



<b>SOP TITLE:</b>	<b>Process for Creating Guidance</b>
<b>SOP NO.:</b>	<b>1-105</b> <b>Numerical Designator:</b> 1 = Administrative and General Procedures 2 = Consensus Standards Development Program (CSDP) 3 = National Environmental Laboratory Accreditation Program (NELAP) 4 = Proficiency Testing Program (PTP) 5 = National Environmental Field Activities Program (NEFAP)
<b>REVISION NO:</b>	<b>0</b>

<b>Committee:</b>	Policy	<b>Approved Date:</b>	08/08/2010
<b>Program Executive Committee:</b>	Not Applicable	<b>Approved Date:</b>	N/A
<b>Policy Committee Reviewed Date:</b>			N/A
<b>TNI Board of Directors Endorsed Date:</b>			09/08/2010
<b>SOP Effective Date:</b>			09/09/2010

## 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 the TNI Board and all TNI committees, executive 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

### 2.1

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 Conformance review: A review undertaken by the Policy Committee or its designee to determine whether proposed guidance meets and does not exceed the definition of guidance.
- 4.2 Disclaimer: A specific statement included in all guidance alerting users about its purpose and application.
- 4.3 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.
- 4.4 Technical review: A review undertaken by the originator of guidance and any designated group to determine the accuracy and utility of the content of guidance.

## 5.0 Unenforceability 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.

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 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, executive committees, councils, or the TNI Board review and establish the need for guidance.
- 7.2 Any person may suggest creating guidance to a TNI group, but only TNI committees, executive committees, councils, and the TNI Board can develop a proposal for creating guidance.

## **8.0 Proposal for Creating Guidance**

- 8.1 Groups authorized to create guidance wishing to do so shall develop a proposal for review by the Policy Committee.
- 8.2 The proposal for creating guidance shall describe:
- 8.2.1 The identity of the group completing the proposal.
  - 8.2.2 The purpose of the guidance.
  - 8.2.3 Whether the guidance communicates, clarifies, or helps implement a TNI Standard requirement.
  - 8.2.4 A justification for developing the guidance.
  - 8.2.5 A summary of the content of the guidance.
  - 8.2.6 The medium and delivery mode for the guidance.
  - 8.2.7 The identity of any parties, other than the originators, that will review the guidance.

- 8.2.8 The level of technical review that the creators believe is necessary to ensure the accuracy and utility of the proposed guidance.
  - 8.2.8.1 There are two levels of technical review: minimal and comprehensive.
  - 8.2.8.2 Proposals for creating guidance that communicates, clarifies or help to implement a TNI Standard should receive a comprehensive level of technical review.
- 8.3 The proposal for creating guidance shall be completed using a form available on the TNI Website. [Note: the form will be developed using the information contained 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.
  - 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 The Policy Committee shall determine the level of review it will provide the proposed guidance for conformance with guidance restrictions.
    - 9.2.2.1 There are two levels of conformance review: minimal and comprehensive.
    - 9.2.2.2 The Policy Committee shall assign a level of review to the guidance commensurate with its purpose and complexity.
    - 9.2.2.3 The Policy Committee may delegate the conformance review of the guidance to another committee, executive committee, council, or an ad hoc workgroup.
- 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 group developing the proposal for guidance shall approve the final version of the guidance following the group's established decision-making rules.

Process for Creating Guidance

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10.2 All final and approved guidance shall be reviewed by the Policy Committee or by a group designated by the Policy Committee for conformance with guidance restrictions to the level specified in the approved guidance proposal.

10.2.1 When this review determines that the guidance meets the restrictions of guidance, the Policy Committee shall label the guidance as "Official TNI Guidance" and clear it for publication.

10.2.2 When this review determines that the guidance does not meet the restrictions of guidance, the Policy Committee or designee group shall return the guidance to its originator with suggestions for revisions.

10.2.3 Guidance that fails the conformance review may be re-submitted for another review by its creators after revisions are completed.

10.3 Committees or program boards may issue draft versions of guidance. Draft versions of guidance shall be labelled "Draft: Not official TNI Guidance".

**11.0 Dissemination of Guidance**

11.1 The committee, executive committee, or Board approving the guidance is responsible for distributing it using the delivery mode specified in the approved proposal for creating guidance.

**12.0 SOP Approval Changes**

Prev. SOP No.	New SOP No.	Date of Change	Description of Change
	1-105		New Document

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

**TNI Group Making Request:**

**Proposed Title for Guidance:**

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

**Purpose of Proposed Guidance:**

**Does the Proposed Guidance Communicate, Clarify, or Help Implement a TNI Standard Requirement?**

**Summary of Proposed Guidance Content:**

**Justification for Proposed Guidance:**

**Delivery Mode of Proposed Guidance:**

**Technical Review of Guidance**

**Minimal**             **Comprehensive**

**Technical Reviewers of Guidance (Names, Affiliations, Qualifications)**

**FOR POLICY COMMITTEE USE ONLY**

**Conformance Review**

**Minimal**       **Comprehensive**

**Conformance Reviewers**

**Policy Committee**       **Other:** \_\_\_\_\_

**Additional Conditions and Recommendations**

**Proposal Approved**

**Proposal Denied**

**Reasons for Denial**