THE NELAC INSTITUTE

SOP TITLE	**Preparation and Approval of Implementation Guidance for the Laboratory Standards**		
SOP NO.	3-114		
REVISION NO.	1.2		

SOP Approval Dates

	Initial Approval	Last Revision	Last Review
Committee: LASEC	5/15/2020	4/27/2023	
Program: NELAP	NA	NA	
Policy Committee Review		9/1/2023	
TNI Board of Directors Endorsement		NA (9/13/2023)	
SOP Effective Date	5/15/2020	9/1/2023	

1.0   Purpose and Applicability

1.1   This Standard Operating Procedure (SOP) describes the process for creating Implementation Guidance (IG).

1.2   IGs concisely address questions related to various laboratory activities by describing strategies for meeting the requirements of the Standard.

1.3   IGs address a single, relatively small topic (typically one individual subsection of the Standard) 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 (*e.g.,* one major topic consisting of multiple subsections). 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) manages the process to create, review and approve IGs.

1.4   An IG is not intended to encompass all possible ways to implement a requirement, but rather to provide a strategy or strategies to address the requirement of the subsection. It is intended to be helpful but not an exhaustive compilation of possibilities.

2.0   Summary

The goal of an IG is to describe strategies for use in the industry to meet a specific standard requirement.

An IG 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.

Any TNI member or committee may originate the creation of an IG by proposing a topic to the LASEC for review and approval of the concept. If approved after review by the LASEC SIR Subcommittee, the Program Administrator will assign an IG number to the proposal, assign an appropriate group to draft the IG, and if the author is not an Expert Committee, notify the appropriate Expert Committee. A completed IG is submitted to the appropriate Expert Committee for review and then delivered to the SIR Subcommittee for preliminary review before being proposed to the LASEC for final approval and publication on the TNI website.

3.0   Related Documents

Policy 1-105 Creation and Use of Guidance

4.1   Definitions

Term	Definition
Disclaimer	A specific statement included in all guidance alerting users about its purpose and application
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
Implementation Guidance	Response to a submittal that does not meet the criteria for a Standard Interpretation Request, but seeks clarification of how to comply with the standard
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

5.0 **Procedure**

5.1 Originating an IG

IGs may originate from a question that was initially submitted as a SIR, from an individual TNI member or from a TNI committee. The concept for an IG must be approved by LASEC prior to development.

5.1.1 The following information is provided to LASEC with any IG request.

5.1.1.1 Requester or committee name;
5.1.1.2 Requester's organization(s) (if not a committee);
5.1.1.3 Requester's contact information;
5.1.1.4 Identification of which Standard(s) the question is related to;
5.1.1.5 Reference to the section of the Standard(s) in question, *i.e.*, Volume, Module, Section, or Chapter and Section Number and
5.1.1.6 Rationale for suggested IG.

5.1.2 After discussions within LASEC, based on the recommendation of the SIR Subcommittee or the Chairs responsible for determining validity of SIRs (as warranted), a simple majority vote is sufficient to approve creation of an IG. The LASEC Chair or Program Administrator (PA) will then notify the requester within five (5) business days after the meeting in which the request was considered.

5.1.3 If the request to create an IG originates outside of an Expert Committee (not from a SIR submission), the relevant Expert Committee is notified that creation of the IG is approved.

5.1.4 If the proposed IG encompasses more than a single requirement of the Standard then it should be developed and approved as a Guidance Document rather than an IG with LASEC.

5.1.5 Upon approval for creation, the Program Administrator for LASEC assigns the IG an identifying tracking number according to the applicable module in Volume 1 and a sequential number, in a manner similar to how SOPs and Policies are numbered. For example, IG 4-006 would be the sixth IG related to items in V1M4, the Chemistry module. The name or title of the IG will indicate its topic and should be as succinct as possible.

5.2 Preparation of Implementation Guidance

5.2.1 When an IG is proposed or when a request for interpretation is not accepted as a SIR, the LASEC Chair or designee may request creation of an IG and appoint a cross-functional team who will answer the question or ask the SIR Subcommittee to draft the IG.

5.2.2 The individual, group or SIR Subcommittee prepares a draft using the template in Appendix A.

5.2.3 IGs include the question, as posed by the submitter or originator, as well as an answer addressing the question. The answer may contain some background information and be further supported by references to all of the relevant and appropriate subsections of all standards in use (if more than one is applicable).

5.2.4 IGs shall be referred to the Chair and PA of the appropriate Expert Committee for review, to ensure that the IG does not conflict with the Standard. The review may be completed by one or more committee members.

5.2.5   After the Expert Committee review is complete, the SIR Subcommittee will perform a final review of the IG, and if deemed satisfactory, the Subcommittee recommends to the LASEC that the IG be approved by a simple majority vote for posting to the TNI website.

5.2.6   Each IG shall include the following disclaimer:

Disclaimer: This material represents the opinion of its authors and may not be the only way of meeting the referenced Standard requirement. 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.

5.2.7   When LASEC review of the IG is complete and the final product approved, the PA forwards it for posting to the TNI website.

5.2.8   IGs on the website are available only to TNI members.

6.0   Document Control

The final IG is published on the TNI website and meets the requirements of the TNI SOP 1-104, Control of TNI Documents. The assigned IG numbers are used for tracking of IGs by LASEC and its SIR Subcommittee and the TNI webmaster.

When a new Standard is adopted, LASEC will work with the various Expert Committees to add appropriate references to the IGs and add those citations to the IG listings on the website, or else determine that the individual IGs are not relevant to the new Standard. It is considered highly unlikely that a best practice will ever become obsolete, but IGs can be retired in the same fashion as SIRs if they are no longer relevant to a new Standard, once that new Standard is no longer in use.

IGs are considered Class II documents according to SOP 1-104.

7.0   References

SOP 1-104, Control of TNI Documents
SOP 1-105, Process for Creating Guidance
SOP 3-105, SIR Management

8.0   SOP Approved Changes

Revision	Date	Description of Change
0	5/15/20	
0.1	3/18/21	Address Policy Committee comments
0.2	5/26/22	Address further Policy Committee comments
1.0	9/22/22	Revised in accordance with removal of delegated authority for SIR Subcommittee to oversee IG development and finalization
1.1	4/27/23	Revisions proposed by Policy Committee.

| 1.2 | 9/1/23 | Added definition for disclaimer for consistency with Policy 1-105 |

Appendix A
Template for Implementation Guidance

TNI Implementation Guidance

Disclaimer: This material represents the opinion of its authors and may not be the only way of meeting the referenced Standard requirement. 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 2** **(**related to Q1**)**	**[Question typed out in bold]** [Response, plain text. May be multiple paragraphs but ideally less than one page] [Second response]

References:	
[specify which standard(s)]	[Specify section number(s) of standard. ISO language may be used as long as it is cited appropriately.]