standard in this SOP may relate to a volume, a module or a section of a volume or module depending on the activities of the Expert Committee.
- 3.3 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

4.0 Related Documents

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| 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 after committee approval and develops a recommendation relevant to the standards' suitability for use in TNI's NELAP, using the definition of suitability in section 3.3 above. LASEC will evaluate the standard under review 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 provide the Expert Committee with its recommendations.
- 5.1.1.3 Following the Expert Committee's publication of a list of proposed items to be included in the standard (which may or may not be accompanied by a draft revision of the standard itself), 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 meet again 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 when the Draft Standard (and any subsequent revisions) is published for comment. 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 3.3 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 (CSDEC.) This may be done through committee comment or by individual LASEC members submitting comments on the draft, or through LASEC members' participation as associate members of the Expert Committee.

5.1.2.2 LASEC may meet with the Expert Committee to discuss any concerns with the modifications made to the Draft Standard as a result of persuasive comments. If agreement is not reached, LASEC will request that the Expert Committee continue trying to accommodate the identified concerns. This process will continue with subsequent revisions of the Draft Standard until both parties believe the standard will be acceptable as a Final TNI standard.

5.1.3 Each Draft Standard (and subsequent revisions) 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 CSDEC 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 Draft Standards 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 Upon its review of a Draft Standard and subsequent revisions of that document, the LASEC will formulate a recommendation prior to the end of the official comment period 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 Draft Standard. 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 Upon approval of the "final" TNI Standard, the LASEC will again review the document and the associated response to comments file, encompassing any changes might have been made in response to comments on the Draft Standard re-vote, as well as any feedback received from the AC. Any comments should address one of the bulleted items in section 3.3 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 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 CSDEC 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 TNI Standard per SOP 2-100 and ultimately present a new revision of the Draft Standard 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

| New SOP Revision | Date of change | Description of Change |
|------------------|----------------|---|
| 1.0 | 7/22/14 | |
| 1.1 | 5/24/15 | Revised to accommodate outcome of ANSI audit and related changes to SOP 2-100 |
| 1.2 | 5/26/16 | Revisions to address concerns of Policy Committee and CSDEC Program Administrator |
| 1.3 | 9/27/16 | Revisions to address concerns of Policy Committee that were neglected in May 2016 revision |
| 2.0 | 7/23/20 | Revision to accommodate changes to CSDEC Standards Development SOP 2-100, made to address findings of the ANSI audit. |

Attachment 1 -- Flowchart for 5.2 – 5.3 (Final Review)

