



SOP TITLE	Standard Interpretation
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REVISION NO.	6.3
PROGRAM	NELAP

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1.0 Purpose and Applicability

- 1.1 This Standard Operating Procedure (SOP) describes the process to use for an interpretation request related to any currently implemented NELAP-adopted Standard and applies only to inquiries involving 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 a specific section of the Standard(s) (see 1.4 below).
- 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 specific sub-section identified in the Standard Interpretation Request (SIR) submission.
- 1.5 This process also presents a procedure for responding to questions that are not valid SIRs but where it may be beneficial to provide operational information about possible ways to comply with the requirements of the specific sub-section in question.

2.0 Summary

Any person requesting an interpretation of any current NELAP-adopted Standard must complete the NELAP "Request for Interpretation (SIR)" Form located on the TNI website (under the Consensus Standards tab, see example in Attachment B below.) 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 Accreditation Council (NELAP AC) Chair and the Laboratory Accreditation Systems Executive Committee (LASEC) Chair. The Chairs of the NELAP AC and the LASEC 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 LASEC 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

SOP 1-105, Process for Creating Guidance
SOP 1-101, Operation of TNI Committees
SOP 1-102, Voting Rules for TNI Committees
SOP 2-100, CSDEC Standards Development Procedure
SOP 3-114, Implementation Guidance Preparation and Approval
Request for Interpretation Form (NELAP), TNI Website

4.0 Definitions

Term	Definition
Implementation Guidance	Response to a submittal that does not meet the criteria for a Standard Interpretation Request but provides supportive advice regarding how a requirement may be fulfilled.

Standard Interpretation

Standard	A document that has been developed and established within the consensus principles of TNI and that meets the approval requirements of TNI procedures. For the purposes of this SOP, only standards currently implemented by NELAP are relevant.
Standard Interpretation	An official explanation of specific questions related to a section or provision in the Standard, where language of the Standard is not clear.
Standard Interpretation Request (SIR)	The formal process for initiating an interpretation or explanation of how a Standard applies to a particular situation, including the review of draft interpretations and adoption of a final approved interpretation.
SIR Subcommittee	A subcommittee of LASEC that reviews Standard Interpretations and makes recommendations to LASEC for its approval and for other aspects of the management of SIRs and Implementation Guidance.
SIR Program Administrator	The TNI staff member(s) 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:

- a. Requester's name;
- b. Requester's organization(s);
- c. Requester's contact address, telephone number, and e-mail address;
- d. Contact information for anyone else who should receive a copy of the response;
- e. Identification of the Standard(s) to which the interpretation is requested; and
- f. 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:

- a. The SIR submission contains only one question;
- b. The question must apply directly and clearly to a cited section of the Standard;
- c. The question is understood without supposition;
- d. 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;
- e. Where possible, the question should be framed in a manner that solicits a "Yes" or "No";
- f. The question has not been posed or phrased to settle a dispute between the laboratory and the AB;
- g. The question is not a "how to" question; and
- h. 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, the SIR process will not provide a resolution. The LASEC 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 contacts the requester to notify him/her of the situation and request that the form be resubmitted or the missing information be provided. Withdrawal and resubmission automatically triggers assignment of a new SIR number.

Note: The initial submission is referred to as “the submission” until and unless the SIR submission is accepted into the SIR process, at which point the term SIR applies.

5.2 Initial Review of the Submission

5.2.1 When the completed form on the website is submitted by a requester, an email notice with the submission is automatically sent to the TNI Program Administrator (PA). The PA forwards the email to the Chairs of the NELAP AC and the LASEC as well as any other PA involved with SIR management.

5.2.2 A tracking spreadsheet of all SIR submissions is maintained by designated TNI staff. A new entry is begun for the submitted SIR. This tracking spreadsheet follows the SIR throughout its active life until it is included into a revised Standard, or other final disposition.

5.2.3 All SIR submissions are tracked (currently in a spreadsheet) that includes, at a minimum the following items:

- a. date submitted
- b. sequential number
- c. submitter and contact information
- d. section of the standard referenced
- e. language of the question submitted
- f. notification date to the submitter plus the action taken
- g. reason for decision if not a valid SIR
- h. Name of committee
- i. date the SIR was referred to a committee for response, if valid SIR
- j. expected response date
- k. date the committee’s response was received
- l. date of LASEC approval
- m. date of posting to the NELAP AC SIR voting website
- n. date of completed vote
- o. date forwarded to website
- p. date of posting to TNI website
- q. final response

5.2.4 The Chairs review the submission against the Standard section cited in the SIR. This review should be completed within five (5) business days. Possible considerations are as follows.

- Does it meet the requirements for a SIR (§5.1.2 above)?

Standard Interpretation

- If it does not meet the requirements for a SIR, is the question suitable to be addressed as Implementation Guidance (IG)?
- Does it get sent back to the requester for additional information?
- a. If an SIR submission asks about a guidance document instead of the standard itself, the section of the standard must be cited as the source of the question.
- b. If the submitted question is unclear or confusing.

5.2.5 Upon completion of the review, the Chairs will email the PA with their individual recommendations.

5.2.5.1 If the two Chairs agree that the SIR is not valid, and they are in the same stakeholder group, then a third party makes the final decision; the third party must be from within LASEC but may not represent an AB (preferably the Vice Chair of LASEC).

5.2.5.2 If the two Chairs cannot come to consensus, then a third party makes the final decision; the third party must be a member of the LASEC.

5.2.6 The outcome of this process will be one of three actions:

5.2.6.1 The submission is deemed valid and forwarded to the appropriate expert committee as an SIR (the submission is now formally identified as an SIR),

5.2.6.2 The submission is determined to be invalid.

5.2.6.3 The submission is determined to be a request for clarification and candidate for an IG.

5.3 Submitter Notification

The submitter is notified of any action on the submission or SIR within five (5) business days after the decision has been finalized.

5.3.1 When the submission is accepted as a SIR, the submitter is also told that the final outcome will be posted on the TNI Website and notification of the final status can be obtained by subscribing to the mailing list for "Standard Interpretations Update Notification List" on the TNI Website under Consensus Standards Development. Included with this notification is the following information:

- a. The SIR log-in number;
- b. The TNI Committee to which the interpretation is assigned; and
- c. An estimated time frame for completion of the process, which includes review and approval by the NELAP AC.

5.3.2 When a submission does not meet the criteria listed in 5.2.1 above, the submitter is notified that the request is rejected.

5.3.3 If the submission is unclear or lacks critical information, the submitter is asked to clarify and resubmit.

5.3.4 If the submission concerns a guidance document, the submitter is asked to resubmit as a question about a particular (cited) section of the standard itself and reference the guidance document so that the committee responding to the SIR can adapt the guidance if needed.

5.3.5 If the submission requests a procedure, the request may be considered as a candidate for an IG, and the submitter will be so notified.

- 5.3.6 If the submission does not meet the minimum criteria to be advanced as a SIR or as an IG, the PA sends a letter of rejection to the submitter.
- 5.3.7 If the requester disagrees with the decision not to advance the submission, he/she may appeal within fifteen (15) calendar days by notifying the PA and providing additional rationale. The appeal is then presented to the entire LASEC at its next meeting and the decision of the full LASEC shall be final.
- 5.4 Preparation for the SIR Interpretation
 - 5.4.1 The LASEC Chair or designee coordinates the initial review of the SIR or clarification request with the Chair and PA of the appropriate committee. The LASEC 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 Edits, such as removal of personal information, references to individuals or organizations, or inappropriate language will be done prior to sending the SIR to the committee for response.
- 5.5 Assignment of SIR to TNI Committee(s)
 - 5.5.1 The PA forwards the SIR to the Chair of the TNI Committee with a request for the committee to provide an interpretation to the LASEC within 60 calendar days. If the Committee Chair thinks more than 60 calendar days will be needed, the Chair shall advise the PA and propose a new date for completion.
 - 5.5.2 If upon review of the SIR, the assigned committee disagrees with the decision that the submission is a valid SIR, the Expert Committee returns a response stating that the language of the standard is clear, with a justification for that disagreement about the validity of the SIR.
 - 5.5.3 The SIR Subcommittee considers the Expert Committee's disagreement at its next meeting and provides a recommendation to LASEC for its consideration.
 - If LASEC agrees with the Expert Committee's justification, the submitter is notified of the change in the decision about the validity of the SIR submission.
 - If LASEC does not agree with the Expert Committee's justification and it is returned to the SIR to the Expert Committee for a response.
- 5.6 Development of the Response to the SIR
 - 5.6.1 Each committee is expected to complete the response to the SIR within 60 calendar days of receipt of the SIR by the Committee Chair, with its deliberation and approval of the interpretation is captured and documented in committee minutes.
 - 5.6.2 The committee is requested to take the following into consideration during this process, as these items are part of the Subcommittee and LASEC reviews of proposed responses to SIRs:
 - a. The interpretation provided must only answer the question posed in the SIR.
 - b. The interpretation must be consistent with the Standard.

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- c. 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.
 - d. The author must write the interpretation in complete sentences with proper grammar and punctuation.
- 5.6.3 Upon completion of the interpretation, the assigned TNI Committee forwards the response to its PA for review to ensure proper grammar and clarity of the interpretation.
- 5.6.4 Once complete, the PA forwards the interpretation response to the LASEC PA.
- 5.7 LASEC Review of the SIR Interpretation
 - 5.7.1 Once the Expert Committee submits its response, the LASEC Chair or PA schedules and coordinates preliminary review of the interpretation with the LASEC SIR Subcommittee at its next monthly meeting.
 - 5.7.2 The SIR Subcommittee reviews the interpretation and develops a recommendation for the full LASEC action on the interpretation. The options are:
 - a. Accept the interpretation as written and forward to the NELAP AC for its agreement that the SIR is enforceable and implementable,
 - b. Reject the interpretation and return it to the authoring committee with explanation of why the interpretation requires modification, or
 - c. Return the interpretation to the authoring committee requesting specific modifications with an explanation of the reason for the request(s).
 - 5.7.3 A super-majority approval of the Subcommittee is necessary to accept the SIR response and recommend acceptance to the full LASEC.
 - 5.7.4 If the Subcommittee is unable to reach a decision, the SIR may be referred to the full LASEC without recommendation.
 - 5.7.5 LASEC reviews the SIR subcommittee's recommendation and votes to approve or reject the recommendation via a super majority vote.
 - 5.7.5.1 When the recommendation is to accept the SIR (see 5.7.2 above) then it will be provided to the NELAP AC for consideration (see 5.8 below). The PA will forward a copy of the interpretation to the Webmaster for posting to the NELAP AC SIR voting site.
 - 5.7.5.2 If the interpretation is deemed unacceptable, then discussion within LASEC must continue until the reason for non-approval is clearly understood. Failure to approve the response is met with automatic return to the SIR Subcommittee, which then resumes negotiation with the expert committee to attain a satisfactory response.
 - 5.7.6 When the SIR is not accepted (either by LASEC or LASEC Subcommittee vote), the SIR is returned to the authoring committee with comments and/or justification for the rejection.

5.8 NELAP AC Review of the LASEC-approved SIR Interpretation

- 5.8.1 NELAP AC review of the interpretation is initiated when the interpretation is posted to the NELAP AC voting website.
- 5.8.2 The LASEC PA notifies either the NELAP PA (if these are not the same individual) or directly notifies the representative for each NELAP AB of this action.
- 5.8.3 Each NELAP AC Accreditation Body (AB) representative reviews the SIR and the response issued by the TNI committee and casts their votes via the SIR voting website. AB representatives are asked to vote (and comment) within forty-five (45) calendar days of the posting. This timeframe includes two weeks notice for final opportunity to object.
- 5.8.4 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 the TNI Voting SOP 1-102.
- 5.8.5 If the interpretation is deemed problematic by the NELAP AC (as noted in the comments section of the voting site), the Chair of the NELAP AC or designee notifies the PA and the Chair of the LASEC and provides 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.
- 5.8.6 The PA and the LASEC Chair then decide on a proper course of action. For example, if the interpretation is rejected for grammatical concerns, the SIR is returned to the TNI authoring 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 and approved by the SIR Subcommittee and the LASEC 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. Expert Committees are urged to explain that their preparation of a SIR response does not constitute the final interpretation, especially when SIRs are discussed in public meetings.

5.9 Implementation of the Interpretation

- 5.9.1 Once the interpretation is accepted by the NELAP AC, the interpretation is sent for posting to the TNI website within five (5) business days of the completion of the NELAP AC's vote.
- 5.9.2 When posted, the interpretation must be implemented by each NELAP AB and Non-governmental AB, the ABs' 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.

6.0 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.

7.0 References

SOP 1-102, Voting Rules for TNI Committees
SOP 1-104, Control of TNI Documents

8.0 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

Revision No.	Date	Description of Change
1.0	1/30/2011	Update to reflect current practices. Flow and format changed.
2.0	8/27/2013	Flow and format changed. Separated LASEC review of SIR from simultaneous review of the SIR by LASEC and AC, so that LASEC 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.
2.1	7/22/2014	Address Policy Committee review comments
3.0	6/27/2017	Update "clarifications" to reflect approved guidance development request for "implementation guidance," and add specifications about content of implementation guidance
4.0	4/13/2019	Improve clarity of implementation guidance contents and add requirement to provide relevant SIRs to expert committees during revision of modules
5.0	4/30/2020	Add timelines for response to submission and sending completed SIR for posting to website; extend expert committee response deadline to 60 days; mention requirement for SIR Subcommittee to be balanced.
5.1	10/22/2020	Add additional timeframes after discussion of updated tracking spreadsheet and revise 5.6.1 to clarify that the SIR Subcommittee is a standing subcommittee authorized in the LASEC Charter to be autonomous
5.2	3/18/2021	Address determination by expert committee that submission is not a SIR and change to require a 2/3 approval vote for SIR response from expert committee (include reference to TNI Voting SOP 1-102). Add definition for SIR and mock-up of webpage for SIR submission.
6.0	9/22/2022	Revision to reflect removal of SIR management authority from the SIR Subcommittee and place it with LASEC. Also add third party / different stakeholder review for non-valid SIRs when LASEC Chair is an AB stakeholder and update appeal process for when expert committee disagrees with SIR validity decision.
6.1	4/27/2023	Additional edits to clarify process in Section 5 and other minor edits.
6.2	9/1/2023	Removed Flow Chart from Appendix A.
6.3	10/13/2023	Revised 5.2.2 and 5.2.3 to reflect current tracking process.

Appendix A– Example SIR Submission Form

(NOT FOR ACTUAL SUBMISSION -- actual submissions must be made via the electronic form on the website)

Standards Interpretation

TNI has established an avenue for resolution of questions submitted electronically on interpretation of the 2003 NELAC Standard and the 2009 and 2016 TNI Standards. The method for submittal is to complete the form below. Use of this entry form ensures that a question is automatically accepted, cataloged and emailed to the NELAP Accreditation Council Chair, the LAS Executive Committee Chair and the TNI Program Administrator for review. A consensus of these three individuals shall determine who oversees the final disposition of the question. Timelines are defined for the NELAP Accreditation Council Chair and LAS Executive Committee Chair to ensure a timely response to the question. Publication of the consensus resolution is then made to the affected parties via email and on the TNI web site.

*Please remember that any disputes between a laboratory and their AB regarding accreditation are to be handled through the appropriate appeals process established by applicable state laws and regulations. Any SIR **submission that originates** with such a dispute may be rejected.*

Your question should be clearly stated and should meet the following criteria:

1. contains only one question;
2. applies directly and clearly to a cited section of the Standard;
3. can be understood without supposition;
4. is compelling, that the language used in the Standard(s) section cited is not clear or might have more than one interpretation;
5. is not a “how to” question or a request for a method interpretation.

Where possible, the question should be framed in a manner that solicits a “Yes” or “No” response. 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.

Please use this form to submit a request for standard interpretation to TNI.

Request for Standards Interpretation

Name*

First

Last

Email*

Phone

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###

####

Organization*

--

Address

--

Street Address

--

Address Line 2

--

--

City

State/Province/Region

--

(drop-down menu)

Postal/Zip

Country

Are there others who should receive the TNI response as well?

Name

--

--

First

Last

Email

--

Name

--

--

First

Last

Email

--

Standard*

☐ 2003 NELAC Standard

☐ 2009 TNI Standard

☐ 2016 TNI Standard

Please enter the volume, module, and section reference of the standard, as applicable and then fully explain the problem in the text field below.

Volume and Module (eg. V1M2)*

Section (eg. C.4.1.7.4)*

Describe the problem:*

(Expandable text box)

Upload a file

Browse

Continue

(continuation page provides info submitted for verification, then an option to return to "Previous" or to "Submit")