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Procedures Governing Standards Development

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Table of Content

	<u>Page</u>
1.0 General	3
1.1 Purpose	3
1.2 Scope	3
1.3 Definitions	3
1.4 Principles	5
2.0 Openness, Lack of Dominance, and Balance	5
2.1 Openness	5
2.2 Lack of Dominance	6
2.3 Balance	6
3.0 Conduct of Committee Business	6
3.1 Meetings	6
3.2 Notification	7
3.3 Decorum	7
4.0 Committee Operations	7
5.0 Standard Development	7
5.1 Expert Committee Activities	7
5.2 Outreach and Information Collection	8
5.3 Voting Draft Standard	9
5.4 Modified Voting Draft Standard	10
5.5 Interim Standard	11
5.6 Modified Interim Standard	11
5.7 TNI Standard	12
6.0 Appeals	12
6.1 General	12
6.2 Compliant	12
6.3 Response	12
6.4 Hearing	13
6.5 Appeals Panel	13
6.6 Conduct of Hearing	13
6.7 Decision	13
7.0 Disposition of Approved and Rejected Standards	13
8.0 Withdrawal of Standards	14
9.0 Publication	14
10.0 Records	14
11.0 Standard Interpretation Policy	14
12.0 Patents in Standards	14
13.0 Metric Policy	15
14.0 References	15
15.0 SOP Approved Changes	15
Appendix 1. Standard Development Process (diagram)	16

## 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 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, with the exception of voting.

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

Procedures Governing Standards Development

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- 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 Executive Committee. See Section 4.
- 1.3.6 *Laboratory* — for purposes of this procedure, 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 *Laboratory Accreditation System Executive Committee* – a group with balanced representation whose duties include ensuring environmental laboratory accreditation standards are suitable for use by TNI.
- 1.3.8 *National Environmental Field Activities Program Executive Committee* – a group with balanced representation whose purpose is to establish and implement an accreditation program for field sampling and measurement organizations.
- 1.3.9 *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.
- 1.3.10 *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:
- Voting Draft Standard* — a standard that has been released in draft form by the Expert Committee and presented for voting
- Modified Voting Draft Standard* -- A revised version of the Voting Draft Standard that has been released in draft form by the Expert Committee following response to comments from the voters, and which will again be presented for voting
- Interim Standard* – a standard that has been approved by the Expert Committee Consensus Body, but is subject to further review by stakeholders, and may be modified and again presented for voting.
- Modified Interim Standard* – a revised version of the Interim Standard that has been released by the Expert Committee following response to comments by voters, and which will again be presented for voting
- TNI Standard* — a standard that has been approved by the Expert Committee Consensus Body.
- 1.3.11 *Standards Review Council* – a voluntary group representing stakeholders from Expert Committees, Accreditation Bodies, Laboratories and others, knowledgeable of the TNI process and the Standard that insures consistency in format of a module or volume of a standard with the Guidelines for Standards Development, editorial and/or grammatical corrections, clarity of content and overall consistency with other modules and volumes of the standard.

- 1.3.12 *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 Opportunity for stakeholders and stakeholder groups, including those who may subsequently adopt the standard as accreditation bodies or be accredited to the standard, to provide input on the ability of a standard to be implemented.
- 1.4.4 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.
- 1.4.5 Timely publication and distribution of minutes of meetings of Expert Committees.
- 1.4.6 Adequate notice of proposed actions.
- 1.4.7 Distribution of ballots to those eligible to vote.
- 1.4.8 Timely and full reports on results of balloting.
- 1.4.9 Careful attention to minority opinions throughout the process.
- 1.4.10 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 10.
- 1.4.11 All TNI standards will conform to ANSI's Commercial Terms and Conditions Policy
- 1.4.12 A Standard, following its approval as a TNI Standard, may be edited for spelling, format and style provided the meaning and intent of any edited section is retained.

#### **1.5 Maintenance of Procedures**

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

### **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

Procedures Governing Standards Development

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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 that operate accreditation programs
  - 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 Executive Committee.

- 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), and webinars may be scheduled as needed. At these meetings and webinars 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 and webinars. 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

Procedures Governing Standards Development

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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 Executive Committee and commenter (ideally as a joint submission) to the TNI Board of Directors for final resolution.

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 2.5, 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.

### **3.3 Decorum**

When comments are made or submitted during Committee operation, such comments should be made in an appropriate manner. Comments should be addressed to the Committee, and not to an individual. The use of names, whether of individuals or of companies, is to be avoided. Comments should address the standard and not personal convictions. At no time should race, religion, or politics be brought up during comments. Should the Committee Chair receive language that does not meet these requirements, 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 TNI "Procedures for Committee Operation" (SOP 2-101).

## **5.0 STANDARD DEVELOPMENT**

### **5.1 Expert Committee Activities**

Procedures Governing Standards Development

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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 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 written input to a committee. Committees shall consider all written comments and suggestions and shall notify the correspondents of the disposition of their comments. The Expert Committees develop a TNI Standard by following the process shown in Appendix 1. This involves first developing a Voting Draft Standard (VDS), and if necessary a Modified Voting Draft Standard (MVDS), an Interim Standard (IS) and a Modified Interim Standard (MIS). 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 voting, or may present only modified sections or clauses of a standard for voting. 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. All stakeholder input is gathered, documented and considered in the standards-writing process.

## **5.2 Outreach and Information Collection**

5.2.1 At the initiation of a project to develop or revise a standard, notification of such activity is announced on the TNI website, to allow for participation by all directly and materially affected persons. Notification shall include the affected volumes/modules and/or sections and clauses, the general nature of the change, the reason/justification for the change and how the change will improve the standard and maintain its ease of implementation. The Expert Committees will actively solicit input from stakeholders and stakeholder groups who may subsequently adopt the standard as accreditation bodies, be accredited to the standard, or use data from accredited entities. These groups may include, but not be limited to, the TNI Laboratory Accreditation System Executive Committee, the TNI National Environmental Field Activities Program Executive Committee, organizations representing the accredited laboratory community, and Federal and State agencies that receive and use environmental test data. Notification is to be made by e-mail to the respective Chairs or stakeholder representatives on the intent to prepare or revise the module or volume with a request for their stated interest in further participation. The responses to this notification are to be received within thirty (30) days of said e-mail notification. The Expert Committees then meet with the interested stakeholders and stakeholder groups by open meeting, webinar or any other form of accessible public communication. Following input, the Expert Committees draft bulleted outlines of the essential items to be included in the standard, and publish them on the TNI website, requesting comments within thirty (30) days of said publication. If this is a revision of an existing TNI standard, the Expert Committees also attach a summary of the changes, with reference to the section/clause numbers of the standard, to show how the proposed standard will be an improvement over the existing standard. Presentation of this summary is repeated at every stage of standard development (VDS, MVDS, IS, and MIS). Depending on the expected controversy of the proposed changes, the Expert Committees may then meet again with the interested stakeholders and stakeholder groups, and the draft bulleted outlines are amended if necessary to reflect further stakeholder input.

5.2.2 If the standard will be a revision of an existing TNI standard, the following records are gathered and maintained during the standards development process:

- all submitted Standards Comment Forms 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 Response to Comments documents from voting on the most recent previous standards development activity;



Procedures Governing Standards Development

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- all comments previously placed on hold that remain on hold;
- all pertinent Standard Interpretation Request resolutions.

### 5.3 Voting Draft Standard

- 5.3.1 The Expert Committees prepare and submit a proposed VDS to the Standards Review Council (SRC). The SRC may advise the Expert Committees of any conflict with other standard modules and volumes, and may advise of any inconsistency with formatting, style, and ANSI requirements. On receiving this input, the Expert Committees may modify the proposed VDS. The resulting VDS is then published for voting on the TNI website.
- 5.3.2 All Committee Members, Affiliates and Associate Committee Members may vote on their committee's VDS. Each Committee Member, Affiliate and Associate Committee Member has one vote. All voting is conducted by electronic ballot. TNI shall indicate conspicuously on the ballot form that negative votes shall be accompanied by written comments related to the proposal, preferably accompanied by proposed alternate language, and that negative votes unaccompanied by such written comments will be recorded as "negative without comments" and without further notice to the voter. TNI is not required to solicit any comments from the "negative without comment" voter.
- 5.3.3 The voting period shall begin immediately on publication of the standard on the TNI website, and the voting period shall last for forty five (45) days. Each Committee Member, Affiliate and Associate Committee Member will vote on one of the following positions:

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

At any time during the voting process, interested stakeholders and stakeholder groups may seek clarification on the intent of the standard through open discussions with the Expert Committees.

- 5.3.4 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.
- 5.3.5 In order for the 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 5.3.6, 5.3.7 and 5.3.8).
- 5.3.6 All written comments accompanying negative or affirmative votes cast by Committee Members, Affiliates and Associate Committee Members shall be recorded and considered publicly, whether by open meeting, webinar, or any other form of accessible public communication. Following its discussion, each written comment shall be ruled persuasive or non-persuasive by a simple two-thirds vote of the Committee Members. No written comment shall be dismissed because it does not provide alternative language or a specific remedy to the vote. The committee may, subject to the restrictions in 5.3.7, 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.

Procedures Governing Standards Development

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- 5.3.7 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 not in the proposed standard and that had not been subject to public review;
  - 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 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.

- 5.3.8 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 standard is appropriate. The committee may modify the standard if such modification will lead to removal of the cause for the negative vote. Any substantive changes will undergo public review. The modified standard must 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. Additionally, each commenter and objector will be provided with an individual report describing the disposition of their comments and the reason for such disposition. All unresolved objections, along with attempts at resolution and any substantive changes will be provided to the Expert Committee Members in order to afford them the opportunity to respond, reaffirm or change their votes. 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 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.
- 5.3.9 If the VDS passes without any persuasive comments, the VDS becomes the TNI Standard (Section 5.7).
- 5.3.10 If the Expert Committee considers the changes it has made to the VDS as a result of persuasive comments will generate little or no controversy, the revised VDS becomes the Interim Standard (IS; Section 5.5).
- 5.3.11 If the Expert Committee considers the changes it has made to the VDS as a result of persuasive comments will be controversial, and may require further opportunity for stakeholder input, the revised VDS becomes the Modified VDS (MVDS; Section 5.4).

#### **5.4 Modified Voting Draft Standard**

The Expert Committees develop a Modified Voting Draft Standard (MVDS), incorporating changes made to the VDS as a result of persuasive comments. The MVDS is published on the TNI website and voting procedure described above in Sections 5.3.2 through 5.3.8 is followed.

- 5.4.1 If the MVDS passes without any persuasive comments, the MVDS becomes the TNI Standard (Section 5.7).

Procedures Governing Standards Development

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- 5.4.2 If the Expert Committee considers the changes it has made to the MVDS as a result of persuasive comments will generate little or no controversy, the MVDS becomes the Interim Standard (IS; Section 5.5).
- 5.4.3 If the Expert Committee considers the changes it has made to the MVDS as a result of persuasive comments will be controversial, the MVDS is again published on the TNI website and taken through the voting procedure described above in Sections 5.3.2 through 5.3.8. This process shall be repeated as many times as the Expert Committee considers necessary until it believes the resulting MVDS will generate little or no controversy. The MVDS then becomes the Interim Standard (IS; Section 5.5).

### **5.5 Interim Standard**

The Expert Committees develop an Interim Standard (IS), incorporating changes made to the VDS or MVDS as a result of persuasive comments. It is the purpose of the IS to allow voters the opportunity to consider whether the changes made to the VDS or MVDS as a result of persuasive comments satisfactorily resolve those comments. Only those changes are voted on at the IS stage, because any section of the standard that did not receive persuasive comments at the VDS or MVDS stage is considered to have passed the voting process. The IS is published on the TNI website and the voting procedure described above in Sections 5.3.2 through 5.3.8 is followed.

- 5.5.1 If the IS passes without any persuasive comments, the IS becomes the TNI Standard (Section 5.7)
- 5.5.2 If the Expert Committee makes changes in response to persuasive comments, the IS becomes the Modified IS (MIS; Section 5.6).

### **5.6 Modified Interim Standard**

- 5.6.1 The Expert Committees develop a Modified Interim Standard (MIS), incorporating changes made to the IS as a result of persuasive comments. The purpose of the MIS is to allow voters the opportunity to consider whether the changes made to the IS as a result of persuasive comments satisfactorily resolve those comments. Only those changes are voted on at the MIS stage, because any section of the standard that did not receive persuasive comments at the VDS or MVDS stage is considered to have passed the voting process. The MIS is published on the TNI website and is taken through the voting procedure described above in Sections 5.3.2 through 5.3.8.
- 5.6.2 If no persuasive comments are received, the MIS becomes the TNI Standard (Section 5.7).
- 5.6.3 If persuasive comments are received, the Expert Committee meets with the commenters publicly, whether by open meeting, webinar, or any other form of accessible public communication, and attempts to reach agreement on a resolution. If agreement is reached, the MIS is modified to satisfy the persuasive comments and becomes the TNI standard.
- 5.6.4 If agreement is not reached and the Expert Committee believes the standard will not be acceptable for implementation by the stakeholders, the standard again undergoes the voting process as a MIS.
- 5.6.5 The above steps (sections 5.6.1 through 5.6.4) are repeated as many times as necessary until the Expert Committee believes the resulting standard will be acceptable for implementation by the stakeholders. The MIS then becomes the TNI standard (Section 5.7).

### **5.7 TNI Standard**

Procedures Governing Standards Development

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- 5.7.1 All individuals who provided votes or who submitted public review comments on a VDS, MVDS, IS or MIS and all unresolved objectors will be so notified and will be informed in writing of their right to appeal. Any appeals registered with TNI must be considered in accordance with Section 6 of these Procedures.
- 5.7.2 The TNI Standard is made available to all interested parties, including standards-adoption organizations. Accompanying the standard will be a form including an overview of the standard; and if the standard is a revision of a previous standard, an explanation of each change, why it was made, and how it has improved the standard.
- 5.7.3 If any appeal is upheld by the appeals panel (see Section 6.5), the affected module or section of the TNI Standard is withdrawn by the Expert Committee that developed that module or section for appropriate disposition.

## **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 on a standard has been found non-persuasive by the vote of the Expert Committee, or whose negative comment remains unresolved, will be advised in writing of the right to appeal the decision in writing. Also, any member of the public who has submitted an objection on a standard that has been found non-persuasive by the vote of the Expert Committee may appeal the decision in writing. The appellant shall file a written complaint with the Executive Director of TNI within thirty (30) days after being informed of the right to appeal. 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 Board of Directors, 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.

#### **6.6 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. This will require the review process to be initiated no later than the 4-year anniversary of the standard.

#### **8.0 WITHDRAWAL OF STANDARDS**

If a TNI standard is withdrawn, this will be conducted in accordance with *ANSI Essential Requirements: Due process requirements for American National Standards*, Section 4.2.13.

## **9.0 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.

## **10.0 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.

## **11.0 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 or TNI staff shall route the request to the NELAP Accreditation Council and/or the Laboratory Accreditation System Executive Committee (LASEC) who may, as necessary work with the appropriate Expert Committee to respond to the interpretation request. SOP 3-105 provides the specific approach developed for addressing these interpretation requests regarding NELAP. Standards interpretation requests outside the scope of SOP 3-105 shall be routed directly to an Expert Committee Chair, the Board of Directors, or other person who can appropriately provide the interpretation. Standards interpretation requests regarding the National Environmental Field Activities Program (NEFAP) will be addressed consistent with SOP 5-106.

## **12.0 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

Procedures Governing Standards Development

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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.

**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 2-101 Procedures for Committee Operations  
SOP 3-105 Standard Interpretation SOP  
SOP 5-106 NEFAP Standard Interpretation SOP

**15.0 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 Rev 2.0	3/12/2015	Modification to SOP based upon Corrective Action Task Force
2-100 Rev 2.0	5/5/2015	Editorial change required by ANSI

Procedures Governing Standards Development

**Appendix 1. Standards Development Process**

