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## 1.0 Purpose and Applicability

These procedures provide the framework to ensure the development of consensus standards in accordance with (1) American National Standards Institute (ANSI) *Essential Requirements* and (2) the requirements of the federal Office of Management and Budget (OMB) Circular A-119.

ANSI *Essential Requirements* apply to activities related to the development of consensus for approval, revision, reaffirmation, discontinuance, and withdrawal of American National Standards (ANS). The following constitutes the minimum acceptable due process requirements for the development of consensus: (i) openness; (ii) lack of dominance; (iii) balance; (iv) coordination and harmonization; (v) notification of standards development; (vi) consideration of views and objections; (vii) consensus vote; (viii) appeals; (ix) written procedures; and (x) compliance with normative ANS policies and administrative procedures.

OMB Circular A-119 defines a voluntary consensus standards body as one having the following attributes: (i) openness; (ii) balance of interest; (iii) due process; (iv) an appeals process; and (v) consensus, which is “*general agreement, but not necessarily unanimity, and includes a process for attempting to resolve objections by interested parties, as long as all comments have been fairly considered, each objector is advised of the disposition of his or her objection(s) and the reason(s) why, and the consensus body members are given an opportunity to change their votes after reviewing the comments.*”

## 2.0 Summary

This document describes the procedures used by TNI in the establishment and operation of Expert Committees in developing Standards, which serve as consensus standard development bodies. The procedures also provide criteria for ensuring openness, lack of dominance, a balance of interests, conduct of business, and provide detailed requirements for the consideration of all comments.

## 3.0 Related Documents

- SOP 1-104 Control of TNI Documents
- SOP 2-102 Procedure for Addressing Conflict of Interest
- POL 1-128 Non-Discrimination and Non-Harassment in TNI Programs and Activities
- POL 1-129 Expected Conduct of Participants in TNI Activities
- TNI Bylaws

## 4.0 Definitions

Term	Definition
<b>Accreditation Body (AB)</b>	Authoritative body that performs accreditation.
<b>Affiliate Committee Member</b>	A person who is not a TNI member but has technical expertise needed by a specific committee, is invited to join the committee, and has full voting privileges.
<b>Associate Committee Member</b>	A TNI member who may participate in a committee, but who does not have voting privileges.
<b>Committee Member</b>	All Elected, Associate, and Affiliate members
<b>Consensus</b>	A participatory process by which a group deliberates as it attempts to make a decision where consensus is not synonymous with unanimity.
<b>Consensus Body</b>	A group whose membership meets the requirements of balance and lack of dominance. The group maintains: (i) openness; (ii) balance of interest; (iii) due process; (iv) an appeals process; and (v) a process to achieve consensus.

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<b>Consensus Standard Development Program (CSDP)</b>	A core TNI Program whose purpose is to develop consensus standards for use in TNI's programs.
<b>Consensus Standard Development Program Executive Committee (CSDP EC)</b>	The committee within TNI that has responsibility for the Consensus Standard Development Program. This executive committee provides oversight to Expert Committees in the development of standards.
<b>Content Management System</b>	TNI's process for document control and archival, which combines both hard copy and Cloud-based applications.
<b>Dominance</b>	A position or exercise of dominant authority, leadership, or influence, by reason of superior leverage, strength, or representation, to the exclusion of fair and equitable consideration of other viewpoints.
<b>Draft Standard (DS)</b>	A standard (volume, module, or section of a module or standard) that has been approved by the Expert Committee and presented for comment.
<b>Due Process</b>	The principle by which any person with a direct and material interest has a right to participate by a) expressing a position and its basis, b) having that position considered, and c) having the right to appeal the resulting decision.
<b>Elected Member</b>	A TNI member who applied for and is approved to participate on a committee and has full voting privileges.
<b>Expert Committee</b>	A committee whose duties include the development and maintenance of consensus standards.
<b>Field Sampling Measurement Organization (FSMO)</b>	Organizations engaged in environmental sampling and field measurement activities.
<b>Laboratory</b>	An organization that collects or analyzes samples in a fixed-base, mobile, or field-testing facility for chemical, and/or physical, and/or bacteriological properties or parameters.
<b>Laboratory Accreditation System Executive Committee (LASEC)</b>	A group within the National Environmental Laboratory Accreditation Program of TNI, with balanced representation whose purpose is to manage TNI's efforts in support of a national program for the accreditation of environmental laboratories.
<b>National Environmental Field Activities Program (NEFAP)</b>	A core TNI Program whose purpose is to establish and implement a program for the accreditation of field sampling and measurement organizations.
<b>National Environmental Field Activities Program Executive Committee (NEFAP EC)</b>	The committee with balanced representation that is responsible for NEFAP.
<b>National Environmental Laboratory Accreditation Program (NELAP)</b>	A core TNI program to establish and implement a program for the accreditation of environmental laboratories.
<b>NELAP Accreditation Council (NELAP AC)</b>	The body that consists of one individual from each recognized NELAP Accreditation Body, appointed by the Accreditation Body which has final authority for implementation of NELAP among participating states for the accreditation of environmental laboratories through development and approval of the policies and procedures that govern NELAP operations and is responsible for ensuring the successful implementation of the program.
<b>Proficiency Testing Program Executive Committee (PTPEC)</b>	The committee responsible for the administration and maintenance of the TNI Proficiency Testing program.
<b>Program Administrator (PA)</b>	TNI staff who provide administrative support to committees and serve at the direction of the Board of Directors and the Executive Director.
<b>Stakeholder Group</b>	Any group of individuals with a direct and material interest in a particular TNI activity and that participates by: a) expressing a

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	position and its basis, b) having that position considered, and c) having the right to appeal. Default Stakeholder Groups are Accreditation Bodies, Laboratories, and Other
<b>Standard Interpretation Request (SIR)</b>	The submission of a request for an interpretation of how a standard applies to a particular situation, including the review of draft interpretations and adoption of a final approved interpretation.
<b>Suitability</b>	Criteria for justification of development of a new standard or modification of an existing standard or part thereof. Criteria include auditable; implementable; understandable; improvement over previous version; clearly written; enforceable; economically neutral or advantageous to stakeholders.
<b>TNI Standard</b>	A document that has been developed and established within the consensus principles of TNI, that meets the approval requirements of TNI procedures, and has been approved by the Expert Committee.
<b>Voting Member</b>	All Elected and Affiliate members

**5.0 OPENNESS, LACK OF DOMINANCE, AND BALANCE**

**5.1 Openness**

- 5.1.1 Participation in standards development activities must be open to all TNI members and to all members of the public who are directly and materially affected by TNI's standards. TNI membership must not be conditional upon membership in any organization nor unreasonably restricted on the basis of technical qualifications or other such requirements. Voting membership on the consensus body must not be conditional upon membership in any other organization nor unreasonably restricted on the basis of technical qualifications or other such requirements. Any member of the public may provide written input on any TNI standard or may provide comment by following the ANSI public comment process. TNI will make a reasonable effort to reach out to non-TNI members who may have an interest in any standard that TNI develops. This may be done by publishing notices on the TNI website, emailing potentially interested parties, having webinars discussing standards or any other option to gather input from non-TNI members.
- 5.1.2 Any standards adoption organizations are invited to participate in the open consensus process. This will generally be accomplished through the ANSI public comment process and emails provided to interested parties.

**5.2 Lack of Dominance**

- 5.2.1 The standards development process must not be dominated by any single stakeholder group, individual, or organization.
- 5.2.2 There is no test required to demonstrate a lack of dominance. If a party feels that a single stakeholder group, individual or organization dominated the standards development process, an appeal should be filed following established TNI procedures (see Section 9).

**5.3 Balance**

- 5.3.1 The standards development process must have a balance of interests. Participants from diverse stakeholder groups must be sought with the objective of achieving balance. There must be a minimum of three (3) stakeholder groups for each Expert Committee.

5.3.2 The criteria for balance are that no single stakeholder group constitutes a majority of committee members on any Expert Committee. The default stakeholder groups are:

- ABs – accreditation bodies that operate accreditation programs,
- Laboratories – laboratories and other organizations (such as FSMOs) directly involved in providing sampling and measurements, and
- Others – consultants, proficiency test providers, state and federal agencies that do not run accreditation programs and all additional interested parties.

The stakeholder groups appropriate in the development of consensus for any given TNI standards activity are a function of the nature of the standards being developed. Expert Committees may determine that additional or different stakeholder groups are appropriate for the Expert Committee’s scope of activity. Requests for changes in the stakeholder group designations for a given Expert Committee must be presented to the CSDP EC, and upon its recommendation, be presented to the TNI Board of Directors for its approval.

## **6.0 CONDUCT OF COMMITTEE BUSINESS**

### **6.1 Meetings**

Generally, there are two (2) public meetings (conferences) per year (a summer meeting and a winter meeting) with webinars scheduled as needed. At these public events, the Expert Committees may present a draft standard or modifications to a standard for discussion and debate by the TNI and non-TNI members in attendance, and to receive input for further development of the standard. Any member of the public may register for, attend, and provide input during these meetings and webinars. Minutes from these meetings are published on the TNI website.

Additional Expert Committee meetings held in-person or virtually are open to any TNI member or Affiliate who has joined the Expert Committee, to any TNI member who chooses to participate in the role of Associate Committee Member, and to any member of the public who requests in writing or by email to the committee chair and Program Administrator to be included for a particular meeting of the committee. After the committee approves minutes from these meetings, they are published on the TNI website and include a list of all attendees. It is permissible to hold closed meetings only when discussing personnel or other sensitive issues.

### **6.2 Notification of Meetings**

Public meetings which may include Expert Committee meetings, are advertised in advance, and are routinely held as “summer” and “winter” meetings. Notices of these public meetings are the responsibility of the TNI Executive Director or his designee, as the conference publicity is considered adequate notice.

Expert Committee meetings, normally held virtually, are typically scheduled monthly at the same day and time (for example, the second Tuesday of each month at 1:00 PM ET). Notices of Expert Committee meetings and/or any necessary modifications of the schedule are the responsibility of the Expert Committee’s PA (or designee).

### **6.3 Decorum**

All correspondence or comments, in whatever form, that are received by Expert Committees must be handled in a non-discriminatory manner. All such correspondence or comments must be addressed in an appropriate and timely manner by the Expert Committees and, when appropriate, responses are provided in writing to authors of the correspondence and/or comments. At no time should race, religion, politics or other potentially discriminatory factors be brought up during discussion of any form of correspondence or comments.

Expert Committee discussions and correspondence must also be completed with professionalism, decorum and in a non-discriminatory manner.

Should the Committee receive language inconsistent with these stipulations, the comment(s) is returned to the commenter asking that these requirements be followed. Refusal to follow these requirements will result in the submitted comment(s) being rejected.

## **7.0 COMMITTEE OPERATIONS**

Committee operations must be in accordance with SOP 2-101 (Procedures for Expert Committee Operation) and SOP 1-102 (Voting Rules for TNI Committees).

## **8.0 STANDARDS DEVELOPMENT**

### **8.1 Summary of the Process**

Expert Committees develop and maintain standards during in-person and virtual meetings. The Committee Members serve in a leadership role in standards development. Committees must consider all comments and suggestions. The Expert Committees develop a TNI Standard by following the process described in this SOP. The principal steps in the process are development of a Draft Standard and, as necessary, one or more sequential revisions of the Draft Standard.

If the standard is a modification of an existing TNI standard, the Expert Committee may choose to present a complete volume or module for consideration, or may present only modified sections or clauses of a standard for consideration. The Committee Chair may delegate the standard-writing process to the Committee Members or to a work group(s).

All TNI Members (and other interested parties) are afforded the opportunity to contribute to the standard development process. Input from all stakeholders (including non-TNI members) is solicited, gathered, documented, and considered in the standards-writing process.

### **8.2 Notification – The First Step in the Development Process**

The need to establish or modify a standard or part of a standard must be determined by the relevant Expert Committee. In the case of development of a new volume or new module of any TNI standard, or for an entirely new volume or module for a new standard, approval of the Board of Directors must be attained prior to proceeding.

A Notification of the Intent (NOI) to establish or modify a TNI standard must be developed by the appropriate Expert Committee utilizing the NOI form presented in Appendix 1. Use of this form ensures that requirements defined for suitability of a new or a modified part of the standard can be met.

This notification includes: (a) an explanation of the need for the standard; (b) how the standard is an improvement over the previous version where applicable; (c) identification of stakeholders (e.g. laboratories, Accreditation Bodies, FSMOs, engineering firms, PT Providers, PT Provider Accreditors, etc.) likely to be impacted by the standard; (d) any potential auditability, enforceability and/or implementation issues that may be encountered; and (e) potential economic impacts on any

of the stakeholders.

After approval by the CSDP EC, the NOI to establish or modify a standard is posted on the TNI website and the following groups/individuals, as applicable, are contacted about the posting:

- interested parties who signed up for a standards activity listserve,
- individuals on an applicable email list,
- TNI committee chairs, the members of the NELAP Accreditation Council, the TNI Board of Directors, and
- other parties expected to have an interest in this process.

This public announcement on the TNI website of the pending standards activity is provided to solicit input and provide the opportunity for participation by all directly and materially affected persons (both non-TNI and TNI members). The announcement may also include a date for a public meeting to receive input. The announcement initiates the beginning of a thirty (30) day period for input on the proposed modifications, or if a new standard, the subject of the standard. All suggestions/input received by the committee is considered in the development of the standard or changes to the standard. As input is the intention of this notification, responses to input received at this stage of the process are not required (although a response may be made at the discretion of the Committee). All input/comments must be documented, however. The CSDP EC PA manages the publication and receipt of comments regarding the NOI.

Public notice of committee efforts to establish or modify a TNI Standard is also made to organizations representing the accredited laboratory community and to appropriate regulatory agencies. This public notice is done via press release, webinar, TNI newsletter article, or other forms of effective communication, as appropriate.

The approval of the NOI to establish or modify a standard as an American National Standard also initiates the transmittal to ANSI of the Project Initiation Notification System (PINS) form. The PINS form is submitted by the CSDP EC PA. The procedure described in *ANSI Essential Requirements*, Section 2.5, is followed.

The PINS is subsequently published in ANSI's weekly newsletter titled *Standards Action*. This publication initiates a separate (and potentially concurrent) thirty (30) day comment period for ANSI participating organizations. (Note that this comment period is separate from the thirty (30) day TNI comment period above, although they may run simultaneously depending on when each is filed.)

All comments received from the PINS announcement by ANSI are addressed according to the procedures presented in Section 8.4, Response to Comments and consistent with *ANSI Essential Requirements* clauses 2.5.1.2 and 2.5.1.3.

If TNI receives written comments within thirty (30) days from the publication date of a PINS announcement in *Standards Action*, and those comments assert that a proposed standard duplicates or conflicts with an existing American National Standard or a candidate ANS that has been announced previously (or concurrently) in *Standards Action*, a mandatory deliberation of representatives from the relevant stakeholder groups must be held within ninety (90) days from the comment deadline. Such a deliberation must be organized by TNI and the commenter and must be concluded before the developer may submit a proposed standard for public review. If the deliberation does not take place within the ninety (90) day period and TNI can demonstrate that it has made a good faith effort to schedule and otherwise organize it, then the developer is excused from compliance with this requirement. The purpose of the deliberation is to provide the relevant stakeholders with an opportunity to discuss whether there is a compelling need for the proposed standards project.

The outcome of any PINS deliberation must be conveyed to ANSI consistent with Clause 2.5.1.3 of *ANSI Essential Requirements*.



### 8.3 Summary and Draft Standard

After the close of the thirty (30) day period following the NOI, input, suggestions, and comments are reviewed by the Expert Committee including those, if any, resulting from the PINS announcement by ANSI, and prior to publication of the Draft Standard for comment, the Expert Committee may meet with the interested stakeholders and stakeholder groups by open meeting, webinar or any other form of effective communication to ensure that suggestions, input, and comments are understood.

The Expert Committee begins the process of preparing the Draft Standard. This process may involve full committees or workgroups focusing on all or part of the changes to the standard. The approach to be used in making these changes is entirely at the discretion of the Expert Committee.

- 8.3.1 If the standard is a revision of an existing TNI standard, the following records are reviewed during the standards development process, as applicable:
- all submitted comments from all stages of the most recent previous standards development activity, complete with the Expert Committee's written deliberations and disposition of those comments;
  - all comments previously placed on hold that remain on hold; and
  - all pertinent Standard Interpretation Request responses.

- 8.3.2 Deliberations within the committee are conducted until the committee has determined that the DS is ready to be presented to all stakeholders. The DS is entered into a content management system and made available to committee members.

- 8.3.3 All Voting Members of the Expert Committee are required to vote on the DS. The vote of the entire committee however accomplished (whether in meeting participation or by e-mail ballot) must be recorded in meeting minutes and is reported and archived. The DS is ready for posting on the TNI website when two-thirds of the Expert Committee votes to approve the DS.

Any Draft Standard posted for review/comment by TNI membership becomes the Final Standard if no persuasive comments are received. For this reason, all Voting Members of the Expert Committee are required to vote on the DS whenever the DS is being proposed to advance out of committee.

- 8.3.4 The voting members must cast votes as follows:
- Affirmative,
  - Affirmative with comment, or
  - Negative with comment.

Abstentions are not allowed when a vote is being called to advance a Draft Standard out of committee at any stage of revision.

- 8.3.5 Any comments that the Expert Committee deems persuasive require that the DS be revised.

- 8.3.6 Any committee member who casts a negative vote on the DS must accompany the vote with written comments, justifying the vote. If possible, the voter should propose alternative language for the Standard.

8.3.6.1 During Committee deliberations, each Expert Committee member may clarify, explain and/or justify their position.

- 8.3.6.2 If a negative comment remains non-persuasive to the committee and unresolved to the negative voting member, the unresolved comment is recirculated to the Expert Committee to provide them the opportunity to reaffirm or change their votes per 8.3.4.
- 8.3.6.3 Such negative votes are documented in writing and the individual(s) who remain(s) as a negative voter has/have the right of appeal consistent with established TNI-procedures as outlined in Section 9.
- 8.3.7 When the Expert Committee has a two-thirds affirmative vote on the DS, comments have been addressed, and LASEC has been notified regarding how previous SIRs have been addressed, the CSDP EC PA Standards Action Public Review Request form (BSR-8) with ANSI. Any comments received because of the announcement of the BSR-8 in the ANSI weekly newsletter are addressed following the same process as any other comment.
- 8.3.8 After voting to approve the DS, the Committee provides a summary of changes including justification for those changes (Appendix 2 contains an example form). The DS and the summary are posted on the TNI website for stakeholder comment and the following groups/individuals, as applicable, are contacted about the posting:
- interested parties who signed up for a standards activity listserve,
  - individuals on an applicable email list;
  - TNI committee chairs, and the members of the NELAP Accreditation Council, the TNI Board of Directors; and
  - other parties expected to have an interest in the DS and summary of changes.
- 8.3.9 The comment period for the DS is ninety (90) days from the website posting. An Executive Committee or the NELAP Accreditation Council may petition CSDP EC for a thirty (30) day extension if an issue arises. All comments must be addressed to the Expert Committee chair and the Expert Committee PA and must be recorded as directed per 8.4. The Expert Committee attempts to capture verbal comments made during any open meeting, webinar, or in any other setting. If a commenter wants to ensure that a comment is addressed, or if the commenter wants a direct response about how the comment was handled, the comment must be submitted electronically.

#### **8.4 Response to Comments**

All written comments received during the DS comment period from any source are logged onto the Response to Comments form.

A comment may be withdrawn by request to the Expert Committee chair and/or the committee's PA.

- 8.4.1 All comments logged onto the Response to Comment form must be considered by the Expert Committee.

Following committee discussion, comments must be ruled persuasive, non-persuasive, or editorial by simple majority vote of the Expert Committee.

Editorial changes are of two types: (1) those which introduce no change in technical content, but correct typographical errors, modify editorial style, change non-technical information, or reduce ambiguity, and (2) those which correct typographical errors in substance (essential information that could be misused).

The Response to Comments form is used to record the committee's persuasive or non-persuasive ruling, any subsequent actions taken by the committee, and any other details the committee deems pertinent. The Response to Comments form is used as the permanent record for each phase of the standard development process. After completion by the Expert Committee, the Response to Comments form is posted on the TNI website as well as being retained in TNI's permanent records. The commenter's contact information is removed from the Response to Comments form prior to posting the document but is still available to committee members for consideration of comments.

Each time the Response to Comments form is used (e.g., DS and revisions of the DS), the final disposition of comments by the committee is posted on the TNI website and the groups/individuals identified in Section 8.3.8 are notified regarding the posting.

- 8.4.2 An Expert Committee may prioritize the comments received and may place a comment on hold until the next revision cycle of the standard if any of the following conditions are met:
- The comment would introduce a new concept to the proposed standard that had not been subject to public review;
  - The comment's proposed language would change the overall intent of the standard as being proposed by the Expert Committee.

In determining whether to place a comment on hold, the Expert Committee may consider relevant factors, including, but not limited to: the extent to which the comment proposes a change that is new and/or substantial; the complexity of the issue(s) raised; and whether sufficient debate and public review has taken place. The commenter is informed, in writing, of the reason the comment is placed on hold. If a commenter does not respond to the committee notification, the comment in question is not considered further.

Any comment placed on hold must be addressed during the next revision cycle of the standard and must be recorded and considered as a comment at that time. Comments placed on hold must be noted in the Response to Comments form.

- 8.4.3 The disposition of written comments is communicated in writing to each commenter. Communication includes the reason for the committee's decision regarding the comment.
- 8.4.3.1 Those who receive notification of the disposition of comments are not required to respond to the Committee.
- 8.4.3.2 The Committee presents the author(s) of non-persuasive comment(s) with the opportunity to expand, explain and/or justify their position.
- 8.4.3.3 Following the commenter's presentation of their position to the committee, the comment is recirculated to the committee members to affirm or change their vote on the comment in question.
- 8.4.3.4 In the event that the comment remains as non-persuasive to the committee and unresolved to the commenter, an appeal may be filed consistent with the procedure in Section 9.
- 8.4.4 If any comments were ruled persuasive, the DS must be revised as described in section 8.5.
- 8.4.5 If the committee rules comments as non-persuasive, the commenter retains the right to appeal per section 9.0.
- 8.4.6 If the DS passes without any persuasive comments, or no comments were

received, the DS becomes final. CSDP EC performs a review of the Standard to assure its implementability and proceeds to Section 8.5.7.

## **8.5 Draft Standard Revisions**

- 8.5.1 If modifications to the DS are necessary due to persuasive comments, the Expert Committee develops a revised Draft Standard (identified as DS Rev.# date) by following the process of review and approval found in Section 8.3. This version should highlight the changes made to the Standard whenever possible.
- 8.5.2 The comment period for the revised DS is a minimum of sixty (60) days and not more than ninety (90) days, and the process for collection and disposition of all comments must be completed as described above.
- 8.5.3 If additional persuasive comments are received during this phase of standard development, ~~a second~~ another revised DS is produced by the Expert Committee. Each revision of the DS is identified with a sequential integer and the date (for example DS Rev.# date) and the entire process is repeated until such time as no additional persuasive comments are received.
- 8.5.4 The committee's response to all comments is addressed as described in Section 8.4. Comments that have been previously ruled upon by the Expert Committee are not re-considered at this stage without the inclusion of new evidence or a new line of reasoning.
- 8.5.5 When the DS (at whatever revision) has received an affirmative two-thirds vote of all Expert Committee members and no further persuasive comments are received, the DS is considered final, and the procedures in Section 8.4.1 are followed for posting and notification. An additional vote to approve the Standard is not required, since any vote to move a DS out of Committee can serve as the vote to make the Standard final (see Section 8.3.3), pending review by the CSDP EC per 8.5.7 or if an appeal is lodged.
- 8.5.6 The Expert Committee Chair, PA, or CSDP EC Chair must ensure the standard is in compliance with SOP 2-103 Format and Style Guide for Consensus Standards.
- 8.5.7 After the expert committee has completed their process, the CSDP EC has a 30-day period to review the standard, Response to Comments, for previously undetected issues of enforceability and for errors made in the review process.
- 8.5.8 If no comments/feedback are made by the CSDP EC, the process is complete. If changes to the standard are necessary, the process returns to Section 8.5.1.
- 8.5.9 When the standard is complete, the standard is made available for distribution in final form. This is the version of the standard subject to consideration for adoption and implementation by any organization wishing to use it for accreditation purposes. At that time, the CSDP EC PA completes and submits the BSR-9 Form (Proposed American National Standard Formal Submittal Checklist) for consideration as an ANS, as appropriate.

## **8.6 TNI Standard**

- 8.6.1 When a Final Standard contains significant changes, an Expert Committee is required to develop and present a webinar regarding the changes to interested parties including laboratories, laboratory assessors and Accreditation Bodies.
- 8.6.2 The TNI Standard is made available for purchase to all interested parties, including

standards-adoption organizations.

- 8.6.3 Upon acceptance by ANSI, the TNI Standard is recognized as an American National Standard and all publications of the standard contains the ANSI ANS logo.
- 8.6.4 TNI, as an ANSI-accredited standards developer, may withdraw approval of existing American National Standards by notification to ANSI consistent with Clauses 4.1.4 and 4.2.1.3.2 of *ANSI Essential Requirements*. Withdrawal actions by TNI of ANS status are preceded by an announcement to all TNI members and a forty-five (45) day comment period to provide an opportunity for TNI members to petition the Board of Directors to retain the standard.
- 8.6.5 The Expert Committee, with the approval of the TNI Board of Directors, may decide to abandon the processing of a proposed new or revised standard or portion thereof. Announcements of such discontinuance of a standards project are posted on the TNI website and immediate notification is made to ANSI.
- 8.6.6 Approved standards are considered for revision or reaffirmation by the appropriate Expert Committee at least once every five (5) years from their date of approval as an ANS. Reaffirmations are accompanied by no non-editorial changes to the text of the standard. Any non-editorial changes in the standard require processing as a revision following the previous process requirements, including recirculation of changes/modifications to the Standard for comment by ANSI, TNI and non-TNI member (public) interested parties. Voting for reaffirmations of the Standard follows the requirements in Section 8.3.3.

Reaffirmations are also provided via the TNI website for additional public comment. Any comments received on the reaffirmation are considered by the Expert Committee and, if ruled persuasive, require re-processing the standard as a revision following the requirements of this SOP.

## 9.0 APPEALS

### 9.1 General

Persons who have directly and materially affected interests, and who have been or may be adversely affected by a procedural action or inaction of TNI, have the right to appeal. Commenters are notified of the disposition of their comments and their right to appeal. The appeal process is open to anyone who files a written appeal with the Executive Director of TNI within thirty (30) days after the Response to Comment form is posted (see Section 8.5.6) on the TNI website. The burden of proof to show adverse effect is on the appellant.

- 9.1.1 The appeal must state the nature of the objection(s) including any adverse effects, the clause(s) of these procedures or the standard that is at issue, actions or inactions that are at issue, and the specific remedial action(s) that would satisfy the appellant's concerns. Previous efforts to resolve the objection(s) and the outcome of each are documented within the appeal.
- 9.1.2 Within seven (7) days of receiving an appeal, the Executive Director notifies and provides a copy of the appeal to the Chair of the TNI Board of Directors and the Chair of the CSDP EC.
- 9.1.3 If an appeal is filed, the Standard does not become final until the appeal process is resolved.

### 9.2 Response

Within sixty (60) days after receipt of the appeal, the Chair of the CSDP EC prepares a written response. The Chair of the CSDP EC may solicit other individuals with specific knowledge of the matter in question to assist with the response. The CSDP EC Chair forwards the response to the TNI Executive Director for review, comment, and/or approval. The approved response is submitted to the appellant by the TNI Executive Director. The response specifically addresses each allegation of fact in the appeal to the extent of the respondent's knowledge.

### **9.3 Hearing**

If the appellant and TNI are unable to resolve the written complaint in a manner consistent with these procedures, the Executive Director schedules a telephone conference hearing with an appeals panel on a date agreeable to all participants, giving at least fifteen (15) working days' notice.

### **9.4 Appeals Panel**

An appeals panel is created that consists of three (3) individuals who are knowledgeable of the issues and familiar with the operation of consensus standards organizations, have not been directly involved in the matter in dispute, and who are not materially or directly affected by any decision made or to be made in the dispute. The TNI Executive Director, with input from the appellant, develops a list of five (5) potential appointees for the appeals panel within fifteen (15) days, and the appellant selects three (3) of those names. This list of three (3) names is submitted to the TNI Executive Committee, which appoints the members of the appeals panel. If the parties to the appeal cannot agree on an appeals panel within a reasonable amount of time, the matter is referred to the TNI Board of Directors, which then appoints members of the appeals panel.

### **9.5 Conduct of the Hearing**

The appellant has the burden of demonstrating adverse effects, improper actions or inactions and the efficacy of any requested remedial action. TNI has the burden of demonstrating that the organization and the CSDP EC took all actions in compliance with these procedures and that the requested remedial action would be ineffective or detrimental. Each party may present evidence, and members of the appeals panel may address questions to individuals. *Robert's Rules of Order* apply to questions of parliamentary procedure for the hearing not covered herein. The appeals hearing proceedings are documented and maintained in TNI's Content Management System.

### **9.6 Decision**

The appeals panel provides a determination to the TNI Board of Directors in writing within sixty (60) days of the conclusion of the hearing, stating findings of fact and conclusions, based on a preponderance of the evidence presented to the appeals panel. The decision of the appeals panel is final, subject to agreement of the TNI Board of Directors (BoD). In the event that the BoD does not agree with the decision, it is returned to the Panel for further discussion. If any appeal is upheld, the affected module or section of the TNI Standard is withdrawn by the Expert Committee that developed that module or section for appropriate disposition and/or redevelopment in accordance with this SOP. If any appeal is denied, then the Standard is final.

## **10.0 PUBLICATIONS**

Any TNI Standard is released for publication only through TNI.

## **11.0 RECORDS**

Records are prepared and maintained to provide evidence of compliance with these procedures. Records include, but are not limited to, membership rolls; minutes of Expert Committee meetings; summaries of membership votes on standards; persuasive and non-persuasive comments,

including comments from committee members; Expert Committee response to comments; draft standards and final approved standards.

## 12.0 STANDARD INTERPRETATION POLICY

Interpretation of any part of any standard is available as a service to the recipient of the standard or to any member of the public, provided a request is submitted on the "Request for Standard Interpretation" form that is available on the TNI website. Refer to SOP 3-105 for NELAP or SOP 5-106 for NEFAP.

## 13.0 PATENT POLICY

TNI complies with the ANSI Patent Policy as presented in *ANSI Essential Requirements* Clause 3.1.

## 14.0 ANTITRUST POLICY

TNI complies with the ANSI Antitrust Policy as presented in *ANSI Essential Requirements* Clause 3.3.

## 15.0 COMMERCIAL TERMS AND CONDITIONS

TNI complies with ANSI Commercial Terms and Conditions as presented in Clause 3.2 of *ANSI Essential Requirements*.

## 16.0 METRIC POLICY

Units of the International System of Units (SI), the modernized metric system, are the preferred units of measurement in TNI standards.

## 17.0 REFERENCES

- SOP 1-102 Voting Rules for TNI Committees
- SOP 2-101 Procedures for Expert Committee Operations
- SOP 3-105 Standard Interpretation Process
- SOP 3-106 Review of Accreditation Standards for Suitability
- SOP 5-106 NEFAP Standard Interpretations
- *ANSI Essential Requirements: Due process requirements for American National Standards*; referred to throughout as *ANSI Essential Requirements*
- *ANSI Standards Action*
- OMB Circular A-119 for Voluntary Consensus Standards Bodies

## 18.0 SOP APPROVED CHANGES

Revision No.	Effective Date	Description of Change
0	3/15/2008	Original SOP approved
1.0	January 2010	TIA language added to 5.5.9
1.1	3/15/2010	Reformat to style guide, added Section 13
2.0	3/12/2015	Modification to SOP based upon Corrective Action Task Force
2.1	5/5/2015	Editorial change required by ANSI
2.2	9/19/2017	Editorial changes to Section 1.3.11 by adding the word "voluntary" and a clause about representation.

Procedures Governing Standards Development

3.0	05/07/2020	Revisions to address the “Lessons Learned” document following completion and adoption of the 2016 TNI Environmental Laboratory Sector Standard and the 2019 ANSI Audit.
3.1	06/11/2020	Editorial changes made to Sections 1.1, 1.3, and 14.0; definitions added for Content Management System and Dominance
3.2	07/17/2020	Editorial changes made to Sections 1.4.2, 2.1.1, 3.3, 5.3.1, 5.4.2, and 5.4.4 per ANSI review; changed references to teleconference and face-to-face meetings to virtual meeting and in-person meeting, respectively.
3.3	08/14/2020	Added abstain to section 5.3.1 per request from ANSI. Added SOP 1-102 to Section 2.0
3.4	1/19/2021	Clarify opportunity for negative votes/comments or objections to present and amend their votes/comments consistent with <i>ANSI ER Section 2.6</i>
4.0	10/09/2023	Revised to reflect approved format, changes in actual practice, and to present the SOP in the active voice’.
4.1	02/08/2023	Revised Affiliate definition; added formatting review of final Standard. Changed ‘shall’ to ‘must’ throughout document.
4.2	03/01/2023	Retained the first bullet in 8.2 and revised the second bullet. Revise 8.3.6 with no change in intent. Revised 8.3.6.2 for clarity. Revised 8.3.6.3 to remove unresolved. Conforming changes to 8.3.8. Revised 8.4.4 and created 8.4.5, and 8.4.6 to clarify the process. Revised 8.5.5 and 8.5.6 for clarity. Removed language from 8.5.7 relative to review by LASEC and NELAP AC.
4.3	04/14/2024	Clarified the role of the CSDP EC in 8.4.6



**Appendix 1. Notice of Intent Form**  
**Notice of Intent to Establish or Modify a TNI Standard**

Expert Committee:		Proposal Date:		CSDPEC Approval Date:	
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TNI Volume/Module	Section(s)

Potentially impacted stakeholders/stakeholder groups:

Nature of the standard to be established or modified.

If a new standard, provide a justification or need for the standard:

If a modification of an existing standard, how will the proposed changes be an improvement over the existing standard:

Any potential conflicts with the other standards and/or Modules of TNI Standards:

Potential economic impact:

Other potential suitability issues (enforceability, implementability, auditability):

Signature of proposal representative:

Date:

**Appendix 2. Justification Form**

**Standard Update - Summary of Suggested Changes and Justification**

Original Text	Suggested Change	Justification
<i>Include current reference and language. (If presented for public view, ISO language should only be referenced.)</i>	<i>Don't need to work on specific language - just summarize change needed.</i>	<i>Why does this need to be changed/updated?</i>

*Note: This table can be used to prepare for a public meeting to seek stakeholder input.*

*Note: When the standard has been developed and is presented as a Draft Standard, a new version of this table is prepared noting the actual changes made to the standard. The "Suggested Change" column will include the actual language from the DS. The "Original Text" column will include the language from the previous (if any) standard. The "Justification" column states the reason for the change and provides any additional comments the expert committee thinks are pertinent.*

### Appendix 3. Response to Comments Form

Title – Volume/Module being drafted											
Disclaimer: The NELAC Institute (TNI) accepts no liability for the content of any comment on a standard.											
Any views or opinions on a standard are solely those of the commenter and do not necessarily reflect those of TNI.											
Comment Number	Vote & Justification (Persuasive/non-persuasive)	Editorial (Y/N)	Section/Clause	Comment	Committee Action	Date Addressed	Committee Comment	Submitter	Submitter Contact Info	Date Submitted	Date & Method of Submitter Notification
1	P		1.2.3.4	Whatever they said	What was done	When	Related info	Name	Email	When	When & how
2	NP		1.0								
3	NP		4.3								
4		Y									

**Tips for easy use after data entry:**

Consider using a different worksheet for each set of comments, all in the same workbook, to distinguish public meetings and various stages of development of the standard/module. An Excel file with this template is available from the committee’s Program Administrator, or you can easily create one from this template.

*Comment Number* – enter these manually in spreadsheet, because if you do previous-cell-plus-one, the numbers will not remain when you sort the spreadsheet/comments into sequential order so that you can work through the text of the document easily.

*Vote* – include brief justification for decision made.

*Section/Clause* – enter the section number referred to in the comment. You will later use this to sort comments so that you can work through them in order, even though you have presumably entered them sequentially as they arrived.

*Comment* – copy the language submitted as comment into this cell. Expand the cell and “wrap text” as needed.

*Committee Action* – record what action the committee decided to take, in complete enough form that you can simply copy this line of the spreadsheet and send it to the submitter later, as notification of action taken.

*Date Addressed* – this should reference the date(s) of the meeting where the comment was discussed and thus recorded in the minutes.

### **Appendix 3. Response to Comments Form cont.**

*Committee Comment* – whatever additional information you believe to be appropriate. Perhaps the alternative action if seriously considered, or something you want recorded for the next round of revisions. Or nothing.

*Submitter, Submitter Contact, and Date Submitted* – these are in the right-most columns so that you can strip them out or conveniently hide them without disrupting formatting when displaying the comments for public discussion. It is acceptable to leave the identities in place while working in committee only, but in minutes, public sessions or webinars, names should not be routinely included unless the commenter was invited to address the committee about the comment, and would thus be identified in the minutes anyway. If you strip out the names, be sure that you make a separate copy of the worksheet first, since you will need them later to notify the submitter of the action taken on their comment, and that will require reuniting name/info with the comments, later. If you hide the identities, consider “protecting” the worksheet before distributing it beyond the committee members.

*Date and Method of Submitter Notification* – for Draft Standards, you must notify the submitter about the disposition of their comments. This column provides an easy way to verify that was done.

REMEMBER: Always save a duplicate copy of any file you will need again, in a different drive or attached to an email somewhere!