



<b>SOP TITLE</b>	<b>Process for Creating Guidance</b>
<b>SOP NO.</b>	<b>1-105</b>
<b>REVISION NO</b>	<b>0.3</b>
<b>PROGRAM</b>	<b>Administration</b>

**SOP Approval Dates**

	<b>Initial Approval</b>	<b>Last Revision</b>	<b>Last Review</b>
<b>Committee: Policy</b>	4/6/2010	4/5/2024	
<b>Program</b>	NA	NA	
<b>Policy Committee Review</b>	NA	NA	
<b>TNI Board of Directors Endorsement</b>	9/8/2010	5/8/2024	
<b>Effective Date</b>	9/9/2010	4/5/2024	

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## 1.0 Purpose and Applicability

This Standard Operating Procedure (SOP) describes the process for creating guidance, from developing a proposal to final approval. This SOP applies to all TNI committees, subcommittees, work groups, and task groups that propose and develop guidance.

Some informational material produced by TNI is dynamic or follows alternative approval processes. Those materials are not covered by this SOP and may be considered Implementation Guidance. Specifically, this SOP does not apply to answers given by programs to frequently asked questions (FAQs), responses to requests for TNI Standards interpretations, and presentations delivered by TNI members, when those presentations are reasonably understood not to constitute guidance.

## 2.0 Summary

This SOP describes the process for developing a proposal for guidance, the proposal's review, and its disposition. The SOP identifies the parties that can originate and approve guidance and specifies a mandatory disclaimer to be included with all guidance.

## 3.0 Related Documents

POL 1-105, Creation and Use of Guidance  
SOP 1-104, Control of TNI Documents  
SOP 3-114, Preparation and Approval of Implementation Guidance for the Laboratory Standards

## 4.0 Definitions

Term	Definition
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.
Disclaimer	A specific statement included in all guidance alerting users about its purpose and application.

## 5.0 Enforceability of Guidance

- 5.1 The purpose of guidance is to better understand a topic in the Standard. Guidance helps, but does not dictate; suggests, but does not demand; explains, but does not proselytize. Guidance shall not impose or circumvent any requirements.
- 5.2 Accreditation bodies or agencies in charge of imposing requirements on those they accredit or accept are discouraged from using TNI guidance to justify or impose actions beyond those required by a TNI standard.
- 5.3 Accreditation bodies or agencies in charge of imposing requirements on those they accredit or accept are encouraged to use TNI guidance to offer suggestions or facilitate compliance with TNI standards.
- 5.4 TNI guidance must include this disclaimer in its entirety prominently:

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

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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.

Individuals that have questions about the applicability, scope, and use of this guidance may contact TNI at [www.nelac-institute.org](http://www.nelac-institute.org).

## **6.0 Format and Style**

- 6.1 Guidance may assume any format and style that facilitates its intended purpose.
- 6.2 Guidance must follow the document control procedures established in SOP 1-104, Control of TNI Documents.

## **7.0 Establishing Need for Guidance**

- 7.1 TNI committees review and establish the need for guidance.
- 7.2 Any person may suggest creating guidance to a committee, but only TNI committees can develop a proposal for creating guidance.

## **8.0 Proposal for Creating Guidance**

- 8.1 Committees desiring to create guidance must develop a proposal for review by the Policy Committee.
- 8.2 The proposal for creating guidance must describe:
  - 8.2.1 Indicate if this is a new or revised guidance.
  - 8.2.2 The title and purpose for the guidance, including justification.
  - 8.2.3 A summary of the content of the guidance, including reference to the applicable standard.
  - 8.2.4 The identity of the committee or program completing the proposal.
  - 8.2.5 The identity of any parties, other than the originators, that will review the guidance.

## **9.0 Disposition of Proposal for Creating Guidance**

- 9.1 The Policy Committee must review all proposals for creating guidance.
- 9.2 If the Policy Committee agrees that the proposal justifies the creation of guidance, the Policy Committee must inform the proposal's originator that it can proceed with the creation of guidance.
  - 9.2.1 The Policy Committee must identify in its response any other conditions that the originators must address before the guidance is approved in final form by the guidance creators.
  - 9.2.2 When the Policy Committee determines that the proposed guidance interprets or helps to implement or comply with a TNI Standard requirement or has the potential for being used for the same purpose, the Committee must review the final product to determine it meets the definition and purpose of guidance.
- 9.3 If the Policy Committee determines that the proposal does not justify the creation of guidance, the Policy Committee informs the originator that it must not create the guidance and issue a recommendation that the originator:

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- 9.3.1 Develop a policy to address the proposal’s subject.
- 9.3.2 Develop an SOP to address the proposal’s subject.
- 9.3.3 Follow the process for creating or modifying a requirement in a standard.
- 9.3.4 Modify the proposal to address any concerns from the Policy Committee.

**10.0 Review and Approval of Guidance**

- 10.1 The committee developing the proposal for guidance must approve the final version of the guidance following the committee’s established decision-making rules.
- 10.2 When the Policy Committee determines that the proposed guidance interprets or helps to implement or comply with a TNI Standard requirement or has the potential for being used for the same purpose, the Policy Committee must review the final product to verify it meets the definition and purpose of guidance.
- 10.3 Once final, Policy Committee requests the Guidance be posted on the TNI website.
- 10.4 Any update or revision to the Guidance, other than editorial changes, requires resubmission and approval by the Policy Committee.

**11.0 SOP Approval Changes**

Revision No	Effective Date	Description of Change
0	9/9/2010	New Document
0.1	9/9/2010	Editorial to reflect 2010 organizational change
0.2	2/19/2016	Add section 11.2 to require approval of updates or revisions to existing guidance
0.3	4/5/2024	Added a mention of Implementation Guidance in Section and added SOP 3-114 to Related Documents. Revised the first sentence in 5.1 for clarity with no change in intent. Shortened the list of items required for a proposal in 8.2 and deleted the form in Appendix A. Added section 9.3.4 related to a modified proposal. Updated section 10 to clarify the review and approval process. Deleted section 11 on dissemination as this is now covered in Section 10. Changed “shall” to “must” throughout out the document.