



SOP TITLE	Procedures Governing Standards Development
SOP NO.	2-100
REVISION NO	3.4
PROGRAM	Consensus Standards Development

SOP Approval Dates

	Initial Approval	Revision Date	Review Date
Committee – CSDP Executive Committee	10-17-07	01-19-21	
Program - CSDP	10-17-07	01-19-21	
Policy Committee Review	03-03-08	01-25-21	
TNI Board of Directors Endorsement	03-12-08	NA	
SOP Effective Date	03-12-08	01-19-21	

Table of Contents

	<u>Page</u>
1.0 General	4
1.1 Purpose	4
1.2 Scope	4
1.3 Related Documents	4
1.4 Definitions	4
1.5 Maintenance of Procedures	7
2.0 Openness, Lack of Dominance, and Balance	7
2.1 Openness	7
2.2 Lack of Dominance	7
2.3 Balance	8
3.0 Conduct of Committee Business	8
3.1 Meetings	8
3.2 Notification of Meetings	8
3.3 Decorum	9
4.0 Committee Operations	9
5.0 Standard Development	9
5.1 Expert Committee Activities	9
5.2 Notification – The First Step in the Development Process	10
5.3 Summary and Draft Standard	11
5.4 Response to Comments	13
5.5 Draft Standard Revisions	14
5.6 TNI Standard	15
6.0 Appeals	15
6.1 General	15
6.2 Response	16
6.3 Hearing	16
6.4 Appeals Panel	16
6.5 Conduct of the Hearing	16
6.6 Decision	16
7.0 Publication	17
8.0 Records	17
9.0 Standard Interpretation Policy	17
10.0 Patent Policy	17
11.0 Antitrust Policy	18
12.0 Commercial Terms and Conditions	18
13.0 Metric Policy	18

Table of Contents cont.

14.0	References	18
15.0	SOP Approved Changes	18
	Appendix 1. Standard Development Process (diagram)	20
	Appendix 2. Notice of Intent Form	22
	Appendix 3. Response to Comments Form	24

1.0 GENERAL

1.1 Purpose

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.”*

1.2 Scope

This document describes the procedures used by TNI in the establishment and operation of Expert Committees in developing Standards, who serve as consensus standard development bodies. The procedures also provide criteria for ensuring a balance of interests, stipulate voting procedures and provide detailed requirements for the consideration of all comments. The procedures cover, but are not limited to, the following topics:

- Openness, Lack of Dominance, and Balance
- Conduct of Business
- Standards Development
- Voting Procedures and Appeals
- Publications
- Records

1.3 Related Documents

- SOP 1-104 Control of TNI Documents
- SOP 2-101 Procedures for Expert Committee Operations
- SOP 3-101 Voting Procedures for General Business and Laboratory Accreditation Matters
- 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

1.4 Definitions

For a definition of terms relating to The NELAC Institute (TNI) officers, committees, and organizational structure, refer to the TNI By-laws.

- 1.4.1 *Accreditation Body (AB)* – The organization having responsibility and accountability for accreditation.

1.4.2 *Committee Membership*

Expert Committee Member – A TNI member with technical knowledge appropriate to the specific committee, with full voting privileges, who applied for and is approved to participate on a committee.

Associate Committee Member – A TNI member who may participate in any committee, but who does not have voting privileges.

Affiliate – A person with special knowledge as a qualified individual and who is not a TNI member. An Affiliate is eligible to fully participate as a Committee Member, with all rights and privileges, including voting. Affiliates are counted as full members on committees and must be accounted for in terms of balance. No more than 30% of members may be affiliates.

NOTE – Voting Members consist of Expert Committee Members and Affiliates, who constitute the Consensus Body.

1.4.3 *Consensus* – A participatory process by which a group deliberates as it attempts to make a decision. Consensus is not synonymous with unanimity, but rather the judgment arrived at through the established discussion, review and balloting indicating general, but not necessarily universal, agreement.

1.4.4 *Consensus Body* – 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.

1.4.5 *Consensus Standard Development Program (CSDP)* – A core TNI Program whose purpose is to develop consensus standards for use in TNI's programs.

1.4.6 *Consensus Standard Development Executive Committee (CSDEC)* – 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.

1.4.7 *Content Management System* – TNI's process for document control and archival, which combines both hard copy and Cloud-based applications.

1.4.8 *Dominance* – 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.

1.4.9 *Draft Standard (DS)* – A standard (volume, module, or section of a module or standard) that has been approved by the Expert Committee and presented for comment.

1.4.10 *Due Process* – 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.

1.4.11 *Expert Committee* – A committee whose duties include the development and maintenance of consensus standards. The number and scope of Expert Committees is not limited and will be determined by the TNI Consensus Standards Development Executive Committee with the approval of the TNI Board of Directors. The Expert Committees are consensus bodies for TNI's ANSI standards development activities.

- 1.4.12 *Field Sampling Measurement Organization (FSMO)* – Organizations engaged in environmental sampling and field measurement activities.
- 1.4.13 *Laboratory* – 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.
- 1.4.14 *Laboratory Accreditation System Executive Committee (LASEC)* – 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. Activities include requesting, developing, and establishing policies and procedures, interpretations of standards, overseeing development of guidance documents and the creation of Implementation Guidance, and any related tools used to implement the NELAP Standard.
- 1.4.15 *National Environmental Field Activities Program (NEFAP)* – A core TNI Program whose purpose is to establish and implement a program for the accreditation of field sampling and measurement organizations.
- 1.4.16 *National Environmental Field Activities Program Executive Committee (NEFAPEC)* – The committee with balanced representation that is responsible for NEFAP.
- 1.4.17 *National Environmental Laboratory Accreditation Program (NELAP)* – A core TNI program that is implemented by governmental agencies recognized as NELAP ABs to accredit laboratories.
- 1.4.18 *NELAP Accreditation Council (NELAP AC)* – The body within TNI's NELAP program comprised of representatives of each NELAP AB and holding final authority for implementation of the program for the accreditation of environmental laboratories.
- 1.4.19 *Other* – TNI Stakeholder group representing all parties except accreditation bodies and laboratories. Examples include consultants, proficiency test providers, state and federal agencies that do not run accreditation programs, etc.
- 1.4.20 *Proficiency Testing Program Executive Committee (PTPEC)* – The committee responsible for the administration and maintenance of the TNI Proficiency Testing program and the Stationary Source Audit Sample program.
- 1.4.21 *Program Administrator (PA)* – TNI staff who provide administrative support to committees and serve at the direction of the Board of Directors and the Executive Director.
- 1.4.22 *Resolution* – The decision by an Expert Committee on how to respond to a comment provided as part of a request for comment or committee vote. The committee may determine to: a) find the comment non-persuasive and make no change, b) find the comment persuasive and make an appropriate change, or c) table the decision on the comment until the next revision cycle of the standard.
- 1.4.23 *Stakeholder Group* – The default stakeholder groups are defined as: Accreditation Bodies (group includes the National Environmental Laboratory Accreditation Program [NELAP]-recognized accreditation bodies, non-NELAP recognized accreditation bodies, the National Environmental Field Activities Program [NEFAP] accreditation bodies, and Proficiency Testing Provider Accreditors [PTPA]), Laboratories (group includes commercial laboratories, municipal laboratories, state laboratories, federal laboratories, field measurement organizations, and field sampling organizations), and Other (group can include federal agencies, regulated industries, and other stakeholder groups such as proficiency testing providers, vendors, contractors, and so forth).

- 1.4.24 *Standard Interpretation Request (SIR)* – The submission of a request for an interpretation of how a standard applies to a particular situation.
- 1.4.25 *Suitability* – 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.
- 1.4.26 *TNI Standard* – 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. While the TNI Standards are composed of volumes and modules, reference to the standard in this SOP may relate to a volume, a module or a section of a volume or module depending on the activities of the Expert Committee.

1.5 Maintenance of Procedures

These procedures are prepared, maintained, and revised by the TNI Consensus Standards Development Executive Committee and approved by the TNI Policy Committee and endorsed by the TNI Board of Directors (BoD). They shall be reviewed at least every five (5) years or more often, if necessary.

2.0 OPENNESS, LACK OF DOMINANCE, AND BALANCE

2.1 Openness

- 2.1.1 Participation in standards development activities shall 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 shall 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 shall 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.
- 2.1.2 Any standards adoption organizations are invited to participate in the open consensus process. This will generally be accomplished through the ANSI public comment process.

2.2 Lack of Dominance

- 2.2.1 The standards development process shall not be dominated by any single stakeholder group, individual, or organization.
- 2.2.2 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 6.0).

2.3 Balance

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

2.3.2 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 shall be presented to the CSDEC, and under its recommendation, be presented to the TNI Board of Directors for its approval.

3.0 CONDUCT OF COMMITTEE BUSINESS

3.1 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 meet to 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.

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. Minutes from these meetings will be 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.

3.2 Notification of Meetings

Public meetings and conferences, 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.

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). Changes to meeting schedules (day and/or time) are publicized on the TNI website with as much notice as is possible. Notices of Expert Committee meetings and/or any necessary modifications of the schedule are the responsibility of the Expert Committee's PA (or designee).

3.3 Decorum

All correspondence or comments, in whatever form, that are received by Expert Committees shall be handled in a non-discriminatory manner. All such correspondence or comments shall be addressed in an appropriate and timely manner by the Expert Committees and, when appropriate, responses are provided in writing to authors of said 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 shall also be completed with professionalism, decorum and in a non-discriminatory manner.

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

4.0 COMMITTEE OPERATIONS

Committee operations shall be in accordance with the latest revision of TNI "Procedures for Expert Committee Operation" (SOP 2-101). Of particular note to Standards Development are the following:

- Committee member requirements
- Committee application and membership management
- Terms of appointment
- Meeting attendance
- Balance and lack of dominance
- Balloting/Voting procedures
 - Voting on administrative matters of the committee (meeting minutes, agenda approvals, etc.) are defined in a Committee's Charter.
 - All matters regarding standards approval requires a two-thirds vote of all committee members.

5.0 STANDARD DEVELOPMENT

5.1 Expert Committee Activities

Expert Committees develop standards by in-person and virtual meetings. The Committee Members serve in a leadership role in standards development. All Expert Committee Members, Affiliates and Associate Committee Members are given the opportunity to provide comments at appropriate times during meetings in a managed process. Any TNI member or any member of the public may provide input or comment to a committee. Committees shall consider all comments and suggestions. The Expert Committees develop a TNI Standard by following the process shown in Appendix 1. 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 will be a modification of an existing TNI standard, the Expert Committees 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 any task group formed from the Expert Committee Members, Affiliates, and Associate Committee Members.

All TNI Members 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.

5.2 Notification – The First Step in the Development Process

The need to establish or modify a standard or part of a standard shall 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 BoD 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 2. 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 CSDEC, the NOI to establish or modify a standard is posted on the TNI website and the following groups/individuals, as applicable, are contacted with regard to the posting:

- interested parties who signed up for a standards activity listserve,
- individuals on an applicable email contact list,
- TNI committee chairs and the members of the NELAP Accreditation Council, 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 will initiate 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 will be 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 CSDEC PA manages the publication and receipt of comments regarding the NOI.

Public notice of committee efforts to establish or modify a TNI Standard will also be made to organizations representing the accredited laboratory community and to appropriate regulatory agencies. This public notice will be 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 will also initiate the transmittal to ANSI of the Project Initiation Notification System (PINS) form. The PINS form will be submitted by the CSDEC PA. The procedure described in *ANSI Essential Requirements*, Section 2.5, will be followed.

The PINS will be 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 will be addressed according to the procedures presented below in Section 5.4, 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 shall be held within ninety (90) days from the comment deadline. Such a deliberation shall be organized by TNI and the commenter and shall 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 will be 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 shall be conveyed to ANSI consistent with Clause 2.5.1.3 of *ANSI Essential Requirements*.

5.3 Summary and Draft Standard

At the close of the thirty (30) day period following the NOI, input, suggestions and comments will be reviewed by the Expert Committee including those, if any, resulting from the PINS announcement by ANSI. The Expert Committee will meet, as necessary and appropriate, 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 will then begin 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.

5.3.1 If the standard will be a revision of an existing TNI standard, the following records 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.

5.3.2 Deliberations within the committee are conducted until the committee has determined that the DS is ready to be presented to all stakeholders. The DS will be entered into compliance management software (such as PowerDMS), where possible and available to committee members. The vote of all committee members will be recorded, and the results of the vote will be archived.

5.3.3 All Expert Committee members are required to vote on the DS. Every opportunity to avail expert committee members of means to registering their vote shall be offered. The vote of

the entire committee however attained (such as through the compliance management software, in meeting participation or by e-mail ballot) is required to be recorded in meeting minutes and is appropriately 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.

5.3.4 The Expert Committee members shall cast votes as follows:

- Affirmative,
- Affirmative with comment,
- Negative with comment, or
- Abstain.

5.3.5 Any comments which upon Expert Committee review are deemed persuasive require that the DS be modified.

5.3.6 Any committee member who casts a negative vote on the DS must accompany said vote with written comments, preferably accompanied by proposed alternate language.

5.3.6.1 All Expert Committee members' comments during voting on the DS will be deliberated by the committee. During Committee deliberations, each Expert Committee member may clarify, explain and/or justify their position. The members may change their vote after said deliberation which will be appropriately recorded.

5.3.6.2 If a negative comment remains non-persuasive to the committee and unresolved to the committee member casting the negative vote, the resultant unresolved comment will be recirculated to the Expert Committee to provide them the opportunity to reaffirm or change their votes on the issue.

5.3.6.3 Any unresolved negative votes will be documented in writing and the individual(s) who remain as an unresolved negative vote has the right of appeal consistent with established TNI-procedures as outlined in Section 6.0 below.

5.3.7 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 CSDEC PA will complete and file the appropriate form (BSR-8) with ANSI. Any comments received as a result of the announcement of the BSR-8 in the ANSI weekly newsletter will be appropriately considered as outlined below.

5.3.8 After voting to approve the DS, the Committee shall provide a summary of changes and a justification for those changes (an example form is provided in Appendix 2). The justification should state the reason for each change and provide any additional comments the Expert Committee thinks are pertinent. The DS and the summary are then posted on the TNI website for stakeholder comment and the following groups/individuals, as applicable, are contacted with regard to the posting:

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

5.3.9 The comment period for the DS is ninety (90) days from the website posting. An Executive Committee or the NELAP Accreditation Council may petition CSDEC 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 below. Electronic submission of comments (i.e., email) is the preferred form of comment provision to the committee. The Expert Committee will attempt to capture verbal comments made during

any open meeting, webinar, or in any other setting. The Expert Committee may add such verbal comments to the Response to Comment form. If this occurs, those comments will be listed as Expert Committee comments. If a commenter wants a comment addressed, or if the commenter wants a direct response about how the comment was handled, the comment must be submitted in writing (i.e., via email or some hard copy format).

5.4 Response to Comments

All written comments received during the DS comment period from any source will be logged onto the Response to Comment form (Appendix 3).

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

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

Following committee discussion, comments shall be ruled persuasive or non-persuasive by a majority vote of the Expert Committee.

The Response to Comments form will be 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 will be used as the permanent record for each phase of the standard development process. After completion by the Expert Committee, the Response to Comments form will be posted on the TNI website as well as being retained in TNI's permanent records and the following groups/individuals, as applicable, are contacted regarding the posting:

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

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 will again be posted on the TNI website and above groups/individuals will be contacted, as applicable.

- 5.4.2 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;
- The comment would propose something that could not be handled properly within the time frame for processing the changes.

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 must be informed, in writing, of the reasons the comment has been placed on hold. If a commenter does not respond to the committee notification, the comment in question will not be 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 Comment form.

- 5.4.3 Any persuasive comment requires the Expert Committee to modify the standard.
- 5.4.4 The disposition of all written comments shall be communicated in writing to each respective commenter. Communication will include the reasons for the committee's decision regarding the comment .
 - 5.4.4.1 Those who receive notification of the disposition of comments are not required to respond to the Committee.
 - 5.4.4.2 The Committee will present the author(s) of non-persuasive comment(s) with the opportunity to expand, explain and/or justify their position.
 - 5.4.4.3 Following the commenter's presentation of their position, the comment will be recirculated to the committee members to affirm or change their vote on the issue.
 - 5.4.4.4 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 6.0 below
- 5.4.5 If any comments were ruled persuasive, the DS becomes a revised Draft Standard. If the DS passes without any persuasive comments, the DS becomes final (proceed to Section 5.5.5).

5.5 Draft Standard Revisions

- 5.5.1 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 Sections 5.3.1 and 5.3.2. This version should highlight the changes made to the Standard whenever possible.
- 5.5.2 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 shall be completed as described above.
- 5.5.3 If additional persuasive comments are received during this phase of standard development, a second revised DS will be produced by the Expert Committee. Each revision of the DS will be identified with a sequential integer and the date (for example DS Rev.# date) and the entire process will be repeated until such time as no additional persuasive comments are received.
- 5.5.4 The committee's response to all comments will be addressed as described in Section 5.4. Comments that have been previously ruled upon by the Expert Committee will not be re-considered at this stage without the inclusion of new evidence or a new line of reasoning.
- 5.5.5 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 procedures in Section 5.4.1 are followed for posting and notification.
- 5.5.6 A period of at least thirty (30) days shall follow the two-thirds affirmative vote of the Expert Committee. This will allow anyone to review the Response to Comments for previously undetected issues of enforceability, for errors made in the review process, or for items that commenters thought had been resolved in a different manner. If no comments/feedback are received after thirty (30) days, the process is complete. If changes to the standard are necessary, the process returns to Section 5.5.1.

- 5.5.7 When the final opportunity for review of comments and submission of appeals requires no further action, then the development of the standard is considered complete, and the standard is made available for distribution in final form. This will be 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 CSDEC PA will complete and submit the appropriate ANSI form (BSR-9) for consideration as an ANS, as appropriate.

5.6 TNI Standard

- 5.6.1 The TNI Standard is made available for purchase to all interested parties, including standards-adoption organizations.
- 5.6.2 Upon acceptance by ANSI, the TNI Standard will be recognized as an American National Standard and all publications of the standard shall contain the ANSI ANS logo.
- 5.6.3 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 must be 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.
- 5.6.4 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 must be posted on the TNI website and immediate notification must be made to ANSI.
- 5.6.5 Approved standards must be 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 shall be accompanied by no non-editorial changes to the text of the standard. Any non-editorial changes in the standard require processing as a revision and must follow the previous process requirement 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 must be accomplished by an individual recorded tally of all members of the relevant Expert Committee.

Reaffirmations will also be provided via the TNI website for additional public comment. Any comments received on the reaffirmation will be considered by the Expert Committee and may require re-processing the standard as a revision and must follow the previously described procedures.

6.0 APPEALS

6.1 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, shall have the right to appeal. Commenters shall be 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 5.5.6) on the TNI website. The burden of proof to show adverse effect shall be on the appellant.

- 6.1.1 The appeal shall 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 shall be noted.

- 6.1.2 Within seven (7) days of receiving an appeal, the Executive Director will notify and provide a copy of the appeal to the Chair of the TNI Board of Directors and the Chair of the CSDEC.
- 6.1.3 If an appeal is filed, the Standard does not become final until the appeal process is resolved.

6.2 Response

Within sixty (60) days after receipt of the appeal, the Chair of the CSDEC shall prepare a written response. The Chair of the CSDEC may solicit other individuals with specific knowledge of the matter in question to assist with the response. The CSDEC Chair shall forward the response to the TNI Executive Director for review. An approved response shall be submitted to the appellant. The response will specifically address each allegation of fact in the appeal to the extent of the respondent's knowledge.

6.3 Hearing

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

6.4 Appeals Panel

An appeals panel is created that shall consist 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 will not be materially or directly affected by any decision made or to be made in the dispute. The TNI Executive Director shall, with input from the appellant, develop a list of five (5) potential appointees for the appeals panel within fifteen (15) days, and the appellant shall select three (3) of those names. This list of three (3) names shall then be submitted to the TNI Executive Committee, which shall appoint 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 shall be referred to the TNI Board of Directors, which shall appoint members of the appeals panel.

6.5 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 CSDEC 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* shall apply to questions of parliamentary procedure for the hearing not covered herein. The appeals hearing proceedings shall be documented and maintained in TNI's Content Management System.

6.6 Decision

The appeals panel shall provide 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 shall be final, subject to agreement of the TNI Board of Directors. In the event that the BoD does

not agree with the decision, it will be 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 the above procedures. If any appeal is denied, then the Standard becomes final.

7.0 PUBLICATIONS

Any TNI Standard shall be released for publication only through TNI.

8.0 RECORDS

Records shall be 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/ballots on standards; persuasive and non-persuasive comments, including comments from committee members; Expert Committee response to comments; draft standards and final approved standards. Minutes of all Expert Committee meetings shall be documented and made available on the TNI website.

9.0 STANDARD INTERPRETATION POLICY

Interpretation of any part of any standard shall be 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.

For the Environmental Laboratory Sector, the website routes the request to the NELAP PA who then seeks the opinions of the Chairs of the NELAP Accreditation Council (AC) and the LASEC to determine whether it is a valid Standards Interpretation Request (SIR). If valid, the SIR is transmitted to the appropriate Expert Committee to respond to the interpretation request. Timelines are defined to ensure a timely response to the question. The LASEC SIR Subcommittee reviews the Expert Committee's response for completeness and it is posted for approval vote by the NELAP AC. Because NELAP Accreditation Bodies are governmental organizations, their pre-acceptance of an interpretation response is essential to ensure that the Standard can be enforced legally. If anything in the interpretation contradicts state laws or regulations, a NELAP AB has the responsibility to veto that interpretation, just as it could veto the Standard as conflicting with state laws and regulations. A final response is provided to the inquirer and a copy of the request and response is posted on the TNI website. SOP 3-105 provides the specific approach developed for addressing these interpretation requests regarding NELAP.

For the Field Sampling and Measurement Organization sector, the SIR request is electronically submitted, and a confirmation receipt is sent to the inquirer. The request is automatically emailed to the National Environmental Field Activities Program (NEFAP) Executive Committee Chair and the NEFAP PA for review. A consensus of these two (2) individuals determines whether the Executive Committee or Expert Committee will oversee the response to the question. Timelines are defined to ensure a timely response to the question. All final responses are sent to the NEFAP Executive Committee for agreement and confirmation that the ABs have implemented or will implement the Standard as described in the interpretation. A final response is provided to the inquirer and a copy of the request and response is posted on the TNI website. SOP 5-106 provides the specific approach developed for addressing these interpretation requests regarding NEFAP.

10.0 PATENT POLICY

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

11.0 ANTITRUST POLICY

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

12.0 COMMERCIAL TERMS AND CONDITIONS

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

13.0 METRIC POLICY

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

14.0 REFERENCES

- SOP 3-105 LASEC Standard Interpretation
- SOP 5-106 NEFAP Standard Interpretation
- *ANSI Essential Requirements: Due process requirements for American National Standards*; referred to throughout as *ANSI Essential Requirements*
- *ANSI Standards Action*

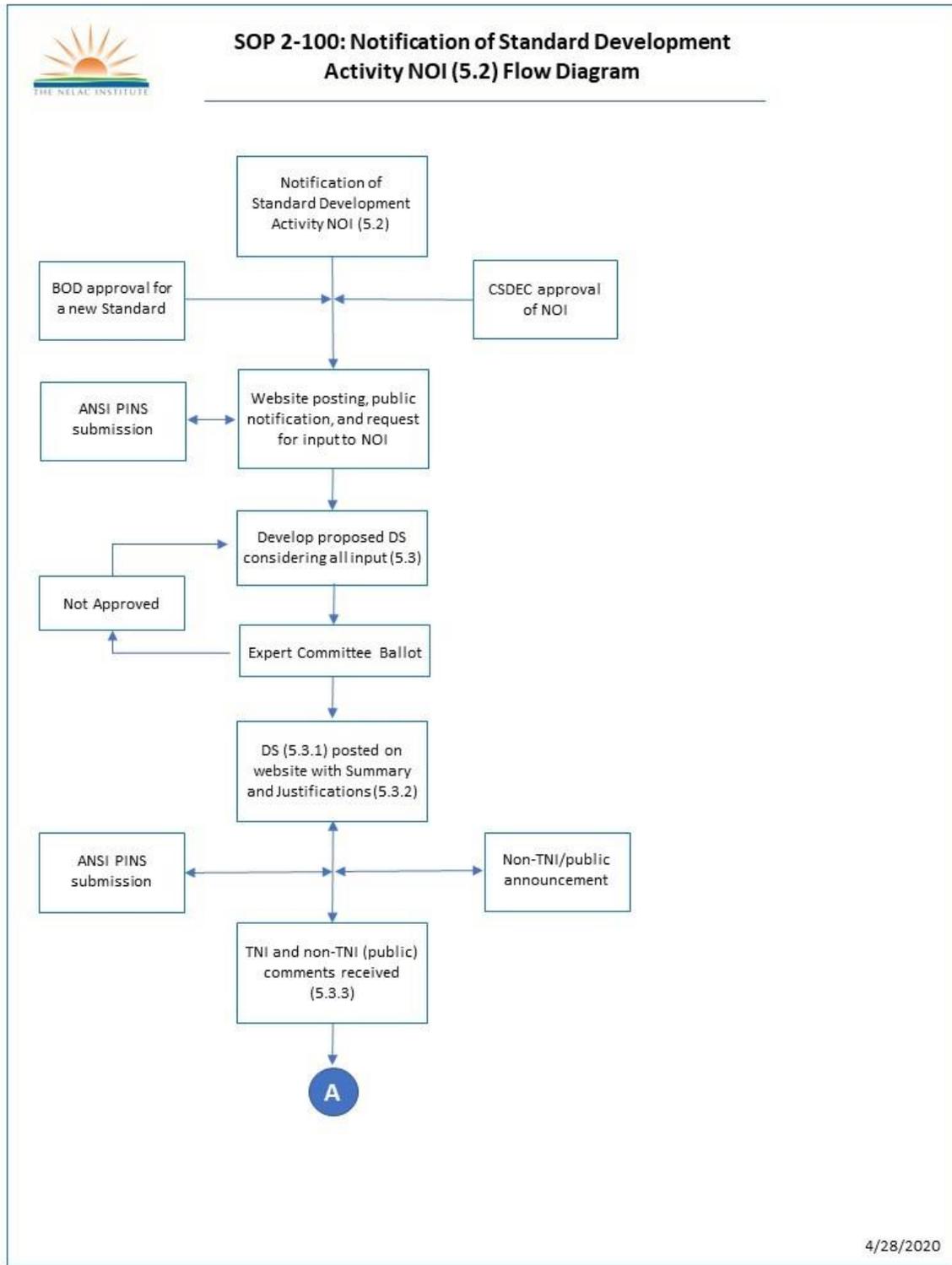
15.0 SOP APPROVED CHANGES

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.
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

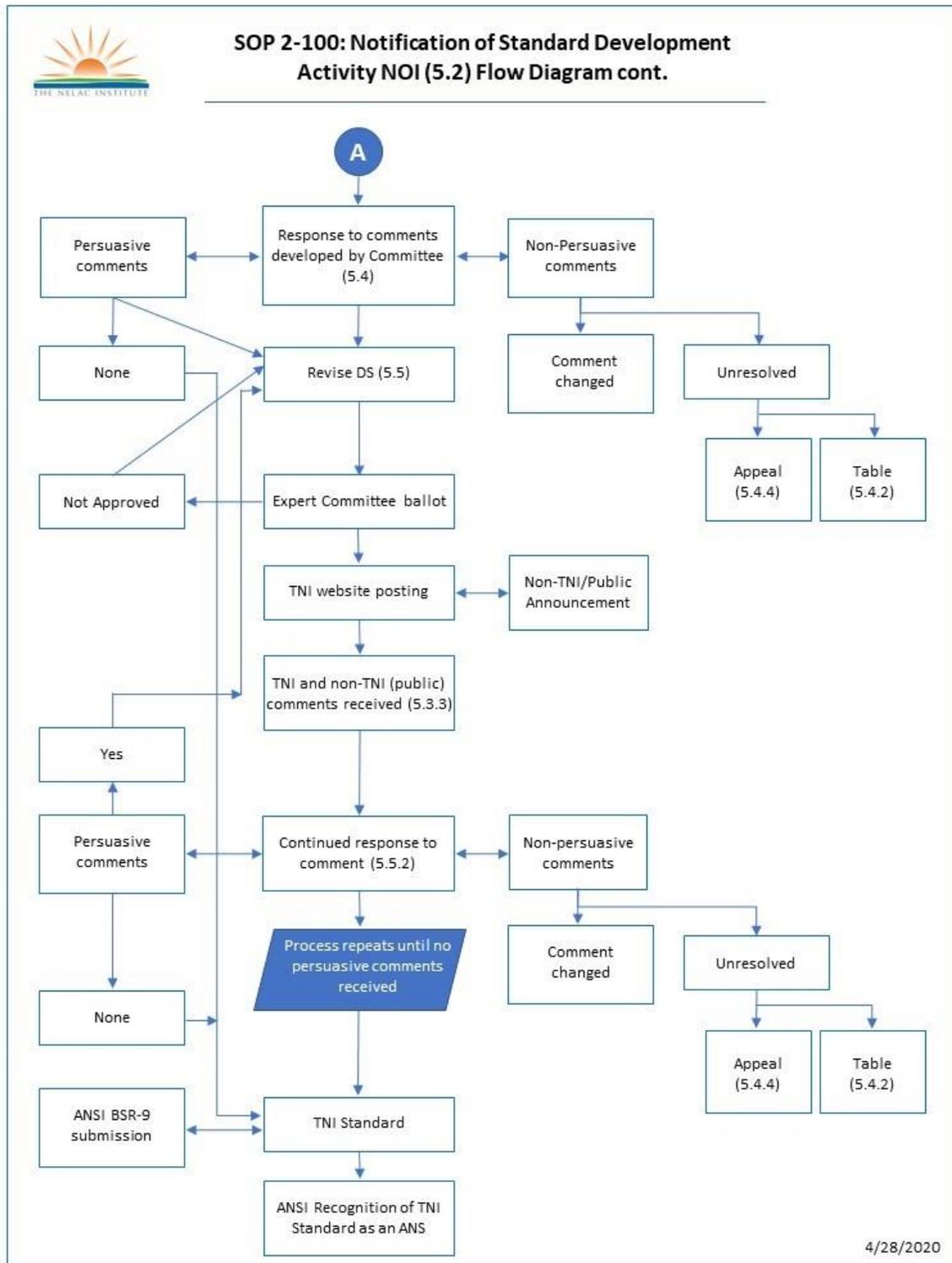
Procedures Governing Standards Development

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>
-----	-----------	--

Appendix 1. Standards Development Process



Appendix 1. Standards Development Process (cont.)



**Appendix 2. Notice of Intent Form
Notice of Intent to Establish or Modify a TNI Standard**

Expert Committee:		Proposal Date:		CSDPEC Approval Date:	
-------------------	--	----------------	--	-----------------------	--

TNI Volume/Module	Section(s)

Potentially impacted stakeholders/stakeholder groups:

Nature of the standard to be established or complete Attachment 1 if change to existing standard:

If a new standard, justification or need for the 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. Notice of Intent Form cont.

**Notice of Intent Attachment 1
 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.

Procedures Governing Standards Development

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!