



SOP TITLE	Process for Creating Guidance
SOP NO.	1-105
REVISION NO	0.2
PROGRAM	Administration

SOP Approval Dates

	Initial Approval	Last Revision Date	Last Review Date
Committee: Policy	4/6/2010	2/19/2016	
Program	NA	NA	
Policy Committee Review	NA	NA	
TNI Board of Directors Endorsement	9/8/2010	NA	
Effective Date	9/9/2010	2/19/2016	

Process for Creating Guidance

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. 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

- 3.1 POL-105, Creation and Use of Guidance
- 3.2 SOP 1 – 104, Control of TNI Documents

4.0 Definitions

- 4.1 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.
- 4.2 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 facilitate in the broadest sense. 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:
 - 5.4.1 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.

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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

6.0 Format and Style

- 6.1 Guidance may assume any format and style that facilitates its intended purpose.
- 6.2 Guidance shall 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 shall develop a proposal for review by the Policy Committee.
- 8.2 The proposal for creating guidance shall describe:
 - 8.2.1 The purpose for the guidance.
 - 8.2.2 Whether the guidance interprets or explains how to comply or implement a TNI Standard requirement.
 - 8.2.3 A justification for developing the guidance.
 - 8.2.4 A summary of the content of the guidance.
 - 8.2.5 The medium and delivery mode for the guidance.
 - 8.2.6 The identity of the committee or program board completing the proposal.
 - 8.2.7 The identity of any parties, other than the originators, that will review the guidance.
- 8.3 The proposal for creating guidance shall be completed using the template included in Appendix A.

9.0 Disposition of Proposal for Creating Guidance

- 9.1 The Policy Committee shall review all proposals for creating guidance.
- 9.2 If the Policy Committee agrees that the proposal justifies the creation of guidance, the Policy Committee shall inform the proposal's originator that it can proceed with the creation of guidance.

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- 9.2.1 The Policy Committee shall 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 shall 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 shall inform the originator that it shall not create the guidance and issue a recommendation that the originator:
 - 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.

10.0 Review and Approval of Guidance

- 10.1 The committee developing the proposal for guidance shall 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 Committee shall review the final product to verify it meets the definition and purpose of guidance.
- 10.3 The committee may issue draft versions of guidance labelled accordingly.

11.0 Dissemination of Guidance

- 11.1 The committee approving the guidance is responsible for distributing it using the delivery mode specified in the approved proposal for creating guidance.
- 11.2 Any update or revision, other than editorial changes, to the originally approved guidance shall require submission of the attached request form and approval of the Policy Committee.

12.0 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

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Appendix A

PROPOSAL FOR DEVELOPING GUIDANCE
[Please Complete and Forward to Policy Committee]

Committee Making Request:

- Original Request Update or Revision of Original Guidance

Proposed Title for Guidance:

Form of Proposed Guidance [e.g. White Paper, Template, Manual, Position Statement]

Purpose of Proposed Guidance:

Does the Proposed Guidance Interprets or Helps Implement of Comply with a TNI Standard Requirement?

Summary of Proposed Guidance Content:

Justification for Proposed Guidance:

Delivery Mode of Proposed Guidance:

Reviewers of Proposed Guidance

FOR POLICY COMMITTEE USE ONLY

Review and Recommendations: