



SOP TITLE	Implementation Guidance Preparation and Approval
SOP NO.	3-114
REVISION NO.	0 (Provisional)

SOP Approval Dates

	Initial Approval	Last Revision Date	Last Review Date
Committee: LASEC	5/15/20		
Program: NELAP	NA		
Policy Committee Review			
TNI Board of Directors Endorsement			
SOP Effective Date	5/15/20		

Index

1.0	Purpose and Applicability.....	3
2.0	Summary.....	3
3.0	Related Documents.....	3
4.0	Definitions.....	3
5.0	Procedure.....	4
6.0	Document Control.....	5
7.0	References.....	5
8.0	SOP Approved Changes.....	5
9.0	Appendix A Implementation Guidance Template.....	6

1.0 Purpose and Applicability

- 1.1 This Standard Operating Procedure (SOP) describes the process to follow for creating Implementation Guidance documents (IGs).
- 1.2 IGs are documents that address questions related to various laboratory practices and problems by clarifying the intent of the Standard or by describing best practices known to the creators. In some but not all IGs, specific sections of the Standard will be addressed.
- 1.3 IG documents are brief, addressing one particular relatively small topic, and are entirely separate from Guidance documents that are typically prepared for broader issues related to understanding the actions required by the standard or a large section thereof. The full Guidance documents require formal approval from TNI's Policy Committee, as described in SOP 1-105 Process for Creating Guidance. The Laboratory Accreditation Systems Executive Committee (LASEC) has approval under this process for complete control over the creation, review and approval of IG documents.

2.0 Summary

An IG document may originate within LASEC as a way of addressing a Standard Interpretation Request (SIR) that does not meet the requirements of a valid SIR as described in LASEC's SIR Management SOP 3-105. Also, any TNI member or committee may originate creation of an IG by proposing a topic to LASEC, and LASEC will review the concept and assign an IG number to the proposal, if approved. Once completed, the IG document is then submitted to LASEC for final approval and publication on the TNI website.

3.0 Related Documents

- 3.1 TNI SOP 1-105 Process for Creating Guidance

4.0 Definitions

- 4.1 Implementation Guidance (IG): 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 Guidance: Non-mandatory information, rendered in any medium intended for communication, which explains, illustrates, or summarizes a subject without imposing requirements, establishing policy, or becoming a standard operating procedure.
- 4.3 Standard: A document that has been developed and established within the consensus principles of TNI and that meets the approval requirements of TNI procedures.
- 4.4 Standard Interpretation: An official explanation of specific questions related to a section or provision in the Standard, where the language of the Standard is not clear.
- 4.5 TNI Program Administrator (PA): The TNI staff member assigned to work with the standards interpretation process.
- 4.6 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 Originating an IG Document

IG documents may originate from a question initially submitted as a SIR, from an individual TNI member or from a TNI committee. If not originating out of the determination of validity of a SIR, the concept for an IG must be approved by LASEC or its SIR subcommittee prior to development, and an IG number assigned.

5.1.1 The following information must be provided to LASEC with the request. In the case of a non-valid SIR, the information will already be available in the SIR submission.

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 Identification of which Standard(s) the question is related to; and

5.1.1.5 The reference to the section of the Standard(s) in question, *i.e.*, Volume, Module, Section, or Chapter and Section Number.

5.1.2 For an IG request from an individual or committee, the request should briefly describe the concept to be elaborated in the IG document.

5.1.3 The LASEC Chair or Program Administrator (PA) will either approve or modify the request after discussions within LASEC or the SIR Subcommittee, and notify the requester (if appropriate) within five (5) business days after the meeting in which the request was considered.

5.1.4 If the body text of the response or answer in the proposed IG document is expected to be more than one or at the most, two pages, it should be considered as a Guidance document (GUI) and proposed to Policy Committee for approval in accordance with the TNI Guidance SOP 1-105, rather than as an IG with LASEC.

5.2 Preparation of Implementation Guidance

5.2.1 When the IG originates with a SIR, the LAS EC 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. The goal of implementation guidance is to describe the best or most accepted practice(s) in the industry to meet the requirement being addressed.

5.2.2 The individual or group developing the IG document will prepare the draft as agreed upon after the initial request.

5.2.3 IG responses will be categorized by subject matter or topic within the standard. They will include the question, as posed by the submitter, as well as an answer addressing the question. The answer may contain some background information and will be further supported by references to the appropriate sections of all standards in use (if more than one is applicable).

5.2.4 IG documents shall be referred to the Chair or designee of the appropriate expert committee for review, to ensure that the Implementation Guidance document does not conflict with the standard.

5.2.5 Each IG 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.

5.2.6 When LASEC review of the IG is complete and the document approved, the PA will forward it to the Webmaster for posting to the TNI website.

5.2.7 IG documents on the website are available only to TNI members.

6.0 Document Control

The final IG document will be published on the TNI website and meet the requirements of the TNI SOP 1-104, Control of TNI Documents.

7.0 References

SOP 1-104: Control of TNI Documents
SOP 3-105: SIR Management

8.0 SOP Approved Changes

Revision No.	Effective Date	Description of Change
0	5/15/20	

Appendix A Template for Implementation Guidance

TNI Implementation Guidance

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.

Module [Number] – [Title of Module]

Subject: [as appropriate]

Question 1 (response beneath, not bold)	[Question typed out in bold] [Response, plain text. May be multiple paragraphs but ideally less than one page] [Second response]
Question 2 (related to Q1)	

References:

[specify which standard(s)]	[Specify section number(s) of standard. If not ISO language, you may quote the language]
------------------------------------	--