

SOP TITLE	Control of TNI Documents
SOP NO.	1-104
REVISION NO	2.3
PROGRAM	Administration

SOP Approval Dates

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Program	NA	NA	
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1.0 Purpose and Applicability

This SOP addresses processes for managing TNI controlled documents, including their retention, access, storage, and disposal.

This SOP applies to all TNI committees, TNI Board of Directors, subcommittees, work groups, and task groups and covers the following types of documents, among others:

- Policies, SOPs, guidance, and other documents published by TNI in hard copy, electronically, or posted on TNI's Website.
- Standard Interpretation Requests (SIRs).
- Records associated with the evaluation of Accreditation Bodies (Abs) and Proficiency Testing Provider Accreditors (PTPAs) recognized by TNI.
- Tables or lists describing fields of proficiency testing (FoPT), method codes, and acceptance ranges.
- TNI consensus Standards.
- Records associated with business confidential information, personnel transactions, and records generated during closed committee or board sessions.

This SOP does not apply to electronic mail messages nor uncontrolled documents.

2.0 Summary

This SOP defines classification of documents controlled by TNI into four classes, depending on their level of dissemination, publication status, retention period, and availability. The SOP specifies procedures for custody and control of documents, their access, and storage. The SOP addresses document revisions, disposal, and withdrawal.

3.0 Related Documents

POL 1-104, Management of Records

SOP 1-115, TNI Newsletter Preparation and Distribution

SOP 1-118, Developing Position Statements

SOP 1-105, Process for Creating Guidance

SOP 2-100, Procedures Governing Standards Development

4.0 Definitions

Term	Definition		
Controlled document	Any TNI document necessary to perform an activity effectively or to ensure that customer and stakeholder requirements are met, including but not necessarily limited to any document intended for public dissemination created or commissioned by a TNI committee or board, a working draft of a document intended for public dissemination, or a document that is necessary to recreate a TNI official activity or proceeding.		
	Note: Examples of controlled documents are consensus Standards, TNI policies, SOPs, guidance, meeting minutes, committee charters, and tables of proficiency testing.		
Document class	Any of four tiers to which a controlled document is assigned based on its importance, dissemination, applicability, and need for permanence.		
Record	A paper or electronic document, or a collection of documents.		

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Control of TNI Documents

Restricted	An access mode of some TNI documents limited to designated TNI members, or to the general public after redaction of selected sensitive information by the Secretary.
Uncontrolled document	Any TNI document that is not a controlled document, including, but not necessarily limited to documents created by an individual, a TNI committee, the Board of Directors or TNI staff whose principal purpose is to facilitate day-to-day operations, is generated as part of conducting recurring committee and board business, and that is not critical for reconstructing a past activity or to interpret an existing controlled document.
	Note: Examples of uncontrolled documents include but are not limited to messages reminding members of upcoming meetings, brochures advertising TNI events, notes conveying instructions for performing a specific clerical task, and letters of appreciation received by a committee chair.

5.0 Classes of Documents

- 5.1 Controlled documents are assigned into four classes by the Secretary or designee:
 - **5.2.1 Class I** documents are final versions of consensus Standards, TNI governance documents, i.e., Bylaws, Strategic Plan, Annual Reports, and Quality Management Plan, FOPT Tables, SIRs and historical versions of any of the above documents.
 - 5.2.2 Class II documents are normative, or are supplementary to Class I documents, or help implement, understand, or interpret them, and may undergo endorsement involving entities beyond the documents' creators. Typical Class II documents are policies, SOPs, guidance, templates and responses to comments issued with votes on standards and other documents that support standards development. Class II documents also include, but are not limited to, documents generated by the Advocacy committee or TNI's Executive Director such as:
 - Articles.
 - Press Releases,
 - Public Comments.
 - White Papers.
 - Position Statements and
 - Reports
 - **5.2.3 Class III** documents reconstruct or relate TNI meetings, proceedings or webinars, or are documents administrative in nature, and are not generally approved or endorsed by entities beyond their authors or relevant committees. Typical Class III documents are meeting minutes, proceedings of symposia and forums and application forms.
 - **5.2.5 Class IV** documents are associated with personnel, financial matters, contractual obligations, assistance agreements, and records associated with educational courses and evaluations of organizations, such as Abs and PTPAs. Confidential documents include, but are not limited to:
 - Business records dealing with contractual agreements.
 - Records that document TNI personnel transactions.
 - Records generated during closed sessions of committee or program meetings.
 - Membership information contained in TNI databases.
 - Any other record that contains sensitive or proprietary information.

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6.0 Custody and Control of Documents

- 6.1 The TNI Secretary is the official custodian of all final TNI controlled documents and is responsible for their management. The Secretary may delegate responsibility for custody to individuals within programs, such as the TNI Executive Director, TNI Program Administrators, or Committee Chairs.
- 6.2 The TNI Secretary ensures that all TNI committees and the Board have systems that facilitate compliance with this SOP.
- 6.3 The TNI Secretary shall prepare and maintain current a list of all Class I and Class II documents. The list shall include, as necessary, a clear identifier, review date and the issue or effective date of all controlled documents.
- 2.2 All controlled documents are securely managed and stored in either: TNI's Content Management System, as hard copy or in a cloud-based system. The TNI Secretary shall ensure that a copy of each obsolete controlled document is retained to provide a historical reconstruction of a document's revisions and amendments in a secure cloud storage environment. Obsolete documents are not posted on the TNI Website, but may be available by request.
- 2.2 TNI committees and staff shall ensure that obsolete controlled documents are not supplied to members and the public except by an expressed request. Any copies retained by TNI of obsolete versions of controlled documents shall be identified accordingly.
 - TNI staff and committees shall ensure that different versions of controlled documents are readily identifiable and distribute or publish only the latest approved version. Controlled documents in electronic format shall have unique file designations.
 - 6.6.1 SOPs shall follow the control documentation requirements specified in the current revision of SOP 1-100 and the file naming convention in SOP 1-116.
 - 6.6.2 Class II documents shall include a date and revision number (e.g., xxxxx-1-31-11-Rev1).

7.0 Access

- 7.1 TNI provides universal access to all documents posted on its website, except for those documents that are available to members only, or those sold for a fee.
- 7.2 Appendix A, <u>Specifications for TNI Controlled Documents</u>, indicates the access mode for and availability of controlled documents in common usage.
- 7.3 Requests for documents not available on TNI's Website shall be directed to the Secretary.
 - 7.3.1 The Secretary or designee shall determine whether the requested document can be supplied or whether it is restricted or confidential.
 - 7.3.2 The Secretary or designee shall supply requested non-confidential documents or direct the requestor as soon as practical to a source for their access.
 - 7.3.3 Access to non-confidential original documents in hard copy may require special arrangements for their review. TNI may charge a fee for providing copies of original hard copy non-confidential documents.
 - 7.3.4 No committee, board or TNI group may use the exemptions granted in this SOP to avoid access to any document that should otherwise be legitimately available.

8.0 Retention Time Period of Documents

8.1 TNI controlled documents are assigned a retention time period commensurate with their importance, applicability, usage, and coverage by regulations. The retention time period of TNI documents in common usage is specified in Appendix A, Specifications for TNI Controlled

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- <u>Documents</u>. Controlled documents not included in the published list will be retained for a minimum of two years.
- 8.2 The previous version of a controlled document that is revised before its retention time expires shall be placed in archive for at least three years or until its original retention time expires, whichever is longer.
- 8.3 The TNI Secretary may extend the retention time of any controlled document beyond the minimum included in the published list.

9.0 Revision, Withdrawal, and Disposal of Documents

- 9.1 Creators or final endorsers of controlled documents are responsible for notifying the Secretary or designee of their revision or withdrawal.
- 9.2 Revised or withdrawn versions of controlled documents must be stored in accordance with Appendix A, Specifications for TNI Controlled Documents.
- 9.3 The TNI Secretary may dispose or direct the disposal of controlled documents that have exceeded their retention time period and notify any materially affected party prior to removal.

10.0 References

SOP 1-100: Format Guidelines for Standard Operating Procedures (SOPs) of The NELAC Institute

SOP 1-116: Development and Approval of TNI Policies and SOPs

11.0 SOP Approved Changes

Revision No.	Effective Date	Description of Change	
0.1	4/1/2009	Update to new format	
1.0	10/5/2012	Added SIRs to list of Class II documents; minor editorial changes and inclusion of Specifications for TNI Controlled Documents as Appendix A	
2.0	7/24/2017	Update due to 5-year review and adoption of TNI QMP. Revised Section 5.2.2 to include Advocacy document	
2.1	12/13/2017	Minor editorial revisions from the TNI Board	
2.2	05/07/2021	Removed Class V documents, added FOPT Tables, significant revision to Appendix, clarifications based on revisions to other SOPs	
2.3	05/21/21	Editorial only: Changed definition of Document class from 5 tiers to 4 tiers.	

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Appendix A

Specifications for TNI Controlled Documents

Final versions of Standards Final versions of Standards Final versions of Standards Final versions of Standards Withdrawn, then 5 years after last use by an AB Historical versions of Class I documents Active FOPT Tables TNI governance documents TNI governance documents Interpretation of Standards For the life of the associated version of Standards] For the life of the corresponding version of a Standard has Website Universion Website Universion Website Universion Website Universion Website Universion Universion Website Universion Standard thas	oility
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been revised	
Committee charters, Policies, SOPs, Advocacy documents Until revised. Website Universal When revised, previous version is retained for three years	al
Guidance, templates, manuals, and checklists When revised or withdrawn, previous version is retained for three years after last use of version by an AB When revised or withdrawn, subscription University University	al
Application forms When revised, previous version is retained for three years Class III	al

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Control of TNI Documents

Document Class	Type of Document	Retention Time Minimum	Access Mode	Availability
	Meeting minutes for all TNI programs, except the Consensus Standards Development Program (CSDP)	Three years	Website	Universal
	Meeting minutes for the CSDP	Five years after last use of a particular standard	Website	Universal
	Proceedings of and presentations made at TNI symposia and forums	Ten years	Website	Universal
	Reports from annual audits and corrective action plans	Three years	By request	
Class IV	Annual Budget	Three years	Restricted	TNI Board, institutions requiring disclosure, and others as determined by the Secretary
	Financial Statements	As required by Internal Revenue Service	Restricted	TNI Board, institutions requiring disclosure, and others as determined by the Secretary
	Third party audit reports and corrective actions (e.g. ISO, Financial)	5 years	Restricted	TNI Board, institutions requiring disclosure, CSDP EC, and others as determined by the Secretary
	Assistance agreements	Five years or as required by awarding institution, whichever is longer	Restricted	TNI Board, institutions requiring disclosure, and others as determined by the TNI Secretary
	Contractual agreements with service providers	Five years	Confidential	Executive Director, TNI Board of Directors
	Personnel files and performance evaluation records	Five years	Confidential	Executive Director, TNI Board of Directors
	Proceedings of closed committee and board sessions	Three years	Confidential	Committee or board members in closed session; TNI Board of Directors
	Completed applications to TNI committees and boards	Three years	Restricted	Committee members and board directors
	Completed AB applications	Five years	By request	Universal except information claimed confidential will not be made available

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Control of TNI Documents

Document Class	Type of Document	Retention Time Minimum	Access Mode	Availability
	Final evaluation reports, responses and recommendations for ABs	Five years	By request	Universal except information claimed confidential will not be made available
	General TNI business correspondence not already identified as Class IV documents	Three years	By request	Universal

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