



<b>SOP TITLE:</b>	Standard Interpretation SOP
<b>SOP NO.:</b>	3-105
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<b>Program Executive Committee:</b>	Laboratory Accreditation System Executive Committee (LAS EC)	<b>Approved Date:</b>	June 27, 2017
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## 1.0 Purpose and Applicability

- 1.1 This Standard Operating Procedure (SOP) describes the process to follow for an interpretation request related to any current NELAP adopted Standard and applies only to inquiries concerning these Standards.
- 1.2 This SOP is not applicable to dispute resolution between any parties involved with the accreditation process – laboratories, an Accreditation Body (AB) or AB contractors. Further, the standards interpretation process is not retroactive and is not intended to substitute for any AB's appeal process. This process is not designed to interfere with a NELAP AB's legal authority to grant, deny, suspend or revoke accreditation, nor is it designed or intended to deal with such issues.
- 1.3 This SOP is not applicable to questions related to how to perform or interpret test methods or other "how to" questions. The procedures in this SOP are applicable to particular, specific sections of the Standard(s), not to an entire Standard.
- 1.4 The interpretation process is not intended to be an exhaustive or comprehensive review of all TNI policies, procedures or entire Standard(s) but only the section identified in the Standard Interpretation Request (SIR) submission.
- 1.5 This process also provides a means to respond to questions that are "clarifications" rather than SIRs.

## 2.0 Summary

Any person requesting an interpretation of any current NELAP adopted Standard completes the "NELAP Request for Interpretation (SIR)" Form located on the TNI website. After the form is submitted, a confirmation receipt is automatically sent to the requester and the SIR is automatically e-mailed to the TNI Program Administrator (PA.) The PA forwards the email to the NELAP Accrediting Council (NELAP AC) Chair and the Laboratory Accreditation System Executive Committee (LAS EC) Chair. The Chairs of the NELAP AC and the LAS EC review the SIR and determine if the interpretation process should advance and if so, which TNI committee will review the SIR and issue the interpretation. The interpretation is prepared by the designated TNI Committee and reviewed by the LAS EC prior to submission of the interpretation for consideration and approval/rejection by the NELAP AC. Timelines for completion of the interpretation are established to ensure a timely process.

## 3.0 Related Documents

- 3.1 TNI SOP 1-105 Rev 0.1 Process for Creating Guidance
- 3.2 TNI SOP 3-101 Voting Procedure for General Business and Laboratory Accreditation Matters
- 3.3 Request for Interpretation Form (NELAP), TNI Website

## 4.0 Definitions

- 4.1 Implementation Guidance: Response to a submittal that does not meet the criteria for a Standard Interpretation Request, but rather seeks clarification of how to comply with the standard. This type of response allows for guidance to be provided regarding how a requirement may be fulfilled.
- 4.2 Standard: Any currently adopted NELAP Standard.

- 4.3 Standard Interpretation: A clear explanation of specific questions related to a section or provision in the Standard, where the language of the Standard is not clear. Questions about compliance with the standard, about analytical methods or about a dispute with an Accreditation Body will not result in interpretations being issued.
- 4.4 TNI Program Administrator (PA): The TNI staff member assigned to work with the standards interpretation process.

## 5.0 Procedure

### 5.1 Initiation of Request for Interpretation

An individual requesting an interpretation of the Standard(s) initiates the request by filling out and submitting the Request for Interpretation Form located on the TNI website.

- 5.1.1 This form is designed to capture the following information:
  - 5.1.1.1 Requester's name;
  - 5.1.1.2 Requester's organization(s);
  - 5.1.1.3 Requester's contact address, telephone number, and e-mail address;
  - 5.1.1.4 Contact information for anyone else who should receive a copy of the response;
  - 5.1.1.5 Identification to which Standard(s) the interpretation is requested; and
  - 5.1.1.6 The reference to the section of the Standard(s) in question, *i.e.*, Volume, Module, Section, or Chapter and Section Number.
- 5.1.2 A SIR submission is valid, when the requester satisfies the following criteria:
  - 5.1.2.1 Each SIR submission must contain only one question;
  - 5.1.2.2 The question must apply directly and clearly to a cited section of the Standard;
  - 5.1.2.3 The question is understood without supposition;
  - 5.1.2.4 The 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;
  - 5.1.2.5 Where possible, the question should be framed in a manner that solicits a "Yes" or "No";
  - 5.1.2.6 The question has not been posed or phrased to settle a dispute between the laboratory and the AB;
  - 5.1.2.7 The question is not a "how to" question; and
  - 5.1.2.8 The question is not a request for a method interpretation.
- 5.1.3 If the question identifies a conflict within the Standard between two or more sections of the Standard, interpretation will not provide a resolution. The LAS EC shall facilitate addressing the conflict through other avenues available within TNI.
- 5.1.4 If information requested on the form is missing or the form is otherwise incomplete or unclear, the TNI Program Administrator will contact the requester to notify him/her of the situation and request that the form be resubmitted.
- 5.1.5 The initial submission will be referred to below as "the submission" until and unless the SIR submission is accepted into the SIR process, at which point the term SIR will apply.

### 5.2 Initial Review of the Submission

- 5.2.1 When the form is submitted by a requester, an email notice with the submission is automatically sent to the TNI Program Administrator (PA). The PA will forward

the email to the Chairs of the NELAP AC and the LAS EC as well as any other PA involved with SIR management.

5.2.2 The Chairs will review the submission against the Standard section cited in the SIR. Possible considerations are as follows.

- Does it meet the requirements for a SIR (§5.1.2 above?)
- If it does not meet the requirements for a SIR, is the question suitable to be addressed as implementation guidance?
- Does it get sent back to the requester for additional information?
- Is the submission rejected due to failure to meet the criteria?

5.2.3 Upon completion of the review, the Chairs will email the PA with his/her recommendation. If the recommendation is to proceed with standard interpretation, the Chairs will also specify which TNI committee should be assigned to develop the interpretation. At this point the submission becomes an accepted SIR.

### 5.3 SIR Submission Classification

5.3.1 If the submission is approved for advancement, the PA will notify the requester in writing with the following information:

- The SIR log-in number;
- The TNI Committee that will prepare the interpretation; and
- An estimated time frame for completion of the process, which includes review and approval by the NELAP AC.

5.3.2 If the submission is determined to be a clarification request, the requester will be notified that the request has been advanced for preparation of implementation guidance.

5.3.3 If the submission is incomplete or unclear, the PA will send a letter requesting more specific information.

5.3.4 If the submission does not meet the minimum criteria to be advanced as a SIR, the PA will send a letter of rejection.

5.3.5 If the requester disagrees with the decision not to advance the submission, he/she may appeal by so notifying the PA and providing additional rationale. The appeal will be presented to the entire LAS EC and its decision shall be final.

### 5.4 Preparation of the SIR Interpretation or Implementation Guidance

5.4.1 The LAS EC Chair or designee coordinates the initial review of the SIR or clarification request with the appropriate committee members. At this point, the LAS EC Chair or designee may provide suggested language or a draft response where the SIR is easily answered and is non-controversial. The goal is to help accelerate the process and reduce response time.

5.4.2 The SIR will be assigned to an appropriate TNI Committee.

5.4.3 Where the SIR is 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 cross-functional team who will answer the question.

- 5.4.3.1 Implementation guidance responses will be categorized by subject matter or topic within the standard. They will also contain the question, as asked by the submitter as well as an answer addressing the question provided. The answer may contain some background information and will be further supported by references to the appropriate sections of the all standards in use (if more than one is applicable.).
- 5.4.3.2 Implementation guidance documents shall be reviewed by at least one subject matter expert, external to LASEC. This would typically be a member of the relevant expert committee. Implementation guidance documents will be posted on the TNI website. The requester will be notified of the response, prior to posting.
- 5.4.3.3 Each implementation guidance document shall include the following disclaimer:

**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.

## 5.5 Assignment of SIR to TNI Committee(s)

The PA will forward the SIR to the Chair of the TNI Committee selected to prepare the interpretation with a request for the committee to provide an interpretation to the LAS EC within 45 calendar days. If the Committee Chair thinks more than 45 days will be needed, the Chair shall advise the PA and propose a new date for completion.

The committee must take the following into consideration during this process.

- 5.5.1 The interpretation provided must only answer the question posed in the SIR.
- 5.5.2 The interpretation must be consistent with the Standard. The interpretation may not create a new requirement or otherwise conflict with the existing Standard. Explanation for the basis of the interpretation must be documented and provided with the interpretation.
- 5.5.3 The author must write the interpretation in complete sentences with proper grammar and punctuation.
- 5.5.4 Each committee will have an internal process to complete the SIR within 30 days of receipt of the SIR by the Committee Chair. The committee deliberation and approval of the interpretation must be captured and documented, preferably in committee minutes. In the event that the committee cannot complete the SIR within 30 days, the PA must be notified with an expected completion date.
- 5.5.5 Upon completion of the interpretation, the assigned TNI Committee will forward the response to its PA for review to ensure proper grammar and clarity of the interpretation. Once complete, the PA will forward the interpretation response to the PA assigned to LAS EC.

## 5.6 LAS EC Final Review of the SIR Interpretation

- 5.6.1 The LAS EC Chair will schedule and coordinate timely review of the interpretation with the LAS EC or with a subcommittee of members from the LAS EC selected by the LAS EC Chair. If a subcommittee is formed to review the interpretation, the subcommittee will function autonomously within LAS EC for SIR matters, but may choose to involve the full LAS EC on any particular matter. The committee members in the subcommittee must be selected so that each stakeholder interest is represented. Representation in the subcommittee, at a minimum, should include both a non-NELAP AB and a NELAP AB. The subcommittee can be maintained as a core group of participants with ad hoc additions depending on the nature of the SIR and the expertise needed. Ad hoc participants may or may not be members of the LAS EC committee.
- 5.6.2 The LAS EC, or the subcommittee if constituted, will review the interpretation as provided by the TNI Committee assigned the SIR to ensure that the guidelines contained within this SOP were followed.
- 5.6.3 If the LAS EC, or subcommittee if constituted, raises a concern with the interpretation, the LAS EC Chair or the PA will notify the Chair of the TNI Committee that prepared the interpretation and work with him/her to resolve the issue. Actions taken may include but are not limited to revision, request for clarification of intent, or suggested editorial or grammatical changes.
- 5.6.4 When LAS EC review of the interpretation is complete and the interpretation is approved by the LAS EC for release to the NELAP AC, the PA will forward a copy of the interpretation to the Webmaster for posting to the NELAP AC SIR voting site.

## 5.7 NELAP AC Review of the Interpretation

- 5.7.1 NELAP AC review of the interpretation is initiated when the interpretation is posted to the NELAP AC voting website.
- 5.7.2 The LAS EC PA will notify the representative for each NELAP AB of this action.
- 5.7.3 The NELAP AC Accreditation Body (AB) representatives will review the SIR and the response issued by the TNI committee individually and cast their votes via the SIR voting website.
- 5.7.4 NELAP AC voting is intended to affirm that the interpretation will be enforceable and does not conflict with State AB laws or regulations. This voting process is performed in accordance with TNI SOP 3-101. This process avoids using excessive AC meeting time.
- 5.7.5 If the interpretation is deemed problematic by the NELAP AC, the Chair of the NELAP AC will notify the PA and the Chair of the LAS EC and provide the rationale and a possible solution to resolve the difficulty. This is not intended to override the consensus-based interpretation process. It is considered necessary as a review step to ensure practical application of the interpretation due to the governmental regulatory nature of how the Standard is used and enforced.
- 5.7.6 The PA and the LAS EC Chair will then decide on a proper course of action. For example, if the interpretation is rejected for grammatical concerns, the SIR will be returned to the TNI Committee for revision. The action taken is situation dependent and therefore not included in this SOP. Any subsequent work on the

interpretation must follow the relevant sections of this SOP. For example, if the SIR is revised by the TNI committee, the revision must be reviewed by the LAS EC, or the subcommittee if constituted, prior to re-posting to the NELAP AC voting site.

**Note:** Interpretations issued by TNI through the SIR process are not considered final and may not be implemented until the interpretation is accepted by the NELAP AC. This ensures that the interpretation can be implemented by the ABs without legislative or regulatory conflict, since such conflict(s) would have been grounds for veto of adopting the Standard originally.

#### 5.8 Inclusion of Interpretations from SIRs in Future Standard Versions

The LAS EC shall work with the Consensus Standards Development Executive Committee to ensure that final interpretations are considered during the development of future versions of the Standard.

### 6.0 Implementation of Interpretation

If the interpretation is accepted by the NELAP AC, the interpretation is posted to the TNI website. When posted, the interpretation must be implemented by each NELAP AB, the AB assessors and by NELAP accredited laboratories. The interpretation remains in effect until such time as the Standard is changed or when another interpretation supersedes prior interpretations.

### 7.0 Document Control

Records of the SIR as well as the final resolution must be recorded on the TNI website and meet the requirements of the TNI SOP 1-104, Control of TNI Documents.

### 8.0 References

- 8.1 SOP 1-104, Control of TNI Documents
- 8.2 SOP 3-101, Voting Procedure for General Business and Laboratory Accreditation Matters

### 9.0 SOP Approved Changes

Original SOP:

Approved by the LASEC: December 1, 2009  
Reviewed by the Policy Committee: January 20, 2011  
Endorsed by the Board of Directors: January 20, 2011

Prev. SOP No.	New SOP No.	Date of Change	Description of Change
N/A	5-101 Rev 0	8/7/10	New Document.
5-101	3-105 Rev 1	1/30/11	Update SOP to reflect current practices. Flow and format of the SOP changed.
5-101	3-105, Rev 2	Various, revision adopted by LAS EC 8/27/13	Flow and format of the SOP changed. Separated LAS EC review of SIR from simultaneous review of the SIR by LAS EC and AC, so that LAS EC review now precedes posting of the SIR to the NELAP AC website. Removed procedures for NELAP AC review because procedure of the NELAP AC is separate from TNI procedures.
	3-105, Rev 2	July 22, 2014	Address Policy Committee review comments
	3-105, Rev 3	May 2017	Update "clarifications" to reflect approved guidance

			development request for "implementation guidance," and add specifications about content of implementation guidance
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Appendix A

### SIR Flow Chart

