



SOP TITLE:	Procedures Governing Standards Development
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1.0 GENERAL

1.1 Purpose

These procedures provide a set of rules to ensure the development of consensus standards in accordance with rigorous democratic procedures and the requirements of the federal Office of Management and Budget (OMB) Circular A-119.

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

Rules concerning the establishment and operations of Expert Committees are provided as well as criteria for ensuring a balance of interests. The procedures also stipulate voting procedures and provide detailed requirements for the consideration of all negative votes. The procedures cover the following topics:

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

1.3 Definitions

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

1.3.1 *Affiliate* — A person with special knowledge as a technically qualified individual and who is not a TNI member. An Affiliate may apply to be on a committee and is eligible to fully participate as a Committee Member, with all rights and privileges, including voting. Affiliates shall be re-approved on an annual basis.

1.3.2 *Expert Committee Member*

Committee Member — a member of an Expert Committee, who participates in the committee's activities and who is assigned an official vote on the Draft Standard according to the principle of balance. The Committee Members constitute the Expert Committee consensus body.

Associate Committee Member — a member of TNI, who may participate in an Expert Committee's activities.

1.3.3 *Consensus* — the judgment arrived at through the balloting and review procedures of these procedures, indicating general but not necessarily universal agreement.

1.3.4 *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.

- 1.3.5 *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 Board. See Section 4.
- 1.3.6 *Laboratory* — for purposes of this policy, an organization that collects samples or a fixed-base, mobile, or field-testing facility for the chemical, and/or physical, and/or bacteriological testing of samples.
- 1.3.7 *Resolution* — the decision by an Expert Committee on how to respond to a comment provided as part of a vote. The committee may determine to rule the comment non-persuasive and make no change, to find the comment persuasive and make an appropriate change, or to table the decision on the comment until the next revision cycle of the standard.
- 1.3.8 *Standard*
- Standard* — a document that has been developed and established within the consensus principles of TNI and that meets the approval requirements of TNI procedures, specifically:
- Working Draft Standard* — a standard that has been released in draft form by the Expert Committee for public discussion and input from the membership.
- Voting Draft Standard* — a standard resulting from modifications made to the Working Draft Standard, as a result of input received, and presented for voting.
- TNI Standard* — a standard that has been approved by the Expert Committee Consensus Body.
- 1.3.9 *Tentative Interim Amendment* — an amendment to a standard resulting from an emergency need, and remaining in effect for a maximum of two (2) years from the date of its adoption.
- 1.3.10 *TNI Member* — an individual that subscribes to the purposes of TNI, pays the required administrative fee, and has an official vote on the standard.

1.4 Principles

Procedures for the development and adoption of voluntary consensus standards shall be in accordance with the following principles.

- 1.4.1 Timely notice of a proposed standard undertaking.
- 1.4.2 Opportunity for interested parties to participate in the deliberations, discussions, and decisions concerning both procedural and substantive matters affecting the proposed standard.
- 1.4.3 Maintenance of records of discussions, decisions, and technical data accumulated in standard development; and records of drafts of proposed standards, proposed amendments, action on amendments, and final promulgation of the standard.
- 1.4.4 Timely publication and distribution of minutes of meetings of Expert Committees.
- 1.4.5 Adequate notice of proposed actions.
- 1.4.6 Distribution of ballots to those eligible to vote.
- 1.4.7 Timely and full reports on results of balloting.
- 1.4.8 Careful attention to minority opinions throughout the process.

1.4.9 All standards development activities take place within the context of these procedures. All communications between TNI and affected stakeholders or standards adoption organizations regarding decisions on standards development issues shall be subject to the records requirements of Section 9.

1.4.10 All TNI standards will, where appropriate, conform to ANSI's Commercial Terms and Conditions Policy

1.5 Maintenance of Procedures

These procedures are prepared, maintained, and revised by the TNI Consensus Standards Development Board.

2.0 OPENNESS, LACK OF DOMINANCE, AND BALANCE

2.1 Openness

Participation shall be open to all TNI members and to all members of the public who are directly and materially affected by TNI's standards development activities. Voting membership 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.

2.2 Lack of Dominance

2.2.1 The standards development process shall not be dominated by any single interest category, individual, or organization. Dominance means a position of 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.

2.2.2 Unless it is claimed in writing to the Chair of the TNI Board of Directors by any directly or materially affected party, that a single interest category, individual, or organization dominated the standards development process, no test for dominance is required.

2.3 Balance

2.3.1 The standards development process should have a balance of interests. Participants from diverse interest categories shall be sought with the objective of achieving balance. There shall be a minimum of three interest categories for any Expert Committee.

2.3.2 The criteria for balance are that no single interest category constitutes a majority of committee members on any Expert Committee. The suggested interest categories are:

- accreditation bodies and other governmental agencies that operate accreditation programs (federal or state);
- laboratories and other organizations directly involved in providing sampling and measurements
- all others (consultants, proficiency test providers, state and federal agencies that do not run accreditation programs, etc.).

The interest categories appropriate to the development of consensus in any given TNI standards activity are a function of the nature of the standards being developed. Expert Committees may determine that additional or different interest categories are appropriate for the Expert Committee's scope of activity. Changes in the suggested interest category designations shall be

documented in the Expert Committee charter and shall be approved by a majority of the Consensus Standards Development Board.

- 2.3.3 Standards adoption organizations are expected to participate in the open consensus process if seeking to develop a standard or seek changes to an existing standard.

3.0 CONDUCT OF COMMITTEE BUSINESS

3.1 Meetings

Generally there shall be two (2) meetings per year (a summer meeting and a winter meeting) where the Expert Committees shall meet to present a proposed standard or amendments to a standard for discussion and debate by the TNI membership, and to receive input for further development of a standard. Any member of the public may register for and attend these meetings. Working meetings of Expert Committees, held face-to-face or via conference calls, will be open to any TNI member or Affiliate who has joined the Expert Committee as a committee member, to any TNI member who chooses to participate in the role of Associate Committee Member, or to any member of the public who requests to be included. Minutes from these meetings will be published on the TNI website. All official votes of Expert Committees require a minimum of two thirds of committee members voting. It is permissible to hold closed meetings only when discussing personnel or other sensitive issues. Issues relating to standards development may not be discussed in closed meetings.

3.2 Notification

Notification of proposed standards activity shall be announced on the TNI website to demonstrate the opportunity for participation by all directly and materially affected persons. This notification shall include: (a) an explanation of the need for the standard; and (b) identification of the stakeholders (e.g., laboratories, engineering firms, PT providers, etc.) likely to be directly impacted by the standard.

If TNI receives written comments within thirty (30) days from the publication date of the announcement, and said comments assert that a proposed standard duplicates or conflicts with an existing consensus standard developed by another recognized organization, TNI will discuss the proposed effort with representatives from the relevant stakeholder groups before TNI will initiate any development work. 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. If another voluntary consensus standards body is in the process of developing or adopting a voluntary consensus standard that would likely be lawful and practical for TNI to use, and would likely be developed or adopted on a timely basis, TNI should not be developing its own unique standard and instead should be participating in the activities of the voluntary consensus standards body. The outcome of such a deliberation shall be conveyed in writing by the TNI Consensus Standards Development Board and commenter (ideally as a joint submission) to the TNI Board of Directors for final resolution.

4.0 COMMITTEE OPERATIONS

Committee operations shall be in accordance with the TNI "Procedures for Committee Operation".

5.0 STANDARD DEVELOPMENT

5.1 Expert Committee Activities

Expert Committees develop standards by telephone conference and/or face-to-face meetings, as appropriate. The Committee Members serve in a leadership role in standards development. All Committee Members, Affiliates and Associate Committee Members will be 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 written input to a committee. Committees will consider all written comments and suggestions and will notify the correspondents of the disposition of their comments. At the initiation of a project to develop or revise a standard, notification of such activity will be announced on the TNI website, to allow for participation by all directly and materially affected persons. Notification of a project to develop or revise a standard as an American National Standard is also transmitted to ANSI using the Project Initiation Notification System (PINS) form, or its equivalent. The procedure described in *ANSI Essential Requirements: Due process requirements for American National Standards*, Section 2.4, is followed. Proposals for new American National Standards and proposals to revise, reaffirm, or withdraw approval of existing American National Standards shall be transmitted to ANSI using the BSR-8 form in order to provide an opportunity for public comment. The comment period shall be a minimum of forty-five (45) days.

The process and schedule for development of a standard is shown in the flowcharts and associated estimated timeline tables included in Appendix I.

5.2 Working Draft Standard

- 5.2.1 During the approximately six-month period preceding a TNI semi-annual meeting, the Expert Committees develop modules of a working draft standard. The Committee Chair may delegate the standard-writing process to the Committee Members or to any task group formed from the Committee Members, Affiliates and Associate Committee Members. All Committee Members, Affiliates and Associate Committee Members are afforded the opportunity to contribute to the standard-development process.
- 5.2.2 An official vote of the Committee Members, with at least two-thirds of the members in concurrence, is required for release of the working draft standard by an Expert Committee for publication. The working draft standard is published at least thirty (30) days prior to the TNI semi-annual meeting at which it will be discussed.
- 5.2.3 The working draft standard is discussed publicly at the TNI semi-annual meeting. At this time, any TNI member or any member of the public may propose changes from the floor for consideration by an Expert Committee, and may also submit to the committee written comments within fifteen (15) days following the meeting.

5.3 Voting Draft Standard

- 5.3.1 Within ninety (90) days following the close of the above comment period after the TNI semi-annual meeting, an Expert Committee may modify the working draft standard from consideration of the comments received during the public debate and those received within the fifteen (15) day timeframe following the TNI semi-annual meeting. The Committee Members vote to accept the modified working draft standard. A two-thirds favorable majority vote of the Committee Members is required for passage. The working draft standard then becomes the TNI Voting Draft Standard.
- 5.3.2 All Committee Members, Affiliates and Associate Committee Members may vote on their committee's modules of the Voting Draft Standard. Each Committee Member, Affiliate and Associate Committee Member has one vote. All voting is conducted by electronic ballot.
- 5.3.3 At least fifteen (15) days prior to voting, the Voting Draft Standard is published, together with an electronic ballot form. TNI shall indicate conspicuously on the ballot that negative votes should be accompanied by written comments related to the proposal and that negative votes unaccompanied by such written comments will be recorded as "negative without comments" without further notice to the voter. Such ballots, however, will not be counted as either negative or positive. TNI is not required to solicit any comments from the negative voter.

5.3.4 At least fifteen (15) days after publication of the Voting Draft Standard, the voting period for ballots shall begin. The voting period shall last for thirty (30) days. Early voting will be permitted; i.e., all votes cast from the date of publication of the electronic ballot form up to forty-five (45) days after the date of its publication will be accepted. Each Committee Member, Affiliate and Associate Committee Member will vote on one of the following positions:

- Affirmative
- Affirmative with comment
- Negative with comment
- Abstain

5.3.5 A negative vote may be withdrawn at any time by written electronic submission to TNI. The voter shall instruct TNI if the withdrawn negative is to be changed to an affirmative vote or to an abstention.

5.3.6 In order for the Voting Draft Standard to pass, an affirmative vote of at least two-thirds of the Committee Members is required, and all written comments accompanying votes cast by Committee Members, Affiliates and Associate Committee Members must be considered and brought to resolution as described below (Sections 5.3.7, 5.3.8 and 5.3.9). Ballot items returned as negative without comment shall be recorded as negative without comment. Ballot items returned unmarked shall be considered as unreturned ballots.

5.3.7 All written comments accompanying negative or affirmative votes cast by Committee Members, Affiliates and Associate Committee Members shall be recorded and considered publicly during the next TNI semi-annual meeting. Each Expert Committee will meet in separate session to consider those comments received on its modules of the standard. These meetings will be open to the public. Following its discussion, each written comment shall be ruled persuasive or non-persuasive by a simple two-thirds vote of the Committee Members present. No written comment shall be dismissed because it does not provide alternative language or a specific remedy to the negative vote. The committee may, subject to the restrictions in 5.3.8, prioritize the comments and may place any comments on hold until the next revision cycle of the standard, if the comments are too numerous to be dealt with in the time-frame available until the TNI Standard is published. 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.

5.3.8 An Expert Committee may prioritize the comments received and may place a comment on hold until the next revision cycle of the standard if all of the following conditions are met:

- The comment would introduce a concept that had not been subject to public review by being included in a related proposal as published in the Voting Draft Standard.
- The comment would change the text proposed by the Expert Committee to the point that the Expert Committee would have to restudy the text of the Voting Draft Standard
- The comment would propose something that could not be handled properly within the time frame for processing the changes.

In making the determination 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 issues raised; and whether sufficient debate and public review have taken place. The negative commenter must be informed, in writing, of the reasons the comment has been placed on hold.

5.3.9 A persuasive negative vote or an objection received from a member of the public will require the Expert Committee to consider whether modification of the Voting Draft Standard is appropriate. The committee may modify the standard, if such modification will lead to removal of the cause for

the negative vote. The modified standard must then be made available through publication on the TNI website, together with a Response to Comments document summarizing all persuasive and non-persuasive votes and their resolution, and any objections received from the public and their resolution, for all Committee Members, Affiliates, Associate Committee Members and the public to review. Within fifteen (15) days of this publication, any Committee Member may change his or her vote, providing written electronic notice to TNI. The vote is then re-tallied and, in order to pass, requires an affirmative vote of at least two-thirds of the combined affirmative and negative votes cast by Committee Members. Within fifteen (15) days the tally from the vote on the Voting Draft Standard is published as: number of affirmative votes; number of persuasive negative votes; number of non-persuasive negative votes; number of negative votes without comment; and number of abstentions.

5.4 TNI Standard

- 5.4.1 If the Voting Draft Standard passes, it becomes the TNI Standard. If any module fails, it is returned to the Expert Committee for processing during the next revision cycle. All individuals who provided votes or who submitted public review comments that were ruled non-persuasive will be so notified and will be informed of their right to appeal. Any appeals registered with TNI must be considered in accordance with Section 6 of this Policy.
- 5.4.1 The TNI Standard is made available to all interested parties, including standards-adoption organizations.
- 5.4.2 If any appeal is upheld by the appeals panel, the affected module or section of the TNI Standard is withdrawn by the Expert Committee that developed that module or section for processing during the next revision cycle.

5.5 Tentative Interim Amendments

- 5.5.1 A module or section of a standard shall not be amended more than once annually except where an amendment is duly processed as a Tentative Interim Amendment. A Tentative Interim Amendment may be processed if the TNI Consensus Standards Development Board determines, after a preliminary review and consultation with the appropriate Expert Committee Chair, that the amendment appears to be of an emergency nature requiring prompt action, and has the endorsement of a Committee Member of the involved committee. It is expected that the Tentative Interim Amendment process will be used infrequently and only in cases where the amendment is expected to be non-controversial.
- 5.5.2 Determination of an emergency nature shall include, but not be limited to, one or more of the following factors:
- a. the standard contains an error or an omission that was overlooked during the regular standard development or revision process;
 - b. the standard contains a conflict with other language;
 - c. the proposed amendment intends to respond to a new Federal regulation or other development; and/or
 - d. the proposed amendment intends to correct a circumstance that has resulted in an adverse impact.
- 5.5.3 Any TNI member or member of the public may submit a proposal for a Tentative Interim Amendment to the Chair of the Consensus Standards Development Board.

The proposal for a Tentative Interim Amendment must describe:

- a. the section(s) of the standard that should be amended;
- b. the rationale for the Tentative Interim Amendment;

- c. the factor(s) that would determine whether the amendment qualifies as a Tentative Interim Amendment;
 - d. the proposed change to the standard, including suggested wording.
- 5.5.4 The Consensus Standards Development Board, in consultation with the Expert Committee responsible for the module or volume of the standard for which the Tentative Interim Amendment is proposed, shall determine whether it is of an emergency nature as defined in Section 5.5.2.
- 5.5.5 If the Consensus Standards Development Board determines that the proposed Tentative Interim Amendment meets the requirements of Section 5.5.2, and if it has the endorsement of at least one Committee Member of the relevant Expert Committee, the proposed Tentative Interim Amendment shall be published together with a notice that any person interested may comment to the Consensus Standards Development Board within fifteen (15) days.
- 5.5.6 After the public comment period is closed, the merits of the proposed Tentative Interim Amendment, and any public comments received, shall be considered by the relevant Expert Committee Members, who shall make any revisions and finalize the amendment. Approval of the Tentative Interim Amendment shall be established if three-fourths of the Expert Committee Members have voted in favor.
- All public comments, tally of the ballot, and the final version of the Tentative Interim Amendment shall be presented in a report to the Consensus Standards Development Board and the TNI Board of Directors. The report shall be published on the TNI website.
- 5.5.7 Tentative Interim Amendments shall become effective twenty (20) days after approval by the Expert Committee Members unless the Chair of the TNI Board of Directors determines, within his/her discretion, that the effective date shall be delayed pending the consideration of an appeal.
- 5.5.8 The following text shall be included in the preface of the TNI Standard:
- “Section x.xx of this document has been processed in accordance with the TNI requirement for a Tentative Interim Amendment. The same or similar amendment will undergo the consensus standards development process within the time-frame specified in SOP 2-100.”
- 5.5.9 A Tentative Interim Amendment may remain in effect for a maximum of two (2) years from the date of its adoption. Within this time period, the section or subsection of the standard that incorporates the Tentative Interim Amendment will be re-introduced as a Voting Draft Standard which will proceed through the normal standards development and voting process.

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. Negative voters shall be notified of the disposition of their negative votes and their right to appeal. The burden of proof to show adverse effect shall be on the appellant.

In connection with an objection articulated during a public comment period, or submitted with a vote, an effort to resolve all expressed objections accompanied by comments related to the proposal under consideration shall be made, and each objector shall be advised in writing (including electronic communications) of the disposition of the objection and the reasons thereof. If resolution is not achieved, each objector shall be informed in writing that an appeals process exists.

6.2 Complaint

Any negative voter, whose negative comment has been found non-persuasive by the vote of the Expert Committee on the Voting Draft Standard may appeal the decision in writing. Also, any member of the public who has submitted an objection on the Voting Draft Standard that has been found non-persuasive by the vote of the Expert Committee on the Voting Draft Standard may appeal the decision in writing. The appellant shall file a written complaint with the Executive Director of TNI within thirty (30) days after the date of publication of the result of the vote on the Voting Draft Standard. Written appeals associated with any other aspect of the standard development process may be filed with the Executive Director of TNI following notification of action or at any time with respect to inaction. The complaint 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. Within seven (7) days of receiving the complaint, the Executive Director will notify and provide a copy of the complaint to the Chair of the TNI Board of Directors and the Chair of the Expert Committee against which the complaint is made.

6.3 Response

Within thirty (30) days after receipt of the complaint, the Executive Director shall prepare a written response that meets the approval of the Board of Directors and the Chair of the affected Expert Committee and will submit the response to the appellant. The response will specifically address each allegation of fact in the complaint to the extent of the respondent's knowledge. The Executive Director may solicit other individuals with specific knowledge of the matter in question to assist with the response.

6.4 Hearing

If the appellant and TNI are unable to resolve the written complaint informally 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.

6.5 Appeals Panel

The appeals panel shall consist of three (3) individuals who are knowledgeable of laboratory accreditation 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 appeal 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 Executive Committee, which shall appoint members of the appeals panel.

6.6 Conduct of the Hearing

The appellant has the burden of demonstrating adverse effects, improper actions or inactions, and the efficacy of the requested remedial action. The respondent has the burden of demonstrating that TNI and the Executive Director took all actions in compliance with these procedures and that the requested remedial action would be ineffective or detrimental. Each party may adduce other pertinent arguments, 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.

6.7 Decision

The appeals panel shall provide a determination to the TNI Board of Directors in writing within thirty (30) days, 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 and shall be endorsed by the TNI Board of Directors.

7.0 DISPOSITION OF APPROVED AND REJECTED STANDARDS

Standards that pass the TNI voting process may be submitted to standards-adoption organizations for consideration. Failed standards may be withdrawn by the committee, or may be reconsidered during the following development cycle. Approved standards must be considered for revision by the appropriate Expert Committee at least once every five (5) years.

8.0 PUBLICATIONS

Any TNI Standard shall be released for publication only through TNI. The standard developed by TNI will be freely available in electronic format, without copyright restriction, to any organization interested in adopting such standards.

9.0 RECORDS

Records shall be prepared and maintained to provide evidence of compliance with these procedures. Records include, but are not limited to, minutes of Expert Committee meetings; summaries of membership votes on standards; persuasive and non-persuasive negative votes, including comments from committee members; Expert Committee response to persuasive negative comments; and final approved standards. Minutes of all Expert Committee meetings shall be recorded and made available on the TNI website.

Records may be in hard copy or electronic format. The Executive Director shall establish written standardized procedures that address the format and storage of records, person(s) responsible for maintaining the records, and records retention and disposal schedules. The procedures shall be approved by the Board of Directors. All records, including those relating to the approval, revision, or reaffirmation of a standard shall be retained for a minimum of five (5) years or one complete standards cycle, whichever is longer. All records related to the withdrawal of a standard shall be retained for five years from the date of withdrawal.

10.0 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. The Executive Director, in consultation with the Board of Directors, shall route the request to an Expert Committee Chair, the Board of Directors, or other person who can appropriately provide the interpretation. On completion of the section of the form providing the interpretation, the form is returned to the Board

of Directors. If no objections are expressed within thirty (30) days by the Board of Directors, the completed form is returned to the person(s) requesting the interpretation.

11.0 PATENTS IN STANDARDS

When a standard requires a material, product, process, or apparatus or constituent thereof, covered by a patent or a pending patent, the Expert Committee shall make efforts to determine whether alternatives to the patented item exist:

- The Expert Committee shall include with the ballot on the standard a statement of willingness to consider alternatives to patented items.
- The standard shall include a footnote requesting interested parties to submit information regarding the identification of alternatives to the patented items.

If the Expert Committee determines by ballot that an alternative is equivalent, the reference to the patented item, by name and number, shall be deleted.

Neither TNI nor any TNI committee shall be responsible for identifying all patents under which a license is required in using a TNI document or for conducting inquiries into the legal validity of those patents which are brought to the Institute's attention. Where applicable, a TNI document shall include a note worded as follows:

"The NELAC Institute takes no position respecting the validity of any patent rights asserted in connection with any item mentioned in this standard. Users of this standard are expressly advised that determination of the validity of any such patent rights, and the risk of infringement of such rights, are entirely their own responsibility."

TNI standards submitted to ANSI for approval as American National Standards shall conform to the ANSI patent policy. The ANSI patent policy may be obtained on the ANSI website.

12.0 METRIC POLICY

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

13.0 SOP Approved Changes

New SOP No.	Effective Date	Description of Change
2-100	3/15/2008	Original SOP approved
2-100 Rev 1	January 2010	TIA language added to 5.5.9
2-100 Rev 1.1	3/15/2010	Reformat to style guide, added section 13
2-100	3/15/2008	Original SOP

APPENDIX I
STANDARD DEVELOPMENT PROCESS AND TIMELINES
STANDARD VOTING PROCESS (A)

Time Line (# Days)	Standard Voting Process Steps
0	1. A working group of Expert Committee (EC) develops the Working Draft Standard (WDS) EC review and consideration.
150	2. WDS is published on TNI website.
180	3. Expert Committee presents and discusses WDS at TNI semi-annual meeting.
195	4. Expert Committee receives written comments on WDS, presented at TNI semi-annual meeting, or during a 15-day period immediately after close of TNI semi-annual meeting.
285	5. Expert Committee considers comments received at TNI semi-annual meeting and written comments received in Step #4, revises WDS, accordingly, and submits to TNI for publication.
300	6. The revised WDS becomes the Voting Draft Standard (VDS) and is published on TNI website with the electronic ballot voting form.
315	7. Expert Committee voting on VDS begins via TNI electronic balloting process.
345	8. Expert Committee voting on VDS closes and votes are tallied as follows: <ul style="list-style-type: none"> ➤ Affirmative ➤ Affirmative with comments ➤ Negative with comments ➤ Abstain
	9. Does the VDS pass by a two-thirds majority vote of Committee Members? If yes, then go to Step #10. If no, then go to Step #1.
	10. Are there any votes (affirmative and negative) with comments? If yes, then go to Step #11. If no, then go to Step #17.
360	11. Expert Committee considers votes (affirmative and negative) with comments publicly at TNI semi-annual meeting.
	12. Are there any comments that are considered persuasive by a two-thirds majority vote of the Committee Members? If yes, then go to Step #13. If no, then no action is taken by the Expert Committee (Step #12a) to modify the VDS and is so noted in the "Response to Comments" document prepared by the EC (Step #14).
	13. Expert Committee considers the need to modify the VDS based on the comment(s) that are considered persuasive. If EC decides to modify VDS, then go to Step #14. If EC decides NOT to modify VDS, then a comment that is found to be persuasive is placed on hold until next revision cycle (Step #13a) at which time it will be addressed by the working group of the EC (Step #1).
480	14. EC prepares and publishes (via TNI website) a modified VDS and/or "Response to Comments" document based on outcome of Steps #12 and #13. EC prepares and publishes ONLY a "Response to Comments" document if the EC takes no action to modify the VDS.
495	15. EC reviews modified VDS and/or "Response to Comments" and may change vote on VDS. Any vote changes must be made in writing (via e-mail, preferably) within 15 days of modified VDS and/or "Response to Comments" document publication.
	16. VDS vote re-tallied based on EC vote changes submitted in Step #15. A two-thirds majority vote of Committee Members is required for passage of the VDS (or modification thereof). If VDS (or modification thereof) passes, then go to Step #17. If VDS (or modification thereof) does not pass, then go to Step #1.
	17. The VDS (or modification thereof) becomes the TNI Standard.

NOTE: To progress from Steps 1, 5 and 13, the Expert Committee (comprised of Committee Members, Affiliates and Associate Committee Members) must vote to accept proposed standard (or standard revisions). A two-thirds majority of Committee Members is required for acceptance of standard (or standard revisions).

Procedures Governing Standards Development

