



SOP TITLE:	Standard Interpretation SOP
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PROGRAM	NELAP

SOP Approval Dates

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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 currently implemented 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 actual requests for interpretation (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 (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

- 3.1 TNI SOP 1-105, Process for Creating Guidance
- 3.2 TNI SOP 3-101, NELAP Voting Procedure for General Business and Laboratory Accreditation Matters
- 3.3 Request for Interpretation Form (NELAP), TNI Website
- 3.4 TNI SOP 2-100, CSDEC Standards Development Procedure

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 developed and established within the consensus principles of TNI and that meets the approval requirements of TNI procedures.

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- 4.3 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.
- 4.4 TNI Program Administrator (PA): The TNI staff member assigned to work with the standards interpretation process.
- 4.5 SIR Subcommittee: A subcommittee of LASEC authorized by its Charter with delegated authority to oversee the management of SIRs and implementation guidance.

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 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 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.
- 5.1.6 All SIR submissions are tracked (currently in a spreadsheet) that includes the following items:
 - a) date submitted

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- 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) date the SIR was referred to a committee for response, if valid SIR
- i) expected response date (with a flag when response time is exceeded)
- j) date the committee's response was received
- k) date of SIR Subcommittee review
- l) date of posting to the NELAP AC SIR voting website
- m) date of completed vote
- n) date of posting to TNI website
- o) date of final notification to submitter that response is available
- p) information about eventual inclusion in revised standard/module, if done

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 LASEC as well as any other PA involved with SIR management.
- 5.2.2 A tracking spreadsheet of all SIR submissions is maintained by a PA, and at this point, a new entry is begun for the submitted SIR. See Attachment B for elements of the tracking spreadsheet, which will follow the SIR throughout its active life until included into a revised standard, or other final disposition.
- 5.2.3 The Chairs will review the submission against the Standard section cited in the SIR. This review should be completed within five business days. 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?
 - If a 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
 - if the submitted question is unclear or confusing
 - Is the submission rejected due to failure to meet the criteria?
- 5.2.4 Upon completion of the review, the Chairs will email the PA with their individual recommendations. If the Chairs disagree, they will reconsider and reach agreement before the PA proceeds. 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.

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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. See LASEC Implementation Guidance Preparation SOP 3-114.

- 5.3.2 If the submission is incomplete or unclear, the PA will send a letter requesting more specific information. If the submission concerns a guidance document, the submitter will be 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.
- 5.3.3 If the submission does not meet the minimum criteria to be advanced as a SIR or as implementation guidance, the PA will send a letter of rejection. A short list of these invalid or rejected SIRs will be distributed by the Program Administrator to the relevant committee quarterly, based on the cited section of the standard in the submission. Additionally, the complete list will be shared with the Small Laboratory Advocate at the same time.
- 5.3.4 Regardless of the response, it should be communicated to the requester within five business days after the decision is finalized.
- 5.3.5 If the requester disagrees with the decision not to advance the submission, he/she may appeal within fifteen calendar days by so notifying the PA and providing additional rationale. The appeal will be presented to the entire LASEC at its next meeting and the decision of the full LASEC shall be final.

5.4 Preparation of the SIR Interpretation

- 5.4.1 The LASEC Chair or designee coordinates the initial review of the SIR or clarification request with the appropriate committee members. At this point, 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 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 LASEC Chair or designee may forward the request to an appropriately appointed cross-functional team who will answer the question or ask the LASEC SIR Subcommittee to draft the guidance. SOP 3-114 addresses the development of Implementation Guidance documents.

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 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.

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.

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- 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 60 calendar 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.
- 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 LASEC.

5.6 LASEC Final Review of the SIR Interpretation

- 5.6.1 The LASEC Chair will schedule and coordinate review of the interpretation with the LASEC SIR Subcommittee within 30 calendar days of when the PA receives the interpretation from the assigned TNI Committee.
- 5.6.2 The Subcommittee is a standing subcommittee authorized in the LASEC Charter. It is composed of members from the LASEC selected by the LASEC Chair and functions autonomously within LASEC for SIR matters, but may choose to involve the full LASEC on any particular matter. The Subcommittee members must be selected so that each stakeholder interest is represented and the subcommittee is balanced. Representation in the subcommittee should include both a non-NELAP AB and a NELAP AB, if possible. The subcommittee is maintained as a core group with occasional ad hoc additions depending on the nature of the SIR and the expertise needed. These ad hoc participants need not be members of the LASEC.
- 5.6.3 The SIR Subcommittee will review the interpretation as provided by the TNI Committee assigned the SIR to ensure that the guidelines contained within this SOP were followed.
- 5.6.4 If the SIR Subcommittee raises a concern with the interpretation, the LASEC 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.
- 5.6.5 When SIR Subcommittee review of the interpretation is complete and the interpretation is approved 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 LASEC 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. AB representatives will be asked to vote within 45 calendar days of the posting. This timeframe includes the required two week notice for final opportunity to object.

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- 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 (as noted in the comments section of the voting site), the Chair of the NELAP AC or designee will notify the PA and the Chair of the LASEC 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 LASEC 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 LASEC, 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.

- 5.7 Once the interpretation is accepted by the NELAP AC in accordance with its Voting SOP 3-101, the interpretation is sent for posting to the TNI website within 5 business days of the completion of the NELAP AC's vote. 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.
- 5.8 The submitter shall be notified that the interpretation is available once it is accepted by the NELAP AC and sent for posting on the website.

6.0 Implementation of Interpretation

The LASEC 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.

- 6.1 When an expert committee announces its intent to revise its module of the Standard, the LASEC Chair or PA shall provide that committee with a listing of all final and approved SIRs that are relevant to the module being revised.
- 6.2 The relevant expert committee will be notified of any additional SIRs that are finalized before the announcement of the Voting Draft Standard for voting and comments.
- 6.3 When the draft module is provided for review and/or voting, the expert committee will advise LASEC of whether and how each final relevant SIR was addressed in the module, or if not addressed, why not.
- 6.4 LASEC will maintain records of whether SIRs were addressed for future Standards or if

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the existing SIR is still necessary (and posted to the TNI website) to make the interpretation known.

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
- 8.3 SOP 3-114, Implementation Guidance Preparation and Approval
- 8.4 CSDEC Standards Development SOP 2-100

9.0 SOP Approved Changes

Original SOP:

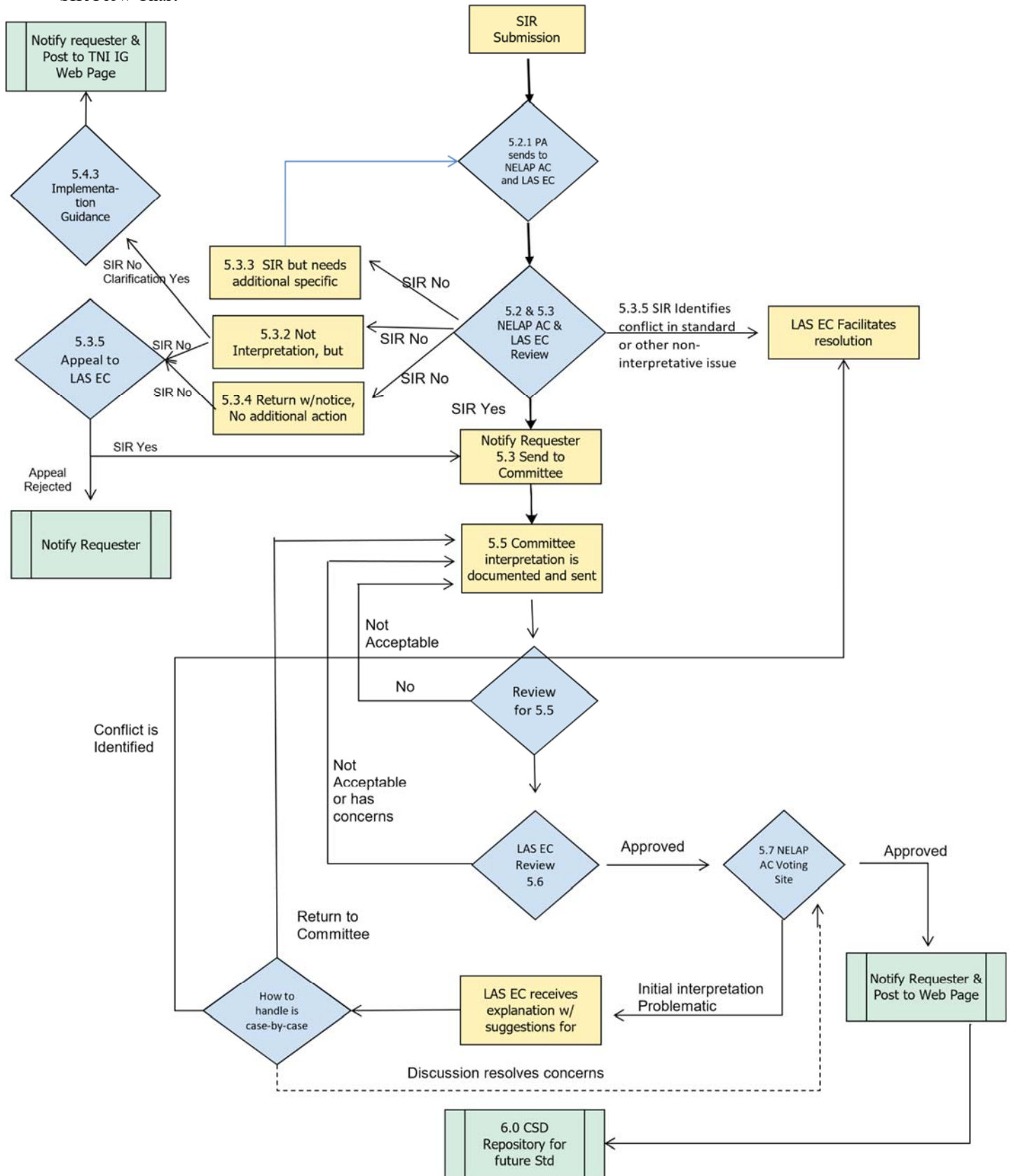
- Approved by the LASEC: December 1, 2009
- Reviewed by the Policy Committee: January 20, 2011
- Endorsed by the Board of Directors: January 20, 2011

Revision No.	Date of Change	Description of Change
0	8/7/10	New Document.
1	1/30/11	Update SOP to reflect current practices. Flow and format of the SOP changed.
2	8/27/13	Flow and format of the SOP 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	7/22/14	Address Policy Committee review comments
3	May 2017	Update "clarifications" to reflect approved guidance development request for "implementation guidance," and add specifications about content of implementation guidance
4	March-April 2019	Improve clarity of implementation guidance contents and add requirement to provide relevant SIRs to expert committees during revision of modules
5	March-May 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	10/22/20	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

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Appendix A

SIR Flow Chart



Attachment B

Data Elements of the SIR Tracking Spreadsheet

- 1) date submitted
- 2) sequential number
- 3) submitter and contact information
- 4) section of the standard referenced
- 5) language of the question submitted
- 6) notification date to the submitter plus the action taken
- 7) reason for decision if not a valid SIR
- 8) date the SIR was referred to a committee for response, if valid SIR
- 9) expected response date (with a flag when response time is exceeded)
- 10) date the committee's response was received
- 11) date reviewed by SIR Subcommittee
- 12) date of posting to the NELAP AC SIR voting website
- 13) date of completed vote
- 14) date of posting to TNI website
- 15) date of final notification to submitter that response is available
- 16) information about eventual inclusion in revised standard/module, if done